December 03, 2008
Our ref.: BvS/DCLPMC/08-LT111

LENORPLASTICS AG
Switzerland

Subject: Lexan* HP2REU – 1H9D036T resin

Lexan HP2REU - 1H9D036T resin is formulated to comply with European Directive 2002/72/EC and its amendments and FDA 21CFR177.1580.

Prospective users of these materials are advised to consult these regulations for more specific details on finished article requirements.

Any addition to these materials beyond our control is the sole responsibility of the manufacturer of the finished article.

We have tested several Lexan resins in the past for conformance to the plastics classifications under the U.S. Pharmacopoeia or ISO 10993. Tests described under the US Pharmacopoeia are identical or very similar to the tests described under ISO 10993 and EN 30993.
These tests include: 1: Systemic Toxicity test, 2: Intracutaneous Toxicity test , 3: Implantation test, 4: Cytotoxicity test, 5: Hemolyses test, 6: Pyrogenicity test, 7: Sensitization test
The tested resins passed the requirements.

Although we have not tested all possible combinations and permutations with the various additives and colorants, we have every reason to expect that subject Lexan resin will pass the requirements of the U.S. Pharmacopoeia (Class VI) and ISO 10993 and EN 30993. The basis for this expectation is that it seems highly unlikely that the presence or absence of small amounts of additives and colorants, present in tightly bound form in the inert resin matrix, would be detectable by any of the biological tests, described under USP (Class VI) and ISO 10993 and EN 30993.

Actual testing of the material device combination is the responsibility of the device manufacturer.

Above mentioned resin is manufactured without the use of latex and contains one additive, which is based on material from animal origin. The concerns relative to BSE/TSE in the context of plastics materials used in contact with food are linked to the use of additives of animal origin: tallow derivatives.

These materials (fatty acids, fatty alcohols, metallic soaps, fatty amines, fatty amides, fatty acid esters, glycerine) are incorporated into plastics as lubricants, slip agents, anti-static agents as well as emulsifiers, anti-oxidants or corrosion inhibitors. They are primarily extracted from tissues of ovine or bovine origin.

The treatments of the supplier greatly exceeds the recommendation of inactivation of TSE laid down (among others) in the Commission Directive 2000/6/EC[1], the “Note for Guidance on Minimizing the Risk

[1] Twenty-fourth Commission Directive 2000/6/EC of February 2000 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products.

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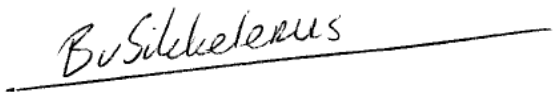
of Animal Spongiform Encephalopathies (TSE) Agents via Medicinal Products" and its updates (EMEA/410/01 rev. 2), as issued by the Committee for Proprietary Medicinal Products of the European Agency, the updated report of APAG of August 2003[2], and also in the revised opinion of the EU Scientific Steering Committee on the Safety of Tallow (June 2001[3]) and the opinion EU Scientific Steering Committee on the Safety of Tallow (April 2003 [3]). These treatments ensure a complete inactivation of any TSE/BSE agent regardless of the source and type of material[4]. Furthermore, these substances are compounded into a polymer matrix at temperatures exceeding those applied in the supplier's process. Finally, the subject resins are converted into the final article using temperatures again exceeding those applied by the supplier.

SABIC Innovative Plastics does not recommend and will not support the use of any SABIC IP products in medical devices intended to remain continuously in the human body for longer than 29 days.

SABIC Innovative Plastics has no control over final product composition nor over processing conditions. It is therefore the responsibility of the manufacturer of the finished article to check compliance with the relevant regulations.

I trust the above information is satisfactory for your needs. Should you require additional information, please don't hesitate to contact me.

Sincerely,



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[2] The Safety of Tallow Derivatives with Respect to Bovine Spongiform Encephalopathy – an Updated Report, August 2003, APAG (=The European Oleochemicals & Allied Products Group)

[3] Scientific Steering Committee: Revised opinion and report on: The safety of tallow obtained from ruminant slaughter by-products - http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html#opinions

[4] This statement is valid for tallow derivatives to be used in plastics materials; the products used in food, animal feed, pharmaceutical and cosmetic applications must comply with additional Directives.

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