

USA (FDA) Food Contact Regulation

DigiPrime[®] 4453

Product Code
DP4453

Site of Manufacture
Michelman, Inc.
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Cincinnati, Ohio 45236-1299 USA

Tel: +1 513 793 7766
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FDA 175.105 Adhesives

All of the components of the above cited product are specifically authorized by FDA for use in food contact adhesives under 21CFR175.105. There are no limitations on coat weight, thickness or loading rate regarding use of this emulsion as a food contact adhesive other than good manufacturing practice. However, 21CFR175.105 requires that adhesives be used under one of three conditions of good manufacturing practice: that they 1) be separated from food by a functional barrier, 2) be used in packaging for dry food only, or 3) contact food only in minimal amounts at side seams and edges.

FDA 175.300 Resinous and polymeric coatings

This Michelman product may be used in the production of food contact coatings under 21CFR 175.300 in contact with all foods except infant formula under conditions of use A-H subject to the extractive limitations in that regulation and the coat weight limitation of 200g/m² wet. These uses will be subject to the extractive limitations under 21CFR 175.300 which are appropriate to the specific use of the coated food contact material.

FDA 175.320 Resinous and polymeric coating for polyolefin films

This Michelman product may be used in the production of food contact coatings under 21CFR 175.320 in contact with all foods except infant formula under conditions of use A-H subject to the extractive limitations in that regulation and the coat weight limitation of 200g/m² wet. These uses will be subject to the extractive limitations under 21CFR 175.320 and 21CFR 177.1310 which are appropriate to the specific use of the coated food contact material.

FDA 176.170 Components of paper and paperboard in contact with aqueous and fatty foods

The use of this Michelman product under 21CFR 176.170 is not subject to any limits on coat weight but its use is subject to the extractive limitations in 21CFR 176.170 and 21CFR 177.1310.

FDA 176.180 Components of paper and paperboard in contact with dry food

The use of this Michelman product under 21CFR 176.180 is not subject to any limits on coat weight but its use is subject to the extractive limitations in 21CFR 177.1310.

Further information on food types and conditions of use are referenced in 21 CFR 176.170 paragraph (c), Tables 1 and 2.

Prepared by

Michelman Regulatory Department
regulatory@michelman.com

The information contained herein relates exclusively to the referenced product. We believe this information to be accurate and reliable as of this date. This declaration of compliance is not intended and should not be construed as an express or implied warranty of any kind. In determining acceptability of this product in your intended application, we recommend you consult the applicable regulations for complete details. This declaration applies to the product as manufactured; it does not apply when the product is modified, such as by processing or storage, or when it is used in conjunction with any third party materials. It is the responsibility of the manufacturer of the finished food contact article to perform any necessary testing to ensure compliance of the finished article to any specific or overall migration requirements under actual, intended, and foreseeable conditions of use. The manufacturer of the finished food contact article is also responsible for verifying possible interactions of the product or its components with foodstuffs, including modification of odor, taste, and consistency. This declaration replaces all previous declarations for the same specification/ product and remains valid until replaced by a newer version from Michelman.

EU Food Contact Regulation

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Regulation (EC) n° 1935/2004 and especially article 3 § 1. a. therein:

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- (a) endanger human health; or
- (b) bring about an unacceptable change in the composition of the food; or
- (c) bring about a deterioration in the organoleptic characteristics thereof.

This product is not intentionally formulated with raw materials liable to endanger human health or bring about an unacceptable change in the composition of the food or a deterioration in the organoleptic characteristics thereof. However, organoleptic testing is not part of the standard quality control testing performed at Michelman on above mentioned product.

Furthermore, the requirements mentioned in article 3 concern the end-packaging which comes in direct contact with the food. Since our products will undergo further processing prior to their use in food packaging applications, it is the duty of the users to verify that the finished items, manufactured according to good technology practice do not modify the organoleptic properties of the food and to make sure that the requirements of Regulation (EC) n° 1935/2004 are met.

Commission Regulation (EU) n°10/2011 as amended.

The intended use of the above cited emulsion in single use direct and indirect food contact coating applications can be considered to be in compliance with the EU regulatory requirements for food contact materials and articles, such as the Framework Regulation (EC) No 1935/2004 and the Plastics Regulation 10/2011/EU, as amended, in case the thickness of the wet coating is limited to about 18 microns for the emulsion.

Policy statement concerning coatings intended to come into contact with foodstuffs – Version 3 (2009)

Compliance is granted by cross reference with Commission Regulation EC n°10/2011 food contact compliance statement.

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Germany Food Contact Regulation DigiPrime® 4453

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BfR XIV. Plastic dispersions.

Compliance is granted by cross reference with Commission Regulation EC n°10/2011 food contact compliance statement.

All clearances are subject to the end-use and extractive limitations cited in the specific regulations.

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