From: Smith, Charles
Sent: 04/12/2012 02:28:06 PM
To: Mullally, Robert; Zhao, Ying
CC: Kieran, Damian
Subject: RE: Marlex HGX-030-01 shipments from China to Belgium and USA
Attachments: Marlex HGX-030-01 Equivalency Testing Rev AB[1].doc

Robert

As just discussed, here is the report we have loaded in PDM that we have shared with the shipper in China as well due to lack of the certification.

Thks

Charlie

-----Original Message-----
From: Mullally, Robert
Sent: Thursday, April 12, 2012 2:08 PM
To: Smith, Charles; Zhao, Ying
Subject: RE: Marlex HGX-030-01 shipments from China to Belgium and USA

Charlie or Mike,

Please go back to the vendor in China and request the actual manufacturing address. What kind of a statement is the following?

"Vendor we bought form in China doesn't have the certification to prove the traceability."

How did all of this resin end up in China if it was made in Texas?

Thanks,
Rob

-----Original Message-----
From: Smith, Charles
Sent: Thursday, April 12, 2012 10:59 AM
To: Mullally, Robert; Zhao, Ying; Kieran, Damian
Subject: RE: Marlex HGX-030-01 shipments from China to Belgium and USA

Robert

Yes

Yes, bag has correct packaging and we tested. Vendor we bought form in China doesn't have the certification to prove the traceability.

The address in Texas for the plant made at is:

La Porte, Texas USA

EXHIBIT
1

Attached is picture showing example of the bags we have bought, all same lot# with address.

thks

Charlie

-----Original Message-----
From: Mullally, Robert
Sent: Thursday, April 12, 2012 10:50 AM
To: Smith, Charles; Zhao, Ying; Kieran, Damian
Subject: RE: Marlex HGX-030-01 shipments from China to Belgium and USA

Hi Charlie,

Is this the same material, Polyproylene HGX-030-1 (Marlex Resin)?

Was it manufactured by Phillips in Texas? Please give me the complete manufacturing address, wherever it was made, China, Texas, Brazil, etc.

Thanks,
Rob Mullally
Boston Scientific Corporation
Import Export Compliance Coordinator
U.S. Licensed Customs Broker
Phone: 617-689-7391

-----Original Message-----
From: Smith, Charles
Sent: Thursday, April 12, 2012 9:53 AM
To: Zhao, Ying; Kieran, Damian; Mullally, Robert
Subject: RE: Marlex HGX-030-01 shipments from China to Belgium and USA

Mike

We worked with Robert on these last shipments. I would suggest once the paperwork is prepared we review with Robert to insure we are all set

Robert

We are having final material (30,000 lbs.) in China forwarded back in three shipments (10,000 Lbs.) to two locations:

1. To Belgium extrusion house we work with

2. &3. To USA, storage facility Gould in Indiana.

I have attached email from back in AUG when we had about 5,000 lbs. shipped here to Marlboro.

Thks

Charlie

-----Original Message-----
From: Smith, Charles
Sent: Thursday, April 12, 2012 7:56 AM
To: Zhao, Ying; Vialle, George

Cc: Kieran, Damian
Subject: RE: Marlex HGX-030-01 shipments

Mike

Last time we had our custom person involved. I assume we should involve them up front and we should be all set. I think they work in Quincy or Natick? George

Do you have info?

First shipment goes to Belgium, not US? I assume the BSC customs contact can address this as well.

thks

Charlie

-----Original Message-----
From: Zhao, Ying
Sent: Thursday, April 12, 2012 3:47 AM
To: Smith, Charles; Vialle, George
Subject: RE: Marlex HGX-030-01 shipments

hi, Charlie and George:

OK, 3 shipments, 5 tons each. 1st to Belgium, then 2nd and 3rd to U.S..
I have talked to the shipper more today, I asked them to handle everything if possible, including packaging, all of paperwork needed for custom clearance in China, shipping on land and by sea, a door-to-door solution. They said they can take care of everything, but BSC needs to prepare for custom handling in U.S.. basically when the goods arrive at U.S. custom, we will need to clear the custom. They will handle all of the shipping, but not U.S. custom. Is this what we did previously on those 2 tons? is this new? can we or a 3rd party we use handle this? any question or concern?

Regards,
Michael

From: Smith, Charles
Sent: Wednesday, April 11, 2012 7:45 AM
To: Vialle, George; Zhao, Ying
Subject: RE: lab test report for Marlex HGX-030-01

Mike

Here is report.

Just to confirm per our meeting this AM; plan is for three shipments splitting material into 5tons each as George states below. Look forward to quote.

Thks

Charlie

-----Original Message-----
From: Vialle, George
Sent: Wednesday, April 11, 2012 7:54 AM
To: Zhao, Ying; Smith, Charles
Subject: RE: lab test report for Marlex HGX-030-01

Michael,
Charlie has the test data. Regarding the shipment to Belgium, I thought we were going to ship 5 tons/10,000 lbs. Can we confirm final quantity with Charlie?

Thanks,
George

-----Original Message-----
From: Zhao, Ying
Sent: Tuesday, April 10, 2012 11:35 PM
To: Smith, Charles; Vialle, George
Subject: lab test report for Marlex HGX-030-01

hi, Charlie and George:

I am working on getting the first 1 ton out to Belgium soon. I was told the lab test result you guys did a few months ago will be helpful to deal with custom. Do you have that, can you send me a copy of the report? It is about the material content itself.

I am working with the shipper on quotes and hope to get the 1st ton out by this week. I am checking on options: whether to combine it with other materials in one container or use dedicated container. this one ton is too small for one container, I was told it can take probably 10 of 1 ton box. Anyway, I will let you know the difference on cost and make a decision with you on this.

I will work with them packing it up extrally for sea water and smell concerns.

Thanks,
Michael

美国海关新规 -

此為美国海关在 AMS进口安全報关之后,推出新的安全報关方案.

10 + 2 的含义:

ISF ----

条款生效日期 :

条款執行日期 :

ISF 由誰发送 ?

(1)

(2)

ISF 如何发送 ?

(1)

(2)

ISF 何時发送 ?

--下十个信息必须在登船

1
2
3
4
5
6
7
8
9
10

******* ZIP code is need of the address ********

就是美国海关安求进口商对十个信息單元的安全申報.

<十个信息資料見附上表格>

进口商

进口商指定的貨代(FORWARDER)或報关行(BROKER)

現有的 AMS 系统

美国海关 ABI 关稅系統.

Seller

Buyer

Importer of Record Number

Consignee number

Manufacturer ID

'Ship to' Party

Country of origin

Harmonized Tariff (HTS#)

Container stuffing location

Consolidator

ISF (10 + 2) - Importer Security Filing

10

2

JAN-26-2009

JAN-26-2010

或

是指十个信息單元,由进口商(Importer)負責申報

是指两个信息單元,由船東(Carrier)負責申報

72 小時前發送.

(REVISED)

NO. OF PACKAGE :
P.O. NO. :
INVOICE NO. :
BOOKING NO.
VESSEL NAME :
VOYAGE NO. :
PORT OF LOADING :
ETD:
CONTAINER NO. :
MASTER B/LADING NO.:
SCAC code:
HOUSE B/LADING NO.: (SAME AS AMS HB NO.)

1	***Seller name and address :*** ***(賣方公司名稱和地址郵編)***
2	***Buyer name and address :*** ***(買方公司名稱和地址)***
3	***Importer of Record Number*** ***Name and address*** ***(进口商的海关登記号/名稱/地址)***
4	***Consignee number(s) :*** ***(收貨人的联邦報稅号碼)***
5	***Manufacturer ID*** ***Name and address*** ***(工厂的代碼 / 公司名稱和地址)***
6	***'Ship to' name and address :*** ***(貨物送達的公司名稱和地址)***
7	***Country of origin of the goods :*** ***(所有貨品的原产地)***
8	***U.S.A. Harmonized Tariff :*** ***(海关关稅編号)***
9	***Container stuffing location :*** ***(貨櫃的裝櫃公司名稱和地址)***
10	***Consolidator name and address :*** ***(拼箱的公司名稱和地址)***

HTS #
3902100090

200 BAGS
ACN0314031
CLEMENTINE MAERSK
US627E
YANTIAN
7/25/2012
SEGU1271710
ANC0314031
ELII
ITL12070145

SHENZHEN YFL INTERNATIONAL LOGISTICS LIMITED
Room 511-512,Building B,Yingdali,Futian,Free Trade Zone,Shenzhen ； Zipcode:518038
BOSTON SCIENTIFIC
500 Commander Shea . Blvd， Quincy, MA 02171, U.S.A.
Attn: Robert Mullally; Tel: 617-689-7391; mail: Robert.Mullally@bsci.com
EIN number: 042695240
Emai Plastic Raw Material(Dongguan)Co., Ltd
22 Xianwei Road, Cheung Muk Tau Plastic Market, Dongguan,Guangdong 523000

Stephen Gould Corp
8351 Northwest Blvd, Indianapolis, IN 46278， U.S.A
CHINA
3902100090
Emai Plastic Raw Material(Dongguan)Co., Ltd
22 Xianwei Road, Cheung Muk Tau Plastic Market, Dongguan,Guangdong 523000
Emai Plastic Raw Material(Dongguan)Co., Ltd
22 Xianwei Road, Cheung Muk Tau Plastic Market, Dongguan,Guangdong 523000

DESCRIPTION
Marlex Polyproplene Resin HGX-030-01

From: Smith, Charles
Sent: 06/07/2012 01:49:07 PM
To: Delaney, JP
CC: Kummailil, John; Sammarco, Carmine
Subject: Re: Counterfeit material from a supplier you use - ACTION REQUIRED

Not ours

Sent from my iPhone

On Jun 7, 2012, at 1:48 PM, "Delaney, JP" <JP.Delaney@bsci.com> wrote:

John- Who was this material being shipped to and what PO was this against?

Charlie- Is this your Marlex project?

JP

From: Kummailil, John
Sent: Thursday, June 07, 2012 11:33 AM
To: Smith, Charles; Delaney, JP
Cc: Sammarco, Carmine
Subject: RE: Counterfeit material from a supplier you use - ACTION REQUIRED

We did not run any tests. The lot numbers in the pic were Evonik lot numbers for a different grade, per Evonik's VP.

The hypothesis is that they re-bagged god knows what grade, or even recycled material, in bags that have the grade # we were looking for.

From: Smith, Charles
Sent: Thursday, June 07, 2012 11:14 AM

EXHIBIT
3

To: Kummailil, John; Delaney, JP
Cc: Sammarco, Carmine
Subject: RE: Counterfeit material from a supplier you use - ACTION REQUIRED

How did you determine it was counterfeit? What material tests did you run?

From: Kummailil, John
Sent: Thursday, June 07, 2012 11:10 AM
To: Smith, Charles; Delaney, JP
Cc: Sammarco, Carmine
Subject: RE: Counterfeit material from a supplier you use - ACTION REQUIRED

The resin we found was in sealed bags and looked pristine.

From: Smith, Charles
Sent: Thursday, June 07, 2012 10:48 AM
To: Kummailil, John; Delaney, JP
Cc: Sammarco, Carmine
Subject: RE: Counterfeit material from a supplier you use - ACTION REQUIRED

Thks, we will review. Our material was in sealed bags and we tested as we had no certification (trail back to Marlex on lot #).

From: Kummailil, John
Sent: Thursday, June 07, 2012 10:19 AM
To: Smith, Charles; Delaney, JP
Cc: Sammarco, Carmine
Subject: Counterfeit material from a supplier you use - ACTION REQUIRED

Hello Guys,

We were looking for Nylon 12 in China and came across possibly counterfeit material form a distributor (Emai), who you use for Carbothane(?) or Marlex – not sure which.

I have asked Helge Batz to determine whether we do other business with Emai and to warn affected parties, if any. I took the task of warning you myself.

I completely understand that you have a well-defined process to ensure that your material is good. This is just a data point to take into consideration. Please take any action you see fit, including doing nothing at all.

Thanks,

John

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

TERESA L. STEVENS,

Plaintiff,

v. CIVIL ACTION NO. 2:16-cv-00265

BOSTON SCIENTIFIC CORPORATION, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the court is the plaintiff's Class Action Complaint [ECF No. 1] ("Complaint") and Motion for a Preliminary Injunction [ECF No. 4]. For the reasons detailed below, the court applies the doctrine of primary jurisdiction to this matter and **REFERS** the issues discussed herein to the United States Food and Drug Administration ("FDA") for initial consideration of the allegations contained in the plaintiff's Complaint and Motion.

I. Procedural History and Background

The plaintiff filed the Complaint on January 12, 2016, against Boston Scientific Corporation ("Boston Scientific") and other entities and alleges various claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), West Virginia Consumer Credit and Protection Act,[1] and West Virginia common law. Also on January 12, 2016, the plaintiff filed a Motion for a Temporary Restraining Order and a Preliminary Injunction. On January 13,

[1] The plaintiff cites to "W. Va. Code § 41A-6-103" in the fourth count of the Complaint; however, such a statutory section does not exist, nor does "Chapter 41A" exist within the West Virginia Code. The court will assume for the purpose of this Order only that the plaintiff intended to refer to the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-6-101, *et seq*.

EXHIBIT
4

2016, the court entered an Order [ECF No. 14] denying the plaintiff's Motion for a Temporary Restraining Order. The plaintiff filed a Motion for Expedited Hearing on Preliminary Injunction and Request to Shorten Time for Any Opposition [ECF No. 16]. On January 15, 2016, the court entered an Order [ECF No. 20] setting a briefing schedule regarding the plaintiff's Motion for Expedited Hearing. On January 19, 2016, the court entered an Order [ECF No. 26] requiring the parties to brief the applicability of the doctrine of primary jurisdiction to this case by noon on January 20, 2016. The parties filed briefs, and the court now considers the matter.

While the factual allegations made by the plaintiff against Boston Scientific are numerous, the court will review only those allegations relevant to the application of the doctrine of primary jurisdiction.[2] The plaintiff filed this action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of herself and a putative class of similarly situated individuals who were implanted with Boston Scientific's transvaginal mesh products after September 2012. Compl. ¶ 1.

Boston Scientific manufactures and markets transvaginal mesh, which is a permanently implantable medical device. Compl. ¶ 10. According to the plaintiff, each year approximately 55,000 women receive a Boston Scientific mesh implant. *Id*. Advantage mesh, which Boston Scientific uses for all of its transvaginal mesh products, is subject to regulation by the FDA. *Id*. The plaintiff alleges Advantage mesh is made from Marlex HGX-030-1 ("Marlex"), a specific and unique polypropylene, and the device was cleared by the FDA under its 510(k) clearance process for medical devices. *Id*. The plaintiff alleges that, if Boston Scientific used anything

[2] It is readily apparent that the documents and factual allegations upon which the plaintiff relies may well be of importance in the multidistrict cases against Boston Scientific.

other than Marlex to form its mesh, "the product would not be Advantage mesh, as approved by the FDA." *Id.*

Marlex is manufactured in pellet form by a joint venture between the Chevron Corporation and Phillips Sumika Polypropylene Company ("Phillips") in LaPorte, Texas. Compl. ¶ 10. The plaintiff alleges Phillips decided to discontinue selling Marlex to Boston Scientific, so Boston Scientific began to run out of Marlex in 2011. *Id.* ¶ 11. According to the plaintiff, Boston Scientific resorted to smuggling counterfeit Marlex pellets out of China, into Belgium and, ultimately, into the United States in an effort to obtain the necessary material. *Id.* Allegedly, this "smuggling" occurred from June 2011 through the fall of 2012. *Id.*

The plaintiff alleges that she and the putative class members were permanently implanted with a counterfeit, adulterated product that was not approved by the FDA under Boston Scientific's original 510(k) application and clearance. *Id.* ¶¶ 15, 18. The plaintiff also alleges that Boston Scientific believed the FDA would likely not clear the use of a mesh made of material other than Marlex under its original 510(k) clearance. *Id.* ¶ 24. Further, the plaintiff alleges serious safety concerns surround this "counterfeit" Marlex resin because little is known of its provenance and testing. *See id.* ¶¶ 59–67.

The plaintiff emphasizes the potential seriousness of the safety concerns associated with the possibility that medical devices manufactured by Boston Scientific contain harmful, adulterated, and counterfeit resin in her Motion for a Temporary Restraining Order and a Preliminary Injunction. In the Motion, the plaintiff largely repeats many of the factual allegations contained in the Complaint. *See* Pl.'s Mot. TRO & Prelim. Inj. The plaintiff argues she and the putative class members all over the country need to make informed decisions about whether to

have mesh implanted or have the device removed and that such personal, medical decisions directly relate to their continued safety. Pl.'s Mem. Supp. Mot. TRO & Prelim. Inj. ¶ 72 [ECF No. 6]. The plaintiff claims the alleged counterfeit mesh "is not some defective headlamp on a Ford pickup. . . . This Counterfeit Product, smuggled by Boston Scientific out of China from a known counterfeiter, is a medical device (subject to FDA regulation) that is permanently implanted into the most intimate part of a woman's body." *Id*. ¶ 74. Further, the plaintiff alleges "[t]here is no doubt that the public health is at issue here." *Id*. ¶ 75. Finally, the plaintiff alleges "[t]he FDA, too, deserves to know the true history behind Boston Scientific's Counterfeit Product, and how it came into the United States without certificates of authenticity, proper provenance, or adequate testing." *Id*.

II. Legal Standard

A. Introduction to the Doctrine of Primary Jurisdiction

The doctrine of primary jurisdiction is a judicially created doctrine that was first invoked by the United States Supreme Court at the beginning of the twentieth century. *See Tex. & Pac. Ry. v. Abilene Cotton Oil Co.*, 204 U.S. 426 (1907); *see also* Nicholas A. Lucchetti, Note, *One Hundred Years of the Doctrine of Primary Jurisdiction: But What Standard of Review is Appropriate for It?*, 59 Admin. L. Rev. 849, 854 (2007). "Under the doctrine of primary jurisdiction a court can refer a technical or factual issue to an administrative agency for expert determination." James W. Hilliard, *Tapping Agency Expertise: The Doctrine of Primary Jurisdiction*, 96 Ill. B.J. 256, 256 (2008). "The development of the primary jurisdiction doctrine is a function of the judiciary's recognition that the adjudicatory authority of regulatory agencies will inevitably overlap with the jurisdiction of traditional judicial courts." Paula K. Knippa,

Note, *Primary Jurisdiction Doctrine and the Circumforaneous Litigant*, 85 Tex. L. Rev. 1289, 1290 (2007). "The doctrine of primary jurisdiction, like the rule requiring exhaustion of administrative remedies, is concerned with promoting proper relationships between the courts and administrative agencies charged with particular regulatory duties." *United States v. W. Pac. R.R. Co.*, 352 U.S. 59, 63 (1956).

B. Historical Background

The doctrine of primary jurisdiction was established in the landmark case of *Texas & Pacific Railway Company v. Abilene Cotton Oil Company.*, 204 U.S. 426 (1907). Louis L. Jaffe, *Primary Jurisdiction*, 77 Harv. L. Rev. 1037, 1042 (1964). In *Abilene Cotton Oil*, a shipper claimed that a published carrier rate was unreasonable and sued the carrier in a state court for the excess. *Tx. & Pac. Ry.*, 204 U.S. at 430. "The Supreme Court held that the action did not lie since the [Interstate Commerce Commission ("ICC")] alone was competent to determine whether the carrier rate was reasonable. Jaffee, *supra*, at 1042. Justice White, writing for the Court, determined that the Commerce Act was "intended to abolish preferences and discriminations by establishing a uniform published rate." *Id.* "If power existed in courts or juries to revise a published rate there could be no uniformity, and this 'would render the enforcement of the [A]ct impossible.'" *Id.* at 1042 (quoting *Abilene Cotton Oil Co.*, 204 U.S. at 441). Thus, the Court determined that the issue of reasonable freight rates should first be decided by the ICC in order to promote regulatory uniformity. *Abilene Cotton Oil Co.*, 204 U.S. at 448.

The Supreme Court's holding in *Abilene Cotton Oil* suggests that an agency should have primary jurisdiction whenever the agency's exclusive control would promote the uniform enforcement of a statute. As the Supreme Court has refined the doctrine, however, it has limited

the holding in *Abilene Cotton Oil*, and additional considerations have emerged in the Court's analysis. Michael Penney, Note, *Application of the Primary Jurisdiction Doctrine to Clean Air Act Citizen Suits*, 29 B.C. Envtl. Aff. L. Rev. 399, 403 (2002).

In *Great Northern Railway Company. v. Merchants' Elevator Company.*, 259 U.S. 285 (1922), the Supreme Court addressed, for the first time, agency expertise in the context of applying primary jurisdiction in a case involving statutory construction. Penney, *supra*, at 404. The case involved another railroad freight dispute. *Great N. Ry. Co.*, 259 U.S. at 288. Merchants' Elevator Company claimed that the railroad violated its government-approved rates and that a special statutory rule allowing the railroad to charge more under certain circumstances did not apply. *Id*. at 288–89. Thus, the complete issue revolved around the interpretation of a statutory provision, and the railroad argued that, under *Abilene Cotton Oil*, the Court should hold that the ICC had jurisdiction over the matter; but the Court disagreed. *Id*. at 290.

First, the Court in *Great Northern Railway Company* noted that issues involving statutory and rule construction are questions of law that courts generally have the capacity to address. *Id*. at 290–91. Second, the Court stated the appellate process could also ensure uniformity because, while issues of construction may arise in federal or state courts, appellate courts could review lower court decisions to ensure a uniform application of the law. *Id*. "The Supreme Court agreed that agency interpretations would promote uniformity, but the Court concluded that this did not automatically support a holding for primary jurisdiction in the agency because granting jurisdiction to the agency was not the *only* means to ensure uniform construction and application of statutes." Penney, *supra*, at 404. The Supreme Court established that the degree of agency

expertise needed to resolve the issue would determine how the Court should allocate jurisdiction. *See Great N. Ry. Co.*, 259 U.S. at 291.

The Supreme Court offered its most complete articulation of the primary jurisdiction doctrine in *Western Pacific Railroad Co.*, 352 U.S. 59 (1956). Knippa, *supra*, at 1297. The Court distinguished the doctrine from other, closely-related legal principles and emphasized the doctrine's two primary purposes: uniform regulation and reliance upon agency experts. *See W. Pac. R.R. Co.*, 352 U.S. at 64.

C. Primary Jurisdiction Is Not Exhaustion of Remedies

In *Western Pacific Railroad Company.*, the Supreme Court took care to distinguish the primary jurisdiction doctrine from the similar doctrine of exhaustion of administrative remedies: "'Exhaustion' applies where a claim is cognizable in the first instance by an administrative agency alone. . . . 'Primary jurisdiction,' on the other hand, applies where a claim is originally cognizable in the courts." *Id*. at 63–64. The doctrine "comes into play whenever enforcement of the claim requires the resolution of issues which, under a regulatory scheme, have been placed within the special competence of an administrative body." *Id*. at 64. Thus, "[i]f the issue is one 'that Congress has assigned to a specific agency,' the doctrine of primary jurisdiction allows the court to stay the judicial proceedings and direct the parties to seek a decision before the appropriate administrative agency." *S. Utah Wilderness All. v. Bureau of Land Mgmt.*, 425 F.3d 735, 750–51 (10th Cir. 2005) (citations omitted) (quoting *Williams Pipe Line Co. v. Empire Gas Corp.*, 76 F.3d 1491, 1496 (10th Cir. 1996)). "The agency is then said to have 'primary jurisdiction.'" *Id*. at 751.

The name "primary jurisdiction," however, is a misnomer because a court must first have subject matter jurisdiction for the doctrine to apply at all. Lucchetti, *supra*, at 853. The doctrine "applies where a claim can originally be addressed in a court but would be better addressed first by an administrative body." 2 Am. Jur. 2d Admin. L. § 456 (2015).

D. When Courts Apply the Doctrine

"There is no mechanical formula for applying the doctrine of primary jurisdiction." *S. Utah Wilderness All.*, 425 F.3d at 751. "In every case the question is whether the reasons for the existence of the doctrine are present and whether the purposes it serves will be aided by its application in the particular litigation." *W. Pac. R.R. Co.*, 352 U.S. at 64.

In earlier cases, the Supreme Court emphasized the desirable *uniformity* that would come from a specialized agency initially deciding certain types of administrative questions. *Id*. at 64. More recently, the Supreme Court has focused of the expert and specialized knowledge of the agencies involved. *Id.* The Supreme Court applies a firmly established principle that "in cases raising issues of fact not within the conventional experience of judges or cases requiring the exercise of administrative discretion, agencies created by Congress for regulating the subject matter should not be passed over." *Far E. Conf. v. United States*, 342 U.S. 570, 574 (1952). Conversely, "the doctrine of primary jurisdiction does not apply where the issue sought to be referred involves a question of law rather than a question of fact requiring technical expertise." Hilliard, *supra*, at 258.

E. Agency Must Have Authority Over Relevant Issues

A court's review of the purposes behind the doctrine of primary jurisdiction, of course, assumes that a specific agency actually *has* authority and expertise over the relevant issues. *S.*

Utah Wilderness All., 425 F.3d at 751 ("All of this assumes that Congress has, by statute, given authority over the issue to an administrative agency."). Accordingly, before a court assesses whether the purposes underlying proper application of the doctrine are present in a particular case, the court must first determine the scope of authority an administrative agency possesses over the issues. *Id.*; *see also* 73 C.J.S. Pub. Admin. L. & Proc. § 114 (2015) ("[T]he court and the administrative agency must have concurrent jurisdiction over the dispute or a portion of it.") (footnote omitted).

F. The Application of the Doctrine Cannot Be Waived

A decision to apply the doctrine to a particular case is in the sound discretion of the court. *See Envtl. Tech. Council v. Sierra Club*, 98 F.3d 774, 789 (4th Cir. 1996) (reviewing for abuse of discretion the district court's decision not to refer a matter pursuant to the doctrine of primary jurisdiction). Further, "[t]he court may raise the issue of primary jurisdiction on its own initiative, and its invocation cannot be waived by the failure of the parties to argue it as the doctrine exists for the proper distribution of power between judicial and administrative bodies and not for the convenience of the parties." 2 Am. Jur. 2d Admin. L. § 456 (2015); *see also Red Lake Band Chippewa Indians v. Barlow*, 846 F.2d 474, 476 (8th Cir. 1988) ("We realize that neither party has raised the issue of primary jurisdiction up to this point. It is well established, however, that its invocation cannot be waived by the failure of the parties to argue it. . . ."). In other words, the court may invoke the doctrine sua sponte.

G. Referring Issues: Staying Judicial Proceedings or Dismissing Without Prejudice

The primary jurisdiction doctrine functions by allowing courts to stay proceedings or to dismiss a complaint without prejudice pending the resolution of an issue before the relevant

administrative agency. 73 C.J.S. Pub. Admin. L. & Proc. § 120 (2015). Federal courts have recognized dismissal of the case without prejudice as a form of referral in applying the doctrine of primary jurisdiction. Hilliard, *supra*, at 259. The doctrine allows a "court to enable a 'referral' to the agency, staying further proceedings so as to give the parties reasonable opportunity to seek an administrative ruling." *Reiter v. Cooper*, 507 U.S. 258, 268 (1993).

A "referral"[3] to the agency does not cause a court to lose jurisdiction; the court may retain jurisdiction, or it may dismiss it without prejudice if dismissal will not unfairly disadvantage the parties. *Id*. at 268–69. A court should choose the approach that provides the parties a reasonable opportunity to seek an administrative ruling. *Id*. at 268. If dismissal of the suit would be prejudicial to one of the parties, it should be stayed. *See Far E. Conf.*, 342 U.S. at 577. "Dismissal of the complaint may be appropriate when the parties can obtain all of the relief that they seek in court in an administrative forum or in an easily initiated suit subsequent to the administrative proceedings." Hilliard, *supra*, at 259. "Where the referral is in the form of dismissal without prejudice, neither party is precluded from seeking judicial review of the administrative agency decision." *Id*.

If a district court dismisses an action without prejudice, a plaintiff must start over before the appropriate agency. Robert B. von Mehren, *The Antitrust Laws and Regulated Industries: The Doctrine of Primary Jurisdictio*n, 67 Harv. L. Rev. 929, 952 (1954). A plaintiff will do this usually by filing a complaint with the agency pursuant to the agency's regulations. *Id*. If the

[3] "'Referral' is sometimes loosely described as a process whereby a court refers an issue to an agency." *Reiter v. Cooper*, 507 U.S. at 268 n.3. "Use of the term 'referral' to describe this process seems to have originated in *Western Pacific*, which asserted that, where issues within the special competence of an agency arise, 'the judicial process is suspended pending referral of such issues to the administrative body for its views.'" *Id*. (quoting *W. Pac. R.R. Co.*, 352 U.S. at 64). "*Mitchell Coal* spelled out the actual procedure contemplated, holding that further action by the district court should 'be stayed so as to give the plaintiff a reasonable opportunity within which to apply to the Commission for a ruling as to the reasonableness of the practice." *Id*. (quoting *Mitchell Coal & Coke Co. v. Pa. R.R. Co.*, 230 U.S. 247, 267 (1913)).

proceedings are stayed, a plaintiff will seek an administrative review of the issues while the court retains jurisdiction. *Id*.

If a court chooses to retain jurisdiction over the case and stay the proceedings, it may employ any one of three types of referral: (1) it may do nothing beyond requiring the parties to apply to the administrative agency for a determination;[4] (2) it may request an amicus curiae brief from the administrative agency; [5] or (3) it may certify questions to the agency.[6] After an agency has resolved an issue within its purview, a court can then proceed to resolve the claim in a manner that is consistent with the agency's resolution.[7] 73 C.J.S. Pub. Admin. L. & Proc. § 120.

III. Discussion

Interestingly, the plaintiff completely avoids any discussion of the FDA, its regulations or statutory authority, or its control over medical device issues in her Brief on Primary Jurisdiction [ECF No. 30]. Even more, the plaintiff does not refer to any of the safety issues that so permeated the Complaint and Motion for a TRO and for a Preliminary Injunction. Instead, the plaintiff points out that her underlying Complaint, on its face, does not invoke the Federal Food, Drug, and Cosmetic Act ("FDCA"), but is a suit based on "continued misrepresentations and fraudulent conduct—namely, [Boston Scientific's] smuggling and sale of counterfeit, Chinese mesh that caused *economic injury*." Pl.'s Br. Primary Jurisdiction 4 (emphasis added). The plaintiff argues that applying the doctrine of primary jurisdiction will not promote national

[4] *See Bernhardt v. Pfizer, Inc.*, No. 00-cv-04042-LMM, 2000 WL 1738645 (S.D.N.Y. 2000); *see also Mitchell Coal & Coke Co.*, 230 U.S. at 267 (permitting the case to be stayed to give the plaintiff a reasonable opportunity to seek an administrative determination); Hilliard, *supra*, at 260.
[5] *See Cole v. U.S. Capital, Inc.*, 389 F.3d 719 (7th Cir. 2007).
[6] *See Phillips v. AWH Corp.*, 376 F.3d 1382 (Fed. Cir. 2004).
[7] Where the agency declines to provide guidance at all or in a timely manner, the court may proceed with the litigation without the guidance. *Owner-Operator Indep. Drivers Ass'n., Inc. v. New Prime, Inc.* 192 F.3d 778, 785 (8th Cir. 1999).

uniformity in the field of regulation, and the court will not benefit from agency expertise. *Id*. at 4–9. The court disagrees.

Initially, the FDCA did not regulate the marketing or approval of medical devices, but Congress authorized the FDA's control over the introduction of medical devices with the enactment of the Medical Device Amendments of 1976 ("MDA"). *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475–77 (1996); *see also* David T. Schultz & D. Scott Aberson, *Be Careful What You Ask For: The FDA's Denials of Citizen Petitions Confirms There is No Such Thing as a Limited Premarket Approval*, 39 Wm. Mitchell L. Rev. 1157, 1159–60 (2013) (stating that the MDA expanded the FDA's authority to regulate medical devices).

Under the MDA, a medical device may not be marketed without FDA approval or clearance based upon a statutory classification system. *See* 21 U.S.C. § 360c; *see also Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir. 1994) ("The MDA gives the [FDA] authority over medical devices and authorizes the FDA to issue implementing regulations."). Medical device manufacturers must register each device with the FDA before beginning manufacture. *Martello*, 42 F.3d at 1168. Devices may be cleared through the FDA's expedited 510(k) premarket notification process if the agency determines that the device is substantially equivalent to a pre-existing approved predicate device. *Lohr*, 518 U.S. at 477–79; *see also* Jeffrey Zigler, John Walsh, & Jack Zigler, *Medical Device Reporting: Issues with Class III Medical Devices*, 62 Food & Drug L.J. 573, 573 (2007) (stating that a manufacturer must demonstrate substantial equivalence to a predicate device that was on the market for the same intended use prior to the establishment of the MDA to justify 510(k) clearance).

Once a device is cleared pursuant to the FDA's 510(k) process, the FDA maintains authority over the manufacturer and the device itself. *See generally* 21 U.S.C. § 360j;[8] 21 U.S.C. § 334;[9] 21 U.S.C. § 351(h);[10] 21 U.S.C. § 374.[11] The FDCA, as amended by the MDA, "imposes a comprehensive set of requirements upon medical devices." *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010). For example, the FDA has explicit authority to require medical device manufacturers to (1) conduct post-market surveillance when their devices will be implanted in the human body for more than one year;[12] (2) follow certain labeling rules;[13] (3) report adverse events related to the use of the device, such as severe injury or death;[14] (4) report when the manufacturer removes a device from the market to reduce a risk to public health;[15] (5) recall a medical device;[16] and (6) adopt a method of tracking a device within the marketplace.[17]

The FDA's domain includes authority to prevent or ameliorate the introduction of adulterated or misbranded drugs and devices into the market. *See* 21 U.S.C. §§ 351–52. "Adulterated medical devices are liable to seizure and condemnation at any time" under the FDCA. *United States v. 789 Cases, More or Less, of Latex Surgeons' Gloves, An Article of Device*, 799 F. Supp. 1275, 1285 (D.P.R.1992) (citing 21 U.S.C. § 334(a)(2)(D)). A manufacturer has no right to conduct a business regulated by the FDCA in an unlawful manner. *United States v. Diapulse Corp. of Am.*, 457 F.2d 25, 29 (2d Cir.1972); *see also United States v.*

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[8] The statute establishes general provisions respecting control of devices intended for human use.
[9] The statute provides authority and a procedure for seizing medical devices.
[10] The statute declares a device adulterated if the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with applicable requirements or agency orders.
[11] The statute authorizes FDA inspections.
[12] 21 U.S.C. § 360*l*.
[13] 21 C.F.R. § 801.1, *et seq.*
[14] 21 C.F.R. § 803.1, *et seq.*
[15] 21 C.F.R. § 806.1, *et seq.*
[16] 21 C.F.R. § 810.1, *et seq.*
[17] 21 C.F.R. § 821.1, *et seq.*

Ellis Res. Labs., Inc., 300 F.2d 550, 554 (7th Cir. 1962) (holding that a company can have no vested interest in a business activity found to be illegal). Further, the FDA has broad enforcement power under the FDCA, including the ability to initiate injunction proceedings,[18] seek penalties,[19] issue "debarments" and deny approval of future device applications,[20] and seek criminal prosecution.[21]

In arguing that the FDA has specialized knowledge over at least part of the issues presented in this case, Boston Scientific states "[t]he FDA is best suited to interpret its 510(k) authorization and to make the threshold scientific determinations necessary to do so." Def.'s Br. Primary Jurisdiction 6 [ECF No. 31]. Further, Boston Scientific argues that, "[n]ot only does the FDA have the peculiar expertise and authority to determine the merits of Plaintiff's essential allegations . . . the FDA has specific experience and expertise to fashion remedial measures as necessary." *Id*. at 7. The court agrees.[22]

The plaintiff asks this court to wield its equitable power to restrain Boston Scientific from marketing, selling, or importing its mesh devices containing the alleged counterfeit

[18] 21 U.S.C. § 332.
[19] 21 U.S.C. §§ 333, 335b.
[20] 21 U.S.C. § 335a.
[21] 21 U.S.C. § 336.
[22] While the FDA does have wide-ranging authority to prevent or ameliorate the introduction of adulterated, misbranded, and unauthorized devices into the market, the FDA does not have inherent authority to revoke or rescind clearance issued under its 510(k) process. *Ivy Sports Med., Inc. v. Burwell*, 767 F.3d 81 (D.C. Cir. 2014). In *Ivy Sports*, the FDA claimed that it was using its inherent regulatory power when it rescinded its substantial equivalence determination for a mesh device implanted after common knee surgeries in order to "rectify an error" in its review process. *Id*. at 85. The D.C. Circuit pointed out that "[t]he Act does not contain an express provision granting FDA authority to reconsider its substantial equivalence determinations," and it held that the FDA should have utilized its explicit statutory authority to reclassify the device. *Id*. at 86–87. The issue of revoking or rescinding a 510(k) clearance is not present here, however. As discussed *supra*, the plaintiff alleges that Boston Scientific's mesh device is, in fact, *not* cleared through the FDA's expedited process because, as she alleges, any Advantage mesh produced without authentic Marlex is not an FDA cleared device. *See* Compl. ¶ 10. Alternatively, the issue presented here could be viewed as one where a cleared device is simply in non-compliance with a previous FDA directive (i.e., the duty to be substantially equivalent to a predicate device). Both characterizations, however, certainly present situations where the FDA may act in the first instance pursuant to its broad regulatory authority over the medical device industry.

polypropylene resin. *See, e.g.*, Pl.'s Mot. TRO & Prelim. Inj. 2. As discussed *supra*, many of the factual allegations contained in the Complaint and supporting documents are based on alleged violations of statutes and regulations over which the FDA exercises its expertise and impressive administrative dominance. Congress established an extensive listing of prohibited acts under the FDCA when it enacted 21 U.S.C. § 331. Further, the MDA, which establishes the expedited 510(k) clearance process, is enforced by the FDA—necessitating many specialized scientific determinations. The FDA is in the best position to determine whether Boston Scientific's mesh device is in compliance with the FDA's own statutes, regulations, and directives—particularly because the FDA was the very agency that cleared Boston Scientific's mesh device in the first place. Accordingly, the court **FINDS** that the principle purposes underlying the application of the doctrine of primary jurisdiction are present here. Imposing the severe equitable relief that the plaintiff seeks would prevent the FDA from taking the first action in an area in which that agency clearly has expertise and an interest in the uniform application of its regulatory framework.

Lastly, there is a remedial administrative process at the plaintiff's disposal to address these important issues. Specifically, the FDA has provided a procedure by which private individuals may initiate an administrative proceeding to petition the FDA Commissioner to take administrative action. *See* 21 C.F.R. §§ 10.25, 10.30. In fact, the FDA, through its regulations, has squarely addressed its view of the doctrine of primary jurisdiction as it applies to its authority:

> [The] FDA has primary jurisdiction to make the initial determination on issues within its statutory mandate, and will request a court to dismiss, or to hold in abeyance its determination of or refer to the agency for administrative determination, any issue which has not previously been determined by the agency

> or which, if it has previously been determined, the agency concluded should be reconsidered and subject to a new administrative determination. The Commissioner may utilize any of the procedures established in this part in reviewing and making a determination on any matter initiated under this paragraph.

21 C.F.R. § 10.25(b). Additionally, the FDA regulations state that the FDA Commissioner will institute a proceeding to determine whether to take some form of administrative action whenever a court holds a case in abeyance for an administrative determination. 21 C.F.R. § 10.25(c). Accordingly, the court **FINDS** that the FDA's own regulations contemplate the application of the doctrine of primary jurisdiction and provide procedures to handle referrals when courts apply the doctrine to issues within the agency's statutory mandate.

The court notes that it does not presently have enough information to evaluate the prejudices or hardships, if any, the parties would suffer should the court dismiss this action without prejudice. The court further notes that the plaintiff would be unable to obtain complete relief with an FDA referral, as this case is brought under the RICO Act and West Virginia substantive law. Accordingly, this case is **STAYED** pending the plaintiff's application to the United States Food and Drug Administration for a determination specific to her allegations regarding Boston Scientific's mesh products. The court **RETAINS** jurisdiction over this case, and the plaintiff is **ORDERED** to file a status report with this court on or before May 1, 2016, regarding her effort to seek FDA consideration of these issues. Once the FDA has taken any action relevant to the plaintiff's allegations, the plaintiff is **ORDERED** to provide such information to the court within fourteen days of receipt. The plaintiff is responsible for providing the FDA with notice of this Memorandum Opinion and Order.

