

MetaLine Polyurethane coatings

■ Pharmaceutical suitability

- Issue:**
- 1.) Use of „**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 760/785/795**“ 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: All product manipulations must be accordingly to the application procedure issued by the manufacturer.

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