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PSS/Weisseneder

REGULATORY INFORMATION

We hereby confirm that our products

MAXITHEN® HP13301 White

comply with the following statements, requirements and legal provisions:

FOOD CONTACT STATUS

According to our suppliers information and when used under the conditions defined in our technical documentation the components we use for manufacturing our preparations (polymers, colourants and additives) are in accordance to Article 3, Par. 1 (a) of Regulation (EC) No 1935/2004 “On materials and articles intended to come into contact with food”.

Furthermore they are in accordance with the conditions laid down for the respective raw material categories in the following provisions:

COLOURANTS:

EU	Purity requirements of the resolution AP (89) 1 „On the use of colourants in plastic materials coming into contact with food“
Germany	Purity requirements of the recommendation IX issued by BfR (German Federal Risk Assessment Institute) in its current version (date of document issue) „Farbmittel zum Einfärben von Kunststoffen und anderen Polymeren für Bedarfsgegenstände“
USA	Code of Federal Regulations (CFR), Title 21 §178.3297 - "Colourants for Polymers" or Food Contact Notification (FCN) or with CFR21, Parts 73, 74, 81 and 82, or with equivalent criteria. Our product may be safely used as colorant within good manufacturing practice according to the provisions and definitions of the Code of Federal Regulations as described in CFR21 §178.3297.

POLYMERS AND ADDITIVES:

EU	Regulation (EU) No 10/2011 „On plastic materials and articles intended to come into contact with food“ in the version valid on the date of issue of this document.
Germany	Bedarfsgegenständeverordnung based upon issue 24th February 2016.
USA	Depending on the use of the relevant polymer carrier system applied in our products - following conformity to the Code of Federal Regulations (CFR), Title 21 apply:

§177.1520 “Olefin-Polymers”, §177.1640 “Polystyrene and rubber-modified polystyrene”, § 177.1630 for Polyethylene phthalate polymers, § 178.2010, Antioxidants and/or stabilizers for polymers, § 184.1 “Substances added directly to human food affirmed as generally recognized as safe (GRAS)”.

RESTRICTIONS, SPECIFICATIONS, SPECIFIC MIGRATION LIMITS AND MAXIMUM DOSAGES

According to Annex I of Regulation (EU) No 10/2011 and CFR, Title 21 the use of our product and the incorporated colorants, additives or adjuvants for plastics in contact with food is restricted in the following cases:

PRODUCT	REGULATED POLYMER	LEGISLATION	RESTRICTION	LIMIT	CONDITION / REFERENCE
HP13301 White	--	Regulation 10/2011	SML	6 MG/KG LM	FCM 433
HP13301 White	--	Regulation 10/2011	SML	6 MG/KG LM	FCM 141
HP13301 White	--	Regulation 10/2011	SML	0,05 MG/KG LM	FCM 483
HP13301 White	--	CFR, Title 21 §178.3297	Usage restriction		Usage conditions A through H as described in CFR, Title 21, §176.170 (c), table 2.

We herewith take reference to Annex II of Regulation (EU) No 10/2011. For certain elements specific migrations limits are to be considered. Since the manufacturer of this product has no influence on subsequent processing, the processor himself of plastic materials and articles is requested to carry out the corresponding tests in line with standard usage of the final article.

The following elements, in form of a chemical compound, are included in above mentioned product:

- Al, SML = 1 mg/kg LM
- Zn, SML = 5 mg/kg LM

The elements Ca, Mg, K and Na as well as ammonium are only added as part of additives permitted by the regulation. There is no specific migration limit (SML) for these elements and ammonium but substance-specific limits as well as limits for food additives may apply, see section “dual use additives”.

EXPLANATIONS:

SML: Specific migration limit of a substance in a plastic article into food or in food simulant, according to Regulation (EC) No 10/2011

SML(T): Sum of specific migration limits of a group of substances in a plastic article into food or in food simulant, according to Regulation (EC) No 10/2011

LM: Food or food simulant

%: Dosage of our product in percent by weight

max.: Maximum dosage of our product indicated as percentage by weight. Condition of a maximum dosage is that the used polymer is containing no further similar substances. Otherwise this has to be taken into consideration.