The **DIRECTS** the Clerk to retire the case to the court's inactive docket. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party and post a copy of this published opinion on the court's website, www.wvsd.uscourts.gov.

ENTER: January 26, 2016

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Cambridge Polymer Group, INC.
Consultation, Testing, and Instrumentation for Polymeric Materials

Thursday, October 13, 2011

Company: Boston Scientific Corporation
Project Number: 11440
Report Number: 1
Project Manager: Turner

Re: Comparison of polypropylene samples

CPG Quote #: 1585B

Client PO #: 6295967

Report Review (all reviewers must be RS1 or above):

Sign: _____ Date: 10/13/2011

Print: Spiegelberg
Role (RS1, RS2, Exec): Exec

Sign: _____ Date: October 13, 2011

Print: van Buren

Role (RS1, RS2, Exec): RS2

Report sign-off and release to client (final review)

Principal Investigator:

Sign: _____ Date: 10/13/2011

Print: Turner

Role: PI

EXHIBIT
5

Cambridge Polymer Group, INC.
Consultation, Testing, and Instrumentation for Polymeric Materials

Thursday, October 13, 2011

To: Dan Burrill,
Boston Scientific Corporation

Re: Comparison of polypropylene samples

Project Manager: Turner
Project Scientist: Adams, Braithwaite, Nugent, Svirkin, Turner, Wilson-Hill
Report Written by: Braithwaite, Nugent, Turner, Wilson-Hill
Report prepared on: 9/29/2011
Report Reviewed by: Spiegelberg, van Buren

Samples: Polypropylene pellets

CPG sample #	Date received	Client sample description
11440-1	9/9/2011	Sample 1, Lot# PP0353133-02
11440-2	9/9/2011	Sample 2, Lot# 6120105
11440-3	9/20/2011	Sample 3, Lot# 2980058

Equipment: Q1000 DSC; Biorad FTS3000 FTIR with UMA500 microscope; Melt flow die; Shodex: Three Linear GPC Column; HP 6890 GC with an HP 5972A MS; Olympus SZ40 stereo microscope with a 0.5X lens and a Jenoptik SpeedCore 5XT digital camera

1 Summary

A series of tests were conducted on the three poly(propylene) samples received. No difference was detected between the three samples for DSC, FTIR, MFI, and GPC. The OIT for sample 11440-2 was slightly higher than the other two, although all oxidation induction times were within minutes of each other. More residue was extracted from sample 11440-2, and the GC-MS indicated that more compounds were present in the extracted residue of sample 11440-2. The survey scan using ICP showed sample 11440-1 with a wider array of trace metals than the other two samples. Optically, there were also some differences between the samples. Samples 11440-1 and 11440-3 showed more occlusions within the pellet, but samples 11440-2 and 11440-3 were more similar in pellet size.

2 Samples

Three samples of polypropylene pellets were received for analysis. The samples were each assigned a unique CPG number.

3 Experimental

3.1 Differential Scanning Calorimetry (DSC)

Differential scanning calorimetry (DSC) measurements were run using a Q1000 DSC (TA Instruments). The instrument was set up according to CPG SOP0044 (rev. 11/8/2010). One specimen from each sample was tested for thermal analysis. Specimens were prepared in standard aluminum pans according to CPG SOP0043 (rev. 10/1/2009). A clean razor blade was used to section a disc specimen for each sample, which was then weighed on a precision balance (AND GR-202, ± 0.01mg). Each specimen was then crimped between a standard aluminum pan and lid. An empty aluminum pan and lid were used as a reference. A 50 mL/min nitrogen purge was used. The test procedure is listed below:

Equilibrate: -50 ºC
Isothermal: 5.00 min
Ramp Rate: 20.00 ºC/min to 200.00 ºC
Mark End Cycle 1
Isothermal: 5.00 min
Ramp Rate: 20.00 ºC/min to -50.00 ºC
Mark End Cycle 2
Isothermal: 5.00 min
Ramp 20.00 ºC to 200.00 ºC
Mark End Cycle 3

Both the first and second heat curves of all samples were analyzed in TA Universal Analysis 2000 software. A glass transition temperature, Tg [°C], was not observed for any of the three samples in either heat cycle. A linear baseline was constructed to analyze the melt peaks from 40 to 190 °C to determine the onset melt temperature, Tm_o [°C], and peak melt temperature, Tm_p [°C], and by integrating the endotherm to determine the mass-normalized heat of fusion, ΔH [J/g].

3.2 Oxidation Induction Time (OIT)

Oxidation induction time (OIT) was determined using a TA Instruments Q1000 differential scanning calorimeter (DSC) according to ASTM D3895-98. One specimen for each of the three samples was tested. A clean razor blade was used to section each specimen to a mass between 5 and 10 mg. The sample was placed into a standard aluminum pan bottom. An empty aluminum pan bottom was used as a reference. Preparation, instrument set-up, and testing were conducted according to CPG SOP0044 (rev. 11/08/2010).

The testing parameters are listed below:

Set Point: 200.00 °C
Purge gas: Nitrogen
Purge rate: 50 mL/min
Oxygen rate: 50 mL/min

The test procedure is listed below:

Equilibrate: 40 ºC
Ramp Rate: 20.00 ºC/min to 200.00 ºC
Isothermal: 5.00 min
Mark End of Cycle 1
Select Gas 2: Oxygen
Isothermal: 120.00 min
Select Gas 1: Nitrogen
Mark End of Cycle 2
Ramp Rate: 20.00 ºC/min to 40 ºC

3.3 Fourier Transform Infrared Spectroscopy (FTIR)

Fourier transform infrared spectroscopy was performed with a Biorad FTS3000 FTIR with UMA500 microscope. The instrument was aligned and calibrated according to CPG SOP0009 (rev. 10/12/2010). A small section was removed from each sample using a clean razor blade to get a section thin enough for analysis. The spectra were collected in transmission mode with the following parameters:

Aperture size: 200 µm
scans/location: 32
Purge: Nitrogen

3.4 Melt Flow Index (MFI)

Testing was conducted per ASTM D1238-10 Procedure A. The samples did not require drying prior to testing. The melt flow analysis was performed with the following conditions:

Temperature: 230°C
Plunger weight: 2.16 kg
Orifice: 0.0825 inches

Two runs were conducted for each sample.

3.5 Gel Permeation Chromatography (GPC)

Gel permeation chromatography (GPC) was performed on all three samples to determine the molecular weight. The samples were filtered prior to analysis. The test parameters for the samples are shown below, with three injections for each sample:

Solvent: TCB, 135 ºC
Column: Shodex: Three Linear
Flow Rate: 1.0 mL/min
Injection volume: 150 µL
Detector: M-150-C (64/25)
Calibration standards: Polypropylenes

3.6 Contamination Detection

The extractable residues from the polypropylene were analyzed using gas chromatography with mass spectroscopy (GC-MS), with comparisons made to the library database. Any differences in components were noted. The procedure is described in detail below.

3.6.1 Extraction for Elutables

All glassware used was cleaned according to CPG SOP0055 (rev. 8/11/2011); the depyrogenation step was not conducted since pyrogen free glassware was not needed. Each sample was added to a 100 mL flask as received. The total mass of the material added was measured and recorded. Hexane (VWR, ACS grade, ≥98.5%) was then added to the flask to cover the sample material, but no more than half the capacity of the flask. The flask was attached to a condenser cooled with circulated water at 5 °C, and then lowered into a stirred oil bath between 68 and 70 °C. The temperature was adjusted to achieve desired refluxing. After refluxing for 24 hours, the flask was removed from the extraction apparatus. The solvent was poured into a clean beaker of known mass; the sample remained in the flask. This process was repeated twice more for a total reflux time of 72 hours, with fresh hexane replacement every 24 hours. The solvent collection beakers were left open to allow the solvent to evaporate. The remaining cumulative extraction residue was weighed daily until the difference between the consecutive masses was less than 5 %. The amount of extracted residue was then determined as function of the total mass. The mass of the extracted residue was divided by the initial mass of the films and converted to a percent.

3.6.2 Gas Chromatography – Mass Spectroscopy (GC-MS)

Gas chromatography-mass spectrometry (GC-MS) was performed on the extracted residue. For each sample, approximately 20 mL of methylene chloride was added to the residue in the beaker. A portion of the dissolved residue was then placed into GC autosampler vials and analyzed. A spectral library database was used for compound identifications. The chromatographic conditions are listed below:

Instrument: HP 6890 GC with an HP 5972A MS
Column: Rxi-5MS, 30 m x 0.25 mm ID x 0.25 µm film thickness
Carrier: Helium; 0.8 mL/min
Injector Temperature: 250 ºC
Injection Mode: Split 10:1
Injection Volume: 1 µL
Oven Temperature Program: Hold 5.0 min at 35 ºC, 10 ºC/min to 300 ºC, hold 5.0 min at 325 ºC

3.7 Inductively Coupled Plasma (ICP) Spectroscopy

Each sample of polypropylene pellets was analyzed. All of the samples were dry ashed at 600 °C; the ash was dissolved in HNO_3 and HCl. After the acid digestion, the total metals content was measured with inductively coupled plasma/mass spectrometry (ICP/MS). An Agilent Model 7700 ICP/MS system was used for the analysis.

3.8 Optical Microscopy

Optical analysis was performed using an Olympus SZ40 stereo microscope with a 0.5X lens and a Jenoptik SpeedCore 5XT digital camera. No special preparation was performed on the samples, with five individual pellets selected at random from the container.

4 Results

4.1 Differential Scanning Calorimetry (DSC)

The data analysis for the DSC test is summarized Table 1. The overlay of the first heat cycle of all samples is shown in Figure 1. The overlay of the second heat cycle of all samples is shown in Figure 2.

There was no glass transition was observed for any of the samples. All samples have a single melt peak between 150 °C and 160 °C. The onset melt temperature increases slightly from the first heat cycle to the second heat cycle for all the samples. In addition, in samples 11440-2 and 11440-3 a small transition is observed at approximately 50 °C in the first heat cycle only. This is possibly due to different crystal sizes arising from different thermal histories. During the controlled cooling cycle, the samples likely form a more uniform crystalline structure. Therefore, the small transition is not observed in the second heat cycle.

Table 1: Summary of onset melt temperature, peak melt temperature, and enthalpy for all samples.

	Heat Cycle 1		
Sample	Onset Melt Temperature [ºC]	Peak Melt Temperature [°C]	Enthalpy [J/g]
11440-1	150.48	164.49	104.9
11440-2	152.26	161.87	112.1
11440-3	151.69	164.54	111.3
	Heat Cycle 2		
Sample	Onset Melt Temperature [ºC]	Peak Melt Temperature [°C]	Enthalpy [J/g]
11440-1	154.14	163.44	106.9
11440-2	154.60	161.79	109.5
11440-3	157.52	163.67	113.2

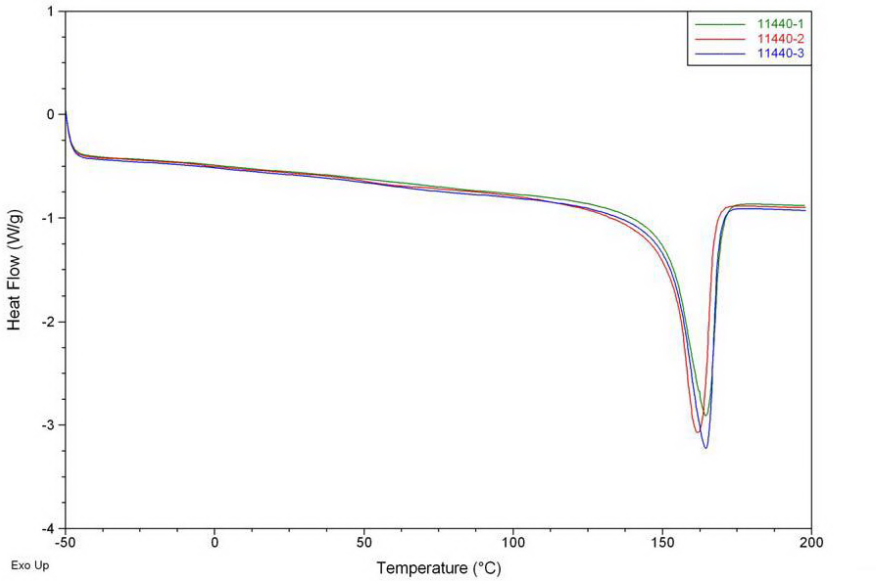


Figure 1: Overlay of curves from the first heat cycle for samples 11440-1 (green line), 11440-2 (red line), and 11440-3 (blue line).

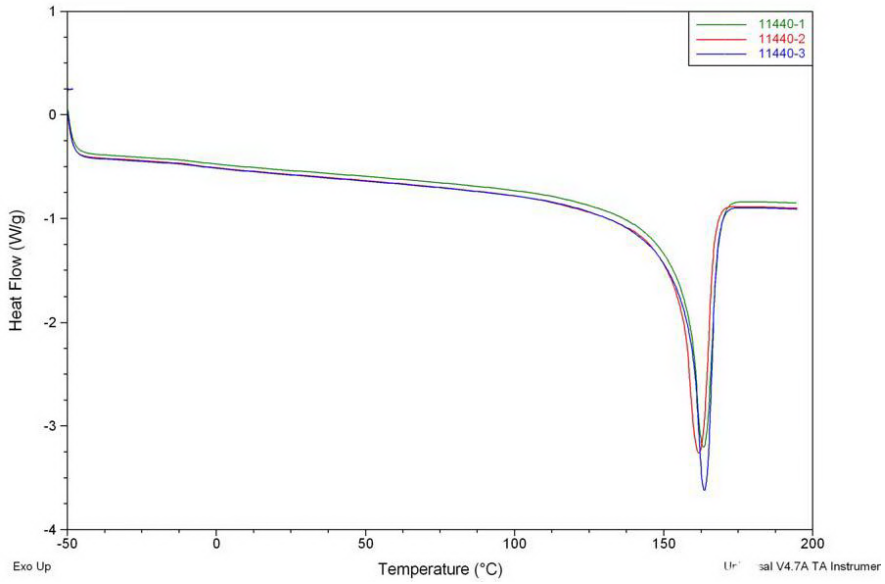


Figure 2: Overlay of curves from the second heat cycle for samples 11440-1 (green line), 11440-2 (red line), and 11440-3 (blue line).

4.2 Oxidation Induction Time (OIT)

The oxidation induction times for each sample are shown in Table 2. Following ASTM D3895-98, the OIT of each sample was determined. Using TA Instruments Universal Analysis 2000 Software, the tangent method was employed and each thermal curve was analyzed. As an example, one can see the tangent method applied to the thermal curve of sample 11440-1 in Figure 3. The oxidation induction time for sample 11440-2 is almost twice the time for the other two samples, although all the measurements are within minutes. The larger oxidation induction time for 11440-2 indicates greater oxidative stability under these test conditions.

Table 2: Oxidation Induction Time results

Sample	Oxidation Induction Time [min]
11440-1	5.61
11440-2	8.23
11440-3	4.49

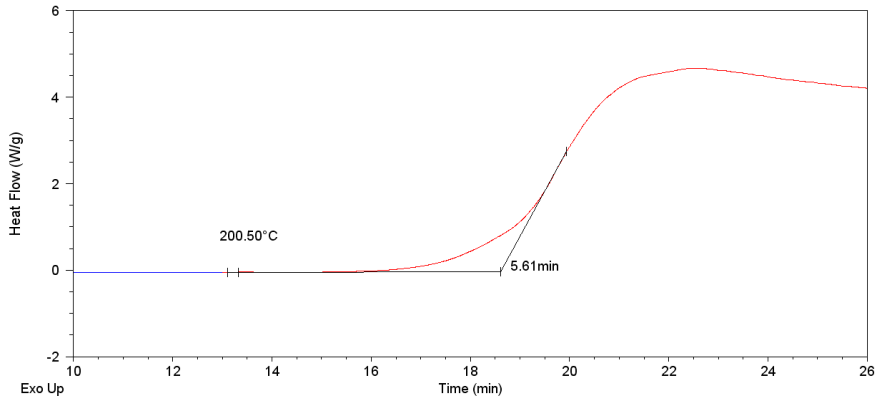


Figure 3: The tangent method employed in determining the OIT of sample 11440-1. The transition from the blue line to the red line indicates the switch from nitrogen to oxygen gas.

4.3 Fourier Transform Infrared Spectroscopy (FTIR)

The FTIR results are shown in Figure 4 and Figure 5. As can be seen, there is no difference between the three spectra.

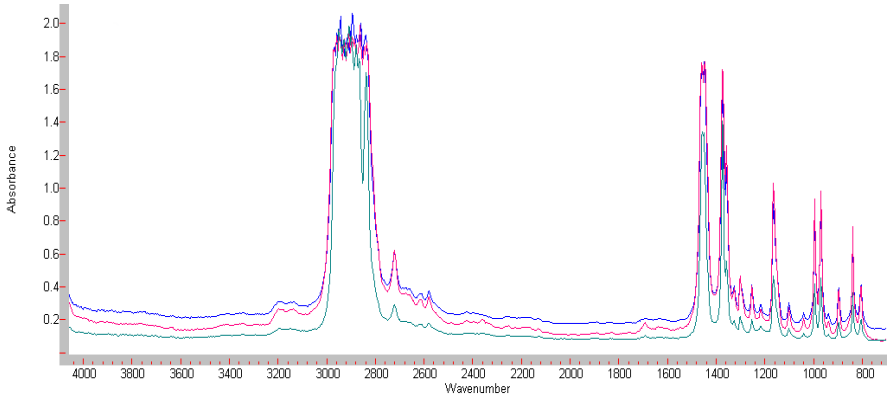


Figure 4: FTIR spectral comparison of sample 11440-1 (green line), 11440-2 (blue line), and 11440-3 (pink line).

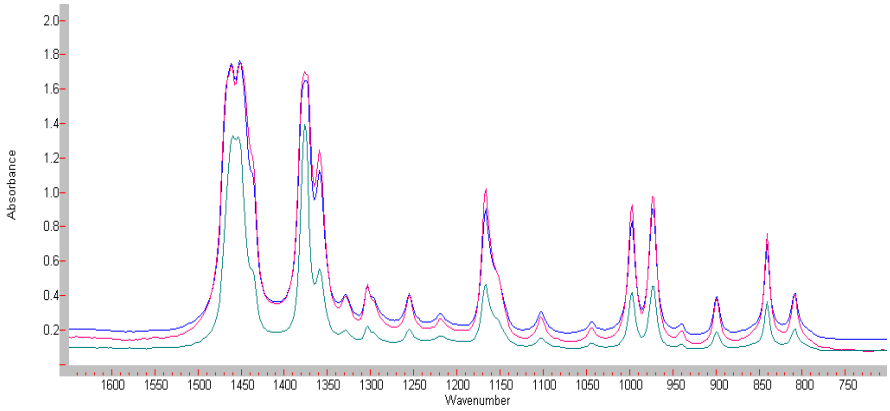


Figure 5: FTIR spectral comparison of sample 11440-1 (green line), 11440-2 (blue line), and 11440-3 (pink line) (expanded scale).

4.4 Melt Flow Index (MFI)

Two runs were conducted on each sample for melt flow index. The results are shown in Table 3. The melt flow index, measured as an average of the two runs, is similar for the three samples but there are slight differences between the samples, with sample 11440-3 having the highest melt flow index.

Table 3: Melt flow index results.

Sample	Time [s]	Mass Extruded [g]		Average Melt Flow Rate [g/10 min]
		Run 1	Run 2	
11440-1	60	0.391	0.389	3.90
11440-2	60	0.375	0.370	3.72
11440-3	60	0.473	0.468	4.70

4.5 Gel Permeation Chromatography (GPC)

The molecular weight moments for all samples, relative to poly(propylene) standards, are shown in Table 4. The calibration curve for the samples is shown in Figure 6. Representative refractive index plots are shown in Figure 7 through Figure 9, and the resulting molecular weight distribution plots are provided in Figure 10 through Figure 12. As can be seen from the spectrum, there is a unimodal distribution of molecular weights as only one peak appears. There is little difference between the molecular weights for the three samples. However, the results are consistent with the MFI results. Sample 11440-2 had the lowest MFI, indicating greater resistance to flow. This sample also had the highest Mz and Mw, which would have the greatest influence on MFI.

Table 4: Molecular weight moments [g/mol] for all samples.

11440-1				
Run	Mn	Mw	Mz	PDI
1	6.76E+04	2.65E+05	7.78E+05	3.93
2	6.83E+04	2.62E+05	7.80E+05	3.84
3	6.82E+04	2.69E+05	7.73E+05	3.94
Average	6.80E+04	2.65E+05	7.77E+05	3.90
St. Dev.	3.91E+02	3.35E+03	3.33E+03	0.06

11440-2				
Run	Mn	Mw	Mz	PDI
1	5.92E+04	2.82E+05	9.01E+05	4.77
2	5.68E+04	2.76E+05	8.36E+05	4.86
3	5.80E+04	2.88E+05	8.86E+05	4.96
Average	5.80E+04	2.82E+05	8.74E+05	4.86
St. Dev.	1.18E+03	5.70E+03	3.39E+04	0.10

11440-3				
Run	Mn	Mw	Mz	PDI
1	5.87E+04	2.55E+05	7.76E+05	4.35
2	6.14E+04	2.63E+05	8.39E+05	4.28
3	6.24E+04	2.62E+05	8.33E+05	4.19
Average	6.08E+04	2.60E+05	8.16E+05	4.27
St. Dev.	1.89E+03	3.94E+03	3.50E+04	0.08

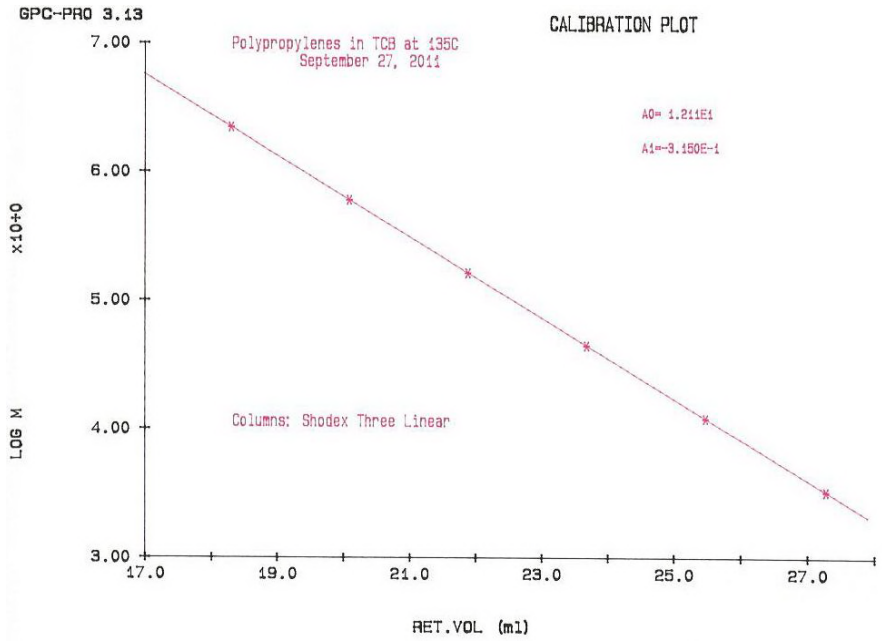


Figure 6: Calibration curve for polypropylenes in TCB at 135 ºC.

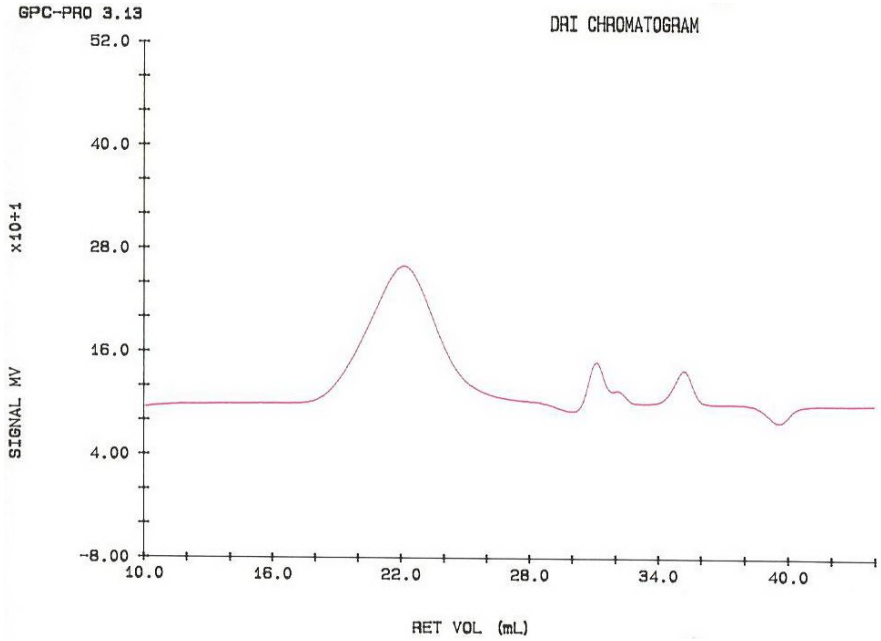


Figure 7: Representative raw refractive index signal for sample 11440-1.

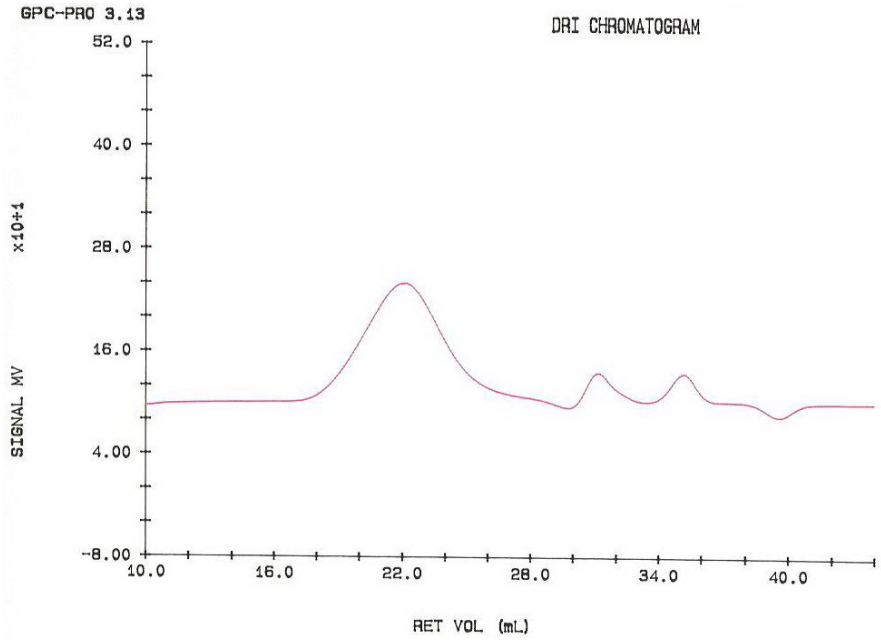


Figure 8: Representative raw refractive index signal for sample 11440-2.

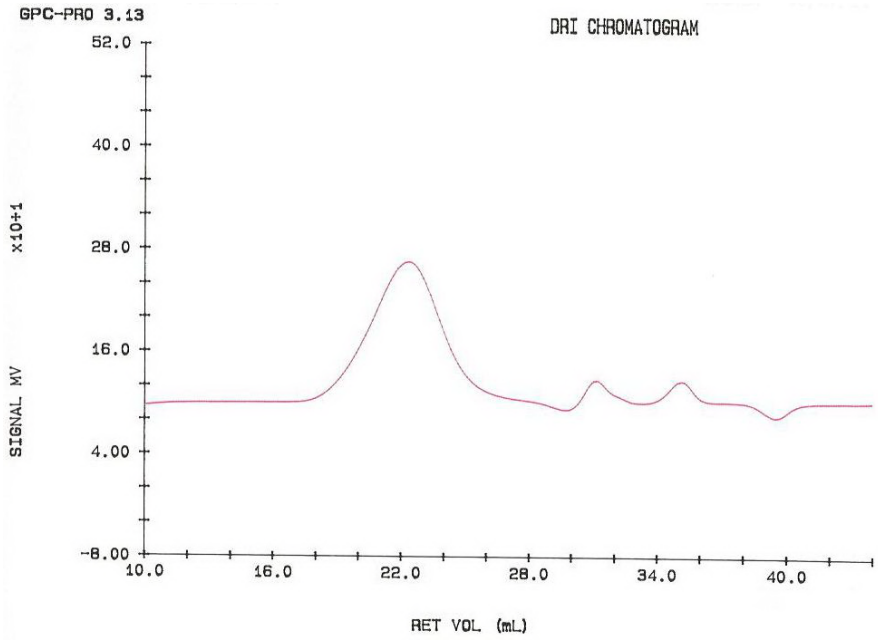


Figure 9: Representative raw refractive index signal for sample 11440-3.

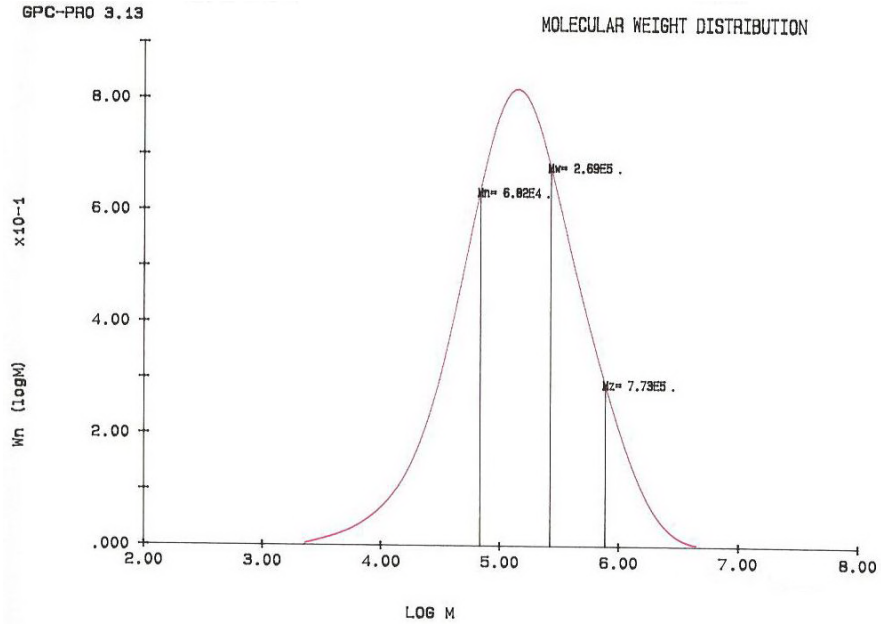


Figure 10: Representative molecular weight distribution for sample 11440-1.

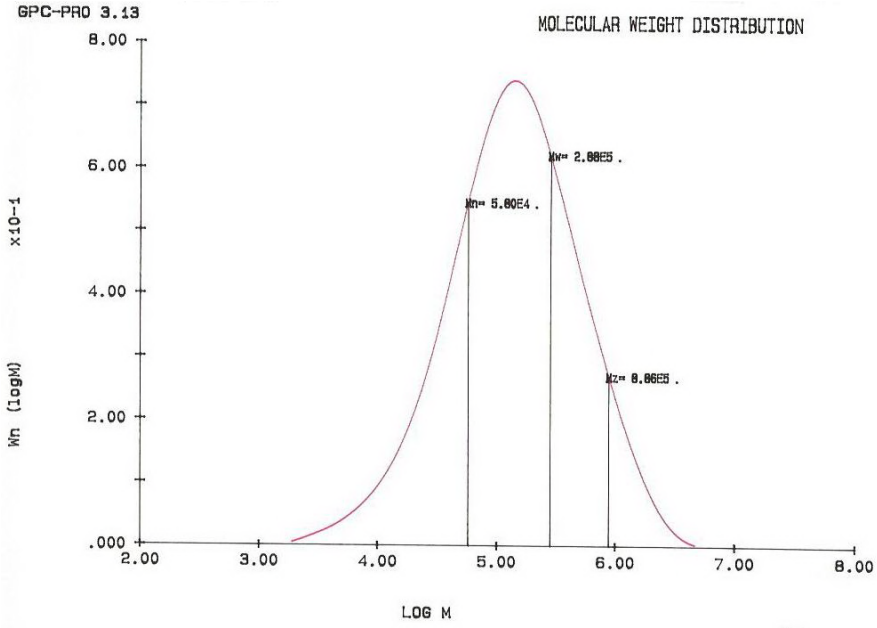


Figure 11: Representative molecular weight distribution for sample 11440-2.

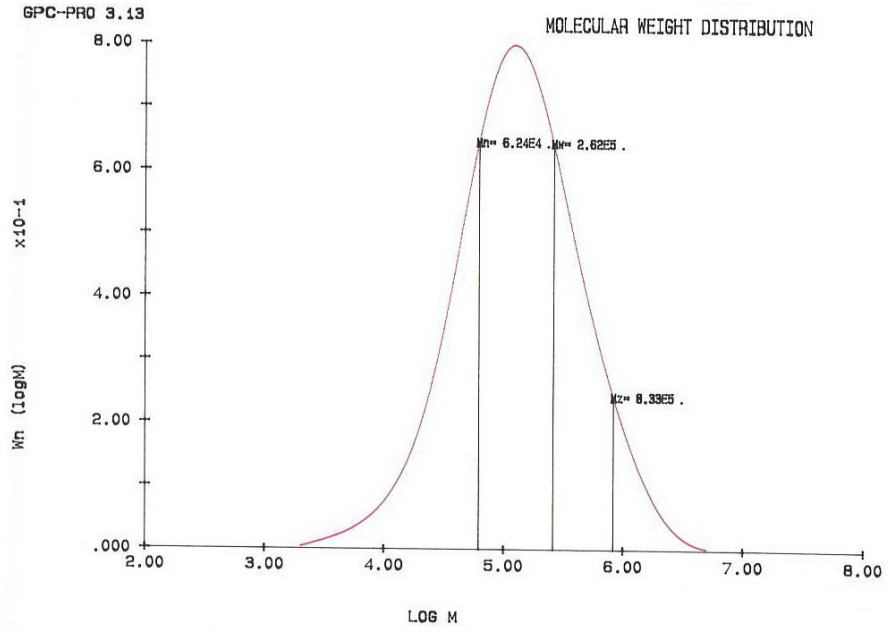


Figure 12: Representative molecular weight distribution for sample 11440-3.

4.6 Contamination Detection

4.6.1 Extraction for Elutables

The amount of extractable residue from the three samples is shown in Table 5. The amount of residue extracted for samples 11440-1 and 11440-3 is very similar. However the amount of residue extracted for sample 11440-2 is more than double the amount extracted for the other two samples.

Table 5: Extractable residue results, based on mass.

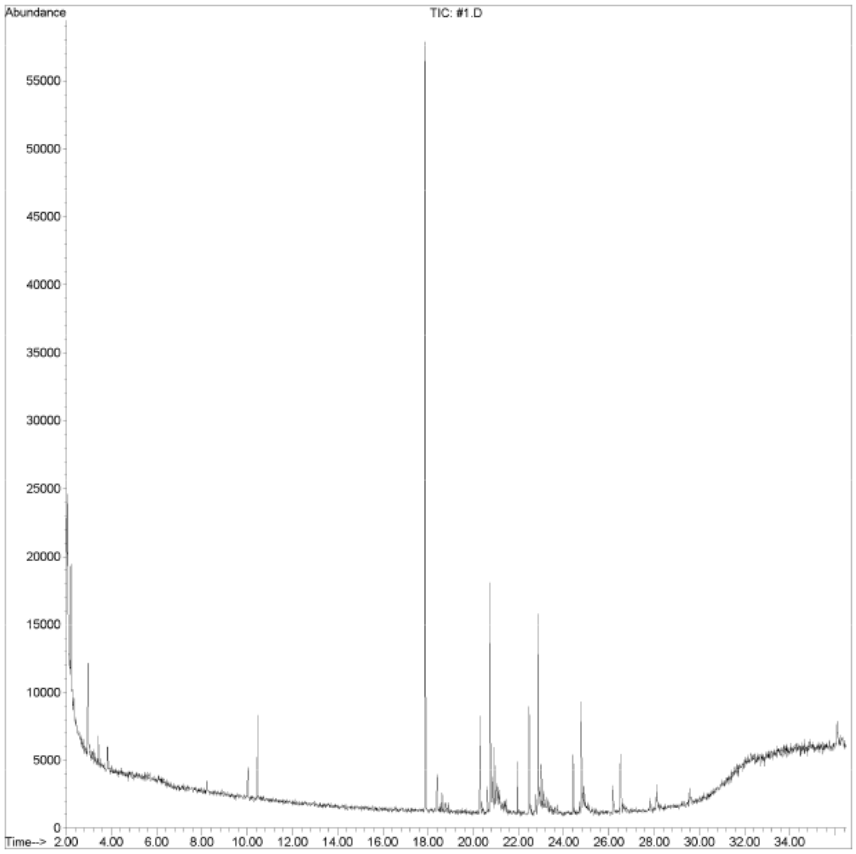
Sample	Mass of Sample [g]	Extracted Residue [mg]	Percent of Total Mass Extracted [%]
11440-1	5.85	37.6	0.64
11440-2	6.01	86.1	1.43
11440-3	6.21	37.9	0.61

4.6.2 Gas Chromatography – Mass Spectroscopy (GC-MS)

The ion chromatograms for the three samples are shown in Figure 13 to Figure 15 with a summary table shown below each figure. The mass spectroscopy identification of the compounds is summarized in Table 6. As shown, the types of fragments detected for the three residue samples are similar but the residue from sample 11440-2 seems to have a higher level of these compounds present. The majority of the extracted compounds are long chain aliphatic hydrocarbons; however there appears to be a few aromatic fragments detected by the GC-MS for sample 11440-2.

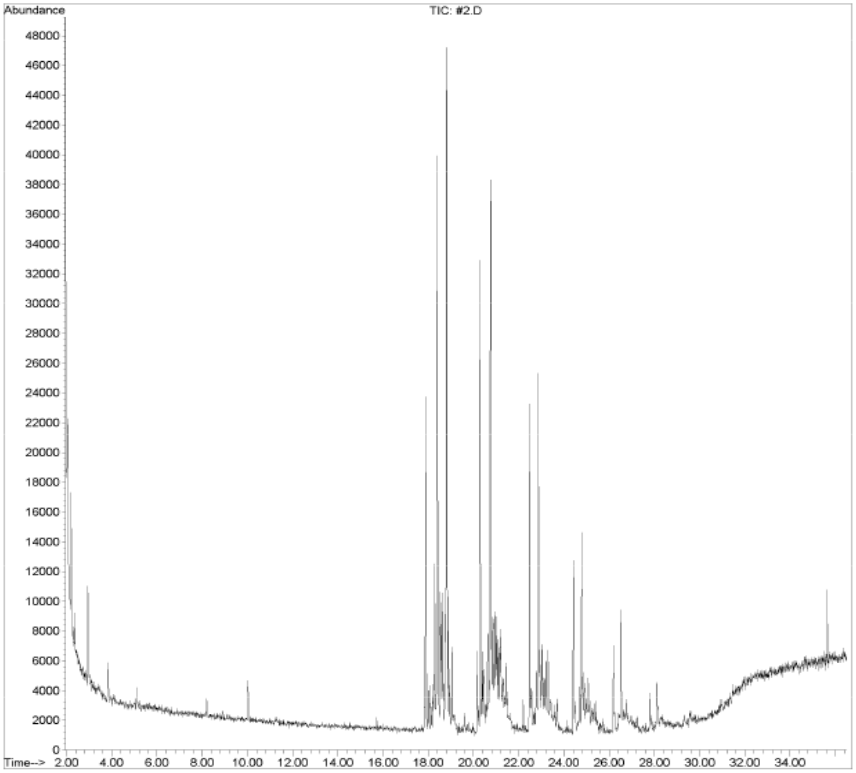
It is most likely that two compounds with the same retention time are the same compound. However, it is difficult to tell the difference between the larger alkanes because they undergo extensive fragmentation

during ionization and appear similar afterwards. The best match found for the mass spectra of each peak is chosen from the spectral library, but this assignment is not definitive.



