



Regulatory Information

All color masterbatches

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Product identifier, manufacturer, and contents

Color Service GmbH & Co. KG manufactures color masterbatches intended for the coloration of plastic articles made of different polymer types. Apart from color pigments, products may contain additives such as antistatics, processing aids, or UV-stabilizers. Suitability for a specific polymer depends on the carrier material of the masterbatch.

This document is a generic statement on Regulatory properties of our color masterbatches. It includes statements on legislations or substances that in our experience are most often requested by our customers, and that -based on the properties of our raw materials- can be given independent of the exact formulation of the masterbatch.

The food contact status of a color masterbatch (SML-substances, restrictions on use or legislative region, and so on) is determined by its exact chemical formulation, which is unique to each masterbatch. It is therefore not possible to include food contact statements in this generic document; for this please refer to an individual product's Declaration of Compliance or Food Contact Status documentation.

This document contains statements on:

REACH (EC 1907/2006)	ELV (2000/53/EC)
RoHS (2011/65/EU)	Conflict Minerals
BSE/TSE	Hazard classification of TiO ₂
WEEE (2002/19/EU)	PBT – TSCA 6(h)
Packaging and packaging waste (94/62/EC; CONEG)	Per- and Polyfluoroalkyl substances (PFAS)
Nanomaterials (2011/696/EU)	Chemical substances not used

Regulatory information

REACH/SVHC; EC 1907/2006 (as amended)

All components/monomers in our products are substances registered under REACH-legislation, or substances exempt from registration. Our products do not contain any substances listed on the SVHC-list (latest update: January 23rd 2024) in quantities over the threshold value of 0.1% (w/w), nor do they contain substances listed in Annex XIV of the REACH-legislation.

In the unlikely situation that a future update adds substances to the SVHC-list that are currently present in one or more of our masterbatches, we will promptly inform you about this. Furthermore, production of such masterbatches and use of raw material(s) containing the offending substance(s) will be discontinued immediately. We will offer you an alternatively formulated product not containing the SVHC-substance(s).

EU Regulation 1272/2013 amends Entry 50 in Annex XVII of REACH (polycyclic aromatic hydrocarbons, PAH's), defining restrictions on articles with rubber or plastic components that come in direct contact with the human skin or oral cavity. The content of each of the 8 defined PAH's in rubber or plastic components is limited to 1 ppm, or further restricted to 0.5 ppm in case the article is classified as a toy or childcare article.

The typical source for PAH's in color masterbatches is Pigment Black 7 (carbon black; CAS 1333-86-4), if present. According to supplier information, typical cumulative content of Entry 50 PAH's in carbon black pigment is in the order of magnitude of 10 - 20 ppm. Carbon black is diluted in a color masterbatch, which then is further diluted in the finished article. This way the contribution of the masterbatch to the PAH content of the finished article at a typical masterbatch dosage is at least a factor 250 smaller than the PAH content of the pigment itself and well within the limit set by EU 1272/2013. If the color masterbatch does

not contain carbon black pigment, EU 1272/2013 is of no concern regarding the contribution of the color masterbatch to the PAH content in the finished article.

RoHS; Directive 2011/65/EU (as amended)

Annex II of Directive 2011/65/EU (Restriction of Hazardous Substances) defines limitations for the content of certain heavy metals and chemical substances in electrical and electronic equipment: cadmium (0.01%), lead (0.1%), mercury (0.1%), hexavalent chromium (0.1%), PBB (0.1%), and PBDE (0.1%).

Amendment EU 2015/863 defines limitations for 4 additional substances: the phthalates DEHP, BBP, DBP, and DIBP; each with a concentration limit of 0.1% (these are the same phthalates as Entry 51 in Annex XVII of the REACH legislation).

Our color masterbatches comply with requirements of Directive 2011/65/EU (as amended).

BSE/TSE

Our products do not contain intentionally added substances from animal origin, though traces of such substances cannot be excluded. The process conditions during the manufacture of our products meet the criteria for "rigorous process", according to EMEA 410 01, Rev. 3, Section 6.4 or Regulation 1774/2002/EC, Annex VI, Chapter III. Under these processing conditions TSE risks are eliminated.

WEEE; Directive 2012/19/EU

Directive 2012/19/EU is the legislation on proper treatment and management of Waste Electrical and Electronic Equipment. Article 8 requires selective treatment for specific materials and components (containing certain substances) defined in Annex VII. The substances listed in Annex VII are:

Asbestos	Brominated flame retardants	CFC's, HCFC's, HFC's
Mercury	Polychlorinated biphenyls	Radioactive substances
Refractory ceramic fibers		

In the formulation and manufacture of our color masterbatches, these substances are not used.

Packaging and packaging waste; Directive 94/62/EC (as amended) and CONEG

Directive 94/62/EC imposes a restriction on the cumulative concentration of the four heavy metals cadmium, lead, mercury, and hexavalent chromium in packaging. The allowable level is set at a maximum of 100 ppm.

In the USA, a similar legislation exists: Model Toxics in Packaging Legislation (formerly referred to as CONEG) where an equal maximum for the same heavy metals is set. The difference between EU and USA legislation is that USA legislation explicitly states that presence of the four heavy metals (within the limit) has to be incidental and not intentional (as opposed to EU legislation where this is not addressed).

