# CONFORMITY REQUIREMENTS FOR COLORANTS

Version 2026-11-26

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 after January 1st 2026 and no longer than 18 months before our request. Versions necessary: DE, UK in any case, CZ, ES, HU, IT, PL and RUS upon request.

All components must be either registered under REACH or exempt from registration. UK-REACH registration is highly appreciated.

## 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)?
  - Does your product contain or possibly yield primary aromatic amines that are not covered by Annex I?
  - Do the raw materials fulfil the conditions regarding high degree of purity from amendment (EU) 2025/351?

- 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” in its current version (see https://bfr.ble.de/kse/faces/DBEmpfehlung.jsp).

## 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.

## STATEMENT ABOUT CONFLICT MINERALS AND CHILD LABOUR IN THE SUPPLY CHAIN – MANDATORY

Specify if there are measures in place to ensure that your supply chain is free of materials produced by child labour as well as from cobalt, gold, tantalum, tin and tungsten from conflict areas (so-called conflict minerals). Any standardized document (e.g. the conflict mineral and cobalt reporting templates from https://www.conflict-minerals.com/ would be highly appreciated) or certificate of membership in associations occupied with these topics (e.g. the Responsible Mica Initiative, https://responsible-mica-initiative.com/) would be highly appreciated.

## PACKAGING AND PACKAGING WASTE REGULATION (PPWR) (EU) 2025/40 - MANDATORY

Please confirm that your product contains no heavy metals (chrome VI, cadmium, lead, mercury) above 100ppm or PFAS (per- and polyfluoroalkyl substances) above 50ppm.

## FURTHERMORE WE HIGHLY APPRECIATE INFORMATION ABOUT THE FOLLOWING TOPICS:

## FOOD CONTACT STATUS USA

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

- 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.

## FOOD CONTACT MERCOSUR

Are your products in accordance with MERCOSUR/GMC/RES Nº 03/92 as well as with Resolutions MERCOSUR/GMC/RES. Nº 02/12 and MERCOSUR/GMC/RES. Nº 39/19 as well as with Resolutions MERCOSUR/GMC/RES. Nº 56/92 and 15/10 for colorants?

## FOOD CONTACT JAPAN

Are any non-colorant components of your product listed in the positive lists that can be found at the Japanese Ministry of Health's webpage https://www.mhlw.go.jp/stf/newpage_05148.html?

Do any restrictions (polymer type, temperature, dosage, etc.) apply to the use of your product?

## FRENCH POSITIVE LIST

Although conformity to Regulation (EU) No 10/2011 is sufficient for lawfully placing food contact materials on the market in France many customers demand conformity to different French regulations that are mostly summarized under the not legally defined term "French Positive List". Do your products fulfil the requirements of any such regulation?

## ITALIAN PRURITY CRITERIA

The Italian "Decreto ministeriale 21 marzo 1973" defines a lower tolerable limit of arsenic than most other EU member state regulations. Although not compulsory when referring to mutual recognition this criteria is sometimes asked for by our customers.

## GLOBAL FOOD CONTACT

Please state any further available information regarding food contact in other countries like India or African countries.

## 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?

## HALOGEN CONTENT

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

## MEDICAL APPLICATIONS

Are your raw materials approved by any standards regulating use in medical or pharmaceutical applications (e.g. Pharmacopoeia, ISO 10993, etc.)?

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

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