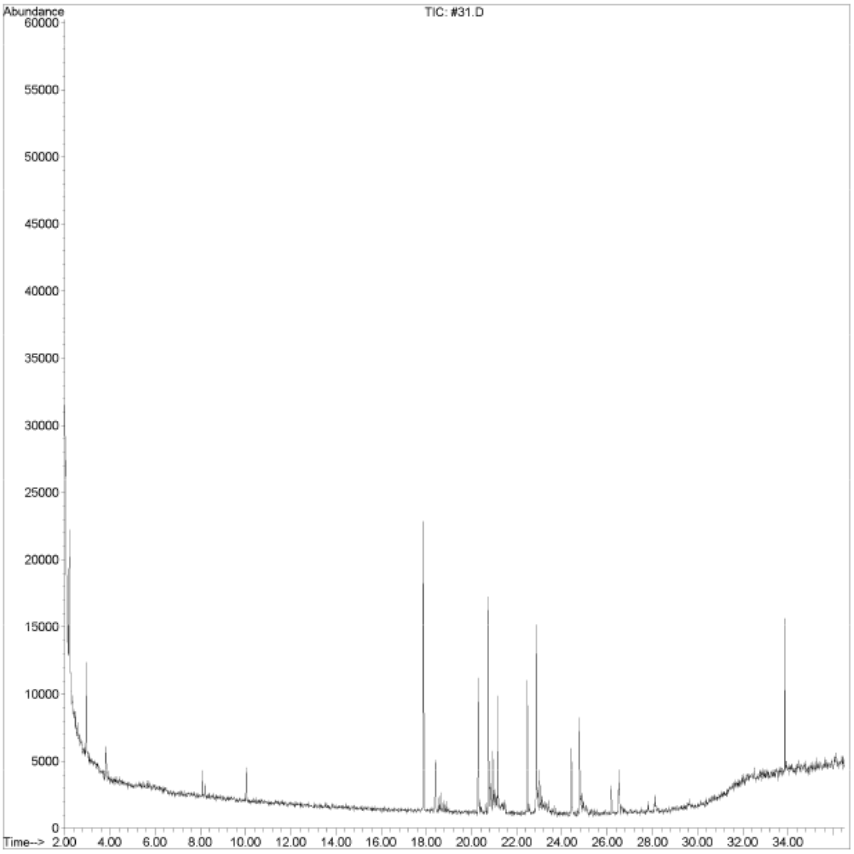
Retention Time [min]	Peak Area ($x10^6$) [counts]	Best Spectral Library Match
17.87	0.96	No acceptable spectral match
20.30	0.15	Pentacosane
20.75	0.31	Tetracosane
22.46	0.14	Tetracosane
22.87	0.25	Nonadecane
24.78	0.16	Heptadecane

Figure 13: Total ion chromatogram for sample 11440-1 including chemical species identification through a spectral library match.



Retention Time [min]	Peak Area (x10^6) [counts]	Best Spectral Library Match
17.87	0.41	Heptadecane
18.29	0.21	Bis dimethylethyl phenol
18.40	0.83	Docosane
18.52	0.20	Tetracosane
18.63	0.19	Tetracosane
18.81	1.01	Hydroxy benzoic acid
20.30	0.55	Tetracosane
20.75	0.82	Tetracosane
20.85	0.22	Tetracosane
22.47	0.35	Nonadecane
22.87	0.46	Pentadecane
24.42	0.20	Tetracosane
24.77	0.22	Heptadecane
26.51	0.19	Pentacosane

Figure 14: Total ion chromatogram for sample 11440-2 including chemical species identification through a spectral library match.



Retention Time [min]	Peak Area ($x10^6$) [counts]	Best Spectral Library Match
17.87	0.31	No acceptable spectral match
20.30	0.17	Pentadecane
20.75	0.31	Tetracosane
22.87	0.21	Tetracosane

Figure 15: Total ion chromatogram for sample 11440-3 including chemical species identification through a spectral library match.

Table 6: Chemical species found in the three samples using GC-MS analysis. The majority of compounds are long chain alkanes, and discretion between chain lengths is challenging. The compounds checked in red are not simple alkanes.

Component	11440-1	11440-2	11440-3
Bis dimethylethyl phenol		✓	
Docosane		✓	
Heptadecane	✓	✓	
Hydroxy benzoic acid		✓	
Nonadecane	✓	✓	
Pentacosane	✓	✓	
Pentadecane		✓	✓
Tetracosane	✓	✓	✓
Unidentified compound	✓		✓

4.7 Inductively Coupled Plasma (ICP) Spectroscopy

The data for the inductively coupled plasma spectroscopy of all samples is summarized in Table 7. There are some common elements between the three samples, however sample 11440-1 showed a larger array of trace metals than the other two samples. All the samples showed high levels of selenium. As this is a rare and toxic element, this result is unusual and should be verified using another technique, such as SEM-EDS.

Table 7: Data summary of all samples for survey scan of metals. Note that *ND* indicates that the element was not detected within the detection limits.

	Concentration by weight [ppm]			
Element	11440-1	11440-2	11440-3	Detection Limit
Be	43.0	ND	ND	0.01
Na	ND	ND	ND	0.05
Mg	ND	ND	ND	0.05
Al	106	ND	25.9	0.01
K	ND	ND	ND	0.10
Ca	ND	ND	ND	0.01
Ti	ND	280	ND	0.01
V	20.9	ND	ND	0.01
Cr	33.1	ND	ND	0.01
Mn	6.8	ND	ND	0.01
Fe	36.1	ND	ND	0.01
Co	16.4	ND	ND	0.01
Ni	27.4	ND	ND	0.01
Cu	14.7	ND	ND	0.01
Zn	ND	ND	ND	0.01
As	ND	ND	ND	0.01
Se	1500	1700	2160	0.01
Sr	29.2	ND	14.8	0.01
Mo	ND	ND	ND	0.01
Cd	ND	ND	ND	0.01
Sn	ND	ND	ND	0.01
Sb	ND	ND	ND	0.01
Ba	10.4	15.7	34.3	0.01
Tl	ND	ND	ND	0.01
Pb	ND	ND	ND	0.01

4.8 Optical Microscopy

Initially, five pellets were drawn from each container and photographed individually. Images for sample 11440-1 are provided in Figure 16, for 11440-2 in Figure 17 and finally 11440-3 in Figure 18. Note that the scale bar should be treated as reference only. In addition, a further 15 specimens (five from each sample group) were removed and photographed at the same time using oblique lighting (see Figure 19). Image analysis was used to determine the long- and short-axis, perimeter and area of the pellets as viewed (see Table 8). Statistically samples 11440-2 and -3 are the same size (p=0.52) with sample 11440-1 statistically smaller. In contrast, samples 11440-1 and 11440-3 visually both exhibit marked internal occlusions, presumably due to different cooling conditions during pelletization. Sample 11440-2 is almost completely devoid of internal occlusions and may have a slightly different surface finish. There was no visible evidence of contaminants in the form of specks or debris, although some images suggest the presence of small fibers. However, given the packaging provided, these are not surprising. Examples are provided in Figure 20.

Table 8: Calculated parameters for images shown in Figure 19

	Axis 1 [mm]	Axis 2 [mm]	Aspect Ratio	Perimeter [mm]	Area [mm^2]
11440-1.1	3.87	3.97	1.03	12.24	11.51
11440-1.2	4.27	3.85	1.11	12.62	12.28
11440-1.3	3.87	3.70	1.04	11.88	10.93
11440-1.4	3.70	3.83	1.03	12.07	11.18
11440-1.5	4.19	3.76	1.11	12.45	12.00
Average	3.98	3.82	1.07	12.25	11.58
St. Dev.	0.24	0.10	0.04	0.30	0.56
11440-2.1	4.79	4.19	1.14	14.02	15.23
11440-2.2	4.44	4.35	1.02	13.57	14.31
11440-2.3	4.36	4.19	1.04	13.47	14.08
11440-2.4	4.52	4.22	1.07	13.63	14.23
11440-2.5	4.65	4.31	1.08	14.20	15.56
Average	4.55	4.25	1.07	13.78	14.68
St. Dev.	0.17	0.07	0.05	0.31	0.67
11440-3.1	4.51	4.08	1.10	13.34	13.59
11440-3.2	4.54	4.27	1.06	13.95	15.09
11440-3.3	4.92	4.24	1.16	14.11	15.17
11440-3.4	3.87	4.74	1.23	13.57	14.07
11440-3.5	3.85	4.77	1.24	13.54	14.03
Average	4.34	4.42	1.16	13.70	14.39
St. Dev.	0.47	0.31	0.08	0.32	0.70

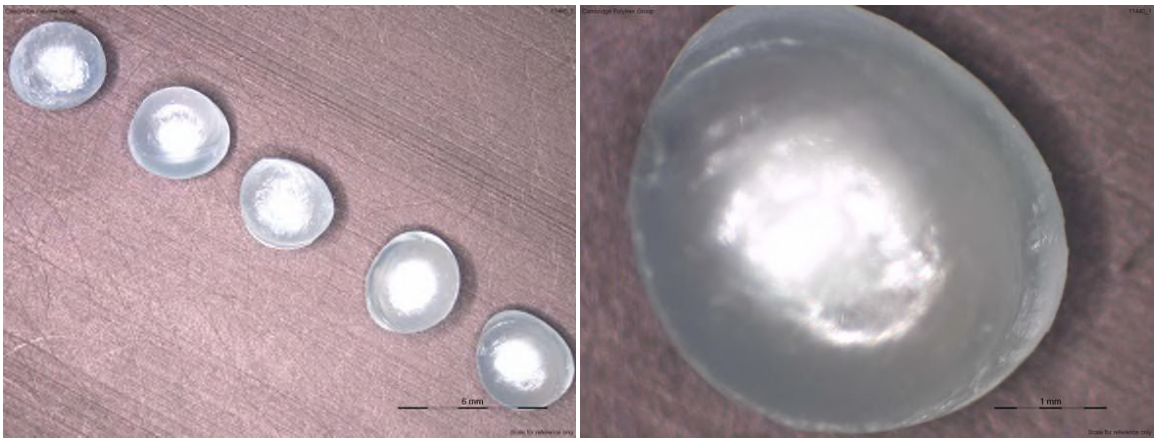


Figure 16: Five randomly obtained pellets for 11440-1. Additional image shows single representative zoom of far right pellet.

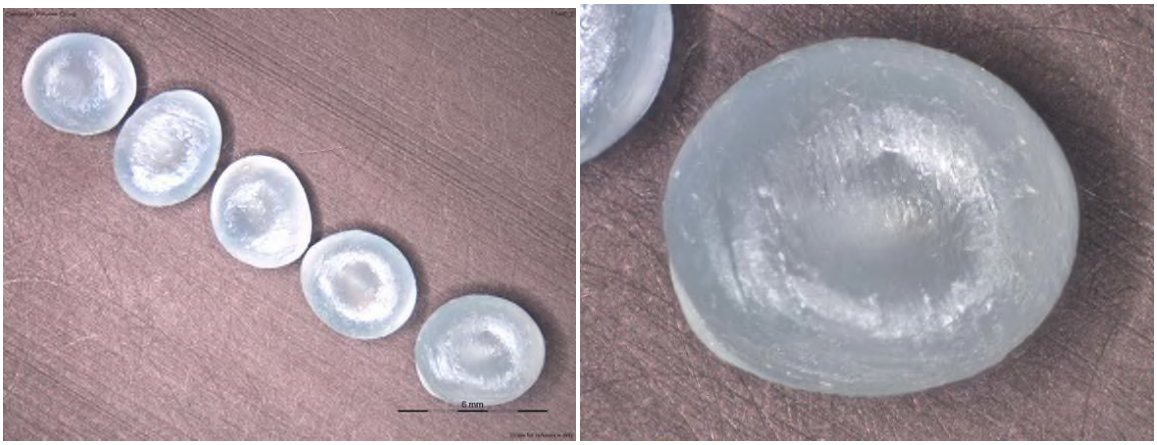


Figure 17: Five randomly obtained pellets for 11440-2. Additional image shows single representative zoom of far right pellet.

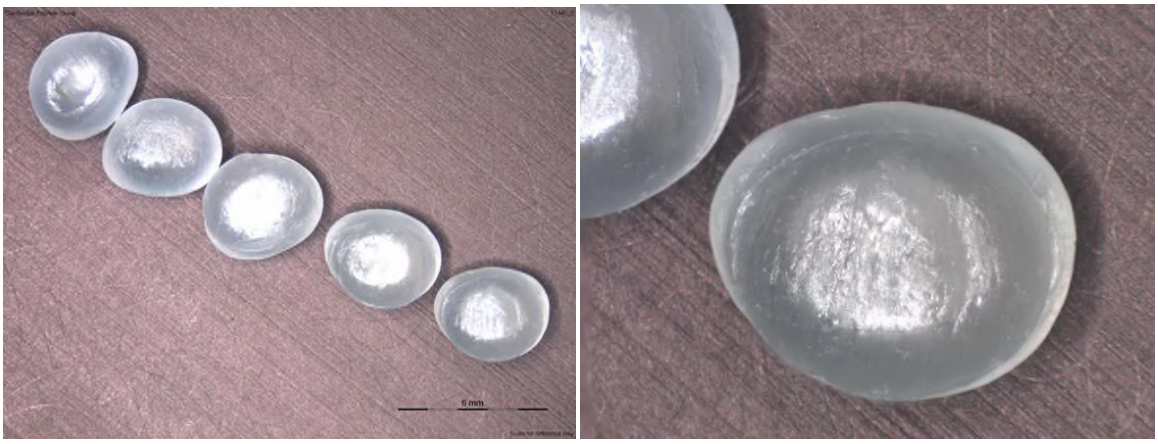


Figure 18: Five randomly obtained pellets for 11440-3. Additional image shows single representative zoom of far right pellet.

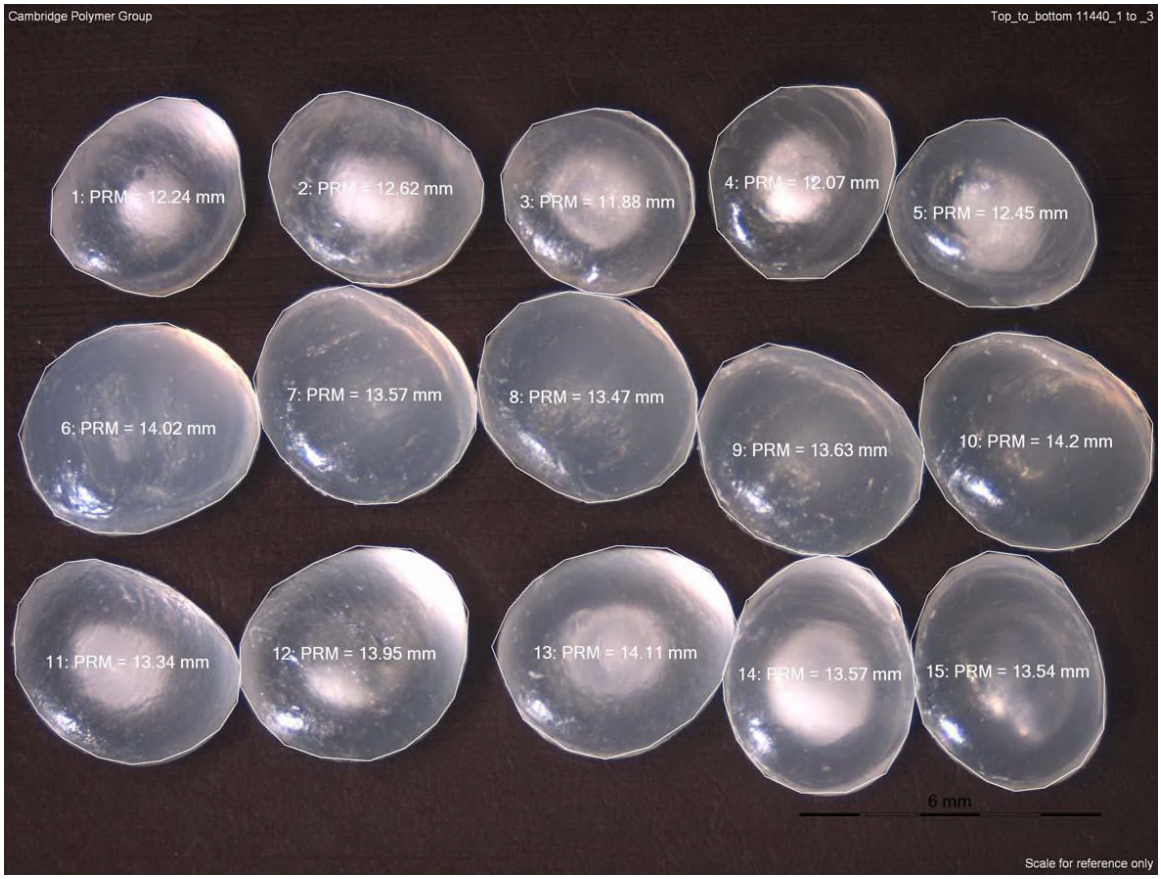


Figure 19: Comparison of all three sample groups with calculated perimeter shown. Other parameters are provided in Table 8.

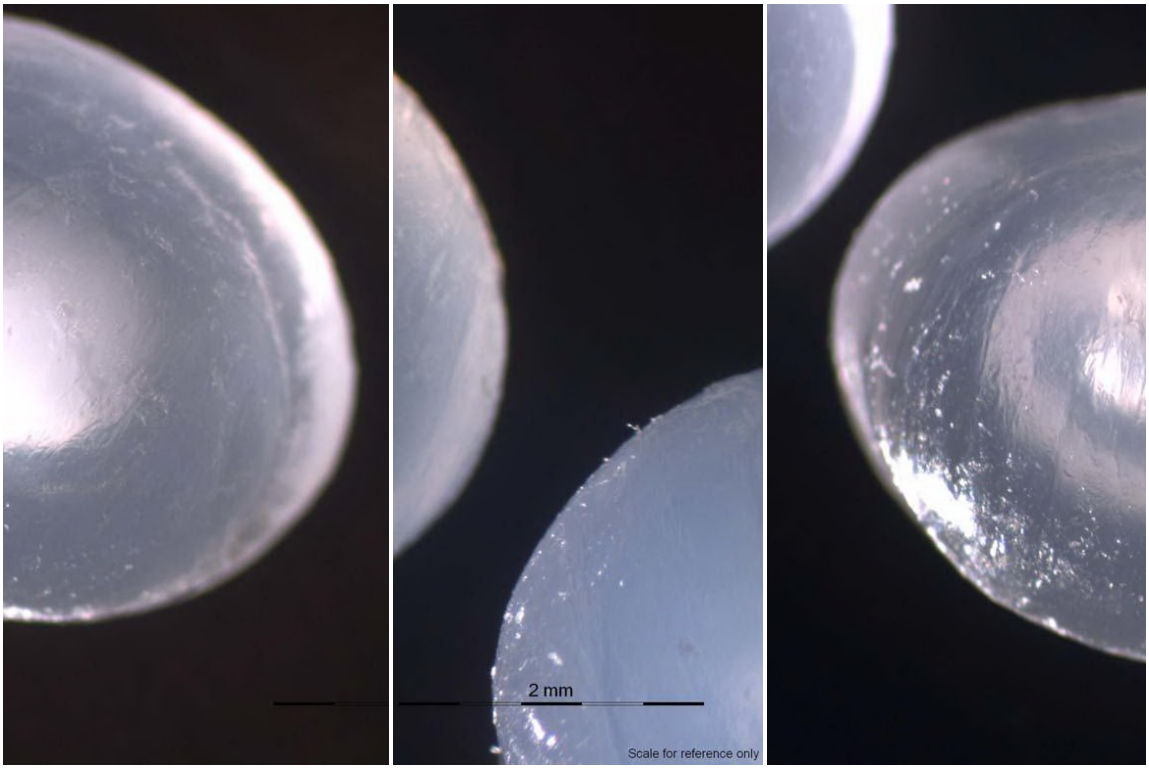


Figure 20: Examples of visible debris on the specimens

News & Events

FDA NEWS RELEASE
For Immediate Release: March 11, 2010
Media Inquiries: Peper Long, 301-796-4671, mary.long@fda.hhs.gov
Consumer Inquiries: 888-INFO-FDA

FDA Issues Warning on Counterfeit Surgical Mesh

Counterfeit polypropylene mesh products marketed as C. R. Bard/Davol

The U.S. Food and Drug Administration today warned health care providers and consumers about counterfeit surgical mesh being distributed in the United States under the C. R. Bard/Davol brand name. Surgical mesh products are used to reinforce soft tissue where weakness exists.

The warning is of particular significance to health care professionals and their patients with surgical mesh implants as well as hospitals and surgical centers, operating room medical professionals and staff, and purchasing and risk managers.

Investigations by the FDA and Bard show that the following products, sizes and lots of counterfeit flat sheet polypropylene surgical mesh are not manufactured by Bard. To date, four product sizes have been identified:

0112650 – Bard Flat Mesh 2”x 4”	Lot 48HVS036
Lot 43APD007	
0112660 – Bard Flat Mesh 10”x 14”	Lot HUSD0629
Lot HURL0336	
0112680 – Bard Flat Mesh 3”x 6”	Lot 43HPD027
	Lot 43HPD032
	Lot HUSG0540
	Lot 43HDP027
Lot HUSE0532	Lot 43LPD507
	Lot HUSF0763
	Lot 43IOD011
	Lot 43IPD038
0112720 – Bard Flat Mesh 6” x 6”	Lot 43FQD327

The FDA is recommending that health care professionals:

Do not use any counterfeit Bard surgical mesh from the lots listed
Carefully examine all manufacturers’ polypropylene surgical mesh products and packaging for lot numbers and anything unusual that might indicate counterfeit mesh
Contact Bard at 800-556-6275 if they think they have one of the counterfeit products
Contact the particular manufacturer if they notice anything unusual or suspicious with any other brand of surgical mesh product or packaging

The FDA also recommends that health care professionals continue to monitor patients for adverse events as they would any patient with an authentic polypropylene surgical mesh implant, if they suspect or know that counterfeit mesh has been implanted.

Patients should contact their surgeon if they experience problems that they think may be related to surgical mesh.

The FDA continues to gather information and data on the counterfeit mesh to better understand its potential public health impact. The agency also is working to determine who may be responsible and how the counterfeiting and distribution occurred.

At this time, the FDA does not know if the counterfeit surgical mesh meets the authentic product’s specifications, including its strength, sterility, or clinical performance. The FDA assessment of the counterfeit mesh and its potential risk to health is ongoing.

Health care professionals who believe they have received counterfeit or suspect product are asked to contact the FDA’s Office of Criminal Investigations at 800-551-3989 or by visiting the Web site at http://www.fda.gov/OCI[12].

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspec a problem with this or any counterfeit surgical mesh, the FDA encourages you to file a voluntary report through MedWatch, the FDA’s Safety Information and Adverse Event Reporting Program.

Health care professionals and consumers are encouraged to report serious adverse events (side effects) that may be related to the use of these counterfeit products to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, fax or phone.

Online: www.fda.gov/MedWatch/report.htm [13]

Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm [14]. Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787
Fax: 800-FDA-0178
Phone: 800-332-1088

Health care providers employed by facilities that are subject to FDA's user facility reporting requirements[15] should follow the reporting procedures established by their facilities.

For more information:

FDA’s Initial Communication: Safety Investigation of Counterfeit Polypropylene Surgical Mesh
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm [16]

#

EXHIBIT 6

RSS Feed for FDA News Releases[17] [what is RSS?[18]]

Page Last Updated: 04/24/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

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2. http://www.addthis.com/bookmark.php
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11. /NewsEvents/Newsroom/PressAnnouncements/2013/default.htm
12. /ICECI/CriminalInvestigations/default.htm
13. http://www.fda.gov/Safety/MedWatch/ucm2005699.htm
14. http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
15. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm
16. http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm203886.htm
17. /AboutFDA/ContactFDA/StayInformed/RSSFeeds/PressReleases/rss.xml
18. ssLINK/ucm144575.htm

For more information and technical assistance contact:

Phillips Sumika Polypropylene Company
P.O. Box 4910
The Woodlands, TX 77387-4910
800.231.1212 ext 4849

Marlex® HGX-030-01

Polypropylene Homopolymer, Fiber Grade, Low Water Carryover

Applications:

- Woven industrial fabric and bags
- Rope and cordage
- Woven carpet backing
- Woven geotextile fabrics

Agency Information:

- Meets FDA Regulation 21 CFR 177.1520 and is suitable for food packaging applications.

Nominal Properties

Property	English	SI	Method
Density	0.905 g/cc	0.905 g/cc	ASTM D1505
Melt Flow Rate, @ 230°C	3.8 g/10min	3.8 g/10min	ASTM D1238
Tensile Strength at Yield, 50 mm/min	5,350 psi	36.9 MPa	ASTM D638
Flexural Modulus, Secant, 1.3 mm/min	230,000 psi	1,590 MPa	ASTM D790
Notched Izod Impact Strength, @ 23°C	0.7 ft*lbf/in	37 J/m	ASTM D256
Heat Deflection Temperature, @ 0.455 MPa	214 °F	101 °C	ASTM D648
Rockwell Hardness, R Scale	97	97	ASTM D785
Shore D Hardness	71	71	ASTM D2240

Mechanical properties were determined using injection-molded specimens 1/8" (3.2mm) thick molded per ASTM D4101, unless otherwise noted.

The nominal properties reported herein are typical of the product but do not reflect normal testing variance and therefore should not be used for specification purposes.

EXHIBIT 7

Boston Scientific Corporation
100 Boston Scientific Way, Marlborough, MA 01752

510(k) Pre-Market Notification

SURGICAL MESH

K020110

January 9, 2002

EXHIBIT
8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 3 2002

Ms. Lorraine M. Hanley
Director
Global Regulatory Affairs
Boston Scientific/Urology
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K020110
Trade Name: Surgical Mesh
Regulation Number: 878.3300
Regulation Name: Surgical mesh, polymeric
Regulatory Class: II
Product Code: FTL
Dated: January 9, 2002
Received: January 11, 2002

Dear Ms. Hanley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices. good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use Statement

510(k) Number (if Known): K020110

Device Name: Surgical Mesh

Indications For Use:

It is intended for treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency and to reinforce soft tissue where weakness exists in the urological, gynecological, or gastroenterological anatomy. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-The-Counter Use (Optional Format 1-2-96)**

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K020110

Boston Scientific
MICROVASIVE

Microvasive Urology
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
508-650-8000
www.bsci.com

January 9, 2002

Food and Drug Administration
Center for Devices and Radiological Health
510(k) Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: **Original Abbreviated 510(k) Premarket Notification for the Surgical Mesh**

Dear Sirs/Madame;

Pursuant to 21 CFR 807.81, Boston Scientific / Urology, hereby submits three copies of this Abbreviated Premarket Notification for the **Surgical Mesh**, and three copies of this cover letter.

The purpose of this current 510(k) premarket notification is to introduce a modification to the Trelex Mesh (K945733) surgical mesh, which has been cleared for reinforcing soft tissue where weakness exists. The proposed device is also substantially equivalent to predicate devices intended for the treatment of stress urinary incontinence (SUI) resulting form urethral hypermobility and/or intrinsic sphincter deficiency. This includes but is not limited to the following procedures: pubourethral support and bladder support, urethral and vaginal prolapse repair, reconstruction of the pelvic floor, and sacro-colposuspension. All these predicate devices are classified in 21CFR 878.3300: Mesh, surgical, polymeric, product code FTL.

Boston Scientific has elected to notify its intent to market the proposed **Surgical Mesh** through an Abbreviated 510(k) submission. Section I of this document includes introductory information as suggested in the Guidance for the Preparation of a Premarket notification Application for Surgical Mesh, March 2, 1999. The "Summary of Safety and Effectiveness" is located in Section III, the "Statement of Intended Use" is in Section IV, and the " Truthful and Accuracy Statement" is located in Section V. The "Declaration of Conformity with Recognized Consensus Standards and Guidances" is provided in Section VI.

At this time, Boston Scientific is not aware that this device is subject to Section 522 of the Federal Food, Drug, and Cosmetic Act (The Act), i.e., Postmarket Surveillance. It is the understanding of Boston Scientific/ Urology that written notification will be received from FDA if this device is subject to section 522 of The Act.

The terms "substantially equivalent","similar", and related terms and descriptions in this notification are defined terms or words of art defined by the Food and Drug Administration as those words are used in the Federal Food, Drug, and Cosmetic Act as amended and the regulations promulgated thereunder and are not to be construed or interpreted for any other purpose.

Boston Scientific/Urology has not publicly disclosed or acknowledged the fact of its intent to market this product to any individual outside its employ, other than disclosures made under commercial agreements containing appropriate safeguards for secrecy. As a result, Boston Scientific/ Urology considers its intent to manufacture this device for distribution under its own label to be confidential commercial information and exempt from public domain. Boston Scientific understands that data contained in this submission will be restricted from release under the Freedom of Information Act for at least 90 days or until concurrence is gained. To the best of our knowledge, conditions of confidentiality in 21CRF807.95 have been maintained.

If you have any questions about the Premarket Notification, please contact me at 508-650-8172.

Sincerely,

Lorraine M. Hanley

Lorraine M. Hanley
Director, Global Regulatory Affairs
Boston Scientific/ Urology
Telephone Number: (508) 650-8172
Fascimile: (508) 650-8144

Administrative Assistant: (508) 647-2573

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Exhibit VIII-1 Material Specifications

Exhibit VIII. Material Specifications

A. Resin CoA and MSDS
B. Monofilament Product Specification

Exhibit VIII. Material Specifications

A. Resin CoA and MSDS
B. Monofilament Product Specification

PHILLIPS CHEMICAL COMPANY
A DIVISION OF PHILLIPS PETROLEUM COMPANY
BOX 792 • PHONE: 713 475-3666
PASADENA, TEXAS 77501-0792

PHILLIPS PLASTICS RESINS
Houston Chemical Complex

April 02, 1997

JHV# 6636-97

FAX: 803-754-7991

Shakespeare Monofilament Co.
6111 Shakespeare Road
Columbia, SC 29223

Kenneth DuPree

This letter will certify that the Marlex* resin shown below, as supplied by Phillips Sumika Polypropylene Company, conforms to our manufacturing specification.

Shakespeare Part Number: 90094

Type:	HGX-030-01
Lot Number:	2971205
P.O. Number:	27376
Date Shipped:	04/01/97
Package:	BAG
Quantity:	44080 LBS.
Melt Flow:	3.5 G/10 MIN

J. H. Vaden
Quality Assurance Manager

For COA questions call Sharon Robinette, 713-475-3625

* Reg. U.S. Pat. Off.

cc: QA-File-RC
D. E. Powell

LOT APPROVED
FOR RELEASE TO
MANUFACTURING
By
Date 4/3/97

VIII-3

Marlex

HIGH PERFORMANCE POLYPROPYLENES

Marlex® HGX-030-01

Polypropylene Homopolymer, Fiber Grade, Low Water Carryover

Nominal Physical Properties (3)	ASTM Test Method	Traditional Units	SI Units
Density (1)	D1505	0.909 g/cc	909 Kg/m^3
Melt Flow, Condition 230 °C/2.16Kg	D1238	3.5 g/10 min	3.5 g/10 min
Tensile Yield Strength (2) *Type 1 Specimen, Rate: 2"/min*	D638	5,200 psi	36 MPa
Flexural Modulus Tangent (1) *Rate 0.5"/min*	D790	260,000 psi	1,792 MPa
Izod Impact Strength (2) Notched, at 73 °F (23 °C) Unnotched, at 73 °F (23 °C)	D256	0.5 ft*lbf/in No Break	27 J/m No Break
Heat Deflection Temperature (2) 66 psi (0.45 MPa) 264 psi (1.82 MPa)	D648	220 °F 150 °F	104 °C 66 °C
Hardness, Shore D (2)	D2240	74	74
Agency Information:	• Meets FDA Regulation 21 CFR 177.1520 and is suitable for food packaging applications		
Suggested Applications:	• Woven Industrial Fabric and Bags, Woven Carpet Backing, Woven Bags, Woven Geotextile Fabrics, Rope and Cordage		

1) Tests performed using compression-molded specimens.
(2) Tests performed using injection-molded specimens.
(3) The nominal properties reported herein are typical of the product but do not reflect normal testing variance and therefore should not be used for specification purposes.

March 1999

Phillips Sumika Polypropylene Company

Material Safety Data Sheet

MARLEX® POLYPROPYLENES (All Grades)

August 29, 1997

PHILLIPS SUMIKA POLYPROPYLENE COMPANY
2625 Bay Area Blvd., Suite 500
Houston, Texas 77058

PHONE NUMBERS
Emergency: (918) 661-8118
Technical Information: (918) 661-3072
For Additional MSDSs: (281) 244-3116
Product Information: (800) 231-1212

A. Product Identification

Synonyms: Plastic
Chemical Name: Propylene Polymers and Copolymers plus Additives
Chemical Family: Olefin Polymers and Copolymers plus Additives
Chemical Formula: Mixture
CAS Reg. No.: Mixture-See Section B for ingredient CAS Reg. No.
Product No.: Marlex Series

Product and/or Components Entered on EPA's TSCA Inventory: Yes

This product is in U.S. commerce, and is listed in the Toxic Substances Control Act (TSCA) Inventory of Chemicals; hence, it may be subject to applicable TSCA provisions and restrictions.

B. Components

This product, as shipped by Phillips Sumika Polypropylene Company, does not meet the definition of a hazardous material as given in 29 CFR Part 1910.1200 (OSHA). Information on this form is furnished as a customer service.

Ingredients	CAS Number	% By Wt.	OSHA PEL*	ACGIH TLV*
Polypropylene	9003-07-0	50-99	NE	NE
or				
Propylene Ethylene Copolymer	9010-79-1	50-99	NE	NE
also may contain:				
Polyethylene	9002-88-4	0-49	NE	NE
Ethylene Butene Copolymer	25087-34-7	0-49	NE	NE
Ethylene-Hexene-1 Copolymer	25213-02-9	0-49	NE	NE
Ethylene-Octene-1 Copolymer	26221-73-8	0-49	NE	NE
Additives	Various	0-4	NE	NE

* Also see Section F, Other Health Effects

C. Personal Protection Information

Ventilation: Use adequate ventilation to control concentration below recommended exposure limits. During molding and extruding processes, local exhaust may be needed to control off gases.

Respiratory Protection: Not generally required unless needed to prevent respiratory irritation from dust or off gases. If necessary during molding and extruding processes, use NIOSH/MSHA approved air purifying respirator equipped with an organic vapor cartridge and face mask. If concentrations of dust are high, use NIOSH/MSHA approved single-use dust respirator.

Eye Protection: Not generally required. Use chemical goggles if needed to prevent irritation from dust or off gases.

Skin Protection: No special garments required. Use heat resistant gloves when handling hot or molten material. When cleaning thermal decomposition off gas condensate from equipment, use full-body, long-sleeved garments to prevent skin contact.

NOTE: Personal protection information shown in Section C is based upon general information as to normal uses and conditions. Where special or unusual uses or conditions exist, it is suggested that the expert assistance of an industrial hygienist or other qualified professional be sought.

D. Handling and Storage Precautions

Wear protective equipment and/or garments described in Section C if exposure conditions warrant. Avoid breathing vapors, mists, fumes or dust. Wash thoroughly after handling. Launder contaminated clothing before reuse.

Store in a closed container. Store in a well-ventilated area. Moving pellets may generate static electric charge. Bond and ground during transfer.

Process only with adequate ventilation. Avoid breathing vapors from thermal processing off gases. Avoid eye or skin contact with thermal processing off gases. Thermal decomposition processing off gas condensate may form on surrounding equipment.

E. Reactivity Data

Stability: Stable
Conditions to Avoid: Not Applicable
Incompatibility (Materials to Avoid): Oxidants

Hazardous Polymerization: Will Not Occur
Conditions to Avoid: Not Applicable
Hazardous Decomposition Products: Carbon oxides and various hydrocarbon gases. Also, see Section F.

F. Health Hazard Data

Recommended Exposure Limits:

Control as Particulate Not Otherwise Classified (PNOC) or Regulated:

	OSHA PEL	ACGIH TLV
Respirable Fraction	5 mg/m3	3 mg/m3
Total Dust	15 mg/m3	10 mg/m3

Acute Effects of Overexposure:

Eye: Dust may cause mechanical irritation. Processing off gas vapors may cause irritation.

Skin: Essentially non-irritating.

Inhalation: Dust may produce mechanical irritation to the mucous membranes of the nose, throat and upper respiratory tract. Processing off gas vapors may cause irritation to the mucous membranes of the upper respiratory tract.

Ingestion: Essentially non-toxic and inert.

Subchronic and Chronic Effects of Overexposure:

Subchronic animal feeding studies have demonstrated no adverse effects with diets containing 5% or less polymer.

Other Health Effects:

Long term exposure to high dust concentrations may cause non-debilitating lung changes.

Thermal decomposition studies on polypropylene indicate that aldehydes (formaldehyde, acrolein, acetaldehyde, propionaldehyde, butyraldehyde, benzaldehyde); ketones (acetone, methyl ethyl ketone) and organic acids (formic acid, acetic acid) may be released during processing. These substances may be irritating to the mucous membranes of the eyes, nose, mouth, throat and lungs. Irritant effects should be transitory and can be eliminated with adequate ventilation.

Formaldehyde, which may be produced during thermal processing, is covered by the Formaldehyde Standard, 29 CFR 1910.1048.

Exposure to carbon monoxide, a combustion product of polypropylene, can result in carboxyhemoglobinemia. Carboxyhemoglobinemia is frequently misdiagnosed as flu.

Chronic exposure to carbon monoxide causes fatigue, poor memory, loss of sensation in fingers, visual disturbances and insomnia.

Subpopulations sensitive to the inhalation of carbon monoxide exist. Carbon monoxide displaces oxygen in the bloodstream and therefore, can adversely affect people with pre-existing heart disease, pregnant women and smokers.

Molten polymer may cause severe thermal burns. The interior of molten masses may remain hot for some time because of low thermal conductivity of the polymer. Use care when disposing of or handling such masses.

Health Hazard Categories:

	Animal	Human		Animal	Human
Known Carcinogen	___	___	Toxic	___	___
Suspect Carcinogen	___	___	Corrosive	___	___
Mutagen	___	___	Irritant	___	___
Teratogen	___	___	Target Organ Toxin	___	___
Allergic Sensitizer	___	___	Specify - No known applicable		

Highly Toxic ___ ___ information.

First Aid and Emergency Procedures:

NOTE: For thermal burns, cool quickly with water and seek immediate medical attention. Do not peel off solidified material.

Eye: Flush eyes with running water for at least fifteen minutes. If irritation or adverse symptoms develop, seek medical attention.

Skin: Wash skin with soap and water for at least fifteen minutes. If irritation or adverse symptoms develop, seek medical attention.

Inhalation: Remove from exposure. If breathing is difficult or irritation develops, seek medical attention.

Ingestion: Give two glasses of water and induce vomiting, only if subject is conscious. Seek medical attention.

G. Physical Data

Appearance:	Opaque, translucent waxy pellets or fluff.
Odor:	Mild
Boiling Point:	Not Applicable
Vapor Pressure:	Not Applicable
Vapor Density (Air = 1):	Not Applicable
Solubility in Water:	Negligible
Specific Gravity (H2O = 1):	Density is 0.88-0.92 g/cm3
Percent Volatile by Volume:	Negligible
Evaporation Rate (Butyl Acetate=1):	Not Applicable
Viscosity:	Not Applicable

H. Fire and Explosion Data

Flash Point (Method Used):	650F (343C) (ASTM D1929)
Flammable Limits (% by Volume in Air):	LEL - Not Applicable UEL - Not Applicable
Fire Extinguishing Media:	Dry chemical, foam or carbon dioxide (CO2)
Special Fire Fighting Procedures:	Evacuate area of all unnecessary personnel. Wear appropriate safety equipment for fire conditions including NIOSH/MSHA self-contained breathing apparatus (SCBA) and other protective equipment and/or garments as described in Section C if exposure conditions warrant. Use water fog or spray to cool exposed equipment and containers.
Fire and Explosion Hazards:	Carbon oxides and various hydrocarbons may be released when burned.

I. Spill, Leak and Disposal Procedures

Precautions Required if Material is Released or Spilled:
Wear protective equipment and/or garments described in Section C if exposure conditions warrant. If concentrations of product dust in air is high, eliminate all poss
ible ignition sources. Control dusts by wetting down with water spray. Spilled pellets may create slipping hazard. Sweep or vacuum up spill and place in drums for recovery or disposal. Keep out of water sources and sewers.

Waste Disposal (Insure Conformity with all Applicable Disposal Regulations):
Recover for reuse, recycle, incinerate for energy or place in a waste management facility.

J. DOT Transportation

Shipping Name: Not Applicable
Hazard Class: Not Applicable
ID Number: Not Applicable
Packing Group: Not Applicable
Marking: Not Applicable
Label: Not Applicable
Placard: Not Applicable
Hazardous Substance/RQ: Not Applicable
Shipping Description: Not Applicable
Packaging References: Not Applicable

K. RCRA Classification - Unadulterated Produc

Prior to disposal, consult your environmental contact to determine if the TCLP (Toxicity Characteristic Leaching Procedure, EPA Test Method 1311) is required. Reference 40 CFR Part 261.

