

FDA Declaration of conformity MetaLine® Elastomeric Coatings – Series 500/700

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.
- 2.) „**MetaLine 592**“ meets (**FDA 21 CFR Sec. 175.300, Table 2 Part E**) and can be used for:
 - I. Nonacid (pH above 5.0), aqueous products
 - II. Acidic (pH 5.0 or below), aqueous products
 - III. 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: March 2017

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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