

CONFORMITY REQUIREMENTS FOR COLORANTS

Version 2018-12-03

Remarks: Condition of any delivering is a location of our contract partner in the EU territory. The required actuality of the following regulations is given by our inquiry date. Some of these requirements are:

SAFETY DATA SHEET EU - MANDATORY

Only acceptable according to REACH regulation (EC) No 1907/2006 and CLP regulation (EC) No 1272/2008 and issued no longer than 18 months before our request. Languages necessary: DE, EN in any case, CZ, ES, HU, IT, PL and RUS upon request.

All components must be either registered under REACH or exempt from registration.

FOOD CONTACT STATUS EU - MANDATORY IF ADVERTISED FOR FOOD CONTACT

- Framework Regulation (EC) No 1935/2004 “Materials and articles intended to come into contact with food”

The colorants delivered to us must be in compliance with this regulation, especially with Article 3 and must not change the conformity of a final article by adding them.

- Plastic regulation (EU) No 10/2011 “Plastic materials and articles intended to come into contact with food”

Colorants are exempted from the obligation to be listed in Annex I of that regulation, but not from the regulation as such. Many pigments and dyes contain additives. So for raw materials used by us we need an information, if there are any additives included or not.

- If yes, are the additives in your product allowed by regulation (EU) No 10/2011, either by article 6 or Annex I (the “Union list”)?
 - Please list and specify a maximum concentration for all additives on the Union list with specific migration limits.
 - Are further additives included?
 - Are any metals from Annex II included? If yes please list them and specify a maximum concentration.
 - Are there any restrictions on the product, considering use, type of food (Annex III), use conditions (Annex V), migration limits?
 - Do your products contain any dual-use additives (food additives allowed in food contact materials as well)?
- GMP Regulation (EC) 2023/2006 “Good manufacturing practice for materials and articles”
Can our products be produced according to this regulation by using your products?
 - Resolution AP (89) 1 “On The Use Of Colourants In Plastic Materials Coming Into Contact With Food”
 - BfR Recommendation IX “Colorants for Plastics and other Polymers Used in Commodities” from 2015

NIAS (NON-INTENTIONALLY ADDED SUBSTANCES) - MANDATORY IF ADVERTISED FOR FOOD CONTACT - MANDATORY IF ADVERTISED FOR FOOD CONTACT

Article 19 of Regulation (EU) No 10/2011 obliges all producers of food contact materials –our customers- to perform a risk assessment for substances that do not need to be included in the Union List. Apart from colorants this also applies to NIAS, no matter if they are impurities, residues from production or side-products. To help our customers with this assessment we need to know the following from our suppliers:

- Do you have a program in place to monitor the presence of NIAS in your products?
- Have you already encountered NIAS in your products?
- Do you perform regular tests about the presence of impurities in your products?
- Do you assess the purity of the raw materials you use on a regular base?
- Do you perform organoleptic assessments of your products?
- Are you aware of typical NIAS formation routes from your chemical synthesis pathways?
- Please specify how you inform your downstream users about any new analytical results or theoretical considerations that may suggest the presence of NIAS in your products.

FOOD CONTACT STATUS USA – HIGHLY APPRECIATED

Specify the relevant FDA paragraphs, allowed polymers and the conditions of use either according to Ch. 21 CFR, the relevant FCN number or the List of Threshold of Regulation Exemption.

FOOD CONTACT STATUS CHINA – HIGHLY APPRECIATED

- Chinese Framework Norm GB 4806.1-2016: The colorants delivered to us must be in compliance with this regulation, especially with Point 3 and must not change the conformity of a final article by adding them.
- Chinese Norm GB 9865-2016, Appendix A, Table A1: All components must be listed in that Annex. Please communicate any appropriate restrictions.
- Chinese Norm GB 9865-2016, Appendix C: Are any metals from that list included? If yes please list them and specify a maximum concentration.

MERCOSUR – HIGHLY APPRECIATED

Are your products in accordance with MERCOSUR/GMC/RES N° 03/92 as well as with Resolutions MERCOSUR/GMC/RES. N° 02/12 and MERCOSUR/GMC/RES. N° 32/07 as well as with Resolutions MERCOSUR/GMC/RES. N° 56/92 and 15/10 for colorants?

USE IN TOYS (EUROPE)

Do your products comply with EN 71-3:2013, EN 71-9:2007 and EN 71-12:2013 as well as with the requirements of directive 2009/48/EC?

USE IN TOYS (USA)

Do your products comply with ASTM F963–11?

TOXIC HEAVY METALS

Please confirm that your product does not intentionally contain the toxic heavy metals lead (Pb), cadmium (Cd), mercury (Hg) or hexavalent chromium (Cr VI) and that the sum of their trace concentration levels does not exceed 100 ppm.

HALOGEN CONTENT

If halogens are part of your product recipe, please indicate the type of halogen (chlorine, fluorine, bromine).

In case of questions to our confirmation demands you are invited to contact:

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