L. Protection Required for Work on Contaminat

Contact immediate supervisor for specific instructions before work is initiated. Wear protective equipment and/or garments described in Section C if exposure conditions warrant.

M. Hazard Classification

___ This product meets the following hazard definition(s) as defined by the Occupational Safety and Health Hazard Communication Standard (29 CFR Section 1910.1200):

___ Combustible Liquid
___ Compressed Gas
___ Flammable Gas
___ Flammable Liquid
___ Flammable Solid
___ Flammable Aerosol
___ Explosive
___ Health Hazard (Section F)
___ Organic Peroxide
___ Oxidizer
___ Pyrophoric
___ Unstable
___ Water Reactive

_X_ Based on information presently available, this product does not meet any of the hazard definitions of 29 CFR Section 1910.1200.

N. Additional Comments

SARA 313

As of the preparation date, this product did not contain a chemical or chemicals subject to the reporting requirements of Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

NFPA 704 Hazard Codes - - - - - - - - Signals

Health : 0	Least - 0
Flammability: 1	Slight - 1
Reactivity : 0	Moderate - 2
Special Haz.: -	High - 3
	Extreme - 4

Phillips Sumika Polypropylene Company

Material Safety Data Sheet

SECTION 1 PRODUCT AND COMPANY IDENTIFICATION

MARLEX® POLYPROPYLENES (ALL GRADES)

Product Use: Coatings
Synonyms: PLASTIC
Product Cas No.: MIXTURE

Company Identification:
Chevron Phillips Chemical Company LP
10001 Six Pines Drive
The Woodlands, TX 77380

Product Information:
MSDS Requests: (800) 852-5530
Technical Information: (800) 852-5531

24-Hour Emergency Telephone Numbers
HEALTH :CT Emergency Information Center (800) 231-0623 or (510) 231-0623
TRANSPORTATION : North America: CHEMTREC (800) 424-9300 or (703) 527-3887
ASIA: (800) ALERTSGS or (800) 25378747 or +65+6542+9595
EUROPE: BIG +32+14+584545 (phone) or +32+14+583516 (telefax)
SOUTH AMERICA SOS-Cotec Inside Brazil: 0800+111+767
Outside Brazil: 55+19+3467+1800

MEDICAL APPLICATION CAUTION: Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

Do not use this Chevron Phillips Chemical Company LP material in medical applications involving brief or temporary implantation in the human body or contact with internal body fluids or tissues unless the material has been provided directly from Chevron Phillips Chemical Company LP under an agreement which expressly acknowledges the contemplated use.

Chevron Phillips Chemical Company LP makes no representation, promise, express warranty or implied warranty concerning the suitability of this material for use in implantation in the human body or in contact with internal body fluids or tissues.

SECTION 2 COMPOSITION/ INFORMATION ON INGREDIENTS

COMPONENT	CAS NUMBER	AMOUNT	EINECS	SYM	R-PHRASES

EXHIBIT 9

PROPYLENE ETHYLENE COPOLYMER	9003-07-0	50 - 99 % weight	NA	NA	NA
POLYPROPYLENE	9003-07-0	50 - 99 % weight	NA	NA	NA
POLYETHYLENE	9002-88-4	< 49 % weight	EXEMPT	NA	NA
POLYETHYLENE HEXENE COPOLYMER	25213-02-9	< 49 % weight	NA	NA	NA
ETHYLENE-OCTENE-1COPOLYMER	26221-73-8	< 49 % weight	NA	NA	NA
POLYETHYLENE BUTENE COPOLYMER	25087-34-7	< 49 % weight	NA	NA	NA
RELATED MATERIALS	VARIOUS	< 4 % weight	NA	NA	NA

Occupational Exposure Limits:

Component	Limit	TWA	STEL / Peak	Ceiling	Notation
PROPYLENE ETHYLENE COPOLYMER	CPCHEM	Not Established	NA	NA	NA
POLYPROPYLENE	CPCHEM	Not Established	NA	NA	NA
POLYETHYLENE	CPCHEM	Not Established	NA	NA	NA
POLYETHYLENE HEXENE COPOLYMER	CPCHEM	Not Established	NA	NA	NA
ETHYLENE-OCTENE-1COPOLYMER	CPCHEM	Not Established	NA	NA	NA
POLYETHYLENE BUTENE COPOLYMER	CPCHEM	Not Established	NA	NA	NA

Control as Particulate Not Otherwise Classified (PNOC). The ACGIH Guideline* for respirable dust is 3.0 mg/m3 and 10.0 mg/m3 for total dust. The OSHA PEL for respirable dust is 5.0 mg/m3 and 15.0 mg/m3 for total dust.

* This value is for inhalable (total) particulate matter containing no asbestos and < 1.0% crystalline silica.

SECTION 3 HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW
Opaque, translucent waxy pellets or fluff, mild odor.

- FORMALDEHYDE MAY BE PRODUCED AT ELEVATED TEMPERATURE.
- DUST MAY PRODUCE MECHANICAL IRRITATION TO THE MUCOUS MEMBRANES OF THE EYES, NOSE, THROAT AND UPPER RESPIRATORY TRACT

IMMEDIATE HEALTH EFFECTS:
Eye: Contact with the eyes may cause irritation due to the abrasive action of the dust. Not expected to cause prolonged or significant eye irritation. Material is dusty and may scratch the surface of the eye.
Skin: Not expected to be harmful to internal organs if absorbed through the skin. Contact with the skin is not expected to cause prolonged or significant irritation.
Ingestion: Not expected to be harmful if swallowed.
Inhalation: Not expected to be harmful if inhaled. The dust from this material may cause respiratory irritation.

SECTION 4 FIRST AID MEASURES

Eye: Flush eyes with water immediately while holding the eyelids open. Remove contact lenses, if worn, after initial flushing, and continue flushing for at least 15 minutes. Get medical attention if irritation persists.
Skin: If the hot material gets on skin, quickly cool in water. See a doctor for extensive burns. Remove contaminated clothing and shoes. Wash skin with soap and water. Wash or clean contaminated clothing and shoes before reuse.
Ingestion: If swallowed, do not induce vomiting. Give the person a glass of water or milk to drink and get immediate medical attention. Never give anything by mouth to an unconscious person.
Inhalation: Move the exposed person to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if breathing difficulties continue.

SECTION 5 FIRE FIGHTING MEASURES

Explosive dust clouds may be produced.
FIRE CLASSIFICATION:
OSHA Classification (29 CFR 1910.1200): Not classified by OSHA as flammable or combustible.
NFPA RATINGS: **Health:** 1 **Flammability:** 1 **Reactivity:** 0
FLAMMABLE PROPERTIES:
Flashpoint: 343°C (649.4°F)
Autoignition: NDA
Flammability (Explosive) Limits (% by volume in air): **Lower:** NA **Upper:** NA

EXTINGUISHING MEDIA: Use water fog, foam, dry chemical or carbon dioxide (CO2) to extinguish flames.

PROTECTION OF FIRE FIGHTERS:
Fire Fighting Instructions: This material will burn although it is not easily ignited. For fires involving this material, do not enter any enclosed or confined fire space without proper protective equipment, including self-contained breathing apparatus. If possible, water should be applied as a spray from a fogging nozzle since this is a surface burning material. The application of high velocity water will spread the burning surface layer.
Combustion Products: Incomplete combustion can also produce formaldehyde. Normal combustion forms carbon dioxide, water vapor and may produce carbon monoxide, original monomer, other hydrocarbons and hydrocarbon oxidation products, depending on temperature and air availability. Highly dependent on combustion conditions. A complex mixture of airborne solids, liquids, and gases including carbon monoxide, carbon dioxide, and unidentified organic compounds will be evolved when this material undergoes combustion.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Protective Measures: Eliminate all sources of ignition in vicinity of spilled material.
Spill Management: Stop the source of the release if you can do it without risk. Contain release to prevent further contamination of soil, surface water or groundwater. Clean up spill as soon as possible, observing precautions in Exposure Controls/Personal Protection. Use appropriate techniques such as applying non-combustible sorbent materials or pumping. Where feasible and appropriate, remove contaminated soil. Place contaminated materials in disposable containers and dispose of in a manner consistent with applicable regulations. Avoid creating dust clouds. Shovel, sweep up or use industrial vacuum cleaner to pick up. Place in container for proper disposal. Reduce airborne dust and prevent scattering by moistening with water.
Reporting: U.S.A. regulations require reporting spills of this material that could reach any surface waters. Report spills to local authorities and/or the U.S. Coast Guard National Response Center

at (800) 424-9802 as appropriate or required.

SECTION 7 HANDLING AND STORAGE

READ AND OBSERVE ALL PRECAUTIONS ON PRODUCT LABEL . REFER TO PRODUCT LABEL OR MANUFACTURERS TECHNICAL BULLETINS FOR THE PROPER USE AND HANDLING OF THIS MATERIAL .

Precautionary Measures: Use caution to avoid creation of dusts and to prevent inhalation of product dust (fines). Avoid contact with product dust. Airborne dust concentrations above 20 mg/l may create a dust explosion hazard. Keep out of water sources and sewers. Spilled pellets may create a slipping hazard. Avoid breathing vapors or fumes which may be released during thermal processing. Do not breathe dust at levels above the recommended exposure limits. Avoid breathing material. Keep container closed. Use only with adequate ventilation. Avoid contact with eyes, skin and clothing. Discard contaminated clothing and shoes or thoroughly clean before resuse. Do not breathe dust. Avoid contaminating soil or releasing this material into sewage and drainage systems and bodies of water.
Unusual Handling Hazards: At extrusion temperatures (>350F, >177C), polyethylenes can release vapors and gases, which are irritating to the mucous membranes of the eyes, mouth, throat, and lungs. These substances may include acetaldehyde, acetone, acetic acid, formic acid, formaldehyde and acrolein. Based on animal data and limited epidemiological evidence, NTP, IARC (2A), and OSHA have listed formaldehyde as a probable human carcinogen. Following all recommendations within this MSDS should minimize exposure to thermal processing emissions.
Static Hazard: Electrostatic charge may accumulate and create a hazardous condition when handling this material. To minimize this hazard, bonding and grounding may be necessary but may not, by themselves, be sufficient. Review all operations, which have the potential of generating an accumulation of electrostatic charge and/or a flammable atmosphere (including tank and container filling, splash filling, tank cleaning, sampling, gauging, switch loading, filtering, mixing, agitation, and vacuum truck operations) and use appropriate mitigating procedures. For more information, refer to OSHA Standard 29 CFR 1910.106, 'Flammable and Combustible Liquids, National Fire Protection Association (NFPA 77), Recommended Practice on Static Electricity' (liquids, powders and dusts), and/or the American Petroleum Institute (API) Recommended Practice 2003, 'Protection Against Ignitions Arising Out of Static, Lightning, and Stray Currents' (liquids).
General Storage Information: Treat as a solid that can burn. Store away from oxidizing materials, in a cool, dry place with adequate ventilation. Bond and ground transfer equipment. DO NOT USE OR STORE near heat, sparks or open flames. USE AND STORE ONLY IN WELL VENTILATED AREA. Keep container closed when not in use.
Container Warnings: Container is not designed to contain pressure. Do not use pressure to empty container or it may rupture with explosive force. Empty containers retain product residue (solid, liquid, and/or vapor) and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, static electricity, or other sources of ignition. They may explode and cause injury or death. Empty containers should be completely drained, properly closed, and promptly returned to a drum reconditioner or disposed of properly. Containers, even those that have been emptied, can contain residues of dusts or solid particulates which may create both health and fire/explosion hazards.

SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

GENERAL CONSIDERATIONS:
Consider the potential hazards of this material (see Section 3), applicable exposure limits, job

activities, and other substances in the work place when designing engineering controls and selecting personal protective equipment. If engineering controls or work practices are not adequate to prevent exposure to harmful levels of this material, the personal protective equipment listed below is recommended. The user should read and understand all instructions and limitations supplied with the equipment since protection is usually provided for a limited time or under certain circumstances.

ENGINEERING CONTROLS:
If handling results in dust generation, special ventilation may be needed to ensure that dust exposure does not exceed the OSHA PEL for nuisance dust. Use in a well-ventilated area. If heated material generates vapor or fumes, use process enclosures, local exhaust ventilation, or other engineering controls to control exposure.

PERSONAL PROTECTIVE EQUIPMENT:
Eye/Face Protection: No special eye protection is normally required. If operating conditions create dust that is not adequately controlled, wear chemical goggles.
Skin Protection: No skin protection is ordinarily required under normal conditions of use. In accordance with good industrial hygiene practices, precautions should be taken to avoid skin contact.
Respiratory Protection: No respiratory protection is normally required. If heated material generates vapor or fumes that are not adequately controlled by ventilation, wear a NIOSH approved respirator. Use the following elements for air-purifying respirators: Organic Vapor and Formaldehyde.
Use a positive pressure, air-supplying respirator if there is potential for uncontrolled release, exposure levels are not known, or other circumstances where air-purifying respirators may not provide adequate protection.

Occupational Exposure Limits:

Component	Limit	TWA	STEL / Peak	Ceiling	Notation
PROPYLENE ETHYLENE COPOLYMER	CPCHEM	Not Established	NA	NA	NA
POLYPROPYLENE	CPCHEM	Not Established	NA	NA	NA
POLYETHYLENE	CPCHEM	Not Established	NA	NA	NA
POLYETHYLENE HEXENE COPOLYMER	CPCHEM	Not Established	NA	NA	NA
ETHYLENE-OCTENE-1COPOLYMER	CPCHEM	Not Established	NA	NA	NA
POLYETHYLENE BUTENE COPOLYMER	CPCHEM	Not Established	NA	NA	NA

Control as Particulate Not Otherwise Classified (PNOC). The ACGIH Guideline* for respirable dust is 3.0 mg/m3 and 10.0 mg/m3 for total dust. The OSHA PEL for respirable dust is 5.0 mg/m3 and 15.0 mg/m3 for total dust.

* This value is for inhalable (total) particulate matter containing no asbestos and < 1.0% crystalline silica.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR: Opaque, translucent waxy pellets or fluff, mild odor.
pH: NA
VAPOR PRESSURE: NA
VAPOR DENSITY (AIR=1): NA

BOILING POINT: NA
SOLUBILITY (in water) : Negligible
SPECIFIC GRAVITY: 0.88 g/cm3 - 0.92 g/cm3

SECTION 10 STABILITY AND REACTIVITY

Chemical Stability: This material is considered stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.
Conditions to Avoid: Not Applicable
Incompatibility With Other Materials: May react with oxygen and strong oxidizing agents, such as chlorates, nitrates, peroxides, etc.
Hazardous Decomposition Products: Low molecular weight hydrocarbons, alcohols, aldehydes, acids and ketones can be formed during thermal processing.
Hazardous Polymerization: Hazardous polymerization will not occur.

SECTION 11 TOXICOLOGICAL INFORMATION

IMMEDIATE HEALTH EFFECTS:

Acute Oral Toxicity: The oral LD50 is not known.
Acute Dermal Toxicity: The dermal LD50 is not known.
Acute Inhalation Toxicity: The inhalation LC50 is not known.

Eye Irritation: This material is not expected to be irritating to the eyes.
Skin Irritation: This material is not expected to be irritating to the skin.

ADDITIONAL TOXICOLOGY INFORMATION:
Long term exposure to high dust concentrations may cause non-debilitating lung changes.

This product contains POLYMERIZED ETHYLENE.
At extrusion temperatures (>350F, >177C), polyethylenes can release vapors and gases, which are irritating to the mucous membranes of the eyes, mouth, throat, and lungs. These substances may include acetaldehyde, acetone, acetic acid, formic acid, formaldehyde and acrolein. Generally these irritant effects are all transitory. However, prolonged exposure to irritating off gases can lead to pulmonary edema. Adequate ventilation should prevent sensory discomfort. Based on animal data and limited epidemiological evidence, NTP, IARC (2A), and OSHA have listed formaldehyde as a probable human carcinogen. Following all recommendations within this MSDS should minimize exposure to thermal processing emissions.
Long-term exposure to high dust concentrations may cause non-debilitating lung changes.

SECTION 12 ECOLOGICAL INFORMATION

ECOTOXICITY:
Fish or birds may eat pellets which may obstruct their digestive tracts.

ENVIRONMENTAL FATE:
This material is not expected to be readily biodegradable.

SECTION 13 DISPOSAL CONSIDERATIONS

Use material for its intended purpose or recycle if possible. This material, if it must be discarded, may meet the criteria of a hazardous waste as defined by US EPA under RCRA (40 CFR 261) or other State and local regulations. Measurement of certain physical properties and analysis for regulated components may be necessary to make a correct determination. If this material is classified as a hazardous waste, federal law requires disposal at a licensed hazardous waste disposal facility.

SECTION 14 TRANSPORT INFORMATION

The description shown may not apply to all shipping situations. Consult appropriate Dangerous Goods Regulations, for additional description requirements (e.g., technical name) and mode-specific or quantity-specific shipping requirements.

Shipping Descriptions per regulatory authority.

US DOT

NOT REGULATED AS A HAZARDOUS MATERIAL OR DANGEROUS GOODS FOR TRANSPORTATION

ICAO / IATA

NOT REGULATED AS A HAZARDOUS MATERIAL OR DANGEROUS GOODS FOR TRANSPORTATION

IMO / IMDG

NOT REGULATED AS A HAZARDOUS MATERIAL OR DANGEROUS GOODS FOR TRANSPORTATION

RID / ADR

NOT REGULATED AS A HAZARDOUS MATERIAL OR DANGEROUS GOODS FOR TRANSPORTATION

SECTION 15 REGULATORY INFORMATION

SARA 311/312 CATEGORIES:

1. Immediate (Acute) Health Effects: YES
2. Delayed (Chronic) Health Effects: NO
3. Fire Hazard: NO
4. Sudden Release of Pressure Hazard: NO
5. Reactivity Hazard: NO

REGULATORY LISTS SEARCHED:

04A = IARC Group 1	12 = TSCA Section 8(a) PAIR	21 = TSCA Section 5(a)
04B = IARC Group 2A	13 = TSCA Section 8(d)	25 = CAA Section 112 HAPs
04C = IARC Group 2B	15 = SARA Section 313	26 = CWA Section 311
05 = NTP Carcinogen	16 = CA Proposition 65	28 = CWA Section 307
06 = OSHA Carcinogen	17 = MA RTK	30 = RCRA Waste P-List
09 = TSCA 12(b)	18 = NJ RTK	31 = RCRA Waste U-List
10 = TSCA Section 4	19 = DOT Marine Pollutant	32 = RCRA Appendix VIII
11 = TSCA Section 8(a) CAIR	20 = PA RTK	33 = MN Hazardous Substance

No components of this material were found on the regulatory lists above.

WHMIS CLASSIFICATION:
This product is not considered a controlled product according to the criteria of the Canadian Controlled Products Regulations.

CHEMICAL INVENTORY LISTINGS:
AUSTRALIA: This material contains components that require notification before sale or importation into Australia.
CANADA: This material contains components that are neither on the Domestic Substance List (DSL) nor on the Non-domestic Substances List (NDSL).
PEOPLE'S REPUBLIC OF CHINA: All the components of this product are listed on the draft inventory of Existing Chemical Substances in China.
JAPAN: This material contains components that require notification before sale or importation into Japan.
KOREA: All the components of this product are on the Existing Chemicals List (ECL) in Korea.
PHILIPPINES: This material contains components that require notification before sale or importation into the Philippines.
UNITED STATES: All of the components of this material are on the Toxic Substances Control Act (TSCA) Chemical Inventory.

EU RISK AND SAFETY PHRASES:
S22: Do not breathe dust.

EU Symbols: NA

SECTION 16 OTHER INFORMATION

NFPA RATINGS: Health: 1 Flammability: 1 Reactivity: 0 Special: NA

(0-Least, 1-Slight, 2-Moderate, 3-High, 4-Extreme, PPE - Personal Protection Equipment index recommendation, *- Chronic Effect Indicator). These values are obtained using the guidelines or published evaluations prepared by the National Fire Protection Association (NFPA).

REVISION STATEMENT: This revision affects all sections please review.

ABBREVIATIONS THAT MAY HAVE BEEN USED IN THIS DOCUMENT:

TLV -	Threshold Limit Value	TWA -	Time Weighted Average
STEL -	Short-term Exposure Limit	PEL -	Permissible Exposure Limit
ACGIH -	American Conference of Government Industrial Hygienists	OSHA -	Occupational Safety & Health
NIOSH -	National Institute of Safety & Health	NFPA -	National Fire Protection Agency
WHMIS -	Workplace Hazardous Materials Information System	IRAC -	Intl. Agency for Research on Cancer
EINECS -	European Inventory of existing Commercial Chemical Sales	RCRA -	Resource Conservation Recovery Act

SARA	- Superfund Amendments and Reauthorization Act.	TSCA	- Toxic Substance Control Act
EC50	- Effective Dose	LC50	- Lethal Concentration
LD50	- Lethal Dose	CAS	- Chemical Abstract Service Number
NDA	- No Data Available	NA	- Not Applicable
<=	- Less Than or Equal To	>=	- Greater Than or Equal To
CNS	- Central Nervous System	MAK	- Germany Maximum Concentration Values

Prepared according to the OSHA Hazard Communication Standard (29 CFR 1910.1200) and the ANSI MSDS Standard (Z400.1) by EHS Product Stewardship Group, Chevron Phillips Chemical Company LP, 10001 Six Pines Drive, The Woodlands, TX 77380

The above information is based on the data of which we are aware and is believed to be correct as of the date hereof. Since this information may be applied under conditions beyond our control and with which we may be unfamiliar and since data made available subsequent to the date hereof may suggest modifications of the information, we do not assume any responsibility for the results of its use. This information is furnished upon condition that the person receiving it shall make his own determination of the suitability of the material for his particular purpose.

From: Ruit, Sandra
Sent: Thursday, August 04, 2005 5:49 PM
To: Farrell, Sean
Cc: Salvaggio, Teresa
Subject: Channel Prime Alliance

Sean -

We need to revise the Purchase order for the HGX030-01 resin to Channel Prime Alliance
Natick ordered 6,000 LBS
Wayne wants 2,800 LBS

Total: 8,800 LBS

Natick wanted the resin stored in two different places. Channel Prime Alliance is waiting for the shipping location. They told me that they did not enter the order with Phillips yet. I told them that it is urgent that the order be placed quickly.

The resin is packaged in 55 LB bags and packaged 4,400LBS per pallet.
I am proposing that 4,400 LBS be stored at Wayne NJ and 4,400 LBS be stored at another location. (Doreen Rao at BSC Watertown was OK with this plan).

I spoke with Betsy Yancy from Channel Prime Alliance and she was not sure how to enter the order. (The bill to address and the ship to address are new in their system. She is also trying to figure out the best way to enter the two ship to addresses.

The best way to resolve the situation may be to change the Natick PO 6009269. These are the options:

1. Increase the Natick PO from 6,000 LBS to 8,800LBS and state Wayne as the ship to address. Wayne can stock transfer to another BSC site after receipt and inspection.
2. Decrease the Natick PO from 6,000 LBS to 4,400 LBS and state the ship to address as determined by Natick. Create a new purchase order for 4,400 LBS delivery to the Wayne NJ site.
3. Increase the Natick PO from 6,000 LBS to 8,800LBS and let Channel Prime Alliance work out the two shipping locations.

(Either way - the Bill to address should be One Boston Scientific Place, Natick, MA. Any way we set up the orders - We will need to work out the financial details with our Accounts Payable people.)

Please contact Teresa Salvaggio if you have time tomorrow to discuss this.
Then someone should contact Betsy Yancy at 800-322-0487 or fax her new orders at fax #.203-831-4330.

Best Regards,
Sandy

EXHIBIT
10

From: Kelly, Mike (Marlboro)
Sent: 07/22/2011 12:05:22 PM
To: Vialle, George
Subject: RE: Uro Polypropylene Resin risk

perfect

Mike Kelly

Multi-Site Vice President, Operations
Boston Scientific
100 Boston Scientific Way
Marlborough, MA 01752
508.683.6812
mike.kelly@bsci.com

"I improve the quality of patient care and all things Boston Scientific"

From: Vialle, George
Sent: Thursday, July 21, 2011 5:24 PM
To: Kelly, Mike (Marlboro)
Subject: RE: Uro Polypropylene Resin risk

The key points are:

- The division did a last Marlex resin buy in '05, purchasing a 7 year supply. This resin is used for all mesh products, $120M annual sales +/-.
- The plan was to validate a new resin prior to run out at end of '12 - that is run out of finished goods
- New resin validation was delayed until Q1/Q2 this year.
- Fire drill at July PIB based on FG inventory coverage falling short of YE '12 projection, due to loss of product to recall, stolen truck and variation to 2005 plan run out date is early Q3 '12.
- Due to FDA anti-mesh position it is highly unlikely FDA would approve any material change
- Only logical path forward is to get more of the old resin
- Resin consultant found 1300 lbs in US, about a year's worth, and 35K lbs in China
- BSC is sending one of our APAC sourcing employees to the Chinese distributor to verify the pedigree of the Chinese resin
- If the Chinese resin is legit we will but 20K lbs and be all set
- If Chinese resin is no good we will continue to look for other sources
- We are also working to have Philips run another batch, one million pound @$2 per pound. We would take what we need and resell the rest.

Not sure 11 bullets is cliff notes short but covers relevant points let me know if you need more info.

From: Kelly, Mike (Marlboro)
Sent: Thursday, July 21, 2011 3:31 PM
To: Vialle, George
Subject: RE: Uro Polypropylene Resin risk

Send me the cliff notes on what happened here. Charlie et al have clogged my email with this topic.

Mike Kelly

EXHIBIT
11

Multi-Site Vice President, Operations
Boston Scientific
100 Boston Scientific Way
Marlborough, MA 01752
508.683.6812
mike.kelly@bsci.com

"I improve the quality of patient care and all things Boston Scientific"

From: Vialle, George
Sent: Thursday, July 21, 2011 3:29 PM
To: Kelly, Mike (Marlboro)
Subject: RE: Uro Polypropylene Resin risk

Thanks, will do once we finalize quantity.

From: Kelly, Mike (Marlboro)
Sent: Thursday, July 21, 2011 3:28 PM
To: Vialle, George
Subject: RE: Uro Polypropylene Resin risk

Regretfully I could store an entire train in there so no problem at all. Let Denis know I ok'd it.

Mike Kelly

Multi-Site Vice President, Operations
Boston Scientific
100 Boston Scientific Way
Marlborough, MA 01752
508.683.6812
mike.kelly@bsci.com

"I improve the quality of patient care and all things Boston Scientific"

From: Vialle, George
Sent: Thursday, July 21, 2011 2:28 PM
To: Kelly, Mike (Marlboro)
Subject: FW: Uro Polypropylene Resin risk

Mike,

If we are able to procure a 10-20 year last buy we would like to split up the inventory and store at multiple locations to protect against catastrophic loss. We will have extrusion vendor Luxilon hold some (1-2 yr supply) and I am going to see if Quincy can take some. What are your thoughts on holding resin at Spencer? 1500 lbs = 1 Gaylord (4x4x4). The ask is 5 pallets' storage.

George

From: Smith, Charles
Sent: Thursday, July 21, 2011 9:16 AM
To: Vialle, George; Howe, Bob; Intoccia, Al
Cc: Wheeler, Mitch; King, Tina; Palumbo, Michael; Kelly, Mike (Marlboro)
Subject: RE: Uro Polypropylene Resin risk

Bob/George

For PO, I assume we want the charged to account other than R&D as this resin will be used for production use.

That is what we did in past, I forget how we insuring cost of resin is included in final end item cost.

I can coordinate initial transfer to Luxilon on first few batch(s).

If we get supply from China we should start the discussion again on BSC site(s) for risk mitigation (not all material being at one site).

If we can get 20,000 lbs that should be 15 to 20 years worth. Current usage about 1K lbs /year. With new launches will go up some, being determined.

Charlie

From: McCaslin, Todd
Sent: Wednesday, July 20, 2011 6:57 PM
To: Intoccia, Al; Sherry, John; Wheeler, Mitch; Batz, Helge (STP); Schwartz, Scott (STP); Bhalakia, Sujal; Smith, Charles; Charest, Ann; Vialle, George; Cuddy, Christopher; Kelly, Mike (Marlboro)
Cc: McCaslin, Todd
Subject: RE: Uro Polypropylene Resin risk

Minutes from today's meeting:

Attendees:

- Al Intoccia, John Sherry, George Vialle, Charlie Smith, Chris Cuddy, Scott Schwartz, Helge Batz, Ann Charest

Discussion & Action Items:

- Phillips Sumika:
  - BSC had requested a "special" run of the Marlex PP resin. Phillips stated that they would have to do a separate run of the reactor, min order would be 1,000,000 lbs, priced at $2/lb.
  - Al Intoccia stated that the Division would be willing to fund this purchase if successful with Phillips. BSC does have options to sell the excess material through resin distributors. This quantity of material would also eliminate the need to do any further resin development for these products.
  - BSC received feedback today from Phillips Account Mgr that they would not be willing to perform this run. Ann Charest obtained and is setting up meeting with the next level of sales management.
  - *Meeting being set up with the Phillips Sales Director ASAP - Will continue to elevate. Ann & Todd*

- 3rd Party Search:
  - RTI (Resin Technologies Inc) was successful in locating 2 lots of material. 1 lot of 700 lbs - virgin material - open gaylord, 1 lot of 600 lbs - contains colored flecks - could be easily be sorted per distributor.
  - *Meeting with Rick from RTI tomorrow to get details for initiation of PO with Distributor - Ann & Todd*
  - *Details will be directed to Charlie Smith for execution of PO*

- China Sourcing:
  - Identified several distributors/brokers in China that claim to have or get the Marlex PP. One has listed 33,000 lbs in stock.
  - BSC Sourcing person located in Shanghai has been contacted to help work with China resin brokers.

- *Charlie Smith to obtain digital pictures of the bags of Marlex HGX-030-01 that we currently have at Luxilon. These will be E mailed to Ann Charest for coordination with Mike Zhao. Target complete 1 - 2 days*
- *Mike Zhao to schedule trip to Guangdong Province to meet with distributor and view inventory (~3 hr flight) prior to purchase. Sourcing team to coordinate with Mike ASAP - 1 - 2 days*

Quality Requirements:

- Since this is a "deviation" from our normal process of buying sheaths from Proxy & extrusion from Luxilon, we need to understand what quality concerns and impact (if any) there are.
- *Chris Cuddy & Mitch Wheeler to develop a response/plan ASAP - target end of week*

Next Update to be sent out Friday afternoon - Meetings to be arranged if a team decision is needed or significant new is available

Let me know if you have any questions
Todd

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com
Redacted (cell)

From: McCaslin, Todd
Sent: Wednesday, July 20, 2011 4:54 PM
To: Intoccia, Al; Sherry, John; Wheeler, Mitch; Batz, Helge (STP); Schwartz, Scott (STP); Bhalakia, Sujal; Smith, Charles; Charest, Ann; Vialle, George; Cuddy, Christopher; Kelly, Mike (Marlboro)
Subject: RE: Uro Polypropylene Resin risk
Importance: High

Folks,
I have attached a summary of the actions taken and current status of the search for additional resin for our meeting today at 5 PM EST.
A few key bullets are also below.
Please contact me if you have any questions or comments.
Thanks,
Todd

Objective:

- Find & procure additional Marlex HGX-030-01 Polypropylene resin to provide additional time for completion of resin replacement activities.

Methods:

- Use a multi pronged approach. 1) Contact Chevron Phillips directly - elevate to Exec level as necessary 2) Use 3rd party resin experts (RTI) 3) Contact BSC resin distributors 4) Use BSC sourcing personnel located in China 5) Contact BSC component manufacturers 6) Use Internal BSC Polymer Science & Engineering network

Status:

- Have taken action on all approach methods.
  - Phillips Sumika: Discussed ability/willingness to produce additional material ($2M cost). Currently unwilling - will elevate up their management chain.

- Have positive results through use of RTI (3rd party resin experts) - found 700 lbs virgin material at Domestic distributor - initiating PO. Have additional 600 lbs at same distributor that may be usable.
- Have information from BSC Sourcing in China that several distributors say they have or can acquire the material. We are investigating.

Next Steps:

- RTI to provide contact information to BSC to initiate PO - 7/21
- BSC Asia Sourcing to get details for purchase of China based material

<< File: Phillips Summika Marlex HGX_030_01 July 20.ppt >> << File: Marlex Uro Resin Search.xls >>

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com
Redacted (cell)

From: McCaslin, Todd
Sent: Wednesday, July 20, 2011 8:05 AM
To: McCaslin, Todd; Intoccia, Al; Sherry, John; Wheeler, Mitch; Batz, Helge (STP); Schwartz, Scott (STP); Bhalakia, Sujal; Smith, Charles; Charest, Ann
Subject: Uro Polypropylene Resin risk
When: Wednesday, July 20, 2011 5:00 PM-5:30 PM (GMT-05:00) Eastern Time (US & Canada).
Where: Con Call

Please plan to call in to review the status on our efforts to mitigate the resin supply risk.

I will send out a summary before the meeting.

Call in information:
877-663-6338
Code: 520661

Urology: Pelvic Sling Material Supply

Phillips-Sumika: Marlex HGX-030-01 (PP)

November 2011 Update

Boston Scientific

History

2005 – Initial Identification of Supply Interruption

- Phillips Summika terminates BSC contract for Marlex HGX-030-01, for use in permanent implant device.
- Contract allows last-time buy of 40K lbs.; BSC purchased 4K (10-yr supply)
- BSC Product Affected: Urology Pelvic Sling
- Revenue @ Risk: $100M Annually

2006-2010 – Production/PD Activity

- Initial discussions with new supplier (Borealis) positive
- Increase in forecast and NPD consumes resin at faster rate than planned
- Stock-out date moves in from 2015 to mid-2013
- In late 2010, Borealis reconsiders and will not sell to BSC for use in permanent implant.

Accomplishments

- Global Sourcing negotiated with distributor in China to hold additional 30K lbs. until BSC completed initial testing,
- Equivalency testing completed in November; Biocompatibility due February 2012. Team is 90% confidant material will be approved.
- Profax (LyondellBasell) has been identified as alternate. Based on Marlex test results, PIB will revisit need to validate an alternate. Currenlty on HOLD.

Expect to mitigate potential BO completely
(34K lbs. = 25+ yr. supply)

- Stand-alone BSC Indemnification/Insurance Agreement developed specifically addressing resin manufacturer's concern for use in implants. Additional tool for future negotiations.

Actions

- Early 2011, Phillips Summika confirms product line discontinued in 2008 timeframe; and declines request for special BSC run due to issue's with reactor. They eventually close domestic PP plant entirely at year-end.
- Global Sourcing locates potential Marlex sources in China; makes on-site visits; confers with R&D and makes initial 4K purchase of material to test.
- In parallel, R&D continues search for alternate material; works closely with Luxilon, the original fiber manufacturer.
- Team from Global Sourcing and Legal initiate discussions on how to mitigate supplier concerns regarding use in implantable devices.

Lesson's Learned

- Increased vigilance required in monitoring consumption of last-time buy volumes. This includes the cessation of NPD with identified material - PD/Division/Site Procurement
- Earlier validation of alternate materials required, even when strategic buys are made – PD
- The need to continue engagement directly with resin manufacturer's to build relationships and mitigate supply issue's has become increasingly important, and has been built into Resin Commodity Strategy – Global Sourcing

Pedersen, John

From: McCaslin, Todd
Sent: Friday, August 05, 2011 2:00 PM
To: Intoccia, Al; Sherry, John; Wheeler, Mitch; Batz, Helge (STP); Schwartz, Scott (STP); Bhalakia, Sujal; Smith, Charles; Charest, Ann; Vialle, George; Cuddy, Christopher; Kelly, Mike (Marlboro); Pedersen, John
Subject: 8/5/11 Update: Uro Polypropylene Resin risk

Attachments: Marlex Uro Resin Search.xls

Folks,
Here is the latest update on the search for the Phillips Sumika Marlex HGX-030-01 Polypropylene resin:

1) Approach Phillips Sumika directly:
- Discussion elevated to Director of Sales (Frank K.). Learned that Phillips had 70K lbs that was scheduled to be shipped to Sumitomo compounding group.
- Elevated to General Manager (Bob Rhoades) on Tuesday 8/2. Received a negative response: *"We are simply not interested in this business at any price, which is still the basis for our past agreement with your company"*
- We have also since learned that Sumitomo is the parent company of Phillips Sumika

2) Utilize 3rd party resin experts:
- Continue to work with RTI (Resin Technology Inc) to search their extensive list of contacts (distributors, suppliers, consumers).
- RTI has provided contact to Asahi Kashi Plastics (Michigan office) to assist BSC. (see below)
- RTI has contacted a large # of companies with no success so far (26 PP clients and 15 Industry contacts).

3) Asahi Kashi (AK) Plastics
- AK plastics is a global company that has over $13.7 B in sales and > 30,000 employees
- AKPlastics is a large customer of Phillips Sumika and Sumotomo.
- We are working with the VP Operations to have them source this material for us.
  - AK - Phillips Sumika directly: They are contacting Phillips to discuss a special run (1 M lbs). AK would take liability and buy for us and arrange for sale of excess.
  - AK - Sumitomo: AK has contacted Sumitomo but the material is not in Sumitomo inventory yet. Expect update early next week. 10-Aug

4) Our distributor and supplier network
- We have contacted 9 polymer distributors and 15 component supplier with no positive results

5) China Sourcing
- Two options have been identified with distributors in China. Michael Zhao (CRM eng) assisting
- Distributor #1: (High risk - no C of C) 1 55 lb bag available and 4000 lbs behind that. Creating PO #1. If all goes smoothly, we can get the 1st bag on next Monday. Shipping to Marlboro for testing
- Distributor #2: $2500 "sourcing" fee required. More reliable company. C of C should be available. PO for ~~several~~ bags by late next week. Shipping to Marlboro for testing. Will purchase the remaining 4000 lbs if tests are ok. 4000 lbs

TM

6) Maquet (old Wayne facility)
- Maquet participated in last time buy with BSC in 2005.
- Using BSC Supply Chain personnel to try to determine quantities in stock.
- Will then contact Mgnt to discuss sale - could use Sr management assistance

Chem * Rob Sandfelder
Maquet * Vito D.
Bob Westfall

Marlex Uro Resin Search.xls (9...

1. Hardship submission
2. 510K LTF vs. submission

Chem - Peter Sells
Phillips

EXHIBIT 13

From: Daignault, Kenneth
Sent: 08/03/2011 12:13:58 PM
To: Raneri, Joe; Sherry, John; Intoccia, Al
Subject: RE: Marlex - Discussion with Phillips

Can we have a third party purchase for us?

Sent from my Windows® phone.

From: Raneri, Joe <Joe.Raneri@bsci.com>
Sent: Wednesday, August 03, 2011 7:51 AM
To: Sherry, John <John.Sherry@bsci.com>; Daignault, Kenneth <Kenneth.Daignault@bsci.com>; Intoccia, Al <Al.Intoccia@bsci.com>
Subject: FW: Marlex - Discussion with Phillips

FYI

From: McCaslin, Todd
Sent: Wednesday, August 03, 2011 7:33 AM
To: Ciulla, Ron; Raneri, Joe; Smith, Charles; Batz, Helge (STP); Charest, Ann
Subject: Marlex - Discussion with Phillips

I have had several communications with Senior Management at Phillips over the past several days. I met with Frank Zakrzewski, Dir Sales on Friday and found out that they do have 70K lbs of material that is in proess of being transferred to a Compounding division. He was pleasant to deal with but said the decision would be made by his boss, who is the General Manager of Phillips Sumika Polypropylene Co. (Bob Rhodes) Bob and I discussed several times today. Unfortunately the result was that Phillips has no interest in dealing with BSC on this material at any price or with any type of indemnification. I will forward his response.

Sent from my Windows Mobile phone

From: Ciulla, Ron
Sent: 07/26/2011 08:36:17 AM
To: Villarreal, Carolina; Courtois, Janice
Subject: FW: Uro Polypropylene Resin risk

fyi

Ronald Ciulla
Urology & Gynecology R&D
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Phone (508) 683-6380

From: Ciulla, Ron
Sent: Monday, July 25, 2011 10:55 AM
To: Cuddy, Christopher; Raneri, Joe; Smith, Charles
Cc: Curran, Sean
Subject: RE: Uro Polypropylene Resin risk

I met with Sean.

