

## **U.S. Food & Drug Administration Status of Certain ACC Silicone Sealants and Rubbers**

### **Introduction**

It is very difficult to offer specific guidance on F&DA compliance for any product without detailed knowledge of its intended application.

The predominant area of interest for silicone elastomer systems is normally contact with aqueous and fatty foods.

The following advice is offered only as a guide based on our current knowledge of the F&DA Regulations at the time of preparation of this statement.

Compliance with aqueous food contact requires the components of the product to meet the requirements and limitations of the Code of Federal Regulations (CFR), Title **21**, Part 177.2600 entitled "Rubber Articles intended for repeated use".

The products under consideration are either Silcoset 151, 152, 153 or 105 which, when fully cured in accordance with Technical Data Sheets, must satisfy the water extraction limits in CFR **21**, Part 177.260 (e). To comply with these regulations Silcoset 105 must be catalysed with less than 1% Curing Agent A.

Compliance with fatty food contact requires the same component compliances but, in addition, the fully cured silicone rubber must satisfy the n-hexane extraction limitations described in CFR 21, 177.2600 (f).

There is a further rider in CFR **21**, 177.2600 (g) that states, "In accordance with good manufacturing practice, finished rubber articles intended for repeated use in contact with food shall be thoroughly cleansed prior to their first use in contact with food".

Let us consider the products mentioned above:

#### **1. Silcoset 151,105 and AS1702**

The components of each of the above products are listed in CFR 21, 175.300 "Resinous and Polymeric Coatings" and in CFR **21**, 177.2600 "Rubber articles intended for repeated use"

Fully cured Silcoset 151 and fully cured Silcoset 105 (using less than 1% Curing Agent A) satisfy the requirements of CFR **21**, 177.2600, sub-paragraphs (e) and (f) for applications involving both aqueous and fatty foods.

#### **2. Silcoset 152, 153, 158 and AS1502**

They are technically very similar silicone sealants to Silcoset 151. The components of these sealants comply with the requirements of CFR **21**, 175.300 and 177.2600, but the cured sealants only satisfy the requirements of sub-paragraph (e) and hence are limited solely to applications involving contact with aqueous foods.

Please note all food regulations are constantly subject to change and we will do our best to keep our customers aware of any changes that may affect our products.