

Relevant Regulations for Colorants in BfR Recommendations

The German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung, BfR), established in accordance with public legislation, is affiliated with the German Federal Ministry of Food and Agriculture. BfR not only conducts independent risk assessment and research, but also provides scientific advice on food safety, product safety, chemical safety, the food chain, animal protection, etc. to the German Federal Government. Since 1958, BfR and its predecessors have issued recommendations on the health assessment of food contact materials. This guidance on food contact materials is not a legal requirement though products will be more widely accepted and recognized if they meet the relevant conditions.

German BfR Recommendation Chapter 9 (BfR IX 2019) addresses the Colorants for Plastics and other Polymers Used in Commodities. The document specifies the following purity levels for colorant substances used in food contact materials:

1. Carbon black used as black pigment has to comply with the purity requirements of Commission Regulation (EU) No 10/2011;
2. 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 (Pb): 100 ppm	Mercury (Hg): 50 ppm	Barium (Ba): 100ppm	Cadmium (Cd): 100 ppm
Arsenic (As): 100 ppm	Selenium (Se): 100 ppm	Chromium (Cr): 1000 ppm	Antimony (Sb): 500 ppm

3. When applied as specified primary aromatic amines (PAA), the PAA 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.

Trust Chem is committed to providing customers with colorant products that meet these requirements and has been following relevant laws and regulations to ensure continuous regulations compliance.