The recommended tests are listed below;

1. Melt flow index
2. FTIR
3. Oxidation Index or Oxidative Induction Time

Will need resin from Luxilon to complete comparison testing.

Should anyone have questions, please ask.

Regards,

Ronald Ciulla
Urology & Gynecology R&D
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Phone (508) 683-6380

EXHIBIT
15

From: Curran, Sean
Sent: Thursday, July 21, 2011 10:50 AM
To: Smith, Charles; Wheeler, Mitch
Cc: Vialle, George; Howe, Bob; Intoccia, Al; King, Tina; Palumbo, Michael; Kelly, Mike (Marlboro); Cuddy, Christopher; Baker, Matthew; McCullagh-Blount, Orla; Ciulla, Ron
Subject: RE: Uro Polypropylene Resin risk

We can lay out a test plan that should allow us to claim equivalence pretty quickly. I will work with Ron to set it up.

Sean

From: Smith, Charles
Sent: Thursday, July 21, 2011 9:35 AM
To: Wheeler, Mitch
Cc: Vialle, George; Howe, Bob; Intoccia, Al; King, Tina; Palumbo, Michael; Kelly, Mike (Marlboro); Cuddy, Christopher; Baker, Matthew; McCullagh-Blount, Orla; Ciulla, Ron; Curran, Sean
Subject: RE: Uro Polypropylene Resin risk

Mitch

There are a couple of test you can run to compare to profile of material on hand.

I just discussed with Ron. We can confirm with Sean and go with these test working with Sean to create a technical report.

We can use this for any concerns on the US based Gaylord that has been partially used as well.

Charlie

From: Wheeler, Mitch
Sent: Thursday, July 21, 2011 9:32 AM
To: Smith, Charles
Cc: Vialle, George; Howe, Bob; Intoccia, Al; King, Tina; Palumbo, Michael; Kelly, Mike (Marlboro); Cuddy, Christopher; Baker, Matthew; McCullagh-Blount, Orla
Subject: Re: Uro Polypropylene Resin risk

Any way to test the resin to ensure it is not counterfeit or contaminated? Sourcing from China is risky. FTIR maybe?

Matt and Orla,

We will need to fast-track qualification of a few distributors.

On Jul 21, 2011, at 9:16 AM, "Smith, Charles" <Charlie.Smith@bsci.com> wrote:

Bob/George

For PO, I assume we want the charged to account other than R&D as this resin will be used for production use.

That is what we did in past, I forget how we insuring cost of resin is included in final end item cost.

I can coordinate initial transfer to Luxilon on first few batch(s).

If we get supply from China we should start the discussion again on BSC site(s) for risk mitigation (not all material being at one site).

If we can get 20,000 lbs that should be 15 to 20 years worth. Current usage about 1K lbs /year. With new launches will go up some, being determined.

Charlie

From: McCaslin, Todd
Sent: Wednesday, July 20, 2011 6:57 PM
To: Intoccia, Al; Sherry, John; Wheeler, Mitch; Batz, Helge (STP); Schwartz, Scott (STP); Bhalakia, Sujal; Smith, Charles; Charest, Ann; Vialle, George; Cuddy, Christopher; Kelly, Mike (Marlboro)
Cc: McCaslin, Todd
Subject: RE: Uro Polypropylene Resin risk

Minutes from today's meeting:

Attendees:

- Al Intoccia, John Sherry, George Vialle, Charlie Smith, Chris Cuddy, Scott Schwartz, Helge Batz, Ann Charest

Discussion & Action Items:

- Phillips Sumika:

- BSC had requested a "special" run of the Marlex PP resin. Phillips stated that they would have to do a separate run of the reactor, min order would be 1,000,000 lbs, priced at $2/lb.

- Al Intoccia stated that the Division would be willing to fund this purchase if successful with Phillips. BSC does have options to sell the excess material through resin distributors. This quantity of material would also eliminate the need to do any further resin development for these products.
- BSC received feedback today from Phillips Account Mgr that they would not be willing to perform this run. Ann Charest obtained and is setting up meeting with the next level of sales management.
- *Meeting being set up with the Phillips Sales Director ASAP - Will continue to elevate. Ann & Todd*

- 3rd Party Search:

- RTI (Resin Technologies Inc) was successful in locating 2 lots of material. 1 lot of 700 lbs - virgin material - open gaylord, 1 lot of 600 lbs - contains colored flecks - could be easily be sorted per distributor.
- *Meeting with Rick from RTI tomorrow to get details for initiation of PO with Distributor - Ann & Todd*
- *Details will be directed to Charlie Smith for execution of PO*

- China Sourcing:

- Identified several distributors/brokers in China that claim to have or get the Marlex PP. One has listed 33,000 lbs in stock.
- BSC Sourcing person located in Shanghai has been contacted to help work with China resin brokers.
- *Charlie Smith to obtain digital pictures of the bags of Marlex HGX-030-01 that we currently have at Luxilon. These will be E mailed to Ann Charest for coordination with Mike Zhao. Target complete 1 - 2 days*
- *Mike Zhao to schedule trip to Guangdong Province to meet with distributor and view inventory (~3 hr flight) prior to purchase. Sourcing team to coordinate with Mike ASAP - 1 - 2 days*

Quality Requirements:

- Since this is a "deviation" from our normal process of buying sheaths from Proxy & extrusion from Luxilon, we need to understand what quality concerns and impact (if any) there are.
- *Chris Cuddy & Mitch Wheeler to develop a response/plan ASAP - target end of week*

Next Update to be sent out Friday afternoon - Meetings to be arranged if a team decision is needed or significant new is available

Let me know if you have any questions
Todd

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com
Redacted (cell)

From: McCaslin, Todd
Sent: Wednesday, July 20, 2011 4:54 PM
To: Intoccia, Al; Sherry, John; Wheeler, Mitch; Batz, Helge (STP); Schwartz, Scott (STP); Bhalakia, Sujal; Smith, Charles; Charest, Ann; Vialle, George; Cuddy, Christopher; Kelly, Mike (Marlboro)
Subject: RE: Uro Polypropylene Resin risk
Importance: High

Folks,
I have attached a summary of the actions taken and current status of the search for additional resin for our meeting today at 5 PM EST.
A few key bullets are also below.
Please contact me if you have any questions or comments.
Thanks,
Todd

Objective:

- Find & procure additional Marlex HGX-030-01 Polypropylene resin to provide additional time for completion of resin replacement activities.

Methods:

- Use a multi pronged approach. 1) Contact Chevron Phillips directly - elevate to Exec level as necessary 2) Use 3rd party resin experts (RTI) 3) Contact BSC resin distributors 4) Use BSC sourcing personnel located in China 5) Contact BSC component manufacturers 6) Use Internal BSC Polymer Science & Engineering network

Status:

- Have taken action on all approach methods.

- Phillips Sumika: Discussed ability/willingness to produce additional material ($2M cost). Currently unwilling - will elevate up their management chain.

- Have positive results through use of RTI (3rd party resin experts) - found 700 lbs virgin material at Domestic distributor - initiating PO. Have additional 600 lbs at same distributor that may be usable.
- Have information from BSC Sourcing in China that several distributors say they have or can acquire the material. We are investigating.

Next Steps:

- RTI to provide contact information to BSC to initiate PO - 7/21
- BSC Asia Sourcing to get details for purchase of China based material

<< File: Phillips Summika Marlex HGX_030_01 July 20.ppt >> << File: Marlex Uro Resin Search.xls >>

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com
Redacted (cell)

From: McCaslin, Todd
Sent: Wednesday, July 20, 2011 8:05 AM
To: McCaslin, Todd; Intoccia, Al; Sherry, John; Wheeler, Mitch; Batz, Helge (STP); Schwartz, Scott (STP); Bhalakia, Sujal; Smith, Charles; Charest, Ann
Subject: Uro Polypropylene Resin risk
When: Wednesday, July 20, 2011 5:00 PM-5:30 PM (GMT-05:00) Eastern Time (US & Canada).
Where: Con Call

Please plan to call in to review the status on our efforts to mitigate the resin supply risk.

I will send out a summary before the meeting.

Call in information:
877-663-6338
Code: 520661

Phillips Sumika: Marlex HGX-030-01
(Polypropylene)
July 14, 2011 Background/Update

Boston Scientific

History

- **July 2005**
  - Contract with Phillips Summika expiring Sept 2005
  - During renegotiation to extend, supplier refuses to continue to sell to BSC for use in Medical Device, but allows lifetime buy per terms of contract (up to 40K lbs maximum allowed)
  - BSC purchased 4K lbs; equivalent to 10 years production
- **June 2010**
  - Considered "Bullpen" project in Urology/Women's Health Sustaining Dashboard PIB
- **October 2010**
  - Charlie Smith's team identifies Borealis resin as suitable replacement; confirmed by results from Nelson Labs
  - Global Sourcing is contacted to begin contract discussions with Borealis
    - Initial discussions positive
- **November 2010**
  - Borealis communicates they have determined "they will not knowingly sell their product for use in medical device"
  - Project reactivated from "Bullpen" in Urology/Women's Health Sustaining Dashboard PIB

Jan - June 2011

- **January 2011**
  - Global Sourcing searches market for additional HGX-030-01
    - PolyOne, Foster, Sabic, RTP, Solvay, Teleflex, Ashland, etc.
- **March 2011**
  - Due to the proliferation of new products and increasing sales, inventory forecasted now to only last 2-3 more years
  - Global Sourcing contacts Phillips Summika directly to purchase additional Marlex.
  - Phillips Summika confirms:
    - Entire HGX-030-01 product line was discontinued several years ago due to low demand
    - BSC can request a special run with following criteria:
      - Not to be used for medical device
      - Minimum buy is 1M lbs, the equivalent of 6 rail cars
      - Material value estimated @ $2M
      - Even if all criteria above is met; no guarantee Phillips Summika management will approve request
  - Decision made to proceed with purchase of Borealis resin through Tier 3 supplier (Luxilon); no direct link to BSC
- **April 2011**
  - Indemnification/Insurance Agreement
    - Stand alone agreement is developed and approved by Legal in anticipation of future discussions with resin suppliers unwilling to sell to BSC for use in medical device
    - Team agrees not to approach current suppliers; use if future negotiations through normal channels unsuccessful
- **Supply Chain**

> MedVenture (Assemblies / Kits)	Tier 1
> Proxy (Mesh)	Tier 2
> Luxilon (Fibers)	Tier 3
> Phillips (Resin)	Tier 4

Prepared by: A Charest, July 14, 2011

EXHIBIT 16

Philips Sumika: Marlex HGX-030-01 (Polypropylene) July 14, 2011 Background/Update

Boston Scientific

- **July 2011**
  - Material selection changed to LyondellBasell Profax material
  - PO placed to have Proxy test Profax material
  - Current inventory of Marlex expected to run out June 2012
  - New Mesh Regulations from FDA introduced

- **July 19 – Option 1**

Supplier Management Outpost in Shanghai Michael (Zhao Ying)

  - Still in evaluation, but we have received a positive read on HGX-030-01 being available in China (Distributor) – Guangdong (Hong Kong)
  - Don't get your hope up yet, still too early
  - One distributor is out, but mentioned that they can get that material within 2 months
  - Another distributor needs to do more ground work, but believes that they have it on stock.
  - Other distributors have the product listed on their web page.

  - **Open questions.**
    - Are we going to place the order, or will Luxilon place the order.
    - Do we have to add this distributor to our AVL

  - **Open questions continued**
    - Can someone write a deviation to avoid assessment/re-qual/FAI
    - Does the product have a shelf life
    - Does the product have storage/handling conditions
    - What questions should we ask that we can confirm that it is the right product and that it was stored/handled properly
    - ……

- **July 19 – Option 2**

RTi has located 1300 lbs domestically

  - 700 lbs virgin resin
  - 600 lbs with minimal black flecks

- ACTIONS:
  - Initiate PO for 700 lbs of virgin resin – Charlie
  - Discuss w/Engineering possibility of using 600 lbs w/flecks – Charlie
  - Global Sourcing will continue to pursue other sources of material, including leads in China.

Prepared by: A Charest, July 14, 2011

From: Batz, Helge (STP)
Sent: 08/05/2011 12:43:23 PM
To: Kelly, Mike (Marlboro); Intoccia, Al; Pedersen, John; Smith, Charles
CC: Charest, Ann; Schwartz, Scott (STP)
Subject: FW: Uro Polypropylene Resin HGX-03-01

Importance: High

Fyi,

We are working on 2 different sources in China. See status of China efforts below the email I sent to Rob Sandfelder.

Helge Batz
Director Materials Management
Boston Scientific CRM
St. Paul, MN
Tel 651-582-5674
helge.batz@bsci.com
www.BostonScientific.com

From: Batz, Helge (STP)
Sent: Friday, August 05, 2011 11:38 AM
To: Sandfelder, Rob
Subject: FW: Uro Polypropylene Resin HGX-03-01
Importance: High

Hi Rob,

Unfortunately we have never met face-to-face although I have been in Shnaghai twice, you are always traveling.

From the email string below you can see that we do have an urgent issue to avoid a $120M impact to BSC Urology.
Uro requires a certain resin what was discontinued in 2005. The orginal manufacturer Phillips also stop making that resin. We have a wolrd-wide search going on to see if there is someone out there who still have left-overs.

About 2 weeks ago we found a distrubutor in China. But within 24hours after we contacted them someone else bought everything. Phillips stopped selling to the medical industry about 7 yrs ago, but still manufactured it till about 5 months ago. Apparently there are others out there who need that material.

My guy on the ground in Shanghai Michael (Zhao Ying in Mahesh's org) found 2 more distributors in China. But they are waiting for purchase orders and payments to start the shipping process. Michael told me that the Shanghai org is waiting for your signature to issue purchase orders and payments. We are talking about small amounts (~$20K) compared to the potential business impacts.

Could you please sign off and also instruct your organization that this is a very time critical topic and we can not loose hours/days. We don't want someone else to buy that material last minute again.

If you have questions feel free to contact me (Cell Redacted) or talk to Michael directly. I do appreciate your help a lot.

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Best
Helge

Status of China

1st PO: waiting for Shanghai office accouting to review and sign off, then country GM needs to sign off. ETA is to make payment on Monday. Plan is to pick up 1st bag from Dongguan on Monday. Distributor will hold on to the rest 2 tons while we perform testing(this distributor already has the inventory). Once confirmed, will ship the rest 2 tons.
2nd PO: same status as 1st PO. waiting for Shanghai's signatures. Plan is to get 2 bags first, perform testing while distributor holds on to the rest 2 tons. This distributor does not have this inventory yet, he must receive payment before he buys. Will push SH office to make payment. hope next Monday or Tuesday.

who is going to pick up material from distributor? I have contacted Brian who is BSC account manager, but he has not provided me the detail local contact info. who will pick it up? And where to ship it to? We will not be able to ship anything without these info. We need this info now.

Regards,
Michael

Helge Batz
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helge.batz@bsci.com
www.BostonScientific.com

From: Kelly, Mike (Marlboro)
Sent: Thursday, August 04, 2011 10:25 AM
To: Schwartz, Scott (STP)
Cc: Sorenson, Brad (BSC); McCaslin, Todd; Pedersen, John; Intoccia, Al
Subject: FW: Uro Polypropylene Resin HGX-03-01
Importance: High

Scott,

I know you are aware of the Marlex shortage issue but I want to impress upon you the business revenue impact which is $120M+. Please stay very close to Todd on this last time buy scenario and let us know what else can be done. The Division resources are at your disposal if that helps. Thx.

Mike Kelly

Multi-Site Vice President, Operations
Boston Scientific
100 Boston Scientific Way
Marlborough, MA 01752
508-683-6812

Redacted-Privilege

From: Raneri, Joe
Sent: 08/04/2011 02:59:04 PM
To: Smith, Charles; Sherry, John; Intoccia, Al; Palmisano, Brent; Horton, Peter; Vialle, George; Goddard, James
CC: King, Tina
Subject: RE: Marlex Mesh Run-out Date Meeting - Action Items

Thanks for the clarifications/additions. Also, Tina will set-up the weekly meetings.

From: Smith, Charles
Sent: Thursday, August 04, 2011 2:35 PM
To: Sherry, John; Raneri, Joe; Intoccia, Al; Palmisano, Brent; Horton, Peter; Vialle, George; Goddard, James
Cc: King, Tina
Subject: RE: Marlex Mesh Run-out Date Meeting - Action Items

clarification in red below

From: Sherry, John
Sent: Thursday, August 04, 2011 2:26 PM
To: Raneri, Joe; Intoccia, Al; Palmisano, Brent; Smith, Charles; Horton, Peter; Vialle, George; Goddard, James
Cc: King, Tina
Subject: RE: Marlex Mesh Run-out Date Meeting - Action Items

Proposed clarifications/additions.
[Peter, Brent, it will probably make sense for the 3 of us to work together on the items on my 'to do' - there is significant overlap.]
John

From: Raneri, Joe
Sent: Thursday, August 04, 2011 12:12 PM
To: Intoccia, Al; Palmisano, Brent; Smith, Charles; Horton, Peter; Vialle, George; Sherry, John; Goddard, James
Cc: King, Tina
Subject: Marlex Mesh Run-out Date Meeting - Action Items

From this mornings meeting: FG's made from Marlex resin will run out in February, 2013.

Here are the Action Items :

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Charlie:

- Find out how much resin (no matter how small) is at our past supplier and at Aim (carrier molder)
- **Understand additional Marlex Resin Proxy holds for their abdominal mesh.** **WE know amount at AIM, I am going to see how much Proxy has they could part with.**
- Provide Peter with actual values for time it takes for Marlex to go from resin to fiber to mesh to device. **Will work with Peter Proxy, this will be based upon batch size.**
- Continue work with vendors on improving yields. Report scrap rates/causes . **More specifically, identify typical fiber and knit mesh batch sizes to quantify possible resin yield improvement with larger fiber extrusion and knit batches.** **Correct, we want to optimize the conversion of the 700 lbs.**

Brent:

- Decide if we should use existing Prefix mesh sub-assemblies into another product
- Strategy for Japan considering long introduction time for approval with new resin
- Check into product return rates and decide on action. Considering cancelling delay billing.
- Revise/update US forecast . **with most current projections for PFR demand**

- **Revise/update US forecast . with assumed Pinnacle Lite launch January 2012.**
- **Force-rank *existing* product considering business value and Marlex resin usage.**

Peter

- Add when we will run out of resin to the model
- **Add fiber inventory, warp inventory to tracking (to model or separate page)**
- Be the one point person to let Proxy and Luxilon know what to run and when.

Al

- Follow-up with Packaging regarding priority for implementation of closure strips and restocking of Pinnacle

John

- work out the details for the following three proposed scenarios:

  1. Resin & FG run-out based on today's history and utilizing an updated forecast and assuming new product launches (i.e. Pinnacle Lite)
  2. Resin & FG run-out based on optimizing the mix of products offered and discontinued.
  3. Considering Japan options. Requiring significant inventory for sale pending approval of new material (18 post submission which requires completed real time aging!)

From: Charest, Ann
Sent: 07/21/2011 10:02:40 AM
To: Smith, Charles; Ciulla, Ron
Subject: FW: Urgent request

Importance: High

Charlie - just left you a vm, but thought you might see this sooner. Our team is in agreement that we need to move quickly on this, and I will be the point person in GS to facilitate the logistics.

Things I need ASAP from Luxilon - please send via e:mail:
1) Picture of the material packaging
2) Copy of the CofC
3) MSDS
4) Picture of actual resin if possible
5) Other requirements we would insist on from the distributor

I will work on getting the vendor contact information for Luxilon so they can connect with them directly.

In office, but best way to get a hold of me is via cell.

Thanks, Ann

Ann Charest
Manager, Global Sourcing, Resin
Boston Scientific Inc.
One Scimed Place, A399
Maple Grove, MN
Office: 763-494-1199
Cell: Redacted

"Defining tomorrow, today."

-----Original Message-----
From: Batz, Helge (STP)
Sent: Thursday, July 21, 2011 8:48 AM
To: Zhao, Ying (STP)
Cc: Charest, Ann; McCaslin, Todd
Subject: RE: Urgent request

Hi,

EXHIBIT 19

Thanks again.

Ann, it clearly shows that we need to move quickly.
Can you please get the infos to Michael (Data sheet, pictures of the packages, pictures of the resin) asap. We should also place an order with that distributor, at least we are first in line when they get more HGX in.

I would contact the Belgian extruder to figure out the logistics of PO placement. But we need to move quickly, either with that one distributor or potential others.
Michael, can you ask the distributor who bought that material. Maybe they are will to sell some of it to us. I would at least buy 2 tons right away.

Best,
Helge

Helge Batz
Director Materials Management
Boston Scientific CRM
St. Paul, MN
Tel 651-582-5674
helge.batz@bsci.com
www.BostonScientific.com

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Thursday, July 21, 2011 7:52 AM
To: Batz, Helge (STP)
Cc: Charest, Ann; McCaslin, Todd
Subject: RE: Urgent request

hi, Helge:

Latest update: the 2nd distributor told me this afternoon that they have sold out all of HGX-030-01, someone else bought all of them today. I can't convience them to hold it for us. We will have to buy, they won't hold for us.
They did say that we can return if we find the material is not right. And they will get more this product next Tuesday or so. I will touch base with them next week.
I also have asked the 5th distributor, which said they had some and it's manufactured in U.S. previously. I will get an update from them tomorrow.
Anyway, since all of distributors are in the same area, I think I will go there on Monday, collect all of info on site, and send all of the options to you and Ann. I will stay there, waiting for you to confirm on which one we will procure. Then help purchase right there on Tuesday, I will not leave there until I make sure we secure the right material .
How is the purchasing process going to work on this one? I am not familiar to that at all.

hi, Ann,

please let me know how we will purchase this one. Will you deal with the distributor directly? Since the time zone difference, if you place order during daytime over there, we will have to wait until daytime here to confirm. Let me know how I can support on purchasing activity if I can on site. And we will need to figure out the shipment logistics as well, since they said they only provide shipment in mainland China, not oversea. I am new to this whole thing.

Let me know if you guys have any other question or suggestion.

Regards,
Michael

From: Batz, Helge (STP)
Sent: Wednesday, July 20, 2011 11:43 PM
To: Zhao, Ying (STP)
Cc: Charest, Ann; McCaslin, Todd
Subject: Re: Urgent request

Michael
Please don't tell them where we will use it. It could scare them away

Great work
Helge

Sent from my iPhone

On Jul 20, 2011, at 11:31 PM, "Zhao, Ying (STP)" <ying.zhao@bsci.com> wrote:

> Hi, Helge:
>
> I am in Suzhou right now, I just contacted them - the 2nd distributor, and asked for holding the material longer, they will let me know soon. The 2nd distributor sounds more professional than others, and their website seems a big player.
> and I will consider to visit them on site this weekend. I don't count on them providing much detailed info like pictures, they seem busy and don't have resource to support, and I want to verify their condition on site too, have to count on myself. I will try to collect as much info as possible and contact Ann. I will check their cancel/return policy as well, just in case. Comparing to $100M business, 2 tons of this material is only about $4k, we might have to play safe.
>
> Do we need to ask if this material is supposed to be used in Medical Implantable? Is there anything special about it or it is just a standard plastic material, and as long as it's PP HGX-030-01, it's fine? I just want to make sure we are getting the right material. Pls let me now if there is any other requirement, besides "PP HGX-030-01 manufactured in U.S.".
> I just realized I had a missing call, maybe it's from the States. Anyway, feel free to call me any time. I will let you know what I find out.
>
> Ann, is there a way I can get hold of you on the weekend if there is a need? Just in case.
My cell is: Redacted
>

>
> Best Regards,
> Michael Zhao
> Supplier Management Asia
> Cardiac Rhythm Management
> Boston Scientific Corp.
> Email: ying.zhao@bsci.com
> Office: 86-21-61419708
> Cell: Redacted
> Unit 4701, Raffles City,
> No. 268 Xizang Middle Road,
> Shanghai, China 200001
>
>
> -----Original Message-----
> From: Batz, Helge (STP)
> Sent: Thursday, July 21, 2011 11:36 AM
> To: Zhao, Ying (STP); Charest, Ann; McCaslin, Todd
> Subject: Re: Urgent request
>
> Michael
> Thanks for the info. We would like to get more info from the 2nd distributor. We are still concerned that the material was not manufactured in the US. We are trying to get pictures from the material so that we can compare it with their package. Can you please ask them to get Infos. Pictures would be great. In order to confirm that it is the original material for the US we thought it would be helpful if you could visit them to look at the material and the condition of the distributor. Like mentioned we need that material to sure a $100M business. Long term implantable. We need to find out as much as possible.
> Ann Charest will be the point person to figure out the logistics to place orders and the other paperwork.
>
> Thanks
> Helge
>
> Sent from my iPhone
>
> On Jul 19, 2011, at 10:25 PM, "Zhao, Ying (STP)" <ying.zhao@bsci.com> wrote:
>
>> Hi, Helge:
>>
>> The 2nd link was from your previous email. Maybe it was re-directed to another product.
>>
>> I looked up this product on alibaba.com, which is the biggest supply/purchase portal. It's all from same city: Dongguan. Found followings:
>>
>> 1) http://detail.china.alibaba.com/buyer/offerdetail/820469000.html
>> This is the one you mentioned. This product is produced in Singapore, not from U.S.. It is about RMB 13.6/kg.
>> Sales is checking on inventory.
>>

>> 2) http://detail.china.alibaba.com/buyer/offerdetail/799536869.html
>> 林程勇 18998089508 , has several tons in Guangzhou office. Produced in U.S. , Has CoC(only provide CoC along with product shipment). About RMB 13900/ton, plus tax/shipping. They can hold 2 tons for us, we must reply no later than tomorrow noon.
>>
>> 3) http://detail.china.alibaba.com/buyer/offerdetail/1018548270.html
>> 13825786965 邓才尧. They have 3~4 tons available. Produced in Singapore, not U.S.. Has CoC(only provide CoC along with product shipment). About RMB 15/kg.
>>
>> 4)http://detail.china.alibaba.com/buyer/offerdetail/1016100443.html
>> Checking.
>> 13580716606 刘奇.
>>
>> 5) http://detail.china.alibaba.com/buyer/offerdetail/850884103.html
>> Tel:13622635639 0769-87782010 谭先生
>> Same company as option 1). Has enough inventory, produced in U.S.. Has CoC.
>>
>>
>> An update: CoC can't be provided before hand, we need to buy first, then they will ship the CoC along with the product, it applies to all.
>>
>> My recommendation is option 2. This is their website: http://www.em-gs.com/ Seems to be a pretty solid distributor.
>> We probably want to initiate a PO ASAP. Need to decide soon. They will not wait for us.
>>
>> Let me know if we want to check product or verify anything on site before we purchase.
>>
>>
>>
>> Best Regards,
>> Michael Zhao
>> Supplier Management Asia
>> Cardiac Rhythm Management
>> Boston Scientific Corp.
>> Email: ying.zhao@bsci.com
>> Office: 86-21-61419708
>> Cell: Redacted
>> Unit 4701, Raffles City,
>> No. 268 Xizang Middle Road,
>> Shanghai, China 200001
>>
>>
>> -----Original Message-----
>> From: Batz, Helge (STP)
>> Sent: Wednesday, July 20, 2011 5:22 AM
>> To: Zhao, Ying (STP)
>> Subject: RE: Urgent request
>>
>> Hi Michael,
>>

>> I am planning to go back to China most likely in November.
>>
>> Can you please check the second source again. The link you sent me points to a different material, not to HGX-030-01.
>>
>> I also found another source from the same area.
>> http://detail.china.alibaba.com/buyer/offerdetail/820469000.html
>>
>>
>> Michael, we are still looking to secure more of that material. But what we also need from the distributor is a Certificate of Compliance.
>>
>> If you have other ways to find someone who has the material that would be great too.
>>
>> So far we have secured about 600 pounds here in the US. In total we probably want 4,000 pounds at least.
>>
>> Thanks
>> Helge
>>
>>
>>
>> Helge Batz
>> Director Materials Management
>> Boston Scientific CRM
>> St. Paul, MN
>> Tel 651-582-5674
>> helge.batz@bsci.com
>> www.BostonScientific.com
>>
>> -----Original Message-----
>> From: Zhao, Ying (STP)
>> Sent: Tuesday, July 19, 2011 4:14 AM
>> To: Batz, Helge (STP)
>> Subject: RE: Urgent request
>>
>> hi, Helge:
>>
>> I am doing fine, thanks. How about you? Let me know if you have plan to visit Asia, will be great to meet you here.
>>
>> I checked with these two local distributors, they both are located in Dongguan, Guangdong. Pretty close to Hong Kong area.
>> 1) http://www.hjcyplas.com/PP/Marlex_PP_HGX-030-01.htm
>> There is no stock, the sales will check with their Hong Kong office and let me know how soon they can get it in stock if it's available. Likely 2 months lead time. I will talk to them tomorrow and update you tomorrow.
>> 2) http://jtplas.net/products/PP/Marlex_AGM-010.html
>> There are 17 bags available. 625 kg/bag. So 2 bags(roughly 2700 lbs) will be enough for us. Unit price is roughly about 22 RMB/kg(shipping fee inside of mainland China is included),

that's RMB 13750/bag, and RMB 27500/2700 lbs. Color is natural white. They can ship any time we want.
>>
>> Let me know if I can support more. Feel free to call my cell any time.
>>
>>
>> Best Regards,
>> Michael Zhao
>> Supplier Management Asia
>> Cardiac Rhythm Management
>> Boston Scientific Corp.
>> Email: ying.zhao@bsci.com
>> Office: 86-21-61419708
>> Cell: Redacted
>> Unit 4701, Raffles City,
>> No. 268 Xizang Middle Road,
>> Shanghai, China 200001
>>
>>
>> -----Original Message-----
>> From: Batz, Helge (STP)
>> Sent: Tuesday, July 19, 2011 12:09 PM
>> To: Zhao, Ying (STP)
>> Subject: Urgent request
>>
>> Hi Michael
>>
>> Hope things are well on china.
>> We do have a critical issue with the Marlboro devision. We need HGX-030-01. Phillips used to build this material and obsoleted it in 2005. I checked several pages on google but they are all in Chinese. I will send another email with the links. Can you please find out whether this material is still available on China. We need at least 2000 pounds.
>>
>> Thanks
>> Helge
>>
>> Sent from my iPhone

From: Zhao, Ying (STP)
Sent: 07/25/2011 03:16:04 AM
To: Charest, Ann; Batz, Helge (STP)
CC: McCaslin, Todd
Subject: RE: Emailing: Marlex C of A.pdf
Attachments: Polyphenylene.JPG

Hi, Ann and Helge:

Today I visited all 5 distributors found from alibaba.com, they all are in Dongguan. It does not look very rosy at all. Here is the result:

1) http://detail.china.alibaba.com/buyer/offerdetail/799536869.html
The best candidate(our previous option 2): a bigger-than-most-others company, headquartered in Guangzhou, has a office in Dongguan. Has storage places in both places. There are more than 30 employees.
They sold the inventory to another distributor last week(they won't share the info of the buyer, I asked). Plan is to have more in tomorrow: Tuesday, they won't know exactly what's in the shipment until the shipment reaches at custom tomorrow in Guangzhou. They will let me know if they have HGX-030-01 made in U.S. or not in this shipment by tomorrow. If they have, I will go to the storage in Guangzhou to verify on site before purchase. This distributor can help explore and find this material if they don't have this one in the shipment tomorrow. I have met the manager face to face and he commit to help on this. Will get more update tomorrow. This one is our best bet now.

2) http://detail.china.alibaba.com/buyer/offerdetail/891940367.html
This distributor does not have any inventory on this material. They don't plan to have it any time soon. Case Closed.

3) http://detail.china.alibaba.com/buyer/offerdetail/1018548270.html
This distributor had 1 ton of HGX-030-01 in Guangzhou office last week. It was made in U.S.. They told me this morning, they have sold all of the those last week and only has made-in-Korea left. They don't plan to have any new material coming in soon. Case closed.

4) http://detail.china.alibaba.com/buyer/offerdetail/1016100443.html
This distributor said they had some in their storage, made in U.S.. Will check out this afternoon. They had one bag shipped from Hong Kong today, and I checked on site. It is Polyphenyplene, not Polypropylene. Everything else is the same, it was made in Texas. But I don't think this is the right material. See the picture attached. I shared with them of the CoA and data sheet, they asked for a picture of the bag and said can help look for it once has the picture of bag. So I will send them the picture once I get it from Ann. There is a hope here, but very limited.

5) http://detail.china.alibaba.com/buyer/offerdetail/960913810.html
This distributor claimed that they have this material, and it's made in U.S.. Their office is in another place: Kunshan, close to Shanghai, their storage is in Dongguan though. They don't have the original package, they had to use blank bags to re-package material since the material was smuggled in from U.S.. If we want, we will have to buy a bag and test out before buy the rest. I don't think we want to pursue with this one though. I will consider it closed unless you guys want to explore more with it.

Overall after the first day on-site visit, we pretty much only have 1 option left: 1). I will touch base with the manager tomorrow to see if they have HGX-030-01 in their new shipment, if not, will ask them help source around.

From our side, pls help get the picture of the bag. That's all we can do right now.

EXHIBIT
20

Will get more update and share with you tomorrow. Please let me know if there is update or anything else I can do here.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Charest, Ann
Sent: Monday, July 25, 2011 11:02 AM
To: Zhao, Ying (STP)
Cc: Batz, Helge (STP); McCaslin, Todd
Subject: RE: Emailing: Marlex C of A.pdf

Michael,

No, we have not. The extruder is located in Belgium that has the material and is currently on shutdown. Our Engineering team in Natick is trying to track someone down to go into the facility and send pictures. Both Todd and I did some searching on the web and were unable to find a picture, most likely because it is a discontinued product.

I think the most important thing is to ensure that they tell you it was made in the US AND the C of C looks similar to what we have sent you. I would recommend you ask them where it was made and let them tell you.

Best Regards, Ann

Ann Charest
Manager, Global Sourcing, Resin
Boston Scientific Inc.
One Scimed Place, A399
Maple Grove, MN
Office: 763-494-1199
Cell: Redacted

"Defining tomorrow, today."

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Friday, July 22, 2011 10:05 PM

To: Charest, Ann
Cc: Batz, Helge (STP); McCaslin, Todd
Subject: RE: Emailing: Marlex C of A.pdf

Hi, Ann:

Any luck on getting the pictures of the bags?

Thanks,

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Charest, Ann
Sent: Thursday, July 21, 2011 11:10 PM
To: Zhao, Ying (STP)
Cc: Batz, Helge (STP); McCaslin, Todd
Subject: FW: Emailing: Marlex C of A.pdf

Attached is the Certificate of Analysis from our last buy which was through a domestic distributor. It has been several years so there may be slight changes to the document since then, but it should contain similar information, disclaimers, etc. I would be firm in requesting a copy, this is not an unusual request to make. Our intent to purchase is strong, or we would not have you go in personally. They should not refuse you. This is also an opportunity to build a relationship with them for future business.

Just got word that Luxilon is officially on shutdown until Aug 1. Charlie's team is trying to track someone down to go into the plant and get us pictures of the bags.

Regards, Ann

Ann Charest
Manager, Global Sourcing, Resin
Boston Scientific Inc.
One Scimed Place, A399
Maple Grove, MN
Office: 763-494-1199
Cell: Redacted

"Defining tomorrow, today."

-----Original Message-----
From: Smith, Charles
Sent: Thursday, July 21, 2011 9:51 AM
To: Charest, Ann
Cc: Ciulla, Ron; Cuddy, Christopher
Subject: FW: Emailing: Marlex C of A.pdf

Ann

Here is Cof C form last buy

Ron

Thks

Charlie
-----Original Message-----
From: Ciulla, Ron
Sent: Thursday, July 21, 2011 10:32 AM
To: Smith, Charles
Subject: Emailing: Marlex C of A.pdf

The message is ready to be sent with the following file or link attachments:

Marlex C of A.pdf

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

INTERNATIONAL ALIBABA GROUP INC.

There's no end in sight for Alibaba's counterfeit problem

by Scott Cendrowski @scendrowski MAY 18, 2015, 7:17 AM EDT

Kering-owned brands Gucci and Yves Saint Laurent have accused Alibaba of profiting from fakes in a new lawsuit.

EXHIBIT 21

News that luxury goods brands are again suing Alibaba for counterfeits sold on its e-commerce platforms is evidence that

the Chinese giant is moving too slowly to clean up counterfeits for Western brands' liking.

Paris-based Kering (PPRUY ▲ 2.32%), the owner of Gucci and Yves Saint Laurent among others, said in the lawsuit that Alibaba's search engines steered customers who input keywords like *cucci* to fake products and counterfeit Gucci bags selling on Alibaba's platforms for $2 to $5, compared to the listed $795 price.

The lawsuit itself doesn't appear damaging to Alibaba. The same luxury goods brands under Kering sued Alibaba last July for hosting counterfeit goods before withdrawing the claims two weeks later.

What is damaging is the perception that Alibaba has made so little progress in nearly a year that the brands decided rather than continuing discussions, they would sue—again.

As part of the lawsuit withdrawal last year, Alibaba and Kering announced in a statement "constructive dialogue" and had "agreed to work together in good faith through the normal business process on ways to enhance intellectual property protection."

Kering's new complaint in U.S. federal court at best indicates a breakdown of dialogue; at worst, it shows Alibaba is failing to strictly police counterfeits and fakes products on its platforms. An Alibaba spokesperson told news outlets the company thinks the lawsuit has no basis.

It's not just Western brands complaining. In January, China's State Administration for Industry And Commerce (SAIC) accused Alibaba of selling fake goods and misleading customers on its biggest shopping platform Taobao.com.

The regulator proved, as the lawsuit does in New York, that Alibaba is vulnerable. Its Taobao.com platform hosts 8-million-plus small sellers, and policing them is a big part of its duty to public shareholders.

The Kering suit in the coming months may provide a window for investors who lopped $30 billion off Alibaba's public market value earlier this year when SAIC released a report criticizing Alibaba's handling of counterfeit goods, whether Alibaba is now fighting fakes vigorously enough.

2 Comments

From: McCaslin, Todd
Sent: 07/28/2011 04:16:10 PM
To: Ciulla, Ron
Subject: RE: marlex grade of polypropylene

I know.....this is the "higher risk" option.
If there is no C of C available at all is this dead? I wonder if we could get a lot # from the bag and contact Phillips (who does not seem to want to talk to us)

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com
Redacted (cell)

From: Ciulla, Ron
Sent: Thursday, July 28, 2011 3:35 PM
To: McCaslin, Todd
Subject: RE: marlex grade of polypropylene

Todd:

Really need a C of C.

Let talk.

Regards,

Ronald Ciulla
Urology & Gynecology R&D
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Phone (508) 683-6380

From: McCaslin, Todd
Sent: Thursday, July 28, 2011 1:01 PM
To: Ciulla, Ron
Subject: FW: marlex grade of polypropylene

FYI

EXHIBIT
22

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com
Redacted (cell)

From: Zhao, Ying (STP)
Sent: Thursday, July 28, 2011 11:15 AM
To: Batz, Helge (STP)
Cc: Charest, Ann; McCaslin, Todd
Subject: RE: marlex grade of polypropylene

An update from today's activities:

Option 1 distributor: has started his sourcing effort for us. relatively this is a high investment with low risk option.

Option 2 distributor: He does not have any CoC, can't provide that at all, this makes me a little nervous. He said he has 2 tons available in Guangzhou storage. Price is RMB 16.5 /kg. We agreed upon a term like this: we will buy the bag that he showed me: 20kg first, and put 10% of total RMB 33K down as deposit. He guarantees to hold those 2 tons for us up to 2 months while we get 1st bag and perform testing. If it passes, we will pay the rest 90% and get the 2 tons; if it fails, we have option to walk away. This way without much hassle we pay about $600 to try it out. I see it's a low investment with high risk option.

Now I feel we have two legs walking.

We are working on purchasing effort now. Got a contract, but need to work with Shanghai office on a Purchase Request first, it needs signatures from local SH office before we can sign contract and place any order. Hope we can get it done tomorrow so that we can sign the contract and place order.

