



UNIPETROL RPA, s.r.o.
Záluží 1
436 70 Litvínov
Czech Republic

MATERIAL DECLARATION

Product: PE LIEN MB 87

As a material manufacturer we declare that PE LITEN 87 fully comply with the Regulation (EC) No. 1907/2006 of the European Parliament and of the Council (REACH). During manufacture of these products, **phthalate-free** catalytic systems have been used and no phthalates have intentionally been incorporated into these products.

In product of PE LITEN MB 87 we incorporate small amounts of zinc stearate derived from fatty acids. These are derived from fat, mainly from **animal origin**.

Attached you will find the BSE/TSE statement from our supplier of stearates – FACI S.p.A. The subsequent extrusions at our factory granulator and when producing the product take place at 200 °C for several minutes. We therefore state that these additives and our product are to be considered safe to use in food, pharmaceutical and cosmetic contact applications with respect to BSE and TSE transmissions.

During the manufacturing of the above product we do not use or intentionally incorporate into it **any biocides** (pesti-, herbi-, insecti-, fungi-, bactericides) and **bisphenols** (A, S, F, etc.).

Eva Budská
unit EKO
UNIPETROL RPA, s.r.o.
CZ-43670 Litvínov
2018-04-19

Disclaimer:

Ultimately customers must make their own determination that their use of our product is safe, lawful and technically suitable in their intended applications.

No liability can be accepted in respect of the use of UNIPETROL RPA' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.



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BSE/TSE STATEMENT

Revision: 28th April 2016

STEARATES STEARIC ACID GLYCERIN ESTERS AMIDES

Herein we certify that according to Commission Regulation (EU) no 142/2011 of 25 February 2011 implementing Regulation (EC) no 1069/2009 of the European Parliament and of the Council (amendment of Regulation (EC) No 1774/2002 of 3 October 2002) the Stearates, Stearic Acid, Glycerin, Esters and Amides produced by FACI S.p.A are obtained exclusively by class 3 animal by-products, or by fats coming from BSE free countries.

Our raw materials are currently purchased in the following countries: Italy, France, Germany and Slovak Republic.

All our suppliers issued a statement concerning their conformity to the following Regulations (EC): no 999/2001 of 22 May 2001, no 1326/2001 of 29 June 2001 and no 1774/2002 of 3 October 2002.

The above mentioned Regulations provide for the removal of specified risk materials and define the working conditions of animal by-products.

According to Regulation (EC) No 1774/2002 our manufacturing plant has been classified as Class 3 'Oleochemical Industry' and according to Regulation No 1069/2009 the Approval Number ABP2032OLCP3 has been assigned.

During our production processes the animal fats undergo the following inactivation treatments:

- Hydrogenation process at a temperature grater than 220 °C for at least 120 minutes at more than 15 bars.
- Hydrolysis or hydrolytic reaction at a temperature grater than 200 °C for at least 120 minutes at more than 20 bars.
- Therefore our inactivation treatment fully exceeds the conditions recommended by:
- Note for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products EMA/410/01 rev. 3 Official Journal of the European Union 2011/C 73/01, 5.3.2011.
- CPMP (Committee for Proprietary Medicinal Products) in the BWP/5136/03, 21 October 2004 (and further amendments)
- Scientific Committee on Cosmetology (24 June 1997), conditions provided at Annex VI chapter III of Regulation (CE) no 1774/2002
- Annex II of Commission Directive 2000/6/EC of 24 February 2000 concerning the risks of BSE and relevant inactivation or removal procedures of agents causing BSE.

FACI S.p.A.
Dr. Paolo D'Amico
Quality Manager