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Food Contact Certificate

Product: ULTRAMID® A3K FC AQUA UNCOLORED

Revision: 01.07.2018 Version: 9.0

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European Union
Presuming appropriate processing the product can be used in the countries of the European Community for food contact materials or articles according to article 3 of Regulation (EC) No 1935/2004 (Regulation (EC) No 1935/2004 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).

The specific restrictions mentioned in Commission Regulation (EU) No 10/2011 most recently amended by Commission Regulation (EU) 2018/213 of 12 February 2018 and Commission Regulation (EU) 2018/831 of 5 June 2018 have to be ensured.

The composition of the product complies with the requirements of the Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food most recently amended by Commission Regulation (EU) 2018/213 of 12 February 2018 and Commission Regulation (EU) 2018/831 of 5 June 2018.

The following restrictions have to be ensured:

- Hexamethylenediamine (FCM-No 305): SML = 2,4 mg/kg

- 1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionamide) (FCM-No 631) : SML = 45 mg/kg

Additional information and/or restrictions are mentioned in Commission Regulation (EU) No 10/2011 as amended for the substances under the respective FCM-No.
(http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF).

The meaning of the abbreviations is:
SML = specific migration limit expressed in mg per kg food
FCM-No = unique identification number of the substance

NIAS (Non Intentionally Added Substances)
Depending on the polymerization and processing conditions the cyclic dimer 1,8-Diazacyclotetradecane-2,7-dione (CAS 4266-66-4) of adipic acid and hexamethylenediamine is formed and might be detected as migrant from final PA-6,6 polymer applications. Based on our toxicological studies and risk assessment a migration restriction of 5 mg /kg food for the dimer is

established. The migration restriction limit must be ensured by the person who places the finished food contact article on the market.

We confirm, that the product is manufactured according to the requirements of Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. BASF meets the demands for risk minimization in the value chain which are required.

Dual Use Additives
No additives are used in the manufacture of the product which are listed in Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food most recently amended by Commission Regulation (EU) 2018/213 of 12 February 2018 and Commission Regulation (EU) 2018/831 of 5 June 2018 and which are at the same time direct additives or flavors for food, as listed in DIRECTIVE 95/31/EC of 5 July 1995 laying down specific criteria of purity concerning sweeteners for use in foodstuffs, DIRECTIVE 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs, and DIRECTIVE 96/77/EC of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners.

USA
The composition of the product complies with the requirements of FDA Regulation 21 CFR 177.1500 "Nylon resins".

The finished article may not be used in contact with alcohol.

Heavy metals
The sum of lead, cadmium, chromium-VI and mercury does not exceed the maximum value of 100 ppm (i.e. 0.01%) as required by the CONEG (Coalition of North Eastern Governors) for the January 1, 1994. Thus, also the maximum value for these elements laid down in Directive 94/62/EEC is met.

F o r n o t i c e : 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. The product must not be used in any medical device and/or pharmaceutical applications.

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.

It is the responsibility of those to whom we supply our products to ensure that any proprietary rights and existing laws and legislation are observed.
The certificate is exclusively for our customers and respective competent authorities. It is not intended

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