DoverPac® Containment Systems

0000-713855 Rev. A

March 03, 2016

To Whom It May Concern,

ArmorFlex® 116 film is certified to be Animal Component Free and of Non-Animal Origin.

ILC Dover defines these terms as follows:

- **Animal Component Free (ACF)**
  A material that contains no ingredients sourced directly from any part of an animal.

- **Non-Animal Origin (NAO)**
  A material that contains no animal sourced ingredients OR that represents no TSE/BSE contamination risk (As shown by risk assessment)

Certain tertiary materials may be derived and/or synthesized from ingredients of animal origin. However the rigorous processes used in the production of these materials fully complies with the recognized conditions for inactivating BSE/TSE agents as specified in Section 6.4 of EMA/410/01 Rev. 3 July 1, 2011. This is attached as Appendix A.

Any questions can be directed to Customer Service at 1-800-631-9567 or customer_service@ilcdover.com.

Sincerely,

William J. Silvestri Jr.
Quality Assurance Manager
silveb@ILCDover.com
(302) 335-3911 x325

ILC DOVER
creating what's next

One Moonwalker Road
Frederica, DE 19946
(800) 631-9567
(302) 335-3911
(302) 335-1320 (FAX)
www.doverpac.com

Appendix A

Section 6.4
of
EMA/410/01 Rev.3

Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products

ILC DOVER
creating what's next

One Moonwalker Road
Frederica, DE 19946
(800) 631-9567
(302) 335-3911
(302) 335-1320 (FAX)
www.doverpac.com

6.4. ***Tallow derivatives***

Tallow is fat obtained from tissues including subcutaneous, abdominal and inter-muscular areas and bones. Tallow used as the starting material for the manufacture of tallow derivatives shall be 'Category 3 material or equivalent', as defined in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption.

Tallow derivatives, such as glycerol and fatty acids, manufactured from tallow by rigorous processes are thought unlikely to be infectious and they have been the subject of specific consideration by CPMP and CVMP. For this reason, such materials manufactured under the conditions at least as rigorous as those given below shall be considered in compliance for this Note for Guidance, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived. Examples of rigorous processes are:

- trans-esterification or hydrolysis at not less than 200 °C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production),
- saponification with NaOH 12 M (glycerol and soap production)
- batch process: at not less than 95 °C for not less than 3 hours,
- continuous process: at not less than 140 °C, under pressure for not less than 8 minutes, or equivalent,
- distillation at 200 °C.

Tallow derivatives manufactured according to these conditions are unlikely to present any TSE risk and shall therefore be considered compliant with this Note for Guidance.

Tallow derivatives produced using other conditions must demonstrate compliance with this Note for Guidance.

One Moonwalker Road
Frederica, DE 19946
(800) 631-9567
(302) 335-3911
(302) 335-1320 (FAX)
www.doverpac.com