



Animal Derived Material Statement – Regulation (EU) 722/2012 & ISO 22442-1

Issued: January 3, 2024

Fort Wayne Metals Research Products, LLC (FWMRP,LLC) understands customer concerns around animal derived substances and their use in the manufacture of our product. In the wire industry, animal derived products in the form of stearates are constituents of drawing powders and oleates in drawing oils. These products play a critical role in the manufacturing process and enable FWMRP,LLC to achieve the desired qualities of the product supplied to our customers. Stearate-based drawing powders are commonly used in cold drawing processes to reduce the diameter of material from 0.375 inches (9.5 mm) down to 0.064 inches (1.6 mm). Drawing oils containing oleates may be used to process material at diameters smaller than 0.064 inches (1.6 mm).

Fort Wayne Metal Research Products, LLC (FWMRP,LLC) has reviewed the requirements laid out in both Regulation (EU) No 722/2012 and ISO 22442-1 regarding medical devices manufactured utilizing animal tissues and their derivatives.

FWMRP,LLC also collects information from its suppliers to determine if the products supplied to FWMRP,LLC conform to Regulation (EU) No 722/2012 and ISO 22442-1. According to the information received from FWMRP,LLC suppliers, the drawing powders and oils supplied to FWMRP,LLC are produced with fatty acids and/or tallow derived from North American and European animals. These fatty acids and/or tallow have been processed in accordance with one or more of the following conditions as stated in both Regulation (EU) No 722/2012; Annex I, Section 3 and ISO 22442-1; Annex C, Section C.5:

- A. 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),
- B. Saponification with sodium hydroxide (NaOH) solution, at a concentration of 12 mol/l (glycerol and soap production)
 - a. Batch process: at not less than 95°C for not less than 3 hours
 - b. Continuous process: at not less than 140°C, under pressure for not less than 8 minutes or equivalent,
- C. Distillation at temperatures exceeding 200°C

The information contained herein is for reference only and, to FWMRP,LLC's knowledge, accurate as of the date of publication. As a custom manufacturer, we require our customers specify their preferred products. As such, it is the customer's responsibility to inspect and test our products in order satisfy as to the suitability of the products for the customer's particular purpose and suitability to the actual circumstances the product is exposed to. Likewise, you (the customer) are also responsible for the appropriate, safe, and legal use, processing and handling of our products in your facilities and your final product(s). This statement shall not be considered a warranty of any kind as FWMRP,LLC's sole warranty for its product(s) is set forth on the Purchase Order Acknowledgement's Terms & Conditions of Sale or as otherwise agreed to, in writing, by the parties.



Regulation (EC) No 722/2012 states the regulation shall not apply to tallow derivatives processed under conditions at least as vigorous as those laid down in Section 3 of Annex I. Furthermore, ISO 22442-1 Annex C, Section C.5 indicates that tallow materials manufactured by a rigorous process are thought unlikely to be infectious and shall be considered as presenting an acceptable TSE risk. The processes outlined above are given as examples of such rigorous processes. Fort Wayne Metals Research Product, LLC's product may contain residual processing aids, such as drawing oils and other lubricants containing animal derived products. FWMRP, LLC encourages its customers to keep this information in mind when performing proper risk evaluations.

Fort Wayne Metals Research Products, LLC

Product Stewardship Team

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