From: Burrill, Dan
Sent: 09/02/2011 09:47:44 AM
To: Cuddy, Christopher; Courtois, Janice; Boden, Mark
Subject: Marlex HGX-030-01 Equivalency Testing - Rev 2.doc
Attachments: Marlex HGX-030-01 Equivalency Testing - Rev 2.doc

Attached is Rev 2 of document with some of Chris's comments and my response to them. Please to a look at this ASAP as I would like to put this into approval by noon today.

Thanks,

Dan

Document Title:	Marlex® HGX-030-01 Equivalency Testing
Document Number:	90708859
Project Name:	Uro/Gyn Sustaining
Project Number:	U0311
Author(s):	Daniel Burrill

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1. **Background:**

An initial lot of Phillips Sumika Marlex® HGX-030-01 Polypropylene Homopolymer 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). A second lot of material has been obtained from the material distributor Emai Plastic Raw Material (Dongguan) Inc. While the material has been supplied in the correct Phillips Sumika bags with an identifiable lot number, no CoA was supplied with this lot, and the distributor is not able to reproduce a CoA. Therefore this document will outline activities that BSC will conduct to ensure the Marlex® HGX-030-01 received from Emai Plastic Raw Material is equivalent to the Marlex received from Channel Prime Alliance. Upon completion of these activities this report will be revised to document all testing, analysis and conclusions.

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2. **Objective**

The purpose of this document is to outline the testing strategy and acceptance criteria that will be used to establish the equivalency of two Phillips Sumika Marlex® HGX-030-01 Polypropylene Homopolymer lots obtained from two different material distributors.

3. **Applicable Documents**

Document Description	**Document Number**	**Document Version** (when applicable)
Procedure to evaluate equivalency of polymers for shelf life	90559224	AA
Global SOP AVL Management	90265075	AJ

4. Materials / Traceability

Two lots of Phillips Sumika Marlex® HGX-030-01 Polypropylene Homopolymer will be tested as part of this work.

Lot No.	Product Description
PP0353133-02	Existing Qualified lot of HGX030-01 obtained from Channel Prime Alliance
6120105	New lot of HGX030-01 obtained from distributor Emai Plastic Raw Material (Dongguan) Inc

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, material property variations from bag to bag are not expected. Therefore samples from both lots will be randomly selected from a single bag. The material samples will then be evaluated at an independent external testing laboratory BSC has determined to be capable of conducting required test to all applicable ASTM/ISO standards. This laboratory shall be documented as an approved supplier per Global SOP AVL Management 90265075.

Table 1 lists the testing that will be conducted to determine equivalency between the two lots.

In determining equivalency of the two polymers, not only will individual results be assessed based on the analysis techniques listed in Table 1, but all data will be assessed in aggregate by internal and independent external subject matter experts (SME).

As test results are reviewed, additional tests may be deemed necessary by the team to establish equivalency. All test results and associated analysis will be added to this document upon completion.

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Comment [c1]: Should we discuss How much we are going to send them and why we are taken a sample from one bag (because we assume homogeneity)?

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Comment [c2]: Is there an ISO cert we can leverage? Of some other GLP cert or something.

Comment [DB3]: As part of the report we will attach Cambridge Polymer's report, we could as for copy of their ISO Cert, though AVL process should cover this.

Table 1: Test Matrix

Test Name	Test Purpose	Expected Results / Analysis Technique
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.
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
Fourier Transform Infrared Spectroscopy (FTIR)	Evaluates the degree of similarity in bulk composition of polymers.	Spectral outputs to be qualitatively assessed by SME.
Melt Flow Index ASTM D1238	Empirical measures of the viscosity of polymers which is an indicator of molecular weight.	Samples are expected to be within 0.5 grams/10 minutes of each other
Gel Permeation Chromatography (GPC)	Measure of molecular weight and molecular weight distribution.	Samples are expected to be within 15% of each other. Qualitative assessment of spectral output by SME will also be conducted.
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.
Inductively Coupled Plasma Spectroscopy (ICP)	Determines primary heavy metal contaminants	Qualitative assessment of spectral output by SME.
Optical Microscopy	Determine presence of bulk contamination	Qualitative visual assessment of pellets by SME.

Comment [c4]: Should we say "Expected results" Is that a better fit? In which case, my go to phrase would be something like "samples are expected to be withing XX% or each other"

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Comment [c5]: I see we list the TM when we can. Consider breaking the tet method. We know we are going with Cambridge…maybe we can list their procedures. This was mentioned by Mitch last … [1]

Comment [DB6]: Although … [2]

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6. Attachments:

Attachment	Description
Attachment 1	Channel Prime Alliance Certificate of Analysis (CoA)
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

Page 5: [1] Comment [c5] **cuddyc** **9/1/2011 10:47:00 PM**
I see we list the TM when we can. Consider breaking the tet method. We know we are going with Cambridge…maybe we can list their procedures. This was mentioned by Mitch last week. A protocol usually has material, sample size, rationale, test method, acceptance criteria.

Page 5: [2] Comment [DB6] **Daniel Burrill** **9/2/2011 9:43:00 AM**
Although Cambridge is managing testing they are not going to conduct all the test, they will outsource some test. We can request TM references in report. I think the test method here is that we are sending samples out to certified independent lab.

Page 5: [3] Deleted **Daniel Burrill** **9/2/2011 8:51:00 AM**
Typically differences greater than 20% are considered significant.

Page 5: [4] Deleted **Daniel Burrill** **9/2/2011 8:51:00 AM**
Typically differences greater than

Page 5: [5] Deleted **Daniel Burrill** **9/2/2011 8:52:00 AM**
Typically differences greater than

Page 5: [6] Comment [c7] **cuddyc** **9/2/2011 8:53:00 AM**
I really liked the "independence" of our lab.

Page 5: [7] Comment [c8] **cuddyc** **9/1/2011 10:46:00 PM**
I really liked the "independence" of our lab.