

STATEMENT ON ORIGIN OF ADDITIVES

We declare under our sole responsibility that, according to the current information provided by our raw material supplier, the raw material used by us for the production of:

Bowls PP, white,

item no. 42594, 42694, 42794, 42894, 42994, 43094, 43194

contains at least one additive derived from tallow.

With respect to the risk of Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE) transmission, we received from our raw material supplier the following information:

1. The raw materials used in the production of animal-derived additives are categorized in cat 3 according to Regulation (EC) 1069/2009 and its implementing Regulation (EC) 142/2011, or originate from countries considered as BSE-free.
2. The tallow derivatives undergo conditions described as rigorous in Regulation 294/2013/EC Art 1 (1) J (Cfr Annex XIII, Chapter X and XI of Regulation 142/2011/EC). In particular, following requirements are stated in Chapter XI:

The following processes may be used to produce fat derivatives from rendered fats derived from Category 1 and Category 2 material:

- 1. transesterification or hydrolysis at a temperature of at least 200 °C, under corresponding appropriate pressure, for at least 20 minutes (glycerol, fatty acids and esters);*
 - 2. saponification with NaOH 12M (glycerol and soap):*
 - 1. in a batch process at 95 °C for three hours; or*
 - 2. in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes; or*
 - 3. hydrogenation at 160 °C at 12 bars (12 000 hPa) for 20 minutes.*
3. BSE has never been found in beef tallow and the World Health Organisation (WHO) stated that tallow does not represent a risk for both human and animal health (OMS/CDS/VPH/95.145).

4. The raw materials used in the production of animal-derived additives undergo during the process a thermal stress that is compliant with the EUP 5.2.8 § 6-4 "Tallow Derivatives" identical to the "Note for Guidance on Minimising the Risk of transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Products" usually known as EMEA 410/01 rev.3. It is noteworthy that EUP 5.2.8 §6-4 states: "Such materials (AN: tallow derivatives) manufactured under the conditions at least as rigorous as those given below (AN: prescriptions on chemical process, temperature and pressure as described in paragraph above) shall be considered in compliance for this chapter, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived."

Furthermore, during pelletization then conversion, the polyolefin plastics are exposed to shearing stress and to temperatures ranging from 160°C to 300°C during 20 seconds to a few minutes. These successive steps help to ensure the complete protection of people's health in respect of TSE for plastic materials used for food-contact, or similar, applications.

All information is based on statements from our raw material suppliers, common experience or printed information and no responsibility is taken for the correctness of the provided information. Furthermore, we cannot exclude that a change in material may become necessary in the future. It is the user's responsibility to determine suitability of the product whether it may be used for the desired application or not.

In addition, we have to point out that the bowls supported by VITLAB GmbH are laboratory articles of general use. The used raw material is not intended to be used for medical, pharmaceutical or healthcare applications and the raw material manufacturer do not support their use for such applications. This product is neither tested nor represented as suitable for medical or pharmaceutical uses by us.

Should you need any further information please do not hesitate to contact us again.

VITLAB GmbH

Grossostheim, 27. January 2025

Wolfgang Nicolaus

Geschäftsführer

Managing Director

i.A. Dr. Stephan Schmidt

Beauftragter Product Compliance

Regulatory Affairs

This letter has been typed and is valid without signature.