



## C-Flex® and Materials of Animal Origin

Since C-Flex® is used primarily in the medical device and biopharmaceutical industries, many of our customers are concerned about the sources of the ingredients in our family of thermoplastic elastomers. All of the raw materials used to produce C-Flex® are synthetic chemicals and are neither sourced from nor come in contact with animal products except one ingredient, polypropylene. The polypropylene resin used in many C-Flex® formulations is itself a synthetic chemical produced from natural gas, but it contains calcium stearate, used as an acid scavenger and lubricant. Its concentration in C-Flex® is typically no more than 128 parts per million.

Calcium stearate is usually made from beef tallow using a series of aggressive chemical reactions. The European Union has been investigating the causes and prevention of BSE, TSE and related diseases since they became widely known and they publish the results of their studies in the Official Journal of the European Union, most recently in C24/6, 28.I.2004. Section 6.4 of the *"Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products"* in this issue states:

"Tallow derivatives, such as glycerol and fatty acids, manufactured from tallow by rigorous processes are thought unlikely to be infectious...such materials manufactured under the conditions at least as rigorous as those given below shall be considered in compliance for this note for guidance...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)..."

Our polypropylene suppliers have certified that the bovine tallow used is sourced only in North America and is produced using conditions that exceed these conditions. In addition, we have documentation on file that the calcium stearate they use has been granted Certificate No. RO-CEP 2001-402-Rev 00 confirming its suitability for use in the European Union.

In September 2004, Consolidated Polymer Technologies introduced new C-Flex® formulations that are certified to be free from any animal derived components. C-Flex® R70-374, the ADCF equivalent to R70-082 60A clear, is now commercially available. For additional information and references please contact the Technical Service department at Consolidated Polymer Technologies, 800-541-6880.

Note: All recommendations and suggestions contained in our printed matter regarding end uses and methods of use are based upon laboratory studies, test results and experience available to us. However, as we cannot control the conditions and circumstances under which our products may be used, users of C-Flex® products have sole responsibility for their use. Consolidated Polymer Technologies, Inc. makes no other warranties, express or implied, and disclaims any warranty of merchantability and fitness for use.

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