



10/2/2018

Part No:	369256
Description:	Liners, Disposable, Polyurethane, JLA-8.1000/9.1000, set of 120

ANIMAL ORIGIN STATEMENT

Dear Valued Customer,

In response to your request for information regarding the presence of *materials of animal origin*.

Based on the information provided to us by our raw materials suppliers, we understand that the reactant ingredients and most additive ingredients used in the manufacture of the TPU resin employed in the products listed below are not of animal source. However some of the TPU resin's additive ingredients are produced from tallow from animal sources. The animal species can be porcine, ovine, caprine and/or bovine. In addition, the animal-sourced raw materials used in these additives are processed in accordance with European Council Decision 1999/534/EC ("Measures applying to the processing of certain animal waste to protect against transmissible spongiform encephalopathies"). Processing of these raw materials satisfies the Decision's requirements for "rendered fats derived from ruminant waste" (glycerol, fatty acids, and esters) of hydrolysis (splitting) at 200°C at corresponding pressure for 20 minutes (Note 1). In fact, splitting conditions for these raw materials typically are at 260° C, 700 PSIG, exceeding the Decision's requirements.

The raw materials also satisfy the requirement in 1999/534/EC that "rendered fats derived from ruminant waste are purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0.15 percent in weight." The raw materials are filtered and distilled before shipment for use in the additives our TPU resin supplier uses and therefore, insoluble impurities levels do not exceed 0.15 percent in weight. Our supplier's confirmed compliance to EMEA 410/01 rev 3 and ISO22442-1(Annex C Section C.5 on Tallow derivatives).

Additionally, during Beckman Coulter's processing and handling, the product does not come in contact or are exposed to any other form of animal derived materials or materials of human origin.

Sincerely,

Jerry L. Mathews
Staff Quality Assurance Engineer