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Food Contact Statement

Product: **Acronal® 3727 X**

Product ID: 30747954

Revision date: January 23, 2020

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Version: 1.0

® = Registered trademark of BASF in many countries

TM = Trademark of BASF

Dispersions and Resins

Dispersions and Resins

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European Union:

Presuming appropriate processing the product can be used in the countries of the European Community for the manufacture of coatings and adhesives on food contact materials or articles according to Article 3,1a of Regulation (EC) No 1935/2004 ("Regulation (EC) No 1935/2004 and its amendments of the European Parliament and of the Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC").

Compliance with the provisions of Regulation (EC) No 1935/2004 especially the suitability of the articles for the given application, the effect on smell and taste of the food, and observance of any given limitations, must be ensured by the person who introduces the articles into circulation (see the last paragraph).

Compliance with the specific restrictions mentioned in the below listed Regulations have to be ensured.

Information on specific migration limits or restrictions can be provided on request to a test laboratory directly.

The "Monomers and Other Starting Substances" used in the manufacture of the product are listed in the Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food and its amendments. The 13th amendment is dated August 8, 2019.

However, the polymer itself is not listed in Regulation (EU) No. 10/2011 as a polymeric additive.

The other components used in the manufacture of the product are either listed in the Regulation (EU) No. 10/2011, are exempted from listing or have positively been evaluated by the EFSA.

This product does not contain any dual use additives as listed in the:

- food additives by Regulation (EC) No 1333/2008, as amended (Union list of food additives: Regulation (EU) No 1129/2011 amending Annex II of Regulation (EU) No 1333/2008);

- flavorings by Regulation (EC) No 1334/2008.

Good Manufacturing Practice

The requirements of the Commission regulation (EC) No. 2023/2006 on good manufacturing practice is applicable for materials and articles intended to come into contact with food. In article 2 it is specified that Regulation (EC) No. 2023/2006 shall apply to all sectors and to all stages of manufacture, up to but excluding the production of starting substances. According to our understanding above mentioned products are not food contact materials but only starting substances for food contact materials because they need to undergo chemical or physical changes before they can be used as food contact materials.



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Therefore, we do not formally comply with regulation (EC) No. 2023/2006. However, the quality management system is certified according to the international standard ISO 9001; a certificate issued by DQS is available. This is also valid for the raw materials used for the production of the above-mentioned products. Moreover, most of the requirements (e.g. documentation, traceability, QA lab, system for Non-Conformances; training of people) of Regulation (EC) No. 2023/2006 are fulfilled or partly fulfilled. For further information about the product properties we refer to the current Material Safety Data Sheet (MSDS), Technical Data Sheet (TDS) and the Information Sheet Product Safety (ISP).

Germany:

The composition of the product does comply with the requirements of recommendation XIV. "Polymer-Dispersionen" (Polymer Dispersions), of BfR, dated 01.06.2019 and therefore also can be used according to recommendation XXXVI "Papier, Kartons und Papen für den Lebensmittelkontakt" (Paper and board for food contact) dated 01.06.2019, provided that it is used in a dispersion conforming chapter XIV and the provided specific restrictions are met.

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.

175.125 – Pressure sensitive adhesives

This product is N O T cleared for use in accordance with FDA Regulation 21 C.F.R. §175.125 "Pressure-sensitive adhesives".

175.300 – Resinous and polymeric coatings

This product is N O T cleared for use in accordance with FDA Regulation 21 C.F.R. §175.300 "Resinous and polymeric coatings on metals".

175.320 – Resinous and polymeric coatings for polyolefin films

This product is N O T cleared for use in accordance with FDA Regulation 21 C.F.R. §175.320 "Resinous and polymeric coatings for polyolefin films".



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

This product is N O T 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".

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

This product is N O T cleared for use in accordance with FDA Regulation 21 C.F.R. §176.180 "Components of paper and paperboard with dry food".

177.1390 – Laminate structures for use at temperatures of 250°F and above

As the product is listed in 21 CFR § 175.105 "Adhesives", it can also be used for the preparation of high-temperature laminates complying with regulation 21 C.F.R. §177.1390 "Laminate structures for use at temperatures of 250 °F and above", provided the limitations given in 21 C.F.R. §177.1390, especially the condition that the product is separated from the interior (food contact) layer(s) by a functional barrier (aluminum foil) as discussed under paragraph (a) of 21 C.F.R. §177.1390 are met.

177.1395 – Laminate structure for use at temperatures between 120°F and 250°F

The product is not directly listed in FDA Regulation 21 C.F.R. §177.1395 "Laminate structures for use at temperatures between 120°F and 250 °F". However these laminated structures may be manufactured from polymers and adjuvants complying with FDA regulation 21 C.F.R. §177.1390, provided the limitations given in 21 C.F.R. §177.1390, especially the condition that the product is separated from the interior (food contact) layer(s) by a functional barrier (aluminum foil) as discussed under paragraph (a) of 21 C.F.R. §177.1390 are met.

China.

The components of the product are N O T listed in the National Standard of the People's Republic of China GB9685-2016 (Hygienic Standards for Use of Additives in Food Containers and Packaging Materials), issued Oct. 19 2016, as amended according to Chinese Ministry of Health (MOH) and National Health and Family Planning Commission (NHFPC).

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.



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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:

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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