Please let me know if you have any question or concern.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

From: Batz, Helge (STP)
Sent: Thursday, July 28, 2011 12:23 AM
To: Zhao, Ying (STP)
Cc: Charest, Ann; McCaslin, Todd
Subject: Re: marlex grade of polypropylene

Ok

Sent from my iPhone

On Jul 27, 2011, at 8:50 AM, "Zhao, Ying (STP)" <ying.zhao@bsci.com> wrote:

hi, Helge:

I talked to the distributor today. He said he knows there is not much on the market and somehow recently people bought this out everywhere. I wonder if someone realized we were searching and stocked them up.
He can spend effort helping us on finding this material. He said he will need to pull some strings, will go to Guangzhou tomorrow since it is still a bigger center over there. He asked for RMB 15K as the service fee. That's for his service, then we pay whatever the regular product price is(retail is a little higher than wholesale). If he can't locate what we need, no fee at all.
Pls let me know if you are OK with this service fee. If OK, I will tell him to start sourcing tomorrow. It won't take long for him to know if there is a possibility.
I feel he's a pretty straight-forward business man, he put everything up-front, seems pretty simple. I feel we can trust him. He can provide a good service with insight.

One thing: he said his company is not a service company. When he dealt with local domestic customers, if it is service fee like this, they just go through personal accounts for the transition; but I told him we will do everything formally, through official channel and pay all of taxes as required. Since service is not part of his company's business scope, he can't provide a receipt which we will need, So his suggestion is to add the service fee to the product price, just quote the product with the service fee and we just pay everything through the product. Hope this make sense to you.

I have communicated to him, we must find the exact product, HGX-030-01. made by Phillips Sumika, made in U.S.. We will not pay a penny if it is not the right product. His service is to make sure he find the exact product for us. This is probably our biggest concern.

He committed as a standard company policy, if it is product quality issue, they will refund. We can ship a bag or two to do some testing before ship the rest of 2 tons. He will provide storage for the 2 tons while we perform testing. If we find out somehow the product does not meet our requirement and we don't want it, they can re-sell the 2 tons for us on the market.

If we decide to move forward, I will leave him all of detail information on this product and start tomorrow.

Please let me know if this is what we want to pursue.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,

Shanghai, China 200001

From: Batz, Helge (STP)
Sent: Wednesday, July 27, 2011 2:53 AM
To: Zhao, Ying (STP); Charest, Ann
Cc: McCaslin, Todd
Subject: RE: marlex grade of polypropylene

Michael,

money does not matter in this case. We want to buy a service. The distributor can talk to the customer an then collect a service fee. Ann and the team would issue a service MRO to pay for it.

helge

Helge Batz
Director Materials Management
Boston Scientific CRM
St. Paul, MN
Tel 651-582-5674
helge.batz@bsci.com
www.BostonScientific.com

From: Zhao, Ying (STP)
Sent: Tuesday, July 26, 2011 11:05 AM
To: Batz, Helge (STP); Charest, Ann
Cc: McCaslin, Todd
Subject: RE: marlex grade of polypropylene

hi, Helge:

No, I did not think of those before. Please let me know our limit on how much extra we are willing to give? to both the distributor and the buyer who bought those.
I will try those options with this limit in my mind. And if it works, how do we pay? Sorry, I have to think of the execution level now. please authorize the details and I will do my best tomorrow.
I do plan to meet him and maybe have lunch together tomorrow. I want to build some relationship for his future support.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,

Shanghai, China 200001

From: Batz, Helge (STP)
Sent: Tuesday, July 26, 2011 11:56 PM
To: Zhao, Ying (STP); Charest, Ann
Cc: McCaslin, Todd
Subject: RE: marlex grade of polypropylene

Michael,

did you offer them money for the info regarding the customer who bought the HGX? Did you also asked them to call the customer to let them know that we are willing to pay above street price.

We have to pull all strings possible.

Helge

Helge Batz
Director Materials Management
Boston Scientific CRM
St. Paul, MN
Tel 651-582-5674
helge.batz@bsci.com
www.BostonScientific.com

From: Zhao, Ying (STP)
Sent: Tuesday, July 26, 2011 10:24 AM
To: Charest, Ann
Cc: Batz, Helge (STP); McCaslin, Todd
Subject: RE: marlex grade of polypropylene

hi, Ann and Todd:

I just got a phone call from the 1st distributor, his team just got the shipment off the custom. Unfortunately there is no HGX-030-01 in this shipment. He has no control what his supplier put into the shipment. So we have to close all of cases on all five distributors, there is no current inventory of HGX-030-01 on the market. It's kind of strange that last week existing inventories from two distributors got all bought out by someone, maybe someone is collecting this material on the market. Hope there is still some left somewhere in China.
So the 1st distributor will start helping me source this HGX-030-01 from tomorrow. I will leave him all of the info I have. By the way, the picture of bag you sent me says: HGX-350, is it the right material? pls confirm me on this. I need to share the right info with him.

I will spend some time helping you on PX1775 tomorrow then. May have to leave that to the distributor as well since so far I have not found any existing inventory.

Helge:
I think based on current situation, priority for me is to know the 1st distributor better, and help build a long-term relationship with him so that he can help us source material in China in the future. Let me know if there is anything else you think I could do while I am here.

Thanks,

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,

Shanghai, China 200001

From: Charest, Ann
Sent: Tuesday, July 26, 2011 9:38 PM
To: Zhao, Ying (STP)
Subject: RE: marlex grade of polypropylene

Thank-you Michael.

Ann Charest
Manager, Global Sourcing, Resin
Boston Scientific Inc.
One Scimed Place, A399
Maple Grove, MN
Office: 763-494-1199
Cell: Redacted

"Defining tomorrow, today."

From: Zhao, Ying (STP)
Sent: Tuesday, July 26, 2011 8:36 AM
To: Charest, Ann
Cc: McCaslin, Todd; Batz, Helge (STP)
Subject: RE: marlex grade of polypropylene

hi, Ann:

There is not much news today. The distributor has not got the up-to-date info about what's inside of the shipment yet. I will have to wait until tomorrow morning for him to update me. Depending on what is in that shipment, we will decide what to do. If there is no right stuff we need from the shipment, I will ask him help me source this HGX-030-01 all around the country, he won't start that before he knows what's inside of his shipment. I will leave him as much info as what we have and count on him source the right stuff through his network here. This is our last hope.
Will update you tomorrow.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted

Unit 4701, Raffles City,
No. 268 Xizang Middle Road,

Shanghai, China 200001

From: Charest, Ann
Sent: Tuesday, July 26, 2011 8:03 PM
To: Zhao, Ying (STP)
Cc: McCaslin, Todd; Batz, Helge (STP)
Subject: FW: marlex grade of polypropylene

Michael,

Here is a picture of a box of Marlex we hope to get stateside. I don't know if it helps you or not. I will be traveling the next three days, but will be available via cell and checking e:mail regularly. Please copy Todd on all communications through Friday so he can respond if needed.

Anything new to report from your end?

Thanks, Ann

Ann Charest
Manager, Global Sourcing, Resin
Boston Scientific Inc.
One Scimed Place, A399
Maple Grove, MN
Office: 763-494-1199
Cell: Redacted

"Defining tomorrow, today."

From: Smith, Charles
Sent: 08/17/2011 04:34:08 PM
To: Jackson, Todd; Kelly, Mike (Marlboro); Vialle, George; Intoccia, Al; Wheeler, Mitch
Subject: RE: update on Option 1 distributor for Marlex from China

Yes , we can cut email chain back at this point, I agree. Here is proposed strategy for us.

1. 4K lbs. here @ Marlboro ASAP. Todd ship by 8-19.
2. 50 lb bag (@ Quincy). 1 lb sample here Friday for current Marlex. Charlie
3. Plan to test # 2 and have results in three weeks (Sooner if possible). Charlie
4. Procure and store 30K lbs @ China. Todd BY 8-19.
5. Report to release 4k lbs. Charlie/Mitch by week of 9/12.
6. Release 30 K @ China. Charlie/Mitch by week of 9/12.
7. Ship 30K to US. George

Please all comment back to me to finalize/adjust this proposed strategy

thks

Charlie

From: Jackson, Todd
Sent: Wednesday, August 17, 2011 4:07 PM
To: Kelly, Mike (Marlboro); Smith, Charles
Cc: Vialle, George
Subject: RE: update on Option 1 distributor for Marlex from China

Charlie,
I would also really challenge whether John Pedersen needs to be included in this lengthy email dialogue. Seems that you and the team would be better served developing a strategy and then informing key people on the leadership team.
-Todd

From: Kelly, Mike (Marlboro)
Sent: Wednesday, August 17, 2011 9:43 AM
To: Smith, Charles
Cc: Jackson, Todd
Subject: RE: update on Option 1 distributor for Marlex from China

I have no responsibility for storage in China.

EXHIBIT 23

Mike Kelly

Multi-Site Vice President, Operations
Boston Scientific
100 Boston Scientific Way
Marlborough, MA 01752
508-683-6812

"Defining tomorrow, today"

From: Smith, Charles
Sent: Wednesday, August 17, 2011 7:57 AM
To: Vialle, George; Zhao, Ying (STP); Wheeler, Mitch; McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

George

That sounds like the best plan. The material doesn't have to be environmentally controlled beyond normal warehouse conditions.

We can start discussion with Luxilon on how much material they can hold for us.

Mike/Todd

Is George proposal ok, can we buy and hold somewhere in our control?

Charlie

From: Vialle, George
Sent: Wednesday, August 17, 2011 7:51 AM
To: Smith, Charles; Zhao, Ying (STP); Wheeler, Mitch; McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

Charlie,
Can we purchase at risk and hold the inventory in secure, environmentally controlled storage in China until testing is complete? The shipping costs are more then the material costs so local storage will save us $ if this material fails testing. Also, I'd like to ship at least 5k lbs additional material directly to Luxilon in Belgium if our testing plan allows. The balance will be sent to the US.

George

From: Smith, Charles
Sent: Wednesday, August 17, 2011 7:10 AM
To: Zhao, Ying (STP); Wheeler, Mitch; Vialle, George; McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China
Importance: High

Mike

Let us review here this AM and get back to you. We do not want to loose the material.

looking still for first bag!!

Charlie

From: Zhao, Ying (STP)
Sent: Wednesday, August 17, 2011 2:10 AM
To: Smith, Charles; Wheeler, Mitch; Vialle, George; McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

hi, Guys:

I talked to the distributor about the extra 15 tons of material today. Here is an update:
2 months hold period is a big risk for him, on this 15 tons amount. He literally needs to buy everything and put into his storage. Since this is not a popular material on the market, he is running risk of holding it longer than 2 months if we decide not to procure at the end. And it's a concern from his cash flow perspective. So his feedback is we need to put down at least 40% of total payment as deposit. This way he will lock in those 15 tons for us. So:
option 1: lock it in, we put down about RMB 123k(about US$ 20k) for this 15 tons extra material. Risk is we will not get it back if we decide not to procure at the end of 2 months.
option 2: we don't do anything now, wait almost 2 months(shipping and testing), until we know the result of testing. Risk is we can't guarantee whether or not we can still find it on the market.

Please let me know which option we want to pursue.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

From: Smith, Charles
Sent: Wednesday, August 17, 2011 2:00 AM
To: Zhao, Ying (STP); Wheeler, Mitch; Vialle, George; McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

Mike

That time period should be fine.. Let me know when material is shipping.

Is there any tracker for the first bag?

thks

Charlie

From: Zhao, Ying (STP)
Sent: Tuesday, August 16, 2011 1:11 PM
To: Smith, Charles; Wheeler, Mitch; Vialle, George; McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

Yes, I have been using 2 months as our option period. I believe I can work out with the distributor if longer-than-that is needed.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

From: Smith, Charles
Sent: Wednesday, August 17, 2011 1:07 AM

To: Zhao, Ying (STP); Wheeler, Mitch; Vialle, George; McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

Mike

That sounds good. Testing/report may take 4 to 6 weeks. Is that going to be ok with the distributor?

Charlie

From: Zhao, Ying (STP)
Sent: Tuesday, August 16, 2011 12:23 PM
To: Smith, Charles; Wheeler, Mitch; Vialle, George; McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

hi, Charlie, George and Mitch:

Based on your inputs, I will do followings:
I will ship out the 2 tons we have procured by air tomorrow. (cost is about US$ 10k)
I will lock in the 15 tons(30k lbs) by signing a contract with the distributor. I will put down a deposit to secure it and hold the 15 tons here while we test out the 2 tons back in Natick. Once we confirm it is the right material, I will procure the 15 tons and we can discuss about what shipment to use by then; If it is not the right material, we will have option not to procure.
Please let me know if you have any concern or question.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

From: Smith, Charles
Sent: Tuesday, August 16, 2011 10:26 PM
To: Wheeler, Mitch; Vialle, George; Zhao, Ying (STP); McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

George

Mitch/I are meeting later this AM on testing regiment.

If the cost by air for $10K for first 4K lbs is accurate, I would plan to air freight all to insure we get to US safely. Sound like an additional $100K to complete this? We can confirm pricing and optimize shipment once we procure.

thks

Charlie

From: Wheeler, Mitch
Sent: Tuesday, August 16, 2011 10:16 AM
To: Vialle, George; Smith, Charles; Zhao, Ying (STP); McCaslin, Todd; Charest, Ann; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

Still awaiting the plan for this and more details to determine our chain of custody and purity documentation needs.

Shipping by sea can introduce contamination from salt water, shipments are also more likely to get lost (10,000 containers lost at sea each year). I would at least break up the 30K lbs order into two shipments if it went by sea.

From: Vialle, George
Sent: Tuesday, August 16, 2011 10:07 AM
To: Smith, Charles; Zhao, Ying (STP); McCaslin, Todd; Charest, Ann; Wheeler, Mitch; Gardner, Donna
Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John; Horton, Peter
Subject: RE: update on Option 1 distributor for Marlex from China

Charlie,
Peter and I have reviewed the HGX-030-01 requirements to cover 10 years of demand, including a 60% yield loss, change over loss, and an 11% CAGR for new products and market growth. Based on these inputs the analytic requirement is 15K lbs. Due to low resin cost/high sales & margin value I'd recommend a 2X factor, 30K lbs, to allow for storage loss, etc.
Do we have all the needed functional feedback, particularly from Mitch and Donna, regarding the pedigree, chain of custody, reg considerations for the distributor product? Also, what is the sampling plan for the purchased material? By batch, bag?

George

From: Smith, Charles
Sent: Tuesday, August 16, 2011 7:06 AM
To: Zhao, Ying (STP); McCaslin, Todd; Charest, Ann; Vialle, George; Wheeler, Mitch

Cc: Batz, Helge (STP); Ciulla, Ron; Intoccia, Al; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor for Marlex from China

Mike

1. I will get with George to confirm determine by end of day today on amount.

2. Thks, We will have to run Lot number to confirm that Phillips made then.

3. **Go by air** on this first shipment. We need it here to complete evaluation and know we have right material.

Charlie

From: Zhao, Ying (STP)
Sent: Tuesday, August 16, 2011 6:20 AM
To: McCaslin, Todd; Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

hi, Todd and Charlie:

The distributor said he can get another roughly 15 tons if we need. Let me know once you guys find out how much more we need to lock in.

He can't locate the CoA for this lot. No luck on that. We have to use the lot # to trace if you can. All of the material, including 2 tons we have and the other 15 tons are all from same lot: 6120105.

Air bill for 2 tons is pretty expensive: 64K RMB(about US$ 10K). By sea is a lot cheaper: about RMB 10K. My recommendation is to ship: 4 bags(100 kg) by air, about RMB 3200, then ship the rest 1.9 tons by sea.(it takes about 5 weeks).
Let me know what shipment you prefer and we will start working on the logistics tomorrow.

Best Regards,
Michael Zhao

From: McCaslin, Todd
Sent: Monday, August 15, 2011 10:28 PM
To: Zhao, Ying (STP); Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

The Phillips Sumika Lot Number for the resin is a 7 digit number. On the picture you sent it would be 6120105.

Do you know how much more material is available? If this works out, we may want to reserve several more tons.

Very nice work! Thanks

Todd

From: Zhao, Ying (STP)
Sent: Monday, August 15, 2011 10:14 AM
To: McCaslin, Todd; Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

Todd:

Could you let me know what a lot # looks like? I can ask them to check each bag.
I have pushed them on daily basis to locate CoA. They have to count on someone else, so it is not directly under control. I should know better tomorrow. This material has changed hands multiple times, and this 2 tons is just a small portion of the whole lot, I was told they will do their best, but can't promise. I think regardless we will still need to perform our testing.

Thanks,
Michael

From: McCaslin, Todd
Sent: Monday, August 15, 2011 10:07 PM
To: Zhao, Ying (STP); Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

Michael,
If you could try to push a bit on getting the C of A this would be a big help. Is there is anything else he needs to get these?

Could we get a list of the manufacturing lot #'s that are in the 2 tons? Maybe we can get them from another source...

Thanks!

Todd

From: Zhao, Ying (STP)
Sent: Monday, August 15, 2011 9:59 AM
To: McCaslin, Todd; Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

Todd:

These 4000 lbs are locked in, we have paid, they are ours, physically in the distributor's office right now, he just received, I have checked on site.

So I will work with the shipping company tomorrow and arrange to ship all of them out to Charlie ASAP.

Please let me know if you have any question or concern.

Regards,
Michael

From: McCaslin, Todd
Sent: Monday, August 15, 2011 9:55 PM
To: Zhao, Ying (STP); Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

We need to lock in all 4000 lbs right away. How do we get payment to insure this is reserved for us? We can decide on how to ship after we get control of it.

We need to work on getting the C of A. Ann, is this something AK plastics may have a path to get for us based upon the lot #'s?

Todd

From: Zhao, Ying (STP)
Sent: Monday, August 15, 2011 9:46 AM
To: Charest, Ann; Ciulla, Ron; Smith, Charles; McCaslin, Todd
Cc: Batz, Helge (STP)
Subject: update on Option 1 distributor

hi, Guys:

I have checked the stock our Option 1 distributor just brought in. It seems the right material. Please see the pictures attached. It was produced in Texas, It is Phillips Sumika, and it's HGX-030-01. He is trying to find CoA, but has not been successful so far.
Our original plan is to get 2 bags first, test them before we get the rest of 2 tons.
But now I feel we have high confidence of this material, please let me know if we should just ship all 2 tons at the same time. I am personally more confident on this material than the one I got from the Option 2 distributor.

We can pick them up at any time, we have 2 tons right here ready.

Regards,
Michael Zhao

From: Puttagunta, Prasad
Sent: 08/31/2011 05:15:38 AM
To: McCaslin, Todd
CC: Charest, Ann
Subject: RE: URGENT: Marlex HGX-030-01

Todd,

We tried two routes to get this information, I called my contacts on the sales side at Sumika and we had our Product manager call the contact on the CofA. Debra Bowen is no longer in that role but we have more recent C of As for material we buy and called the current contact listed on the paperwork, as well as their quality leader. Unfortunately, we received the same answer. The lot number on the bag is not a lot number in their system. My guess is that the material was repackaged in China from a bulk container and given a new lot number that may mean something to the Chinese distributor.

As I mentioned in a separate e-mail, I have been unable to discover who the Chinese distributors are, and Phillips Sumika will not take responsibility for the material sold their.

Prasad

N. Prasad Puttagunta

Phone: 517-223-5136

Cell : [redacted]

npputtagunta@akplastics.com

From: McCaslin, Todd [mailto:Todd.McCaslin@bsci.com]
Sent: Tuesday, August 30, 2011 11:06 AM
To: Puttagunta, Prasad

EXHIBIT
24

Cc: Charest, Ann
Subject: RE: URGENT: Marlex HGX-030-01

Prasad,

I have a question (and maybe a suggestion) for you.

I have attached the "old" C of A from Philips Sumika. There is a contact listed on the bottom "for questions...call Debra Bowen at 832-813-4916"

I was wondering if someone from AK could contact the phone # listed (who knows if it is still accurate or not) and ask about the lot # that we have identified on our bags the were procured from the alternate source (picture attached).

I'm just hoping that someone in the department that prepares C of A's may help.

If you have already taken this route, I apologize for the redundant thought.

Thanks

Todd

Todd McCaslin

Global Sourcing Director

Boston Scientific Corporation

(508) 650-8337

mccaslit@bsci.com

[redacted] (cell)

From: Puttagunta, Prasad [mailto:npputtagunta@akplastics.com]
Sent: Thursday, August 25, 2011 12:10 PM
To: Charest, Ann
Subject: RE: URGENT: Marlex HGX-030-01

Ann,

I met with my contacts this morning at Phillips Sumika in Houston and I was not able to discover who their brokers are in China or Singapore.

From what I gather, they sell excess material to brokers in the USA that off shore the material through their contacts. I believe this material would have been excess material that PS had at one time, or it was near prime or transitional material that they sold to a broker in the Texas area who sent it overseas. PS does not certify any material they release to the "secondary" market.

The lot number is not the PS data base, so it may be a number that was made up by the person that packaged the material.

PS does not have an office in Singapore but their parent company does and they only sell material from the middle east and Asia through that office. The other materials are from these secondary brokers.

I will send the e-mail on the testing we can do separately.

Prasad

N. Prasad Puttagunta

Phone: 517-223-5136

Cell : [redacted]

npputtagunta@akplastics.com

From: Charest, Ann [mailto:Ann.Charest@bsci.com]
Sent: Wednesday, August 24, 2011 12:53 PM
To: Puttagunta, Prasad
Subject: URGENT: Marlex HGX-030-01
Importance: High

Prasad,

1) Is the lot number invalid for the US and Singapore?

2) Would PS be willing to tell us who their Singapore distributors are? Our contact is reluctant to release this information, which of course means it could be counterfeit.

3) When might I expect your e:mail per our discussion last week, regarding what you've been able to find through PS and test services AK might be able to offer BSC?

Thank-you for your continued assistance.

Best Regards, Ann

Ann Charest

Manager, Global Sourcing, Resin

Boston Scientific Inc.

One Scimed Place, A399

Maple Grove, MN

Office: 763-494-1199

Cell: [redacted]

"Defining tomorrow, today."

From: Puttagunta, Prasad [mailto:npputtagunta@akplastics.com]
Sent: Monday, August 15, 2011 4:18 PM
To: Charest, Ann
Subject: RE: Marlex HGX-030-01

Ann –

I have been told by someone in the quality organization at Phillips Sumika that the lot number below is not valid.

Can you send me a picture of the bag and the lot number. I will check again.

Prasad

N. Prasad Puttagunta

Phone: 517-223-5136

Cell : [redacted]

npputtagunta@akplastics.com

From: Charest, Ann [mailto:Ann.Charest@bsci.com]
Sent: Monday, August 15, 2011 10:38 AM
To: Puttagunta, Prasad
Subject: Marlex HGX-030-01
Importance: High

Prasad,

We believe we have located material in China and the lot number is 6120105. The distributor does not have a Certificate of Compliance on file. We've have pictures of the bags, they are unopened and have the LaPorte, TX address on them. Would it be possible to ask you to use your connections at Phillips Sumika to obtain a copy of the CofC for us?

Thank-you again for your assistance in this task.

Best Regards, Ann

Ann Charest

Manager, Global Sourcing, Resin

Boston Scientific Inc.

One Scimed Place, A399

Maple Grove, MN

Office: 763-494-1199

Cell: [redacted]

"Defining tomorrow, today."

From: Smith, Charles
Sent: 08/15/2011 10:28:59 AM
To: McCaslin, Todd; Zhao, Ying (STP); Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
CC: Batz, Helge (STP); Raneri, Joe; Intoccia, Al; Wheeler, Mitch; Vialle, George; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor Marlex from China
Attachments: 08142011143.jpg; 08142011144.jpg; 08142011145.jpg; 08142011146.jpg; 08142011147.jpg

Importance: High

Ann/Mike/Todd

1. **These pictures look great**. If these bags are not open, then we have some leverage with Part/Lot# that are on them.

We had been discussing that we had a railroad car situation and that material had been packaged by someone other than Phillips.

2. I need to work with George/Mike so we had a place to put this into HOLD here.

3. How much more can we get if it looks like this??

thks

Charlie

From: McCaslin, Todd
Sent: Monday, August 15, 2011 10:07 AM
To: Zhao, Ying (STP); Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

Michael,
If you could try to push a bit on getting the C of A this would be a big help. Is there is anything else he needs to get these?

Could we get a list of the manufacturing lot #'s that are in the 2 tons? Maybe we can get them from another source...

Thanks!

EXHIBIT 25

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com
Redacted (cell)

From: Zhao, Ying (STP)
Sent: Monday, August 15, 2011 9:59 AM
To: McCaslin, Todd; Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

Todd:

These 4000 lbs are locked in, we have paid, they are ours, physically in the distributor's office right now, he just received, I have checked on site.

So I will work with the shipping company tomorrow and arrange to ship all of them out to Charlie ASAP.

Please let me know if you have any question or concern.

Regards,
Michael

From: McCaslin, Todd
Sent: Monday, August 15, 2011 9:55 PM
To: Zhao, Ying (STP); Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

We need to lock in all 4000 lbs right away. How do we get payment to insure this is reserved for us? We can decide on how to ship after we get control of it.

We need to work on getting the C of A. Ann, is this something AK plastics may have a path to get for us based upon the lot #'s?

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com
Redacted (cell)

From: Zhao, Ying (STP)
Sent: Monday, August 15, 2011 9:46 AM
To: Charest, Ann; Ciulla, Ron; Smith, Charles; McCaslin, Todd
Cc: Batz, Helge (STP)
Subject: update on Option 1 distributor

hi, Guys:

I have checked the stock our Option 1 distributor just brought in. It seems the right material. Please see the pictures attached. It was produced in Texas, It is Phillips Sumika, and it's HGX-030-01. He is trying to find CoA, but has not been successful so far.
Our original plan is to get 2 bags first, test them before we get the rest of 2 tons.
But now I feel we have high confidence of this material, please let me know if we should just ship all 2 tons at the same time. I am personally more confident on this material than the one I got from the Option 2 distributor.

We can pick them up at any time, we have 2 tons right here ready.

Regards,
Michael Zhao

From: Mullally, Robert
Sent: 07/20/2012 04:44:27 AM
To: brian.greaney@am.kwe.com; KWECHISF@am.kwe.com
Subject: ISF form for July 25th Departure from China
Attachments: 10+2 (2).xls

Hi Brian,

Attached is the ISF form for our next shipment of resin from China. Please use the following information to clear this entry.

3902.10.0000

Made by:

Dongguan Sunmei Plastic Raw Material Co., Ltd.

No.1, R-Building, New Railway Freight Yard

BaiGuoDong Industrial Zone, Zhangmutou

Dongguan, Guangdong 523000

China

Please contact me if there are any questions.

Thanks,

Rob Mullally

Boston Scientific

Import Export Compliance Coordinator

US Licensed Customs Broker

EXHIBIT 26

617-689-7391

From: Smith, Charles
Sent: Friday, July 20, 2012 7:17 AM
To: Mullally, Robert; Kieran, Damian; Zhao, Ying
Cc: Vialle, George
Subject: FW: ISF form for 2nd 5 tons to U.S.

Mike

Thks

Rob

Attached is ISF form

thks

Charlie

From: Zhao, Ying
Sent: Friday, July 20, 2012 5:43 AM
To: Smith, Charles
Subject: ISF form for 2nd 5 tons to U.S.

Hi, Charlie:

Attached is the doc for our ISF filing of the 2nd 5 tons. PIs forward to the right people who will perform this preparation. We need to get it ready before 7/25.

Thanks,

Michael

DHL GLOBAL FORWARDING

1 0101

BOSTON SCIENTIFIC CORP
500 COMMANDER SHEA BLVD
QUINCY, MA 02171

DATE	OUR REF. NO
8/20/12	537400587 BJC

THE MERCHANDISE DESCRIBED BELOW WILL BE ENTERED AND FORWARDED AS FOLLOWS:

IMPORTING CARRIER	LOCATION	FROM PORT OF / ORIGIN AIRPORT
CLEMENTINE MAERSK 6271	B&N AND SANTA FE RAILWAY	YANTIAN, CHINA

B/L OR AWB NO.	ARRIVAL DATE	FREE TIME EXP.	LOCAL DELIVERY OR TRANSFER BY (DELIVERY ORDER ISSUED TO)
ANLCACN0314031	8/16/12		OEI INT.

HAWB NO.	ENTRY NO.	CUST. REF. NO.
ITL12070145	336-7400587-5	

FOR DELIVERY TO	ROUTE
STEPHEN GOULD CORP 8351 NORTHWST BLVD. JEANNE SMITH INDIANAPOLIS, IN 46278 TEL: 260-471-2228 FAX: 508-650-8967	

NO. OF PKGS.	DESCRIPTION OF ARTICLES, SPECIAL MARKS & EXCEPTIONS	WEIGHT	DO NOT USE
200 PCS	MARLEX POLYPROPYLENE # of Containers: 1 SEGU1271710 20 I VVU40090136 M ANLC ACN0314031 H ITL12070145 Notify: BOSTON SCIENTIFIC CORP 610 PLEASANT ST WATERTOWN, MA 02172 508-650-8097 FAX: 508-650-8967 References: ITL12070145 CI Numbers: YFL201206001	11464 LB 5200	

ORIGINAL DELIVERY ORDER

I.T. Date 8/09/12

INLAND FREIGHT

PREPAID/COLLECT
Collect

Received in Good Order
By:

DHL Global Forwarding
As Agents Only
Agents for
BOSTON SCIENTIFIC CORP

DELIVERY CLERK: DELIVER TO CARRIER SHOWN ABOVE

CONFIDENTIAL
BSCM11500004626

EXHIBIT
27

DEPARTMENT OF HOMELAND SECURITY
U.S. Customs and Border Protection CST# 305
PAPERLESS

RadixGrpInt DBA DHL GLBL FWDG
10601A Seymour Avenue
Franklin Park, IL 60131
PH: 847-233-7900
FAX:847-233-5185

ENTRY/IMMEDIATE DELIVERY

ABI Certified

19 CFR 142.3, 142.16, 142.22, 142.24

Form Approved
OMB No. 1651-0024
Exp.01-31-2012

Broker Code: 336

1. ARRIVAL DATE	2. ELECTED ENTRY DATE	3. ENTRY TYPE CODE NAME	4. ENTRY NUMBER
081612		01 Consumption	336-7400587-5
5. PORT	**6. SINGLE TRANS. BOND**	**7. BROKER/IMPORTER FILE NUMBER**	
3901		537400587 BJC 0101	
	8. CONSIGNEE NUMBER		**9. IMPORTER NUMBER**
	04-269524000		Same

10. ULTIMATE CONSIGNEE NAME
BOSTON SCIENTIFIC CORP
500 COMMANDER SHEA BLVD
QUINCY, MA 02171

11. IMPORTER OF RECORD NAME
Same

12. CARRIER CODE	13. VOYAGE/FLIGHT/TRIP	14. LOCATION OF GOODS-CODE(S)/NAME(S)
ANLC	6271	I145 B&N AND SANTA FE RAILWAY
15. VESSEL CODE/NAME		
CLEMENTINE MAERSK		

16. U.S. PORT OF UNLADING	17. MANIFEST NUMBER	18. G.O. NUMBER	19. TOTAL VALUE
3001			12704

20. DESCRIPTION OF MERCHANDISE
MARLEX POLYPROPYLENE

21. IT/BL/AWB CODE	22. IT/BL/AWB NO.	23. MANIFEST QUANTITY	24. H.S. NUMBER	25. COUNTRY OF ORIGIN	26. MANUFACTURER NO.
I	VVU40090136		3902.10.0000	US	USPHISUM1000THE
M57078 H	ANLCACN0314031 ELIIITL12070145	200			

27. CERTIFICATION

I hereby make application for entry/immediate delivery. I certify that the above information is accurate, the bond is sufficient, valid, and current, and that all requirements of 19 CFR Part 142 have been met.

SIGNATURE OF APPLICANT Attorney-In-Fact
X RadixGrpInt DBA DHL G

PHONE NO. 847-233-7900

DATE 8/17/12

28. CBP USE ONLY

☐ OTHER AGENCY ACTION REQUIRED, NAMELY:

☐ CBP EXAMINATION REQUIRED.

☐ ENTRY REJECTED, BECAUSE:

29. BROKER OR OTHER GOVT. AGENCY USE

Exam Site: I145 B&N AND SANTA FE RA
Container #:
SEGU1271710 200

DELIVERY AUTHORIZED:	SIGNATURE	DATE

ABI Electronic Release
I certify that proper release for this cargo has been received from CBP
RadixGrpInt DBA DHL GLBL FWDG
Authorized by:
Released: 8/17/12 19:25

From: Smith, Charles
Sent: 11/21/2011 08:05:54 AM
To: Zhao, Ying (STP); Vialle, George; Hines, Saron
CC: Cotton, Derek; du Halgouet, Tanguy; McCaslin, Todd; Batz, Helge
Subject: RE: Packaging of the Marlex from China distributor for shipment

Mike

We can over bag, but we should not open bags and repack. We would have to worry about contamination. Let us know how you make out tomorrow.

Thks

Charlie

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Monday, November 21, 2011 11:00 AM
To: Vialle, George; Smith, Charles; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; McCaslin, Todd; Batz, Helge (STP)
Subject: RE: Final payment of Marlex from China distributor

hi, guys:

To play safe about the 10 tons material we ship to U.S., I think it is better to split them into two small containers and have 5 tons in each just in case of any accident, like falling over to sea, etc., during the shipment. I think it is worth the fee for extra container. Who knows what may happen, I went to a suppliy chain conference last week and heard about all of risks in logistics and it made me nervous.

Just to give you a heads up. Last time due to it's by air and small amount, the 2 tons was not "inspected" by the custom. The shipper basically put a blank bag over the original bag. This time since it has 3 containers and by sea, likely custom will inspect them. The shipper told me that the inspector is pretty good at their job and we will need to "re-pack" all 600 bags. I have not seen them by myself yet, but if it is the same bag as previous 2 tons we bought, they all have details about where it was procuded originally on the outside of bags. Per import/export law in China, it is very hard to export stuff out if it was procuded from oversea without the original and correct paperwork. For this material, we have lost all of the original paperwork so we can't prove that was legally imported into the country. and if we don't get rid of the original bags or the writing on the bags when we claim they are from China(we have to say they are from China since we don't have original paperwork attached), if it is caught by custom, we will be in trouble. Therefore the shipper told me it is better to consider to re-pack all of them or find a way to get rid of all of the words/writing on the bags. I will talk with the distributor tomorrow and see what we can likely do on site. I plan to go there in later this week. I think that will be the only time I can for sure know how we should deal with it. I will spend days on site to take care of it. I expect a lot of work sine there are 600 bags of 25 kg materials and this sounds a new task to me, and maybe the distibutor as well.
This is so far what's going on and I will keep you posted as it goes.

Regards,
Michael Zhao

From: Vialle, George
Sent: Thursday, November 17, 2011 9:35 AM

To: Zhao, Ying (STP); Smith, Charles; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Michael,
Thank you. The crating and wrapping look good. Any additional bracing inside the container will be helpful. Could you press them on placement on the ship, we would be willing to pay a modest fee for this service. Thanks for your continued diligence and help.
Regards,
George

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Thursday, November 17, 2011 8:31 AM
To: Vialle, George; Smith, Charles; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

I checked with shipper. They can change container if it has any smell(if any, it is chemical smell), cost is less than US$ 1K. Also they will pack the container as showed in the pics attached to prevent from water and smell. They can try to pack it inside of the container in a way to prevent from shifting inside of the container, cost should be reasonable, they have not told me about the amount as it will depend on how the bags fit in the container. They don't have any control on where the container will be placed on the ship though, can't do much about that part.
Do we have concern on temperature? It will reach 50c during shipment by sea. I don't think we have concern on that, but want to double check with you all.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: [redacted]
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Vialle, George
Sent: Tuesday, November 15, 2011 10:09 PM
To: Zhao, Ying (STP); Smith, Charles; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Michael,
We discussed and have additional thoughts. Can we get a container that does not smell? We would be willing to pay a modest fee for this. Also, can we specify where the container will be loaded on the ship? We would like to avoid an exposed location that could cause water damage or loss of the container overboard into the ocean.

Thanks,
George

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Tuesday, November 15, 2011 8:36 AM
To: Vialle, George; Smith, Charles; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Yes, that's what I have mentioned to the shipper. We will pack it better. if there is any other idea from our side, pls let me know.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: [redacted]
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Vialle, George
Sent: Tuesday, November 15, 2011 9:34 PM
To: Zhao, Ying (STP); Smith, Charles; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Can the product be bagged/wrapped in plastic to prevent potential contamination?

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Tuesday, November 15, 2011 8:25 AM
To: Smith, Charles; Vialle, George; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

My understanding is any kind of smell, he does not know in advance either, could be from anything potentially, just a caution on smell. Have we encountered any this kind of problem before?

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: [redacted]
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Smith, Charles
Sent: Tuesday, November 15, 2011 9:21 PM
To: Zhao, Ying (STP); Vialle, George; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Mike

Can we define smell? Are we talking about food products , animals??

Charlie

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Tuesday, November 15, 2011 8:19 AM
To: Vialle, George; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; Smith, Charles; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Hi, guys:

Is there any concern over smell during shipment? The shipper asked me about this today. We will have dedicated container for our product, but he wondered if we care about the smell caused by other container. Maybe sometimes other products can have strong smell. Do we know any measure to protect our product from this kind of potential "contamination"?

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: [redacted]
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Vialle, George
Sent: Tuesday, November 15, 2011 3:01 AM
To: Zhao, Ying (STP); Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; Smith, Charles; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Michael,
Yes, please ship everything by sea.

Regards,
George

-----Original Message-----
From: Zhao, Ying (STP)

Sent: Monday, November 14, 2011 10:53 AM
To: Vialle, George; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; Smith, Charles; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Charlie, Saron and George:

Sure, I will communicate this to the shipper and try my best to take care of this when I go there next week.
So we want the total 15 tons all shipped by sea? Both to Belgium and U.S.? correct?

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: [redacted]
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Vialle, George
Sent: Monday, November 14, 2011 9:45 PM
To: Hines, Saron; Zhao, Ying (STP)
Cc: Cotton, Derek; du Halgouet, Tanguy; Smith, Charles; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Michael,
Per Saron's comments can you make sure that the resin is loaded in a manner that will prevent it from shifting inside the container while in transit?

Regards,
George

-----Original Message-----
From: Hines, Saron
Sent: Friday, November 11, 2011 10:04 AM
To: Vialle, George; Zhao, Ying (STP)
Cc: Cotton, Derek; du Halgouet, Tanguy; Smith, Charles; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

George, loading the container properly to make certain the product is secure and does not shift about inside the container is paramount.

If the container is full, the contents themselves will help minimize shifting. If the container is not full, the product can and will shift if it not braced properly, creating the potential for damage.

Saron Hines
Global Transportation Manager

Global Supply Chain Operations
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
Office - 508-647-2503
Fax - 508-650-8545
hiness@bsci.com

-----Original Message-----
From: Vialle, George
Sent: Friday, November 11, 2011 9:47 AM
To: Hines, Saron; Zhao, Ying (STP)
Cc: Cotton, Derek; du Halgouet, Tanguy; Smith, Charles; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Saron,
Thanks for the feedback. Damage/loss is the primary concern and we have enough material already in Marlborough to cover the leadtime. Based on cost and damage considerations Ocean is emerging as out preferred shipment method. In addition to having a dedicated container, is there anything else we should be doing to ensure the product is not damaged in transit?

Regards,
George

-----Original Message-----
From: Hines, Saron
Sent: Friday, November 11, 2011 9:29 AM
To: Zhao, Ying (STP); Vialle, George
Cc: Cotton, Derek; du Halgouet, Tanguy; Smith, Charles; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

As a precaution, air freight is always more susceptible to damage than ocean freight due to many touch points and extra handling.

If damage is a major concern, consider shipping via ocean if you can afford the transit time. Not only will you save money, but you will reduce the probability of damage considerably.

Saron Hines
Global Transportation Manager
Global Supply Chain Operations
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760
Office - 508-647-2503
Fax - 508-650-8545
hiness@bsci.com

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Friday, November 11, 2011 2:11 AM
To: Vialle, George; Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; Smith, Charles; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Hi, George:

I talked to the guy from KWE who quoted me. Yes, it is based on 5 tons to Belgium and 10 tons to U.S..
If by sea, our shipment will be in dedicated container, no other stuff will be mixed with it; if by air, depending on the packing situation, it may be mixed with other product.
I have expressed our concern over damage during shipment, before the actually shipment, I will enforce the requirement again to avoid the loss on damage.

So let me know how we want to ship.

Regards,
Michael

-----Original Message-----
From: Vialle, George
Sent: Thursday, November 10, 2011 3:54 AM
To: Zhao, Ying (STP); Hines, Saron
Cc: Cotton, Derek; du Halgouet, Tanguy; Smith, Charles; McCaslin, Todd
Subject: RE: Final payment of Marlex from China distributor

Michael,
Thanks for the shipping cost information. Can you confirm that this costing is based on sending 5 tons to Belgium and 10 tons to the US? The lower cost for Ocean shipment is attractive (7.77 HKD = 1 USD, conversion cost updated below) but we must be sure that the product is safe and secure during ocean shipment. Ideally we would have a dedicated container for each shipment. If that is not possible we would want the shipment in a sealed container with other material shipping to Belgium and Indianapolis to minimize opportunities for damage, contamination, and theft. Can we get more info from KWE on how the product will be handled?

