MetaLine® Elastomeric coatings

Title 21 - Food and drugs

Chapter I - Food and drug administration (FDA)

Department of health and human services

Subchapter B - Food for human consumption (continued)

Issue:

- 1.) Use of "MetaLine 580/590/598 and MetaLine 760/785/795" coatings in direct contact with foodstuffs and **pharmaceutical** parts.
- 2.) Use of "MetaLine 592" coating to comply for the use under the FFDCA and all applicable food additive regulations as a repeated food contact surface and for potable (drinking) water applications.

- Specifications: 1.) Code of Federal Regulations (FDA) 177.1680 (title 21) Polyurethane resins derived from a reaction of HMDI (Methylene di-(cyclohexylisocyanate) and polytetramethylene ether glycol or Polyurethane resins derived from TDI (Toluene Diisocyanate) and polytetramethylene ether glycol.
 - 2.) Code of Federal Regulations (FDA) 21 CFR Sec. 175.300, Table 2 Part E - Polyurethane resin category CAS 373833-28-1 derived from a reaction of MDI (Diphenylmethane-diisocyanate) with 1,4-butanediol and polytetramethylene ether glycol.

Results:

- 1.) "MetaLine 580/590/598 and MetaLine 760/785/795" meet (FDA) 177.1680 (title 21) and can be used in contact with bulk quantities of dry food containing no free fat or oil on the surface resp. corresponding parts used for pharmaceutical purposes.
- "MetaLine 592" meets (FDA) 21 CFR Sec. 175.300, Table 2 Part E and can be used for:
 - Nonacid (pH above 5.0), aqueous products
 - П. Acidic (pH 5.0 or below), aqueous products
 - 111. Aqueous, acid or nonacid products containing free oil or fat
 - IV. Dairy products and modifications
 - V. Low moisture fats and oils
 - VI. Beverages (containing alcohol and non-alcoholic)
 - VII. Bakery products

Validity:

All product manipulations must be accordingly to the application procedure issued by the manufacturer.

Date: April 2011

On behalf:

We hereby confirm that the products mentioned above meet the FDA requirements and can be used safely for the intended contact service.

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Manu Sepana









