



SUPEROL NK™, GLYCERIN, USP/FCC
STAR NK™, GLYCERIN

BSE- Animal Derived

Dear Glycerin Customer:

In response to your request regarding BSE in bovine animals and inquiries pertaining to the origin of bovine-derived materials relative to our non-Kosher Glycerin, please be advised the following:

Procter & Gamble's non-Kosher Glycerine is derived from naturally occurring vegetable oils and animal fat (primarily coconut oil, palm kernel oil, palm oil, soybean oil & tallow). We use solely North American bovine and porcine domestically sourced tallow for our glycerin (bovine/porcine born, raised and slaughtered in North America). We do not import tallow for use in our North American manufacturing plants.

The positive test result for BSE, in a single cow in Washington State in December '03 is cause for further evaluation of the safeguards provided in the US for the protection against BSE. The investigation and action steps announced by USDA, FDA and the beef processing industry will determine both the cause of the incident and the control of the involved materials to ensure continued safety of the food and tallow supply.

The United States Department of Agriculture (USDA) has had a BSE surveillance system since 1986. In 1989, the USDA banned imports of live bovine and ovine animals and animal products from the UK and later extended the ban to all BSE infected countries as listed in 9CFR Part 94. In 1997, the FDA banned the use of mammalian protein in cattle feed providing another significant barrier. In addition, the US Federal government has taken other steps to protect human and animal health against BSE. In combination, these measures provide assurance that the domestic tallow supply offers minimal risk of BSE infectivity. We continue to monitor our tallow supply to ensure that our sources are contained to those areas where the proper safeguards to BSE transmission are in place.

As a result of the surveillance program identifying the single animal with BSE, further steps to prevent this incident from becoming widespread have been triggered. The USDA has confirmed the animal was born in Canada, prior to the 1997 ban on ruminant feeding of potentially infected mammalian tissue, the major route of transmission. The present feeding ban will control the risk of transmission to make sure that isolated cases do not become a large outbreak. The rendered products from this cow have been accounted for and have not entered the tallow supply. The incident review is raising the appropriate questions about the traceability of animals, quantity of testing and the disposition of donor animals.

Additionally, rendered tallow is known to be low risk with respect to BSE, as the BSE agent is protein based and does not reside in the fat. We use only high grades of purified tallow in the production of our tallow based oleochemicals. Manufactured products derived from rendered tallow and subjected to rigorous processes of extraction and purification is considered unlikely to present any risk of contamination. Our oleochemical products are highly processed materials, having been subjected to high temperature and pressure conditions or chemical reactions that are known to be terminally hostile to the BSE agent.

From the starting triglycerides (oil or fat) to the finished refined glycerin there are a number of processing steps required. These include hydrolysis (or fat splitting), esterification or saponification of the triglycerides, followed by pretreatment of the crude glycerine, glycerin distillation and finally post-treatment via carbon bleaching.

P&G's crude glycerine sources are from either internal production or external purchases. The crude glycerine (both obtained internally & purchased externally) is derived from hydrolysis, transesterification or saponification of the fats & oils depending upon the source. P&G's nonkosher crude glycerine (tallow sourced) suppliers are active members of the

Soap & Detergent Association, and participated in a 1997 survey conducted by the SDA to collect data from oleochemical and soap industries on all aspects of their operations. The data collected confirm that the rigorous processes used in the production of the tallow derivatives, including glycerine, meet or exceed the recognized conditions for inactivating the BSE agent as defined by the EU Scientific Steering Committee in various opinions since March 1998, and as laid down in EU legislation, including Directive 1999/82/EC; Commission Directive 2000/6EC, the 24th adaptation to Council Directive 76/768/EEC:

Transesterification or hydrolysis of at least 200C, at corresponding pressure for 20 minutes
Saponification with NaOH of at least 12 Molar Batch process at 95C for three hours or Continuous process at 140C, 2 bar for 8 minutes or equivalent conditions

The crude glycerine is further processed in a number of purification steps including vapor-phase distillation at temperatures greater than 166C. Non-kosher Glycerin, USP is manufactured in accordance with „Good Manufacturing Practices“ for bulk pharmaceutical excipients, and tested for purity to meet all U.S. Pharmacopoeia monograph specifications for Glycerine. Our manufacturing facilities are subject to periodic audits by the FDA, self audited on a regular basis by trained auditors according to our Quality Assurance program, as well as by pharmaceutical customers sending their own trained staff.

Based on these rigorously controlled operating conditions, the harsh temperatures, pressures and residence times used in the production of Glycerin, and the exclusive utilization of animal fats meeting prescribed quality specifications and originating in North America, we would not expect BSE to be an issue as it relates to our non-Kosher Glycerine.

PGC continues to closely follow the scientific developments in the understanding of the causes, transmission, and elimination of BSE and related TSE's and take appropriate precautions to ensure that the glycerin supplied to our customers employs the protections supported by scientific evidence.

If you have any further questions, please inform your P&G account representative. He or she will work with the proper P&G resources to make sure your question is addressed.

Sincerely,

THE PROCTER & GAMBLE

COMPANY Regulatory Affairs
P&G Chemicals¹

¹ IMPORTANT NOTE This technical product information, while believed to be accurate and reliable, is given without guarantee or warranty of any kind expressed or implied. Purchaser assumes all risk in acting on this information provided by Procter & Gamble representatives. Individual requirements vary, and each

purchaser is urged to perform their own tests, experiments and investigations in the use of Procter and Gamble products and for purposes of determining compliance with applicable Federal, State and local laws and regulations. Nothing contained herein shall be construed as a recommendation to use any product in connection with existing patents covering any material or its use. Moreover, no license is to be implied under any Procter & Gamble patents relating to uses of the above described chemicals other than those uses specifically mentioned herein.