

This is an unofficial translation. Only the German version is binding.

IX. Colorants for Plastics and other Polymers Used in Commodities

As of 01.02.2015

Colorants¹, as referred to in this recommendation, are all substances which give color, including those possibly used as vehicles or production and processing aids, as well as any technically unavoidable contaminants.

There are no objections to the use of colorants for coloring plastics and other polymers² in the manufacture of commodities in the sense of § 2, Para. 6, No 1 of the Food and Feed Code (Lebensmittel- und Futtermittelgesetzbuch), provided that they are suitable for this purpose including the requirement of no visible migration to foodstuffs during proper use of the commodity³. Moreover, the following requirements have to be fulfilled:

If for plastics within the meaning of Commission Regulation (EU) No 10/2011 colorants are used in form of preparations⁴, the binders they contain are subject to this Regulation. This recommendation applies without qualification to all materials not included under the term "plastic" in the Commission Regulation (EU) No 10/2011, used in the manufacture of food-contact commodities.

If preparations of colorant used for materials other than plastics that are produced by using other binders, pasting agents, or necessary production aids, the substances listed in the Commission Regulation (EU) No 10/2011 and the substances listed in the table below may be used, either alone or in combination with one another.

Table: Substances for preparations of colorant for materials other than plastics

Substance	Maximum amount of use ^a
Oleoyl-N-methyl glycine	0.3 %
Tri-2-ethylhexyl phosphate	in total 0.2 %
Polyester of adipic acid with 1,3-butanediol and 1,6-hexanediol	
Oleic acid, monoethanolamide	
Condensation products of aromatic sulfonic acids with formaldehyde	0.1 %
Condensation product of toluenesulfonamide and formaldehyde	0.1 %

^abased on the colored component of the finished product

¹ According to DIN 55943, "colorant" is a generic term for all color giving substances.

² In this Recommendation the term "other polymers" refers to elastomers, as well as high-polymer substances used as coatings and binders in the paint and varnish industry.

³ see 24th Communication on the testing of plastics, Bundesgesundheitsblatt 15 (1972) 285

⁴ As a rule, preparations of organic pigments are added in quantities amounting to less than 1.0 %, and preparations of inorganic pigments in quantities amounting to no more than 5.0 %.

The substances listed in the table may be used for a transitional period until 1 January 2018. It is intended to transfer the existing limits for formulating agents for colorants that are used for materials other than plastics to guidance values for migration into food. For substances that will be needed even after the transitional period an application on the basis of the "Note for Guidance" of the European Food Safety Authority is needed (see: http://www.bfr.bund.de/en/database_bfr_recommendations_on_food_contact_materials_formerly_plastics_recommendations__-1711.html).

Purity requirements for colorants

Carbon black used as black pigment has to comply with the purity requirements of Commission Regulation (EU) No 10/2011⁵.

Moreover, colorants must also comply with the following purity requirements:

1. Concentrations of the following substances soluble in 0.07 N hydrochloric acid, determined according to DIN 53770⁶, must not exceed the given amounts (based on the colorant):

Lead	0.01 %
Arsenic	0.01 %
Mercury	0.005 %
Selenium	0.01 %
Barium	0.01 %
Chromium	0.1 %
Cadmium	0.01 %
Antimony	0.05 %.
2. When applied as specified primary aromatic amines may not be released from the finished food contact material in a detectable amount. The detection limit is 0.01 mg/kg and applies to the sum of the released primary aromatic amines. Additionally, primary aromatic amines classified as carcinogens in classes 1A and 1B of the CLP Regulation (EC) 1272/2008 may not be released referred to the single substance with a detection limit of 0.002 mg/kg food or food simulant. Azodyes, that can break down into primary aromatic amines classified as carcinogens in classes 1A and 1B of the CLP Regulation (EC) No 1272/2008 must not be used.

Remark: Colorants used to color foodstuffs are technically unsuitable for coloring plastics. Colorants used to color plastics, depending on the particular plastic, are required to withstand temperatures ranging from approximately 150° to 300 °C while the plastic is being processed. Experience shows that suitable colorants for plastics are insoluble pigments which become so firmly imbedded in the plastic material that they do not migrate when coming into contact with foodstuffs. In contrast, there is a danger that improper use of commodities containing soluble colorants may result in their migration into the food.

⁵ Measurement of the extinction of the cyclohexane extract according to the 23rd Communication on the testing of plastics, Bundesgesundheitsblatt 15 (1972) 268

⁶ See DIN 53770: "Testing of pigments; determination of matter soluble in hydrochloric acid", Parts 1 - 7, 13 and 14.