Saron,
If you have any input please share with the team.

Thanks,
George

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Wednesday, November 09, 2011 2:17 AM
To: Smith, Charles; Vialle, George; McCaslin, Todd
Cc: Cotton, Derek; du Halgouet, Tanguy; Hines, Saron
Subject: RE: Final payment of Marlex from China distributor

OK, our accounting lady has not processed it yet. She is doing it right now. I will let you know once it's paid off.

Now I got the cost estimate from KWE eventually. Here is the comparison between air and sea on time and cost. A big difference on cost.

	air time	air cost	sea time	sea cost
U.S	5~7 days	HKD 204,595/USD $26.3K	36~39 days	HKD 29,795/USD $3.8K
Belgium	5~7 days	HKD 372,195/USD $47.9K	36~39 days	HKD 18,415/USD $2.4K
		USD$74.2K total		USD $6.2K total

Please let me know how we want to ship these 15 tons.

Regards,

Michael Zhao

-----Original Message-----
From: Smith, Charles
Sent: Tuesday, November 08, 2011 11:01 PM
To: Zhao, Ying (STP); Vialle, George; McCaslin, Todd
Cc: Cotton, Derek; du Halgouet, Tanguy; Hines, Saron
Subject: RE: Final payment of Marlex from China distributor

Work with George and Sharon on the shipping, they have the lead with you.

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Tuesday, November 08, 2011 9:57 AM
To: Smith, Charles; Vialle, George; McCaslin, Todd
Cc: Cotton, Derek; du Halgouet, Tanguy; Hines, Saron
Subject: RE: Final payment of Marlex from China distributor

hi, Charlie:

I will check with our accouting tomorrow. We have issued a PO, accouting here needs to place that and transfer the fund.

I need help on shipping. The KWE we used before is very slow on quoting me the cost and time on by air and by sea. I have pushed a few times and still have not got an answer.
Let's try another shipper. I am sure someone will want this business. This does not make sense. Do we have an alternative?

Regards,
Michael

From: Smith, Charles
Sent: Tuesday, November 08, 2011 6:10 AM
To: Zhao, Ying (STP); Vialle, George; McCaslin, Todd
Cc: Cotton, Derek; du Halgouet, Tanguy; Hines, Saron
Subject: RE: Final payment of Marlex from China distributor

Mike

Any update on the final payment?

Thks

Charlie
-----Original Message-----
From: Zhao, Ying (STP)
Sent: Thursday, October 27, 2011 11:33 PM
To: Smith, Charles; McCaslin, Todd; Vialle, George
Cc: Intoccia, Al; Cotton, Derek; du Halgouet, Tanguy
Subject: RE: update on Option 1 distributor Marlex from China

Hi, Charlie:

That's good, we got the right material.

I will work on the PO. It has to be done though Finance group in China and get cross charge to you later on.
I am on a trip to St. Paul now and will be back to Shanghai on 11/6. I will work with multiple parties in Shanghai office once I get back to take care of the payment. Also I plan to check out the material and make sure it is all from same lot and they are still in good shape before we ship them out. Last time the packing caused some damage and I will communicate to the shipper to prevent it this time. Based on my schedule, I think I can get it done around 11/12.
Last time we did shipping by air, it was 2 tons, we have 15 tons this time, by sea or by air? It will be very expensive if by air. George can work with me on the shipping details?

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: [redacted]
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001
-----Original Message-----
From: Smith, Charles
Sent: Thursday, October 27, 2011 10:10 PM
To: Zhao, Ying (STP); McCaslin, Todd; Vialle, George
Cc: Intoccia, Al; Cotton, Derek; du Halgouet, Tanguy
Subject: RE: update on Option 1 distributor Marlex from China

Todd

Please proceed with final payment cross charge. George is starting to work on logistics as well, so we will talk further on that.

thks

Charlie

-----Original Message-----
From: Smith, Charles
Sent: Friday, October 21, 2011 7:06 AM
To: Zhao, Ying (STP); McCaslin, Todd
Cc: Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Mike

Yes we are pretty confident with testing to date. We will get back to you next week.

thks

Charlie
-----Original Message-----
From: Zhao, Ying (STP)
Sent: Thursday, October 20, 2011 8:54 PM
To: Smith, Charles; McCaslin, Todd

Cc: Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Hi, Charlie:

Sounds great, so it is the material we are looking for?

The rest amount due is about US$ 24K by mid of Nov. for these 15 tons.

Best Regards,
Michael Zhao
-----Original Message-----
From: Smith, Charles
Sent: Friday, October 21, 2011 2:23 AM
To: Zhao, Ying (STP); McCaslin, Todd
Cc: Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Todd/Mike

Looking good, what is the final cross charge dollar amount we owe

Thks

Charlie
-----Original Message-----
From: Smith, Charles
Sent: Friday, October 14, 2011 7:48 AM
To: Zhao, Ying (STP)
Cc: McCaslin, Todd
Subject: RE: update on Option 1 distributor Marlex from China

We just received external data summary late yesterday, we have internal technical team working on our review/report later today.

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Friday, October 14, 2011 5:30 AM
To: Smith, Charles
Cc: McCaslin, Todd
Subject: RE: update on Option 1 distributor Marlex from China

Hi, Todd and Charlie:

Pls let me know once the report is out. Hope it is the right material. Thanks.

Best Regards,
Michael Zhao

-----Original Message-----
From: Smith, Charles
Sent: Wednesday, September 28, 2011 6:00 PM
To: Zhao, Ying (STP); McCaslin, Todd
Cc: Charest, Ann; Podmore, Adrienne; Vialle, George; du Halgouet, Tanguy
Subject: RE: update on Option 1 distributor Marlex from China

Mike

Thks

Todd

Have you had any luck on lot number or certification?

Sent from my Verizon Wireless Phone

-----Original Message-----
From: Zhao, Ying (STP) <ying.zhao@bsci.com>
Sent: Wednesday, September 28, 2011 3:50 AM
To: Smith, Charles <Charlie.Smith@bsci.com>; McCaslin, Todd <Todd.McCaslin@bsci.com>
Cc: Charest, Ann <Ann.Charest@bsci.com>; Podmore, Adrienne <Adrienne.Podmore@bsci.com>; Vialle, George <George.Vialle@bsci.com>; du Halgouet, Tanguy <HALGOUET@bsci.com>
Subject: RE: update on Option 1 distributor Marlex from China

Hi, Charlie:

The due date of final payment is: 11/15. It seems we have enough time buffer for us to decide after 10/14.
The 15 tons are under control at the distributor.
We have not been able to locate any lot traceability with the distributor.

Best Regards,
Michael Zhao

-----Original Message-----
From: Smith, Charles
Sent: Tuesday, September 27, 2011 3:45 AM
To: Zhao, Ying (STP); McCaslin, Todd
Cc: Charest, Ann; Podmore, Adrienne; Vialle, George; du Halgouet, Tanguy
Subject: RE: update on Option 1 distributor Marlex from China

Mike/Todd

Equivalency Testing in progress, results by OCT 14.
We have update in PIB this coming Thursday AM.
Just want to confirm the date for final payment of the 30K lbs. still in china and the amount still due.

Thks

Charlie

-----Original Message-----
From: Smith, Charles
Sent: Wednesday, August 31, 2011 9:36 AM
To: Zhao, Ying (STP); McCaslin, Todd
Cc: Charest, Ann; Horton, Peter; Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Mike

Thks.

Charlie

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Wednesday, August 31, 2011 9:30 AM
To: Smith, Charles; McCaslin, Todd
Cc: Charest, Ann; Horton, Peter; Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Charlie and Todd:

I have asked the distributor today. He will try to trace it as much as he can. He will let me know if he can find anything related to the lot traceability.
He confirmed me again on the lot #, they all are from the same lot.
Will let you know if I hear anything.

Regards,
Michael

From: Smith, Charles
Sent: Tuesday, August 30, 2011 10:41 AM
To: Zhao, Ying (STP); McCaslin, Todd
Cc: Charest, Ann; Horton, Peter; Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Ok. thks.

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Tuesday, August 30, 2011 11:33 AM
To: Smith, Charles; McCaslin, Todd
Cc: Charest, Ann; Horton, Peter; Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Hi, Charlie:

That is 15 tons, 15,000 kgs, 600 bags (25 kg/bag). Same bag as those you already received. They are from the same lot. I asked the distributor this question many times and he assured me on this. I think we can trust him based on what he has provided us so far.

Regards,
Michael

-----Original Message-----
From: Smith, Charles
Sent: Tuesday, August 30, 2011 11:26 PM
To: Zhao, Ying (STP); McCaslin, Todd
Cc: Charest, Ann; Horton, Peter; Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Mike

Can you confirm actual amount and that it is in bags, and same lot#.

Thks

Charlie

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Tuesday, August 30, 2011 11:22 AM
To: McCaslin, Todd
Cc: Smith, Charles; Charest, Ann; Horton, Peter; Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Hi, Todd:

I am doing fine, thanks. Will start another traveling from this Friday. Hope you are doing well.

We have paid 40% of the payment and got the 15 tons locked in. The distributor has the material, and will hold on it for 2 months and a half while we perform testing. We are in good shape on this one.
I will talk to the distributor more tomorrow. Will keep you posted.

Thanks,
Michael

-----Original Message-----
From: McCaslin, Todd
Sent: Tuesday, August 30, 2011 11:12 PM
To: Zhao, Ying (STP)
Cc: Smith, Charles; Charest, Ann; Horton, Peter; Vialle, George
Subject: RE: update on Option 1 distributor Marlex from China

Michael,
Hi Hope you are doing well.

I have a few questions...

1) Could you please let us know what the status of the payment and lock in of the 15 tons of material

2) We are still having difficulty tracing the lot # that was on the bag back to Phillips Sumika. Could you continue to work with the Broker to try and determine the chain of custody this material has had since being produced at Phillips. Where did the broker we bought from get the material and could we talk to them (do they have paperwork?). We need to try to keep tracking this to provide an answer to QA. We are anticipating a lot of questions from our QA group.

Thanks
Todd

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Monday, August 22, 2011 12:41 AM
To: Smith, Charles; McCaslin, Todd; Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Subject: RE: update on Option 1 distributor Marlex from China

hi, Charlie:

The 2 tons material has been shipped out of Hong Kong on 8/21. They should arrive in U.S. by Monday your time.
This material is likely the right material, from our Option 1 distributor. Let me know once you get it.
Attached please find the shipping info.

Regards,
Michael

From: Smith, Charles
Sent: Friday, August 19, 2011 4:40 AM
To: Zhao, Ying (STP); McCaslin, Todd; Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Cc: Batz, Helge (STP); Raneri, Joe; Intoccia, Al; Wheeler, Mitch; Vialle, George; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor Marlex from China

Mike

If you feel this is best, will follow your judgment.

Thks

charlie

Sent from my Verizon Wireless Phone

From: Zhao, Ying (STP) <ying.zhao@bsci.com>
Sent: Thursday, August 18, 2011 11:12 PM
To: Smith, Charles <Charlie.Smith@bsci.com>; McCaslin, Todd <Todd.McCaslin@bsci.com>; Charest, Ann <Ann.Charest@bsci.com>; Horton, Peter <Peter.Horton@bsci.com>; Cuddy, Christopher <Christopher.Cuddy@bsci.com>; Ciulla, Ron <Ron.Ciulla@bsci.com>
Cc: Batz, Helge (STP) <helge.batz@bsci.com>; Raneri, Joe <Joe.Raneri@bsci.com>; Intoccia, Al <Al.Intoccia@bsci.com>; Wheeler, Mitch <Mitch.Wheeler@bsci.com>; Vialle, George <George.Vialle@bsci.com>; Kelly, Mike (Marlboro) <Mike.Kelly@bsci.com>; Pedersen, John <John.Pedersen@bsci.com>
Subject: RE: update on Option 1 distributor Marlex from China

hi, Charlie:

I understand your concern.
But everything has been arranged, it involved multiple parties. Nothing is simple when you deal with China's custom/export. I think one bag is faster, but not that much, they will go through same procedure and flight. Just in case we don't cause confusion to other parties, can we stay with the current plan?

Thanks,

Best Regards,
Michael Zhao

From: Smith, Charles
Sent: Friday, August 19, 2011 10:04 AM
To: Zhao, Ying (STP); McCaslin, Todd; Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Cc: Batz, Helge (STP); Raneri, Joe; Intoccia, Al; Wheeler, Mitch; Vialle, George; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor Marlex from China

Ok

Can you air one bag today separate as it should get here quicker than the whole lot?

thks

Sent from my Verizon Wireless Phone

From: Zhao, Ying (STP) <ying.zhao@bsci.com>
Sent: Thursday, August 18, 2011 9:45 PM
To: Smith, Charles <Charlie.Smith@bsci.com>; McCaslin, Todd <Todd.McCaslin@bsci.com>; Charest, Ann <Ann.Charest@bsci.com>; Horton, Peter <Peter.Horton@bsci.com>; Cuddy, Christopher <Christopher.Cuddy@bsci.com>; Ciulla, Ron <Ron.Ciulla@bsci.com>
Cc: Batz, Helge (STP) <helge.batz@bsci.com>; Raneri, Joe <Joe.Raneri@bsci.com>; Intoccia, Al <Al.Intoccia@bsci.com>; Wheeler, Mitch <Mitch.Wheeler@bsci.com>; Vialle, George <George.Vialle@bsci.com>; Kelly, Mike (Marlboro) <Mike.Kelly@bsci.com>; Pedersen, John <John.Pedersen@bsci.com>
Subject: RE: update on Option 1 distributor Marlex from China

hi, Charlie:

The bag you received is from our Option 2 distributor. We decided to source from 2 distributors in parallel to increase our chance, one with higher risk, one with lower risk. The one just arrived at your place is from the higher risk distributor. Based on what I saw here, I was not confident on this material, but you guys decided to get some samples, so we went ahead and bought a bag for you to test out. Seems this is not the material we are looking for. We may not pursue more on this one then.

The 2 tons we are about to pick up today are from Option 1 distributor. The pictures I sent you are from this material, I have high confidence on this material. We are working on locking in another 15 tons of the same material, same lot.

I believe we are on the right path. Please let me know if you have any question or concern.

Best Regards,
Michael Zhao

From: Smith, Charles
Sent: Friday, August 19, 2011 4:33 AM
To: McCaslin, Todd; Zhao, Ying (STP); Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Cc: Batz, Helge (STP); Raneri, Joe; Intoccia, Al; Wheeler, Mitch; Vialle, George; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor Marlex from China
Importance: High

Mike

bag is here, doesn't match pictures from your end? see attached of bag that arrived.

thks

Charlie

From: Smith, Charles
Sent: Monday, August 15, 2011 10:29 AM
To: McCaslin, Todd; Zhao, Ying (STP); Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Cc: Batz, Helge (STP); Raneri, Joe; Intoccia, Al; Wheeler, Mitch; Vialle, George; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor Marlex from China
Importance: High

Ann/Mike/Todd

1. These pictures look great. If these bags are not open, then we have some leverage with Part/Lot# that are on them.

We had been discussing that we had a railroad car situation and that material had been packaged by someone other than Phillips.

2. I need to work with George/Mike so we had a place to put this into HOLD here.

3. How much more can we get if it looks like this??

thks

Charlie

From: McCaslin, Todd
Sent: Monday, August 15, 2011 10:07 AM
To: Zhao, Ying (STP); Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

Michael,
If you could try to push a bit on getting the C of A this would be a big help. Is there is anything else he needs to get these?

Could we get a list of the manufacturing lot #'s that are in the 2 tons? Maybe we can get them from another source...

Thanks!

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com<mailto:mccaslit@bsci.com>
[redacted](cell)

From: Zhao, Ying (STP)
Sent: Monday, August 15, 2011 9:59 AM
To: McCaslin, Todd; Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

Todd:

These 4000 lbs are locked in, we have paid, they are ours, physically in the distributor's office right now, he just received, I have checked on site.

So I will work with the shipping company tomorrow and arrange to ship all of them out to Charlie ASAP.

Please let me know if you have any question or concern.

Regards,

Michael

From: McCaslin, Todd
Sent: Monday, August 15, 2011 9:55 PM
To: Zhao, Ying (STP); Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

We need to lock in all 4000 lbs right away. How do we get payment to insure this is reserved for us? We can decide on how to ship after we get control of it.

We need to work on getting the C of A. Ann, is this something AK plastics may have a path to get for us based upon the lot #'s?

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com<mailto:mccaslit@bsci.com>
[redacted](cell)

From: Zhao, Ying (STP)
Sent: Monday, August 15, 2011 9:46 AM
To: Charest, Ann; Ciulla, Ron; Smith, Charles; McCaslin, Todd
Cc: Batz, Helge (STP)
Subject: update on Option 1 distributor

hi, Guys:

I have checked the stock our Option 1 distributor just brought in. It seems the right material. Please see the pictures attached. It was produced in Texas, It is Phillips Sumika, and it's HGX-030-01. He is trying to find CoA, but has not been successful so far.
Our original plan is to get 2 bags first, test them before we get the rest of 2 tons.
But now I feel we have high confidence of this material, please let me know if we should just ship all 2 tons at the same time. I am personally more confident on this material than the one I got from the Option 2 distributor.

We can pick them up at any time, we have 2 tons right here ready.

Regards,
Michael Zhao

From: Zhao, Ying (STP)
Sent: 12/01/2011 06:56:41 PM
To: Vialle, George
CC: Smith, Charles
Subject: RE: Two ton shipment Option 1 distributor Marlex from China

George:

We took a chance, the shipper who handled it was not "over-cautious", it was a different person.
It was smaller amount, and by air. Overall there is less chance to be audited if small amount and by air.
This time, this handler does not want to take any chance therefore we are planning for the worst scenario basically.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: 86-186-2182-5362
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Vialle, George
Sent: Friday, December 02, 2011 2:39 AM
To: Zhao, Ying (STP)
Cc: Smith, Charles
Subject: FW: Two ton shipment Option 1 distributor Marlex from China

Michael,
Could you review the attached paperwork for the original 2000 kilo resin shipment? How were we able to export without debagging the resin or indicating that the product was manufactured in China?

Regards,
George

-----Original Message-----
From: Smith, Charles
Sent: Thursday, December 01, 2011 9:33 AM
To: Vialle, George
Subject: FW: Two ton shipment Option 1 distributor Marlex from China

Here is info

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Monday, August 22, 2011 12:41 AM
To: Smith, Charles; McCaslin, Todd; Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Subject: Two ton shipment Option 1 distributor Marlex from China

EXHIBIT
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hi, Charlie:

The 2 tons material has been shipped out of Hong Kong on 8/21. They should arrive in U.S. by Monday your time.
This material is likely the right material, from our Option 1 distributor. Let me know once you get it.
Attached please find the shipping info.

Regards,
Michael

From: Smith, Charles
Sent: Friday, August 19, 2011 4:40 AM
To: Zhao, Ying (STP); McCaslin, Todd; Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Cc: Batz, Helge (STP); Raneri, Joe; Intoccia, Al; Wheeler, Mitch; Vialle, George; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor Marlex from China

Mike

If you feel this is best, will follow your judgment.

Thks

charlie

Sent from my Verizon Wireless Phone

From: Zhao, Ying (STP) <ying.zhao@bsci.com>
Sent: Thursday, August 18, 2011 11:12 PM
To: Smith, Charles <Charlie.Smith@bsci.com>; McCaslin, Todd <Todd.McCaslin@bsci.com>; Charest, Ann <Ann.Charest@bsci.com>; Horton, Peter <Peter.Horton@bsci.com>; Cuddy, Christopher <Christopher.Cuddy@bsci.com>; Ciulla, Ron <Ron.Ciulla@bsci.com>
Cc: Batz, Helge (STP) <helge.batz@bsci.com>; Raneri, Joe <Joe.Raneri@bsci.com>; Intoccia, Al <Al.Intoccia@bsci.com>; Wheeler, Mitch <Mitch.Wheeler@bsci.com>; Vialle, George <George.Vialle@bsci.com>; Kelly, Mike (Marlboro) <Mike.Kelly@bsci.com>; Pedersen, John <John.Pedersen@bsci.com>
Subject: RE: update on Option 1 distributor Marlex from China

hi, Charlie:

I understand your concern.
But everything has been arranged, it involved multiple parties. Nothing is simple when you deal with China's custom/export. I think one bag is faster, but not that much, they will go through same procedure and flight. Just in case we don't cause confusion to other parties, can we stay with the current plan?

Thanks,

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com<mailto:ying.zhao@bsci.com>
Office: 86-21-61419708

Cell: 86-186-2182-5362
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

From: Smith, Charles
Sent: Friday, August 19, 2011 10:04 AM
To: Zhao, Ying (STP); McCaslin, Todd; Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Cc: Batz, Helge (STP); Raneri, Joe; Intoccia, Al; Wheeler, Mitch; Vialle, George; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor Marlex from China

Ok

Can you air one bag today separate as it should get here quicker than the whole lot?

thks

Sent from my Verizon Wireless Phone

From: Zhao, Ying (STP) <ying.zhao@bsci.com>
Sent: Thursday, August 18, 2011 9:45 PM
To: Smith, Charles <Charlie.Smith@bsci.com>; McCaslin, Todd <Todd.McCaslin@bsci.com>; Charest, Ann <Ann.Charest@bsci.com>; Horton, Peter <Peter.Horton@bsci.com>; Cuddy, Christopher <Christopher.Cuddy@bsci.com>; Ciulla, Ron <Ron.Ciulla@bsci.com>
Cc: Batz, Helge (STP) <helge.batz@bsci.com>; Raneri, Joe <Joe.Raneri@bsci.com>; Intoccia, Al <Al.Intoccia@bsci.com>; Wheeler, Mitch <Mitch.Wheeler@bsci.com>; Vialle, George <George.Vialle@bsci.com>; Kelly, Mike (Marlboro) <Mike.Kelly@bsci.com>; Pedersen, John <John.Pedersen@bsci.com>
Subject: RE: update on Option 1 distributor Marlex from China

hi, Charlie:

The bag you received is from our Option 2 distributor. We decided to source from 2 distributors in parallel to increase our chance, one with higher risk, one with lower risk. The one just arrived at your place is from the higher risk distributor. Based on what I saw here, I was not confident on this material, but you guys decided to get some samples, so we went ahead and bought a bag for you to test out. Seems this is not the material we are looking for. We may not pursue more on this one then.

The 2 tons we are about to pick up today are from Option 1 distributor. The pictures I sent you are from this material, I have high confidence on this material. We are working on locking in another 15 tons of the same material, same lot.

I believe we are on the right path. Please let me know if you have any question or concern.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com<mailto:ying.zhao@bsci.com>
Office: 86-21-61419708
Cell: 86-186-2182-5362

Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

From: Smith, Charles
Sent: Friday, August 19, 2011 4:33 AM
To: McCaslin, Todd; Zhao, Ying (STP); Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Cc: Batz, Helge (STP); Raneri, Joe; Intoccia, Al; Wheeler, Mitch; Vialle, George; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor Marlex from China
Importance: High

Mike

bag is here, doesn't match pictures from your end? see attached of bag that arrived.

thks

Charlie

From: Smith, Charles
Sent: Monday, August 15, 2011 10:29 AM
To: McCaslin, Todd; Zhao, Ying (STP); Charest, Ann; Horton, Peter; Cuddy, Christopher; Ciulla, Ron
Cc: Batz, Helge (STP); Raneri, Joe; Intoccia, Al; Wheeler, Mitch; Vialle, George; Kelly, Mike (Marlboro); Pedersen, John
Subject: RE: update on Option 1 distributor Marlex from China
Importance: High

Ann/Mike/Todd

1. These pictures look great. If these bags are not open, then we have some leverage with Part/Lot# that are on them.

We had been discussing that we had a railroad car situation and that material had been packaged by someone other than Phillips.

2. I need to work with George/Mike so we had a place to put this into HOLD here.

3. How much more can we get if it looks like this??

thks

Charlie

From: McCaslin, Todd
Sent: Monday, August 15, 2011 10:07 AM
To: Zhao, Ying (STP); Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

Michael,

If you could try to push a bit on getting the C of A this would be a big help. Is there is anything else he needs to get these?

Could we get a list of the manufacturing lot #'s that are in the 2 tons? Maybe we can get them from another source...

Thanks!

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com<mailto:mccaslit@bsci.com>
(339) 223 - 2426 (cell)

From: Zhao, Ying (STP)
Sent: Monday, August 15, 2011 9:59 AM
To: McCaslin, Todd; Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

Todd:

These 4000 lbs are locked in, we have paid, they are ours, physically in the distributor's office right now, he just received, I have checked on site.

So I will work with the shipping company tomorrow and arrange to ship all of them out to Charlie ASAP.

Please let me know if you have any question or concern.

Regards,
Michael

From: McCaslin, Todd
Sent: Monday, August 15, 2011 9:55 PM
To: Zhao, Ying (STP); Charest, Ann; Ciulla, Ron; Smith, Charles
Cc: Batz, Helge (STP)
Subject: RE: update on Option 1 distributor

We need to lock in all 4000 lbs right away. How do we get payment to insure this is reserved for us? We can decide on how to ship after we get control of it.

We need to work on getting the C of A. Ann, is this something AK plastics may have a path to get for us based upon the lot #'s?

Todd McCaslin
Global Sourcing Director
Boston Scientific Corporation
(508) 650-8337
mccaslit@bsci.com<mailto:mccaslit@bsci.com>
(339) 223 - 2426 (cell)

From: Zhao, Ying (STP)
Sent: Monday, August 15, 2011 9:46 AM
To: Charest, Ann; Ciulla, Ron; Smith, Charles; McCaslin, Todd
Cc: Batz, Helge (STP)
Subject: update on Option 1 distributor

hi, Guys:

I have checked the stock our Option 1 distributor just brought in. It seems the right material. Please see the pictures attached. It was produced in Texas, It is Phillips Sumika, and it's HGX-030-01. He is trying to find CoA, but has not been successful so far.
Our original plan is to get 2 bags first, test them before we get the rest of 2 tons.
But now I feel we have high confidence of this material, please let me know if we should just ship all 2 tons at the same time. I am personally more confident on this material than the one I got from the Option 2 distributor.

We can pick them up at any time, we have 2 tons right here ready.

Regards,
Michael Zhao

From: Smith, Charles
Sent: 02/21/2012 10:54:03 AM
To: Vialle, George
CC: Kieran, Damian
Subject: FW: Shipment of Marlex Resin from China - Export Options

FYI

-----Original Message-----
From: Smith, Charles
Sent: Tuesday, February 21, 2012 8:22 AM
To: Zhao, Ying (STP)
Subject: RE: Shipment of Marlex Resin from China - Export Options

Mike

I will talk to others here in next few days, thks

Charlie

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Tuesday, February 21, 2012 2:15 AM
To: Smith, Charles
Subject: RE: Shipment of Marlex Resin from China - Export Options

Hi, Charles:

I have talked to a few parties here who handle shipment. Everyone says that the chance of being audited is very low. And it should not be a problem most likely. But of course no one will make a guarantee.
My suggestion is split the material, maybe 2~3 tons each time and ship them out separately. This way, amount is small and there is very low chance to be inspected. We can do multiple shipments to get them all out.
Pls discuss with the members and let me know if we want to move forward.
Again, this is the easiest way to get them out.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell:Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Smith, Charles
Sent: Friday, February 17, 2012 9:04 PM

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To: Zhao, Ying (STP)
Cc: Kieran, Damian
Subject: RE: Shipment of Marlex Resin from China - Export Options
Importance: High

Mike

thks. I will follow-up on our end.

Thks

Charlie

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Friday, February 17, 2012 7:50 AM
To: Smith, Charles
Subject: RE: Shipment of Marlex Resin from China - Export Options

Hi, Charles:

No, actually no one has answered me on that. We still have our material in the storage here, I went to check a couple of weeks ago, it is in good condition. The distributor has taken good care of it. I think at least we don't need to worry about its condition while we look for a solution.

Best Regards,
Michael Zhao
Supplier Management Asia
Cardiac Rhythm Management
Boston Scientific Corp.
Email: ying.zhao@bsci.com
Office: 86-21-61419708
Cell: Redacted
Unit 4701, Raffles City,
No. 268 Xizang Middle Road,
Shanghai, China 200001

-----Original Message-----
From: Smith, Charles
Sent: Friday, February 17, 2012 4:53 AM
To: Zhao, Ying (STP)
Subject: RE: Shipment of Marlex Resin from China - Export Options

Have you heard back from anyone state side yet?

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Tuesday, January 24, 2012 10:41 AM
To: Kieran, Damian; Smith, Charles
Cc: du Halgouet, Tanguy
Subject: RE: Shipment of Marlex Resin from China - Export Options

hi, Damian:

I checked with the forwarder you recommended, they can't do it either.
Only option now is to get this material waived, contact the attorney and find a way to get this material out in a legal/formal way.
I have sent email out asking for the contact info but I have not received any answer yet. If you could, pls let me know how to contact the attorney and I will follow up.

Thanks and Regards,
Michael Zhao

From: Kieran, Damian
Sent: Tuesday, January 24, 2012 7:39 AM
To: Zhao, Ying (STP); Smith, Charles
Cc: du Halgouet, Tanguy
Subject: RE: Shipment of Marlex Resin from China - Export Options

Hi Michael,
Can you provide status on getting this resin moved out of China? Anything we can do to help?

Thanks,
Damian

-----Original Message-----
From: Zhao, Ying (STP)
Sent: Tuesday, January 03, 2012 11:22 AM
To: Smith, Charles; Kieran, Damian
Cc: du Halgouet, Tanguy
Subject: RE: Shipment of Marlex Resin from China - Export Options

I remember it is about $500 per month, something like that. We will pay through a PO, the way we purchased the material. BSC China pays first, then cross charge to you.

I will confirm the details with distributor once I get back to China in mid of Jan. I am on vacation these 2 weeks.

Regards,
Michael

From: [redacted]
Date: March 5, 2016 at 12:47:09 AM PST
To: [redacted]
Subject: RE: Boston Scientific Mesh News

Here is the latest response from our President Karen Prange about the allegation of this attorney over the resin.....

March 3, 2016
Dear Valued Customer:
Thank you for your inquiry concerning our mesh devices. We understand you may have questions about the recent, unfounded allegations made about the resin used in our mesh devices.
Boston Scientific's mesh devices are made from Marlex HGX 030-01, a particular polypropylene resin produced by Phillips Sumika in LaPorte, Texas. In 2011, Phillips Sumika, confirmed to Boston Scientific that it had discontinued production of that particular grade of Marlex due to low demand, and Boston Scientific's existing distributors could not guarantee a continuing supply over the next several years, so we located an alternative distributor with an available supply of the correct resin. Once we located that distributor, we ran samples of the resin it supplied to us through a thorough and rigorous battery of chemical tests, prior to its use, to ensure that it was the same grade of Phillips Sumika-produced, Marlex resin that we had previously used, and that it met material, design, and biocompatibility specifications for our mesh devices.
In particular, in addition to conducting multiple chemical tests, Boston Scientific had testing performed at each step of the mesh manufacturing process to confirm that the newly-sourced resin performed like previous lots of Marlex obtained from other distributors. This testing included extruding the resin and testing fibers for various properties, including tensile strength, elongation at break, and knot strength. The fibers extruded from the newly sourced resin as well as the mesh and finished products all met the standards set for previous lots of resin. The same was true of biocompatibility testing.
Boston Scientific is confident that the resin used in the manufacture of our mesh devices is neither counterfeit nor adulterated, and we have a robust quality system, which includes rigorous procedures and controls relating to the materials and components used in our products to ensure that remains the case. The Company has also discussed the allegations about the mesh resin with the FDA. As you may know, the FDA has posted the following reference to the allegations on its website:
The FDA is aware of allegations that Boston Scientific vaginal mesh devices may have contained counterfeit materials. We are examining those allegations to determine any necessary and appropriate next steps. We are currently not aware that the alleged contamination contributes to adverse events associated with these products.
Boston Scientific is dedicated to patient safety. We stand behind our products, the materials used in those products and our commitment to women's health.
Sincerely,
Karen Prange
Senior Vice President and President of Urology and Pelvic Health
Boston Scientific Corporation

EXHIBIT
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JOE WILSON
Market Development Manager
Boston Scientific
Urology and Women's wilsonj7@bsci.com
C. 949-232-9457

Boston Scientific
Advancing science for life™

From: [redacted]
Sent: Friday, March 04, 2016 6:59 PM
To: [redacted]
Subject: Fwd: Boston Scientific Mesh News

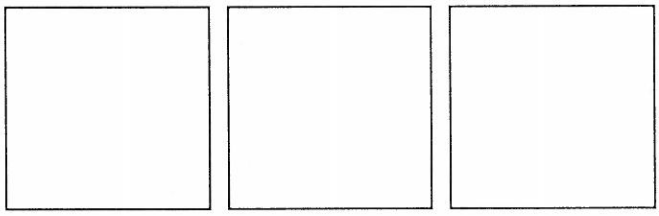
Any truth to the below?

Best regards,

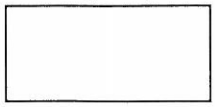
[redacted] MD
Director, Female Pelvic Medicine and Reconstructive Surgery
St. Josephs Hospital, Orange, CA
Kern Medical Center, Bakersfield, CA
Clinical Professor OB/GYN
Keck/University of Southern California School of Medicine, Los Angeles, CA

Begin forwarded message:

From: "Boston Scientific Mesh News" <Boston_Scientific_Mesh_News@mail.vresp.com>
Date: March 4, 2016 at 5:06:02 PM PST
To: [redacted]
Subject: Boston Scientific Mesh News
Reply-To: "Boston Scientific Mesh News" <reply-7b85709cfe-4e3d9bf383-663b@u.cts.vresp.com>



January 15, 2016 By Brad Perriello



Boston Scientific smuggled counterfeit resin for pelvic mesh

A purported class-action racketeering lawsuit filed this week accused Boston Scientific (NYSE:BSX)

of illegally smuggling counterfeit resin made in China to make pelvic mesh, after its original supplier allegedly refused to continue providing the product because it's not supposed to be implanted in humans. Boston Scientific won 510(k) approval from the FDA in 2002 for the Advantage Mesh, Advantage Fit and Lynx mesh products, manufactured using the Marlex polypropylene resin made in Texas by a joint venture between Chevron and Phillips, the lawsuit alleged.

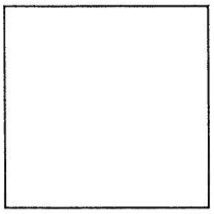
But by 2005, Phillips allegedly decided to stop supplying Marlex to Boston Scientific because it's not compatible with human tissue. By 2011, Boston was running out of Marlex and projected it would have none by the fall of 2012. At stake, according to the complaint, was the $120 million worth of pelvic mesh products Boston Scientific sold each year.

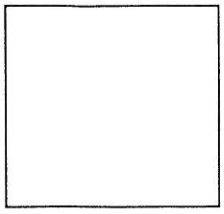
"After failing to convince the manufacturer, Phillips, to sell it any more Marlex, BSX made the fateful decision to smuggle counterfeit Marlex out of China," according to the complaint.

The company then allegedly bought 34,000 pounds of polypropylene resin from a Chinese firm, EMAI Plastic Raw Material Co. of Guandong, projecting that it would be enough to last until 2032. The companies allegedly conspired to put counterfeit labels, including fake lot numbers, designed to look like Phillips markings, on the Boston Scientific product and then allegedly "overbagged" the shipments with blank labels to get them past Chinese and U.S. customs.

The complaint charges Boston Scientific and co-defendants EMAI, Luxilon and Proxy with racketeering, mail fraud, wire fraud, intentional and negligent misrepresentation, unfair and deceptive acts and practices, fraud and unjust enrichment. Stevens asked Judge Joseph Goodwin for a jury trial, temporary and permanent injunctions barring the manufacture and sale of products using the allegedly fake Marlex, a warning to the public about it, punitive and consequential damages, legal costs, pre- and post-judgment interest and a temporary restraining order.

Learn more





Boston Scientific
Advancing science for life™

January 25, 2016

Dear Valued Customer:

Thank you for your inquiry concerning our mesh devices. We understand you may have questions about the recent, unfounded allegations made about the resin used in our mesh devices.

Boston Scientific is confident that the resin used in the manufacture of our mesh devices is neither counterfeit nor adulterated. Boston Scientific has a robust quality system, which includes rigorous procedures and controls relating to the materials and components used in our products. The resin used in the manufacture of our devices has been appropriately tested to ensure that it matches, and is equivalent to, the resin that we have historically purchased from other distributors, that it meets material, design, and biocompatibility specifications for our mesh devices.

Boston Scientific is dedicated to patient safety. We stand behind our products, the materials used in those products and our commitment to women's health.

Sincerely,

Karen Prange

Karen Prange
Senior Vice President and President of Urology and Pelvic Health
Boston Scientific Corporation

Document Title:	Marlex® HGX-030-01 Equivalency Testing
Document Number:	90708859
Project Name:	Uro/Gyn Sustaining
Project Number:	U0311
Author(s):	Daniel Burrill
Contributor(s):	Sean Curran Mark Boden

TABLE OF CONTENTS

1. Executive Summary:

Phillips Sumika has discontinued production of Marlex® HGX-030-01, a Polypropylene Homopolymer grade. Therefore, Boston Scientific (BSC) obtained the same polymer from a second source (material distributor). This document outlines the results of the analytical testing that BSC conducted, in accordance with the Marlex Certification Project Tracking Plan 90726537, to ensure the new lot of Marlex® HGX-030-01, received from Emai Plastic Raw Material, is equivalent to the existing lot of Marlex® HGX-030-01 received from Channel Prime Alliance, used by BSC for mesh production.

The current BSC lot of Phillips Sumika Marlex® HGX-030-01 Polypropylene Homopolymer (sample 1) was obtained from the material distributor Channel Prime Alliance in Charlotte NC. A Certificate of Analysis (CoA) was supplied for this lot of Marlex® HGX-030-01 (refer to Attachment 1). The second lot of material (sample 2) was obtained from the material distributor Emai Plastic Raw Material (Dongguan) Inc. While the material has been supplied in the correct Phillips Sumika bags all with the same distributor lot number, there was no CoA supplied with this lot, and the distributor is not able to produce the CoA. Marlex® HGX-030-01 is a standard material made by Phillips Sumika that has no post processing steps other than packaging.

In addition to the two lots of material mentioned above a third sample (sample 3) of Marlex® HGX-030-01 was obtained from Proxy Biomedical for comparison purposes. This sample was provided with a CoA from Phillips Sumika.

The results for the Differential Scanning Calorimetry, Oxidation Induction Time, Fourier Transform Infrared Spectroscopy, Melt Flow Index, Gel Permeation Chromatography, Gas Chromatography – Mass Spectrometry, Inductively Coupled Plasma Spectroscopy and Optical Microscopy indicate that the new lot of HGX030-01 obtained from distributor Emai Plastic Raw Material (Dongguan) Inc., is equivalent to the existing qualified lot of HGX030-0.1. The minor differences observed in the test results were not unexpected when testing lots made from various points in time.

2. Objective:

The purpose of this document is to outline the analytical testing strategy, acceptance criterion and test results that were used to establish the chemical equivalency of two Phillips Sumika Marlex® HGX-030-01 Polypropylene Homopolymer lots obtained from two different material distributors.

3. Applicable Documents:

Document Description	Document #	Document Version
Procedure to evaluate equivalency of polymers for shelf life	90559224	AA
Global SOP AVL Management	90265075	AJ
Marlex Certification Project Tracking Plan	90726537	AA

4. Materials / Traceability:

Three lots of Phillips Sumika Marlex® HGX-030-01 Polypropylene Homopolymer were tested as part of this work.

Sample	Distributor Lot No.	Phillips Sumika Lot No.	C of C Date	Product Description
1	PP0353133-02	2951877	06/15/2005	Existing Qualified lot of HGX030-01 obtained from Channel Prime Alliance
2	6120105	Unknown	Unknown	New lot of HGX030-01 obtained from distributor Emai Plastic Raw Material (Dongguan) Inc
3	Unknown	2980056	03/05/2008	Lot obtained from Proxy Biomedical for comparison testing, Proxy provided CoA from Phillips Sumika

5. Experimental Method:

Polypropylene can be made from the monomer propylene by Ziegler-Natta polymerization or by metallocene catalysis polymerization. These commercial manufacturing processes are large and typically generate thousands of pounds per hour. Given the size of these processes and the nature of the material bagging operations, it is expected that any given bag represents the entire lot. Therefore samples were selected from a single bag of material. The material samples were evaluated by Cambridge Polymer Group, Inc., an independent external testing laboratory BSC determined to be capable of conducting required test to all applicable ASTM/ISO standards. This laboratory is documented as an approved supplier per Global SOP AVL Management 90265075.

