

Animal Derivative & Bovine Spongiform Encephalopathy (BSE)

SEKISUI Voltek's Volara®, Volextra® and VolaraBLOCK® foam products can contain Zn stearate which is a "tallow derivative". Our supplier reports that tallow derived fatty acid can be sourced from cattle, pork and poultry stock. The concern to the public stems from the use of cattle or beef stock. It is known that beef products can contain Bovine Spongiform Encephalopathy (BSE).

The USDA prohibits the importation of meat and edible products from ruminants that have been in regions where BSE exists or in regions that present an undue risk of introducing BSE into the United States. Notably, a second USDA regulation that prohibits the importation of processed animal fat, including tallow, from BSE regions and those regions that present an undue BSE risk expressly excludes "tallow derivatives" from the prohibition. 9

C.F.R. § 95.4. Undoubtedly, the USDA recognizes that such products are so highly processed so as to be of extremely low risk. See 66 Fed. Reg. 42,595 (August 14, 2001). Namely, tallow fatty acids and their salts are processed at high temperature, high pressures, and in many cases in a chemical environment (alkaline).

In keeping with this understanding, the Commission of the European Communities (EC) has published guidance on safe processing methods for tallow derivatives for use in cosmetics and medicinal products. According to EC directives and guidelines, tallow derivatives are considered safe if they are manufactured via transesterification or hydrolysis at a minimum of 200°C and an appropriate corresponding pressure for 20 minutes (to obtain glycerol, fatty acids, and fatty acid esters). See 2000/6/EC and 2001 OJ C 286 (October 12, 2001).

We have received assurances from our supplier that they and their suppliers meet or exceed these time, temperature, and pressure conditions during production of stearic acid from beef tallow. Thus, the processing conditions for the tallow derivatives used in the manufacture of tallow-derived metallic stearates comply with EMEA 410 Rev. 3, Section 6.4 ("Tallow Derivatives") as published in the Official Journal on July 1, 2011. This is the current version of EMEA 410.

In conclusion, some Volara, Volextra and VolaraBLOCK products contain tallow derived Zn stearate which is both exempt from import prohibition by the USDA and considered safe according to EC directives and guidelines. It is Sekisui Voltek's goal to support all products in the marketplace and with respect to medical devices and numerous Volara grades have been evaluated by NAMSA testing with no negative results. Tests include cytotoxicity agarose overlay, oral toxicity, primary skin and ocular irritation.