

## TECHNICAL STATEMENT

### Animal Origin Statement

In plastic industry many of the polymers includes small amount of stearates derived from fatty acids. The following can be stated about the fat delivery chain:

- It is guaranteed that the original fat supply comes from the countries with no BSE and that specific risk materials are not used. Thus the requirements of 2000/418/EC and 2001/2/EC regulating the use of materials presenting risks as regards transmissible spongiform encephalopathies (TSE) are fulfilled
- The process of making these stearates include hydrolysis, esterification and hydrogenation in different variations depending on the supplier of stearates. These steps includes processing conditions with the temperature above of 235 °C and pressures above 30 bars with retention time up to several hours. Then the final product is obtained through fractionation, neutralisation and purification.
- In addition for above, the granulation process at plastic raw material resin suppliers takes place in temperatures around 200 °C for several minutes.
- In addition of all this. We are processing our plastic raw materials in temperatures more than 250 C in several minutes before final product is finished

As a summary, conditions of the production chain of stearates far exceeds stringent requirements of Regulation (EC) No 1774/2002, "Note for Guidance on Minimizing the Risk of Transmitting AnimalSpongiform Encephalopathy Agents via Medicinal Products" (EMA/410/01 rev.3) and the report WHO/CDS/VPH/95.145. For these listed reasons any virus or bacteria or substance causing immunological diseases (TSE; BSE; CJD) is not expected to occur and WIPAK® and STERIKING® products are to be considered safe to use in pharmaceutical and medical applications with respect of BSE and TSE transmissions.

All of our raw materials are approved by EU and FDA.

#### ***Wipak, Medical***

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