

MetaLine® Serie 500 - Elastomeric armouring

Pharmaceutical approval

Issue: Use of "**MetaLine Serie 500**" coatings in direct contact with foodstuffs and pharmaceutical parts. "**MetaLine Serie 500**" are sprayable urethane compounds that complies for 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.
- 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**" meets (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: This declaration of conformity covers coatings being manufactured in **white colour** only. All product manipulations must be accordingly to the application procedure issued by the manufacturer.

Date: May 2000

On behalf: Dipl.-Ing. Thomas Schramm