Table 1 lists the testing that was conducted to determine equivalency. In determining equivalency of the polymer samples one and two, not only were the individual test results assessed, based on the analysis techniques listed in Table 1, but all data was assessed in aggregate by internal and independent external subject matter experts (SME).

Sample 3 was evaluated as part of this work as it was a second lot of HGX030-01 with a known origin. This sample was used as a second known data point to help assure that testing was conducted properly and to provide some insight on potential lot to lot differences.

6. Results Summary:

The following is summary of the results found in Attachment 6 - Cambridge Polymer Group Report # 11440-2 of this report.

Table 1: Summary of Test Results

Test Name	Test Purpose	Expected Results / Analysis Technique	Results
Differential Scanning Calorimetry ASTM D3418	Measure thermal transition characteristics of the polymers.	Melt Temperature (T_m) will be evaluated. Samples are expected to be within 5°C of each other.	Acceptable
Oxidative Induction Time (OIT) ASTM D3895	Highly accelerated stress test used to determine long term stability equivalence of polymers.	Samples are expected to be within 20% of each other (ASTM D3895 indicates within 75%)	Acceptable[1]
Fourier Transform Infrared Spectroscopy (FTIR)	Evaluates the degree of similarity in bulk composition of polymers.	Spectral outputs to be qualitatively assessed by SME.	Acceptable
Melt Flow Index ASTM D1238	Empirical measures of the viscosity of polymers which is an indicator of required processing conditions.	Samples are expected to be within 0.5 grams/10 minutes of each other	Acceptable[2]
Gel Permeation Chromatography (GPC)	Measure of molecular weight and molecular weight distribution.	Samples are expected to be within 15% of each other (excluding PDI). Qualitative assessment of spectral output by SME will also be conducted.	Acceptable
Gas Chromatography/ Mass Spec (GC-MS)	Determines masses of volatile additives, for determining the chemical composition of a sample: as well as contaminant detection.	Qualitative assessment of spectral output by SME.	Acceptable
Inductively Coupled Plasma Spectroscopy (ICP)	Determines primary heavy metal contaminants	Qualitative assessment of spectral output by SME.	Acceptable
Optical Microscopy	Determine presence of bulk contamination	Qualitative visual assessment of pellets by SME.	Acceptable

[1]Results were outside of expected results range; refer to section 6.2 for rationale.

[2]The third lot (Sample 3), which was tested for reference only, was outside of the expected range; however, lots 1 and 2 were within the expected results range.

6.1 Differential Scanning Calorimetry (DSC):

The DSC results in Table 2 indicate that all three samples have similar thermal characteristics, and that the melt temperature of each sample is within the expected 5°C range.

Table 2: DSC Summary Results

Heat Cycle 1			
Sample	Onset Melt Temperature (°C)	Peak Melt Temperature (°C)	Enthalpy (J/g)
1	150.48	164.49	104.9
2	152.26	161.87	112.1
3	151.69	164.54	111.3
Heat Cycle 2			
Sample	Onset Melt Temperature (°C)	Peak Melt Temperature (°C)	Enthalpy (J/g)
1	154.14	163.44	106.9
2	154.60	161.79	109.5
3	157.52	163.67	113.2

6.2 Oxidative Induction Time (OIT):

The OIT results are listed in table 3. Sample 1 and Sample 2 are within ~ 32%, and all samples are within the ASTM D3895 range of 75% to be considered equivalent. While the difference between sample 1 and sample 2 is slightly larger than the anticipated 20% listed in Table 1 the results are within minutes of one another and shall be deemed equivalent based upon the ASTM recommendation of 75%. The increased oxidation induction time for sample 2 is an indicator of greater oxidative stability. Given the potential age difference between these lots it is not unexpected to see the below differences in the OIT. As the material ages and antioxidant constituents are consumed the OIT will decrease. Additionally there is inherent to lot to lot variability in OIT performance.

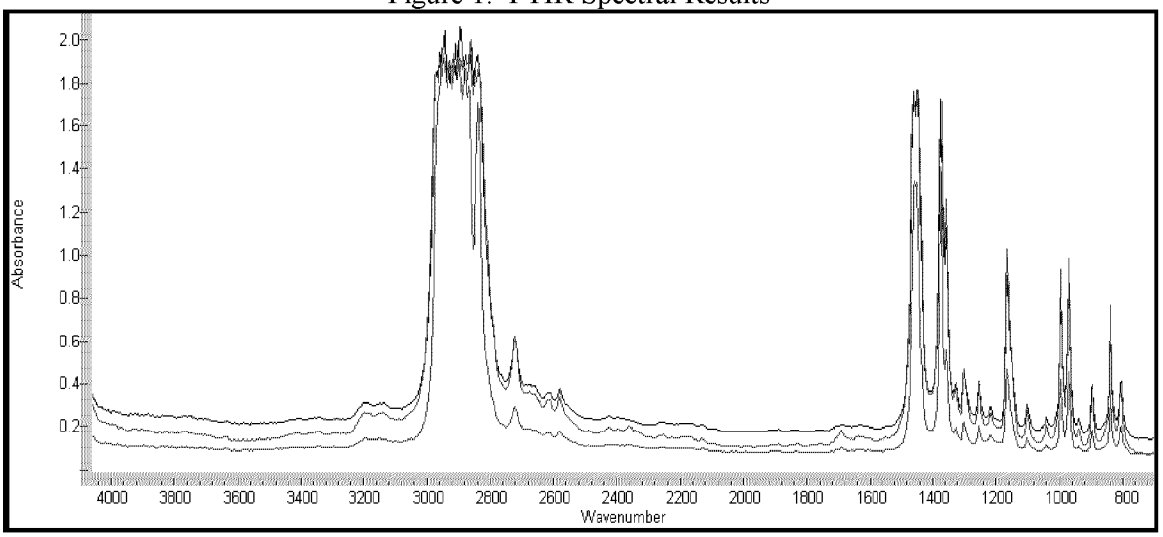
Table 3: OIT Summary Results

Sample	**Oxidation Induction Time (min)**
1	5.61
2	8.23
3	4.49

6.3 Fourier Transform Infrared Spectroscopy (FTIR):

Figure 1 summarizes the FTIR results. There are minimal (insignificant) differences between the three samples spectra; there were no additional peaks identified that would indicate a material difference.

Figure 1: FTIR Spectral Results



Sample 1 - **Green Line** Sample 2 – **Blue Line** Sample 3 – **Pink Line**

6.4 Melt Flow Index (MFI):

Table 4 summarizes the MFI results. Each sample was tested twice and averaged. Samples 1 and 2 are within the expected range of 0.5 g/10 min. Sample 3, which was run for comparison purposes only, has a slightly higher MFI rate than samples 1 & 2. This is an indicator of the potential lot to lot variation in MFI for Marlex® HGX-030-01.

Table 4: MFI Results

Sample	Time (s)	Mass Extruded (g)		Average Melt Flow Rate (g/10 min)
		Run 1	Run 2	
1	60	0.391	0.389	**3.90**
2	60	0.375	0.370	**3.72**
3	60	0.473	0.468	**4.70**

6.5 Gel Permeation Chromatography (GPC):

Table 5 summarizes the molecular weight moments for all three samples. The results for Mn, Mw and Mz are all within the expected 15% range. The polydispersity index (PDI) M_w/M_n does not have the same expected results as the individual moments (Mn, Mw and Mz). Typically polymers with PDI values from 3-5 are considered to have narrow molecular weight distributions. The PDI values observed in this work are consistent for a polypropylene with a narrow molecular weight distribution.

Table 5: Molecular Weight Moments (g/mole)

Sample	M_n	M_w	M_z	PDI
1	6.80E+04	2.65E+05	7.77E+05	3.90
2	5.80E+04	2.82E+05	8.74E+05	4.86
3	6.08E+04	2.60E+05	8.16E+05	4.27

6.6 Extraction for Elutables:

Table 6 summarizes the extraction for elutables test results for each sample. The samples were refluxed in Hexane for 72 hours; refer to section 3.6.1 of Attachment 6 for further details. While samples 1 and 3 are very similar, sample 2 has almost twice the amount of extract. There is no acceptance criteria for the amount of extract as this is the initial step of sample prep for the Gas Chromatography – Mass Spectrometry (GS-MS) testing, this is simply an observation. However based upon GC-MD and OIT test results, the level of extract is consistent with the presence of additional stabilizer.

Table 6: Extract Results

Sample	Mass of Sample (g)	Extract (mg)	Percent of Total Mass Extracted (%)
1	5.85	37.6	0.64
2	6.01	86.1	1.43
3	6.21	37.9	0.61

6.7 Gas Chromatography – Mass Spectrometry (GC-MS):

The mass spectrometric identification of compounds is summarized in Table 7 (refer to section 3.6.2 Gas Chromatography – Mass Spectroscopy in Attachment 6). The three samples had similar fragments detected in the extract. All the extracted compounds are long chain aliphatic hydrocarbons, which is to be expected from polypropylene. Aromatic fragments identified as Bis Dimethylethyl Phenol and Hydroxy Benzoic Acid was found in sample 2. These are common by-products of polymer stabilizers. Given the increased OIT performance of sample 2 and the higher level of extract obtained it is not unexpected to see additional levels of stabilizer present in Sample 2.

Table 7: GC-MS Results Summary

Component	Sample 1	Sample 2	Sample 3
Bis dimethylethyl phenol	ND	✓	ND
Docosane	ND	✓	ND
Heptadecane	✓	✓	ND
Hydroxy benzoic acid	ND	✓	ND
Nonadecane	✓	✓	ND
Pentacosane	✓	✓	ND
Pentadecane	ND	✓	✓
Tetracosane	✓	✓	✓
Unidentified compound	✓	ND	✓

Note: ND means fragment was not detected

6.8 Inductively Coupled Plasma (ICP) Spectroscopy:

Table 8 summarizes the ICP results for elemental survey scan. Sample 1 shows a larger array of trace metals than sample 2 &3, potentially due to post polymerization handling differences. Sample 2 shows the presence of Titanium (Ti), used in the polymerization process as part of catalysis package. All three samples show the presence of Selenium (Se) a polymer stabilizer used with polypropylene.

Table 8: ICP Results for Survey Scan

	Concentration by weight (ppm)			
Element	**Sample 1**	**Sample 2**	**Sample 3**	**Detection Limit**
Be	43.0	ND	ND	0.01
Na	ND	ND	ND	0.05
Mg	ND	ND	ND	0.05
Al	106	ND	25.9	0.01
K	ND	ND	ND	0.10
Ca	ND	ND	ND	0.01
Ti	ND	280	ND	0.01
V	20.9	ND	ND	0.01
Cr	33.1	ND	ND	0.01
Mn	6.8	ND	ND	0.01
Fe	36.1	ND	ND	0.01
Co	16.4	ND	ND	0.01
Ni	27.4	ND	ND	0.01
Cu	14.7	ND	ND	0.01
Zn	ND	ND	ND	0.01
As	ND	ND	ND	0.01
Se	1500	1700	2160	0.01
Sr	29.2	ND	14.8	0.01
Mo	ND	ND	ND	0.01
Cd	ND	ND	ND	0.01
Sn	ND	ND	ND	0.01
Sb	ND	ND	ND	0.01
Ba	10.4	15.7	34.3	0.01
Tl	ND	ND	ND	0.01
Pb	ND	ND	ND	0.01

Note: ND means element was not detected within detection limits

6.9 Optical Microscopy:

There was no visible evidence of contamination in the form of specks or debris on any of the samples. Small differences in pellet shape, size and opacity were observed. These differences are not unexpected and are typical lot to lot variation most likely caused by differences in cooling conditions during pelletization.

7. Conclusion:

The comparison of test results from sample 1 and 3, both lots of HGX030-0.1 with CoA, indicates that there were no testing issues encountered during this work.

The results for the DCS, OIT, FTIR, MFI, GPC and Optical Microscopy tests clearly indicate that samples 1 and 2 are equivalent. The results for the GC-MS tests of hexane extractible materials indicate that sample 1 and 2 have similar fragment types in the extract although sample 2 has a higher level of these compounds. While the majority of the extracted compounds are long chain aliphatic hydrocarbons, there are a few aromatic fragments, indicative of common anti-oxidants, detected in sample 2 that were not detected in samples 1 or 3. Additionally the ICP testing found a low level of Ti in sample 2 and did not detect any in samples 1 or 3. These small differences found between samples 1 and 2 in extractables and trace metals are not significant enough to present a short term or long term mechanical performance difference.

Based upon this testing the new lot of HGX030-01 obtained from distributor Emai Plastic Raw Material (Dongguan) Inc. is equivalent to the existing qualified lot of HGX030-01. The minor differences observed in the test results were not unexpected when testing lots made from various points in time and exposed to different storage conditions.

8. Attachments:

Attachment	Description
Attachment 1	Sample 1 CoA: Existing lot obtained from Channel Prime Alliance
Attachment 2	Marlex® HGX-030-01 Technical Data Sheet
Attachment 3	Marlex® HGX-030-01 MSDS
Attachment 4	Photos of bags containing new resin lot (sample 2)
Attachment 5	Sample 3 CoA; supplied with Proxy Biomedical sample
Attachment 6	Cambridge Polymers Test Report #11440-2

From: Smith, Charles
Sent: 11/21/2011 04:08:41 PM
To: Cuddy, Christopher; Burrill, Dan
Subject: RE: Marlex HGX-030-01 Equivalency Testing CR# 1092208

Importance: High

I have signed CR, thks for keeping this on target for review today per timeline. I know it took a lot of effort.

From: Smith, Charles
Sent: Thursday, November 17, 2011 7:23 AM
To: Cuddy, Christopher
Cc: Burrill, Dan
Subject: RE: Marlex HGX-030-01 Equivalency Testing

Chris

Let's talk today when you get in thks.

Charlie

From: Burrill, Dan
Sent: Thursday, November 17, 2011 7:12 AM
To: Cuddy, Christopher
Cc: Smith, Charles
Subject: RE: Marlex HGX-030-01 Equivalency Testing

Chris,

1. There was never an acceptance criteria we have expected results. Additionally we are not removing the original expected results. The report addresses why we feel

EXHIBIT
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OIT results are acceptable even though they do not meet the expected results. I see no need for deviation.

2. This is a tech report that describes some testing and draws a conclusion on that testing. I have not been tasked to develop a project plan. I think you need to discuss this with Charlie.

Dan

From: Cuddy, Christopher
Sent: Wednesday, November 16, 2011 11:34 PM
To: Burrill, Dan
Subject: RE: Marlex HGX-030-01 Equivalency Testing

Right I only made comments so they would be easier to see and we could discuss if needed. I only feel strongly about the 2 below.

1. The change/clarification in acceptance criteria for OIT. Our acceptance criteria was 20%. We moved toward the ASTM (which I don't have a copy and isn't available on IHS). That was a clever solution, but it still did not meet acceptance criteria. I put a lot of weight on the discussion that the results were favorable for sample 2…that the risk of having a higher OIT is lower than having a low OIT. Anyway, now that we revisit this, should it be a deviation?

2. The conclusion could be misleading. Nowhere in this document does it refer to a parent plan or other pieces of the puzzle. Standing alone, this document could be misconstrued. That could be why we got some hostile feedback from someone a couple weeks ago. I recommend we make reference to the grand plan or other associated activities. There is no MRB or SCAR. Perhaps our vendor's vendor's vendor will have an MRB as part of their process, but I think our job is to have a project plan – high level with just a few lines items.

From: Burrill, Dan
Sent: Wednesday, November 16, 2011 1:48 PM
To: Cuddy, Christopher
Subject: Marlex HGX-030-01 Equivalency Testing

Chris,

I believe you only made comments, did not actually change anything. To better see your comments removed the red lines from document. Please review attached as I have attempted to address your comments.

Thanks,

Dan

TITLE	Marlex® HGX-030-01 Mechanical Testing Protocol - Slings
DOCUMENT NUMBER	90740928
PROJECT NAME AND NUMBER	Uro/Gyn Sustaining / U0311
AUTHOR/CONTRIBUTORS	Carolina Villarreal
APPROVALS	Approvals and approval dates are captured through electronic signature within the PDM system.

Table of Contents

1.0 BACKGROUND

Phillips Sumika has discontinued production of Marlex® HGX-030-01, a Polypropylene Homopolymer grade. Therefore, Boston Scientific (BSC) obtained the same polymer from a second source (material distributor). While the material has been supplied in the correct Phillips Sumika bags with an identifiable lot number, there was no CoA supplied with this lot, and the distributor is not able to reproduce the CoA. The second lot of material was obtained from the material distributor Emai Plastic Raw Material (Dongguan) Inc
This document outlines the strategy for the mechanical testing that BSC will conducted to ensure the new lot of Marlex® HGX-030-01, received from Emai Plastic Raw Material, is equivalent to the existing lot of Marlex received from Channel Prime Alliance through the current manufacturing process.

2.0 PURPOSE

The purpose of this document is to outline the testing strategy and acceptance criteria that will be used for the lot 6120105 base resin, Marlex® HGX-030-01, to determine lot equivalence when evaluated with the current manufacturing processes at Luxilon, Proxy, AIM and MedVenture Technology Corporation (MTC) to be used in the urethral slings family products.

3.0 SCOPE

The scope of this protocol is to outline the functional material testing that will be conducted for the base resin Marlex® HGX-030-01 received from Emai Plastic Raw Material (Dongguan) Inc at Luxilon, Proxy, AIM, MTC and BSC. The material information is listed in Table 1:

Table 1. Base resin - Material information

MATERIAL NUMBER	DESCRIPTION	LOT NUMBER	QUANTITY (KG)
90207538-01	Polypropylene Resin (Marlex® HGX-030-01)	6120105	Natural: 25kg

All product produced during this build, will be considered non-saleable until final acceptance is documented.

Testing will apply in the representative products for the nominal conditions detailed in Table 2.

Table 2. List of the Representative Product Family

PROXY / LUXILON / AIM COMPONENT INFORMATION		
BSC NUMBER	**PART NUMBER**	**DESCRIPTION**
34106700	PPS50046	Polypropylene Monofilament Yarn - 6 mil (Nat)
34114200-02	400010008 ES012 - 002	Advantage Mesh Sheet
90409292-01	90409292	Carrier Base
90409293-01	90409293	Carrier cover
MEDVENTURE PRODUCT INFORMATION		
CATALOG NUMBER	**UPN PRODUCT NUMBER**	**DESCRIPTION**
850200	M0068502000	Advantage™ System
85020005	M006850200051	Advantage™ System, Box 5
850211	M0068502110	Advantage Fit™ System
850211	M0068502111	Advantage Fit™ System, Box 5
68504000	M0068504000	Obtryx™ System – Curved - Single
68504001	M0068504001	Obtryx™ System- Curved - 5-Pack
68505000	M0068505000	Obtryx ™ System – Halo -Single
68505001	M0068505001	Obtryx™ System – Halo - 5-Pack
850-700	M0068507000	Solyx™ SIS System – Single
850-700	M0068507001	Solyx™ SIS System – 5 Pack
68503000	M0068503000	Lynx Suprapubic Sling System
68503001	M0068503001	Lynx System 5-Pack
68506000	M0068506000	Pre-pubic Sling - Single
68506001	M0068506001	Pre-pubic Sling - 5-Pack

Since all base resin Marlex® HGX-030-01 extrusion parameters will remain the same, no worst case has been selected at Luxilon.

4.0 REFERENCE DOCUMENTS

Document Number	Description
90036920	Corporate SOP Capability of Variable Data
90030419	Corp SOP Design Verification Sampling/ Process Validation Sampling Plans
S842767-00	Corp SOP Risk Analysis
S842769-00	CORP SOP DESIGN VERIFICATION
90356869	Solyx Risk Analysis Report
90301643	Solyx Product Specification
90082464	Lynx Risk Analysis Workbook
90078003	Lynx System Product Specification
90055034	Advantage Product Specification

Document Number	Description
90055035	Advantage Risk Analysis Workbook
90106687	Obtryx Risk Analysis Workbook
90104642	TTFS Product Specification
90141370	PPS Product Specification
90141908	Pre-Pubic Risk Analysis Workbook
90732450	BCA - Marlex HGX-030-01 Mesh

5.0 BUILD CONDITIONS

Boston Scientific (BSC)

BSC will supply the base resin Marlex® HGX-030-01 to Luxilon and AIM to manufacture the components needed, to perform this protocol.

Luxilon Industries NV (Luxilon)

Luxilon will extrude the base resin Marlex® HGX-030-01 utilizing current approved manufacturing process standards as per their Quality System. Luxilon will then ship the fiber to Proxy for the Mesh processing.

For the purpose of this protocol, a copy of the results obtained will be sent to BSC and the Certificate of Compliance will be sent to Proxy.

PPS50046 - Polypropylene Monofilament Yarn - 6 mil (Nat)

Characteristic	Unit	Value	Tolerance	Measurement Standard	Key Performance / Process Characteristic
Denier (Weight in grams per 9,000 meters)	Den	152	± 10	Spool Average	**Key Performance**
Dtex (Weight in grams per 10,000 meters)	Dtex	170	± 11	Spool Average	**Key Performance**
Outer Diameter	µm	152	± 16	WIQA Spool Average	**Key Performance**
Tensile Strength	N	9.6	Min	Spool Average	**Key Performance**
Elongation At Break	%	22	± 7	WIQA Spool Average	**Process Characteristic**
Knot Strength[1]	N	7	± 1	WIQA Batch Average	**Process Characteristic**
Shrinkage[1]	%	8	± 3	Shrinkage will be measured using a hot air oven at 132°C (270°F) for 10 minutes. Batch Average	**Process Characteristic**
GDP[1] (Gram Denier Point)	%	3	± 1	WIQA Batch Average	**Process Characteristic**

[1] These are specific process characteristics that are evaluated at Luxilon per their Quality System

Proxy BioMedical (Proxy)

Proxy will receive the fiber from Luxilon, weave and knit the mesh and build the mesh sheets. The mesh sheet (34114200-02/AG) will be produced in accordance with the current manufacturing process standards as per their current Quality System. Traceability will be maintained through lot number assignment and recorded for all components.

All testing will be performed as per test specimen requirement detailed in the applicable test method listed in the table below and mesh sheets will be shipped directly to MTC.

ES012 – 02 Engineering Design Specification Proxy Biomedical Knit-BSC Advantage Mesh

Test	Min Performance Required	Sample Size & Acceptance Criteria	Specification	Test Method
Thickness[1]	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	0.0026" ± 0.006"	MPS012
Courses per inch (CPI)[2]	95%/ 95%	n = 30, Ppk ≥ 1.21, Pp ≥ 1.24	25 -26	QAP068
Wales per inch (WPI)[2]	95%/ 95%	n = 30, Ppk ≥ 1.21, Pp ≥ 1.24	12 ± 1	QAP068
Aerial Density[3]	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	100 g/m^2 ± 38%	QAP047
Tensile Strength Machine Direction[3]	95%/ 95%	n = 30,Ppk ≥ 0.74	≥37 (lbf)	QAP059
Elongation Test Machine Direction[3]	95%/ 95%	n = 30,Ppk ≥ 0.74	4.1%-14.7%.	QAP060
Device Stiffness[3]	95%/ 95%	n = 30, Ppk ≥ 0.74	≤ 10 (bending length in cm; average face and back) @ 1.1cm width	QAP061
Burst Strength[3]	95%/ 95%	n = 30, Ppk ≥ 0.74	≥ 66 (psi)	QAP062

[1] n=30, Ppk ≥ 0.75, Pp ≥ 0.82 per BSC's internal requirements of 95% confidence of 95% reliability (LTPD 5%) for a risk level I characteristic (2-sided spec.) per Corp SOP Design Verification/Process Validation Sampling Plans 90030419.

[2] n=30 Ppk ≥ 1.21, Pp ≥ 1.24 per BSC's internal requirements of 95% confidence of 95% reliability (LTPD 0.3%) for a risk level II characteristic (2-sided spec.) per Corp SOP Design Verification/Process Validation Sampling Plans 90030419.

[3] n=30, Ppk ≥0.74 is BSC's internal requirements of 95% confidence of 95% reliability (LTPD 5%) for a risk level I characteristic (1-sided spec.) per Boston Scientific Corp SOP Design Verification/Process Validation Sampling Plans 90030419 & Boston Scientific Corp SOP Design Verification S842769-00. Some of these characteristics may not be RI=I in BSC's dFMEAs listed in section 4.0, but will be tested to those requirements for this protocol.

For the purpose of this protocol, a copy of the results obtained will be sent to BSC and the Certificate of Compliance will be sent to MTC.

AIM Plastics (AIM)

Base resin Marlex® HGX-030-01 will be injected in the mold at AIM during 2 hours, utilizing current approved manufacturing process standards as per their Quality System. Carrier base (90409292-01) and carrier cover (90409293-01) will then be shipped to MTC for processing. Samples will be randomly pulled from the production run from each cavity to perform the following measurements:

CARRIER BASE (90409292-01)

Characteristic	Min Performance Required	Sample Size & Acceptance Criteria	Specification	Measurement standard
Critical dimension Q1	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.040 ± .003	Vision system
Critical dimension Q2	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.043 ± .003	Vision system
Critical dimension Q3	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.047 ± .002	Vision system
Critical dimension Q4	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	2 X .051 ± .005	Vision system
Critical dimension Q5	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	2 X .058 ± .005	Vision system
Critical dimension Q6	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.125 ± .005	Vision system
Critical dimension Q7	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	4 X .030 ± .003	Vision system

n=30, Ppk ≥ 0.75, Pp ≥ 0.82 per BSC's internal requirements of 95% confidence of 95% reliability (LTPD 5%) for a risk level I characteristic (2-sided spec.) per Corp SOP Design Verification/Process Validation Sampling Plans 90030419.

CARRIER COVER (90409293-01)

Characteristic	Min Performance Required	Sample Size & Acceptance Criteria	Specification	Measurement standard
Critical dimension Q1	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	4 X .034 ± .002	Vision system
Critical dimension Q2	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.041 ± .003	Vision system
Critical dimension Q3	95%/ 95%	n = 30, Ppk ≥ 0.75, Pp ≥ 0.82	.104 ± .005	Vision system

n=30, Ppk ≥ 0.75, Pp ≥ 0.82 per BSC's internal requirements of 95% confidence of 95% reliability (LTPD 5%) for a risk level I characteristic (2-sided spec.) per Corp SOP Design Verification/Process Validation Sampling Plans 90030419.

For the purpose of this protocol, a copy of the results obtained will be sent to BSC and the Certificate of Compliance will be sent to MTC.

A summary for the general process for the proposed Marlex® HGX-030-01 testing in this protocol is shown in flow chart on Figure 2

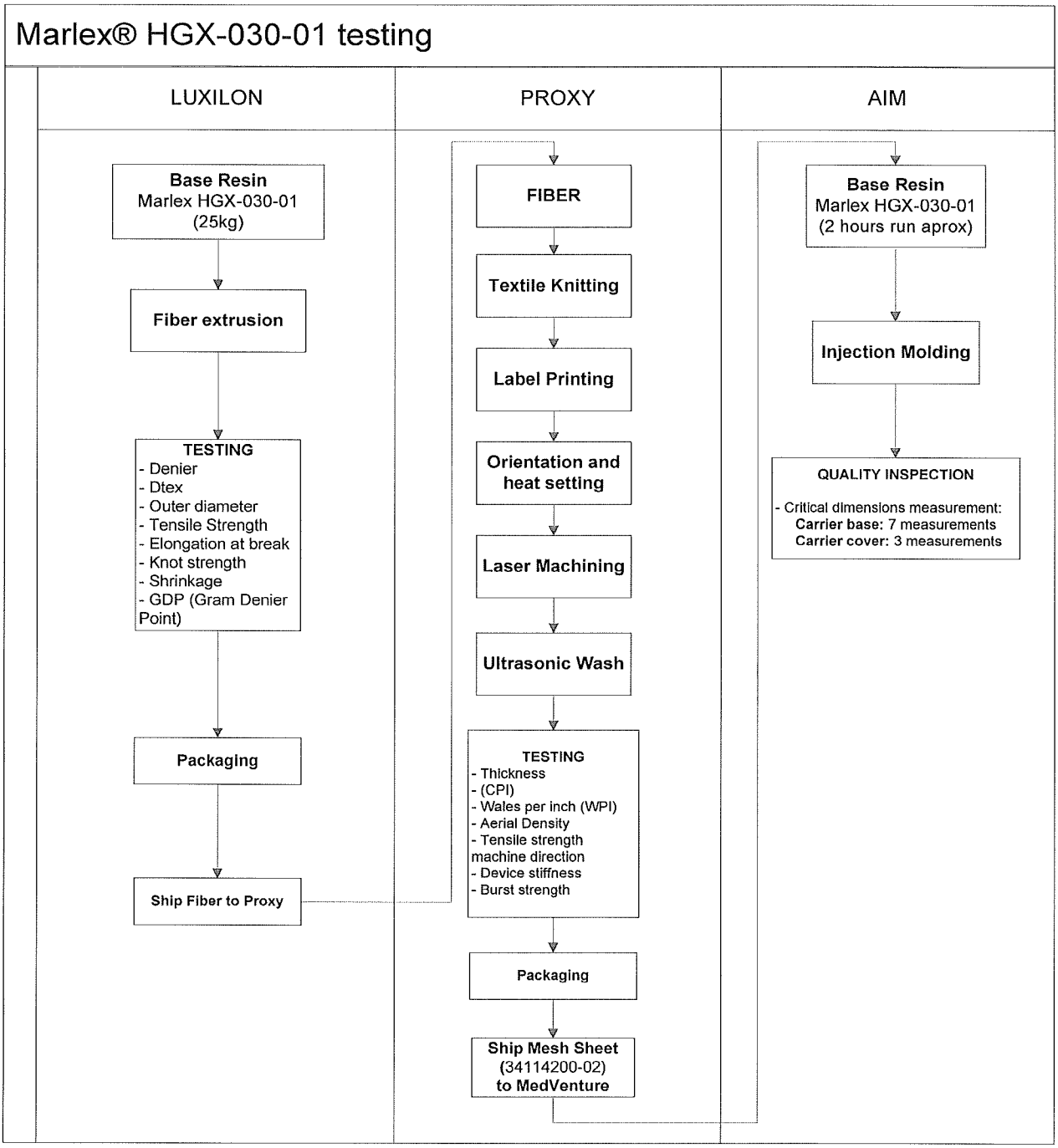

Figure 2. Flowchart for Marlex® HGX-030-01 to be used in the urethral sling family products

6.0 DATA ANALYSIS AND RECORD RETENTION

BSC will review all documentation and data generated from each vendor, compile the information, perform data analysis and update this technical report to include all results obtained.

Boston Scientific

Defining tomorrow, today.™

APPROVAL FOR OFFICIAL DOCUMENT

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Version: 01
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- **Direct lookup in PDM**
- **Shop Floor Paperwork**
- **Officially stamped or otherwise identified as current**

Approval Signature

Name	Role	Vote	Activity	Date Signed
Carolina Villarreal	AUTHOR	Accept	Final Review	18 Jan 2012 15:29 EST

FW: NOTES: Marlex Mesh Run-Out Date

To: "Recipients, AndersL2" <"/o=bsci/ou=bscexc1/cn=recipients/cn=andersl2">, "Recipients, SHREEVED" <"/o=bsci/ou=bscexc1/cn=recipients/cn=shreeved">, "Recipients, PEREIRAP" <"/o=bsci/ou=bscexc1/cn=recipients/cn=pereirap">, "Recipients, TahR" <"/o=bsci/ou=bscexc1/cn=recipients/cn=tahr">, "Recipients, GravesT" <"/o=bsci/ou=bscexc1/cn=recipients/cn=gravest">

Cc: "Recipients, GoddardJ" <"/o=bsci/ou=bscexc1/cn=recipients/cn=goddardj">

From:
Olivieri, Steve
Sent:
09/15/2011 09:29:23 AM
To:
Pereira, Peter; Tah, Richard; Graves, Thomas;
Anderson, Lauren (Marlborough); Shreeve, David
CC:
Goddard, James
Subject:
FW: NOTES: Marlex Mesh Run-Out Date

Pete, Richard, Tom and Lauren,

An FYI just to keep you in the loop regarding the new Marlex shipment, etc. (see thread below). Regarding bullet point 2, we are moving forward with Marlex. If the material from China didn't meet testing requirements, we may be told to switch back. However, I've been told by Jim and Al that we're to move forward with Marlex.

The risk we run is a repeat of the animal study if Marlex samples are underway.

Steve

From: Wheeler, Mitch
Sent: Wednesday, September 14, 2011 6:31 PM
To: Smith, Charles; Intoccia, Al; Palmisano, Brent; Vialle, George; Sherry, John; Gardner, Donna; Courtois, Janice
Cc: Cherkady, Girish; Raneri, Joe; Olivieri, Steve; Daignault, Kenneth; Newell, Kevin; Goddard, James; Cuddy, Christopher; Riek, Nichole
Subject: RE: NOTES: Marlex Mesh Run-Out Date

Full project plan needs to be developed and loaded into PDM

———

From: Smith, Charles
Sent: Wednesday, September 14, 2011 6:16 PM
To: Intoccia, Al; Palmisano, Brent; Vialle, George; Sherry, John; Wheeler, Mitch; Gardner, Donna
Cc: Cherkady, Girish; Raneri, Joe; Olivieri, Steve; Daignault, Kenneth; Newell, Kevin; Goddard, James; Cuddy, Christopher; Riek, Nichole
Subject: NOTES: Marlex Mesh Run-Out Date

Notes from our meeting on Tuesday afternoon: Attendees were: Al, George, Mitch, and I.

Purpose: To review status of current Marlex tracked per matrix/table we assembled last few months.

We also used this meeting to review the effects of three inputs/outputs:

1. New Finish goods end sales date will be completed in next few days with updated Marketing numbers for sales. Current end date is expected to move out a few months.

2. Allowing use of the current material on the Biologic and Atlas programs: AL has requested we review impact on current material if we use on these programs. Some discussion has been held over past few weeks on this.

ACTION ITEM # 1: Charlie will work with Jim Goddard, team leaders, and George to insure inputs are loaded in table to calculate the effect of materials on hand. The effect will then be reviewed again by Al/George to determine if we should complete request.

3. Use of the 34,000 lbs. procured from China distributor: Material testing will be completed by end of month with drafted report expected to be in place. What additional testing will be needed was discussed. It was agreed to complete additional run of material through production. Based upon volume and processes it was determined we will use the Pinnacle family.

ACTION ITEM #2: Charlie will work with Mitch and current Team under Joe to have material moved through extrusion to final assembly via a protocol. Upon completion of report release into production can be completed/accessed in additional to the material testing.

Thks

Charlie

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From: Cuddy, Christopher
Sent: 10/13/2011 10:33:42 AM
To: Graves, Thomas
Subject: FW: PP marlex china 109 nat & 100blue

Keeping you in the loop. I'm guessing the team will need help someday.

From: Smith, Charles
Sent: Thursday, October 13, 2011 8:48 AM
To: Cuddy, Christopher; Courtois, Janice; Villarreal, Carolina; Burrill, Dan
Cc: Raneri, Joe; Sherry, John; Intoccia, Al; Wheeler, Mitch; Vialle, George
Subject: FW: PP marlex china 109 nat & 100blue

Team

Here is info to date after verbal just had with Dean, email is from Thierry @ Luxilon

Charlie

From: Dean King [mailto:Dean.King@proxybiomedical.com]
Sent: Thursday, October 13, 2011 8:38 AM
To: Raneri, Joe; Smith, Charles
Subject: FW: PP marlex china 109 nat & 100blue

FYI

From: Thierry Beyltiens [mailto:thierry.beyltiens@luxilon.be]
Sent: 13 October 2011 13:39
To: Dean King
Cc: Nico Van Malderen
Subject: PP marlex china 109 nat & 100blue

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Dean,

During the run the filament broke a few times at the spinneret so we were not able to make the 130 / 5 spools.

We will start back on Monday 17th and normally will finish Tuesday afternoon.

We slightly adapted the spinneret- and melt temperature because we saw some roughness on the filament.

We have tested the rougher filament and the smooth (higher temp) on tensile elongation shrinkage,… and we found no significant difference compared to the previous batches.

The change in temperature is ,as far as we can see now, in a normal range caused by small difference between the batches of the raw material.

Thierry

Thierry Beyltiens,

Regulatory Affairs Manager

Luxilon Industries NV

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Fax:(32)3.3263324

From: Smith, Charles
Sent: 10/25/2011 10:51:24 AM
To: Riek, Nichole; Goddard, James
Subject: FW: Bio assessment for China lot of Marlex : no certification available.

Importance: High

FYI

From: Smith, Charles
Sent: Tuesday, October 25, 2011 10:41 AM
To: Batty, Jessica; Beckord, Hollie
Cc: Hood, Alan M.; Burrill, Dan; Heroux, Adam
Subject: RE: Bio assessment for China lot of Marlex : no certification available.

Jessica

Thks

Hollie

Feel free to call Dan or myself as needed.

thks

Charles Smith, PMP®

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(cell) 978 671-4495

From: Batty, Jessica
Sent: Tuesday, October 25, 2011 10:21 AM
To: Beckord, Hollie
Cc: Smith, Charles; Hood, Alan M.; Burrill, Dan; Heroux, Adam
Subject: FW: Bio assessment for China lot of Marlex : no certification available.
Importance: High

Hi Hollie!

The team that is working on the mesh PFR and sling products has encountered a new challenge that we need your help with. A new lot of Marlex material has been discovered in a warehouse in China that the team has been working to qualify for use. There is no certification available for the lot, but the engineering group has conducted testing to verify the identity of the material and they are now comfortable saying that the lot is Marlex and is suitable for use. During the testing, however, some small differences were discovered between the existing Marlex material and this new lot. We would like your help in determining whether these differences are significant to the composition of the material and therefore to biocompatibility.

Dan Burrill (cc'd) is leading the engineering side of the effort and he will have the best understanding of the testing was performed and the concerns that exist with the materials. If you could take a look at their data (attached in the email below) and provide your feedback/recommendations on the situation that would be very helpful. Please note that this is a pressing situation and we would really appreciate your consideration as soon as possible. If you have any questions please feel free to give me a call!

Thank you!

Jess

Jessica Batty

Boston Scientific Corporation

Biocompatibility Specialist I

Corporate Toxicology and Biocompatibility Services

P - 508.650.8473

battyj@bsci.com

From: Smith, Charles
Sent: Tuesday, October 25, 2011 9:58 AM
To: Batty, Jessica
Cc: Heroux, Adam; Goddard, James; Burrill, Dan; Riek, Nichole
Subject: Bio assessment for China lot of Marlex : no certification available.
Importance: High

Jessica

Here is information to pass along to Hollie for review. Dan is leading the report effort of the material testing we just completed:

1. Raw data on from test house. PDF

2. Equivalency testing Protocol as approved in PDM.
http://pdmprd.bsci.com/Windchill/servlet/WindchillAuthGW/wt.enterprise.URLProcessor/URLTemplateAction?action=ObjProps&oid=VR%3Aext.bsc.doc.BSCDocument%3A2515852803

3. Summary slide deck of our internal review, Dan can provide latest copy of this, as needed

4. We are currenlty working on report as discussed.

We are available as needed to discuss with Hollie. I can set-up meeting, let me know.

Thks

Charlie

From: Cuddy, Christopher
Sent: 08/24/2011 10:15:20 AM
To: Wheeler, Mitch
Subject: FW: Marlex Equivalency Testing
Attachments: Channel Prime Alliance Lot CofA.pdf; Marlex HGX-030-01 MSDS.pdf; Marlex HGX-030-01 Equivalency Testing.doc; Marlex HGX-030-01 Technical Data Sheet.pdf

FYI
I'm sure Dan and team are having a difficult time establishing acceptance criteria. I'll try to calibrate with you before I give feedback.
By the way, I see it's called a tech report. I did agree that Tech report was a good document type for PDM, but will make sure it's appropriately named.

From: Burrill, Dan
Sent: Wednesday, August 24, 2011 7:42 AM
To: Smith, Charles; Cuddy, Christopher; Ciulla, Ron
Subject: Marlex Equivalency Testing

I have drafted a technical report that outlines the proposed testing that has been discussed in various emails and meetings. Please review and provide me any feedback you may have. I will wait to hear from you before putting document into PDM for approval.

Thanks,
Dan

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