ND: Not Detectable; detection limit assigned in accordance with second subparagraph of Article 11(4) of the Regulation

LOD: Limit of detection

The fact if a migration limit value is maintained or not, can only be determined at the final article, because this is a result of the packaging system that consists of used colourant, polymer and additives together with the foodstuff itself.

NON INTENTIONALLY ADDED SUBSTANCES (NIAS)

Regulation (EU) No 10/2011 obliges manufacturers of food contact articles to assess the formation and migration of non-intentionally added substances (NIAS) in their products as well as it obliges the producers of materials of intermediate stage to transfer all data necessary to perform this assessment to their customers. In order to fulfil this obligation we want to give you the following information:

Due to the ubiquitous antioxidative stabilisation of plastics the following NIAS may be theoretically present in our masterbatches and in final articles:

2,6-di-tert-butyl-p-benzoquinone (CAS 719-22-2, Cramer Class II)
2,6-di-tert-butyl-4-ethylphenol (CAS 4130-42-1, Cramer Class II)
3,5-di-tert-butyl-4-hydroxybenzaldehyde (CAS 1620-98-0, Cramer Class II)
3,5-di-tert-butyl-4-hydroxy acetophenone (CAS 14035-33-7, Cramer Class II)
7,9-di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione (CAS 82304-66-3, Cramer Class III)
3-(3,5-di-tert-butyl-4-hydroxyphenyl) methylpropanoate (CAS 6386-38-5, Cramer Class II)
3-(3,5-di-tert-butyl-4-hydroxyphenyl) propanoic acid (CAS 20170-32-5, Cramer Class II)
2,4-di-tert-Butylphenol (CAS-No.: 96-76-4, Cramer class II)
Tris-(2,4-di-tert-butylphenyl)phosphate (CAS 95906-11-9, Cramer Class III)
Short-chained (up to C12) alkanes

We are in constant communication with our suppliers about the topic of NIAS. Up to the date of issue of the present declaration we were not informed about further potential NIAS in their products that are subject to any restrictions or thresholds in foodstuff. We will inform you immediately if this should change.

As an ISO certified company we have a quality control system in place, which ensures the usage of raw materials according to their specifications, especially concerning thermal stability, time/temperature profiles and other parameters. In this context we take care to stick to the processing conditions that were set by our suppliers. Also considering this kind of NIAS we constantly gather information from literature and inter-trade organisations about known issues with certain raw materials and processing steps to be ready to modify our processing conditions if the need should arise.

To be on the safest side possible we would like to refer to the processing conditions that we describe in our technical data sheets. The processing temperatures mentioned in these information materials are derived from our suppliers' information. Up to a holding time of at maximum 5 minutes the probability of NIAS formation is negligibly small at this temperature in clean processing equipment.

DUAL USE ADDITIVES

Our product contains a functional additive with a chemical identity that is listed as food additive in Regulation (EC) No 1333/2008 or (EC) No 1334/2008, whereupon the products used by us do not have a regulative status as direct food additives:

- E470a

GOOD MANUFACTURING PRAXIS (GMP) ACCORDING TO REGULATION (EC) NO 2023/2006

Our company fulfils the demands of regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food so far as our products are within the scope of this regulation. Particularly the traceability demand is fulfilled for our raw materials and products.

DISCLAIMER:

Concerning the conformity to the laws and regulations mentioned in this document we refer to the information received from our suppliers and want to inform you that the analytical control of limits and possible trace contaminations of the substances mentioned above in our products is not designated.
The persons and entities placing food contact article or a material on the market must ensure through appropriate measurements that these materials and articles comply with the appropriate rules and standards as well as the legally prescribed restrictions and limits (as OML, SML values) and that they do not bring about an unacceptable change in the composition and/or a deterioration in the organoleptic characteristics of food.

We hope this information is of service to you.

Best regards
i.A. Dr. Christian Martschitsch
Team Leader Product Stewardship

++This document is generated electronically and is valid without signature++