

KRAIBURG TPE GmbH & Co. KG · Friedrich-Schmidt-Str. 2 · 84478 Waldkraiburg · Germany

MeLuna Innovationen aus Kunststoff

Hr. Krüger

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12.12.2011

Confirmation for THERMOLAST® M MT grades

Dear Sirs

This is to confirm that in the formulation of the compound(s) THERMOLAST® M **TM3MED** and **TM4MED**, KRAIBURG TPE GmbH & Co. KG

- does not add substances of animal origin;
According to information from our supplier one ingredient in our compounds contains small amounts of stearates or other materials derived from fatty acids. These are derived from fat, mainly from animal origin.
The following can be stated about the fat delivery chain:
The suppliers guarantee that their fat supply comes from countries with no BSE and that specific risk materials are not used. Thus the requirements of the EU Regulation 1326/2001 and Commission Decision 2001/2/EC regulating the use of materials presenting risks as regards transmissible spongiform encephalopathies (TSE) are fulfilled.
The process of making stearates include hydrolysis, esterification and hydrogenation steps in different variations depending on the supplier. The common features are that these steps include processing conditions with temperatures above 235°C, pressures above 30 bars with retention times up to several hours. The final product is obtained through fractionation, neutralisation and purification.
The subsequent extrusions at our factory granulator and when producing the product take place at 200°C for several minutes.
The production chain of stearates thus far exceeds the stringent requirements of 200°C for 20 minutes in Annex VI, chapter III of EU Regulation 1774/2002, in EU Directives 2000/6/EC and 1999/82/EC (referring to Document EMEA/410/01-Final, latest version: Rev. 2 – October 2003) and in the Report WHO/CDS/VPH/95.145, meaning that any virus, bacteria or substance causing immunological diseases (TSE, BSE, CJD) is destroyed.
In the FDA document FR Doc 04-15881 (14.07.2004) on "Use of materials derived

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from cattle in human food and cosmetics" tallow derivatives are excluded from "Prohibited cattle materials".

Therefore our supplier state that these materials and our product are to be considered safe to use in food, pharmaceutical and cosmetic contact applications with respect to BSE and TSE transmissions.

However, the compound has not been tested for these chemical substances.

This information is based on our current knowledge and shall not absolve the customer of the responsibility to make tests for his intended process purpose.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'C. Stolzenberg', is written over the printed name and company information.
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