From: Boden, Mark
Sent: 09/01/2011 04:18:24 PM
To: Burrill, Dan; Cuddy, Christopher; Courtois, Janice
Subject: Marlex HGX-030-01 Equivalency Testing mb edits.doc
Attachments: Marlex HGX-030-01 Equivalency Testing mb edits.doc

I've made a couple of additional edits.

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

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1. Executive Summary: 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. This testing is also intended to identify potential contamination and confirm that the material did not suffer degradation due to being subjected to adverse storage conditions.

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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

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4. Materials / Traceability

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

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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

Samples from both lots will be randomly selected. The material samples will then be evaluated at external testing laboratories 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.

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

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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 external subject matter experts (SME).

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

Test Matrix

Test Name	Test Purpose	Analysis Technique Comments
Differential Scanning Calorimetry ASTM D3418	Measure thermal transition characteristics of the polymers.	Melt Temperature (T_m) will be evaluated. Typically differences greater than 5 °C are considered significant.
Oxidative Induction Time (OIT) ASTM D3895	Highly accelerated stress test used to determine long term stability equivalence of polymers.	Typically differences greater than 20% are considered significant.
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 measurement of the viscosity of polymers which is an indicator of molecular weight and polymer structure.	Typically differences greater than 0.5 grams/10 minutes are considered significant
Gel Permeation Chromatography (GPC)	Measure of molecular weight and molecular weight distribution.	Typically differences greater than 15% are considered significant. Qualitative assessment of graphical output will also be conducted.
Gas Chromatography/ Mass Spec (GC-MS)	Determines masses of volatile additives, for determining the chemical composition of a sample, and/or 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.

Table 1

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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	Channel Prime Alliance Lot C_of_A

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