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Food Contact Statement

Product: **Epotal® CF 430**

Product ID: 30676121

Revision date: 43622

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Version: 2.0

® = Registered trademark of BASF in many countries

TM = Trademark of BASF

Dispersions and Resins

Prepared by:

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US FDA

USA: Title 21 Code of Federal Regulations (21 C.F.R.):

175.105 – Adhesives

This product is cleared for use in accordance with 21 C.F.R. §175.105 "Adhesives", provided that the person who introduces the finished article into circulation has to ensure that the article meets the requirements of FDA 21 C.F.R. §175.105, such as a functional barrier to protect the food against migration from the adhesive.

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

This product is cleared for use in accordance with FDA Regulation 21 C.F.R. §176.170 "Components of paper and paperboard in contact with aqueous and fatty foods", provided that the food contact surface complies with the extractive limitations prescribed in paragraph (c) of §176.170.

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

This product is cleared for use in accordance with FDA Regulation 21 C.F.R. §176.180 "Components of paper and paperboard with dry food" provided the limitations given are met.



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NOTE:

Food Contact Notification (FCN) 815:

The product is subject of Food-Contact Notification (FCN) 815, which has become effective August, 14th 2008 following review by the United States Food and Drug Administration (FDA).

The product may be used as an adhesive applied on plastics, films, paper and paperboard, and metal or coated metal used for packaging and holding all food types intended for single- and repeated-use articles.

The product will be used in single- and repeated-use articles in contact with all Food Types (I-IX) under Conditions C through G as described in Table 1 and 2 in FDA website: (<http://www.cfsan.fda.gov/~rdb/opa-fcn3.html>).

The application rate of the product will be no greater than 0.039 g/in².

Therefore the product may be used for applications according to 21 FDA C.F.R. §175.105, 175.125, 175.300, 175.320, 176.170 and 176.180.

The product can NOT be used for applications according to 21 C.F.R. §177.1390 and 177.1395.

Note to Regulation 21 C.F.R. §176.170:

5-Chloro-2-methyl-4-isothiazolin-3-one (CAS-No. 26172-55-4) and 2-methyl-4-isothiazolin-3-one (CAS-No. 2682-20-4) mixture at a ratio of 3 to 1:For use only:

1. As an antimicrobial agent for polymer latex emulsions in paper coatings at a level not to exceed 50 parts per million (based on isothiazolone active ingredients) in the coating formulation.
2. As an antimicrobial agent for finished coating formulations and for additives used in the manufacture of paper and paperboard including fillers, binders, pigment slurries, and sizing solutions at a level not to exceed 25 parts per million (based on isothiazolone active ingredients) in the coating formulations and additives.

Note to Regulation 21 C.F.R. §176.180:

1,2-Benzisothiazolin-3-one (CAS Registry No. 2634-33-5): for use only as a preservative in paper coating compositions and limited to use at a level not to exceed 0.02 mg/in² (0.0031 mg/cm²) of finished paper and paperboard.

For notice :

Appropriate conditions have to be applied when processing the product. The suitability of the articles for the application concerned, including their effect on smell and taste of the food, and observance of any given limitations (for example overall migration, specific limits and other analytical requirements) must be tested and ensured in each case by the person who places any finished food contact article on the market.

BASF makes no warranties, express or implied, concerning the suitability of above-mentioned product for use in any medical device, pharmaceutical application and/or their packaging. It is the responsibility of BASF's customer to determine whether the above-mentioned product is safe, lawful and technically suitable for use in any medical device, pharmaceutical application and/or their packaging.

This product is produced to comply with pre-established specifications and purity limits.

The production of this product is carried out in production units with the necessary quality control systems, which enable traceability through all stages of production.

DISCLAIMER:



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All information contained in this document is given in good faith and is based on sources believed to be reliable and accurate at the date of publication of this document.

THIS STATEMENT EXPIRES 18 MONTHS AFTER THE DATE OF ISSUE or in case of regulatory changes before such date. Please ask for a new confirmation if needed.

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