Our color masterbatches comply with the maximum content of 100 ppm, while the 4 heavy metals are not intentionally used in the formulation and manufacture.

Nanomaterials; Commission Recommendation 2011/696/EU

Recommendation 2011/696/EU proposes a standard definition of the term 'nanomaterial'. The colorants and additives used in our color masterbatches are fixed in the polymer matrix as fine particles or dispersed pigments and are not in agglomerated or aggregated form. A release of nanomaterials during production in your company and exposure of the end user or consumer is therefore excluded.

ELV; Directive 2000/53/EC

Article 4.2(a) of Directive 2000/53/EC prohibits the use of cadmium, lead, mercury and hexavalent chromium in materials and components of vehicles (besides Annex II exemptions). Per homogenous material a maximum concentration of these four heavy metals is tolerated: 0.1% by weight for lead, mercury, and hexavalent chromium; 0.01% for cadmium.

Our color masterbatches comply with these maximum concentrations.

Conflict Minerals; Regulation EU 2017/821 and Dodd-Frank Act (USA)

Title XV of the Dodd–Frank Wall Street Reform and Consumer Protection Act (USA, 2010) provides legislation concerning so-called conflict minerals (cassiterite, columbite-tantalite, gold, wolframite and their derivatives to obtain tin, tantalum, gold and tungsten) being sourced in and around the Democratic Republic of the Congo.

Similar legislation exists in the EU: Regulation 2017/821 governs the same materials through due diligence obligations for EU importers.

In the formulation or manufacture of this masterbatch these conflict minerals are not used. To the best of our knowledge, we are not aware of conflict minerals being used in our raw materials.

Hazard classification of titanium dioxide (EU 2020/2017)

Amendment EU 2020/217 to the CLP Regulation (EC 1272/2008) has classified titanium dioxide (TiO₂; Pigment White 6) as a hazardous substance: Carcinogenic Category 2; suspected of causing cancer through inhalation. The classification is valid for TiO₂ in a specific form as worded in EU 2020/2017: *“the classification as a carcinogen by inhalation applies only to mixtures in powder form containing 1% or more of titanium dioxide which is in the form of or incorporated in particles with aerodynamic diameter ≤ 10 μm”*.

Popularly worded: the classification only applies to small breathable dust particles of TiO₂ or particles containing TiO₂.

Many of our masterbatches contain TiO₂, and because of the specific definition of what products are affected by the classification (mixtures in powder form with particle size ≤ 10 μm), none of our masterbatches which are products in the form of pellets (not powder) clearly larger than 10 μm, are going to be classified as carcinogenic products as result of the presence of TiO₂. The new classification of TiO₂ does not change the existing hazard classification (if any) of our masterbatches.

The classification of TiO₂ has no consequences for the status of finished plastic articles that our customers manufacture and have been colored with our masterbatches. Finished plastic articles obviously are not products characterized as “mixtures in powder form”.

PBT – TSCA 6(h)

According to their formulation, our products do not contain any substances that are persistent, bioaccumulative and toxic according to the criteria of the REACH Regulation Article 57d. The following substances listed under Section 6(h) of the Toxic Substances Control Act (TSCA) are not part of the formulation.

- 2,4,6-TTBP, CAS No.: 732-26-3
- PIP (3:1), CAS No.: 68937-41-7
- PCTP, CAS No.: 133-49-3
- HCB, CAS No.: 87-68-3
- Deca BDE, CAS 1163-19-5

These substances cannot be formed during the manufacture of our products either, so their presence is not to be expected.

Per- and polyfluoroalkyl substances (PFAS)

The national authorities of Denmark, Germany, the Netherlands, Norway and Sweden have submitted a proposal to ECHA to restrict per- and polyfluoroalkyl substances (PFAS) under REACH. Following consultations, opinion development and the Commission's decision, the restriction could enter into force in 2026 to 2027 at the earliest. Several trade associations, including those representing dyes, intend to use the consultation process to challenge the overly broad definition of PFASs and to highlight the serious implications for the European chemical industry.

The EU's very broad definition proposal means that substances containing a CF₃ group are also subject to the definition as PFASs. Color Service uses colourants with such a CF₃ group in some products, but the products do not show any PFAS common properties like mobility, persistence, water solubility, etc. If you would like a product-specific confirmation, please specify the material concerned.

Chemical substances not used in our color masterbatches

In the formulation and manufacture of our color masterbatches none of the following substances are intentionally used (non exhaustive list); however, we do not analyze or test for these substances.

Aromatic amines
Asbestos
Bisphenol B, F, S
Brominated and chlorinated flame retardants
Diarylide pigments
Dimethyl fumarate
Dioxin
Latex
Drinkable ethanol (Halal)
Epoxy derivatives (BADGE, BFDGE, NOGE; as defined in EC 1895/2005)
Furan
Known allergens (as defined in EC 1169/2011, as amended)
Nonylphenol and nonylphenol ethoxylates
Organotin compounds
Ozone depleting substances (as defined in EC 1005/2009)
Persistent organic pollutants (POP) (as defined in EU 2023/1608)
Phthalates
Polychlorinated biphenyls/terphenyls
Substances from animal origin (eliminating BSE/TSE risks)
Perfluorooctanoic acid (PFOA), its salts and related compounds
Perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride

In addition, for color masterbatches declared as suited for food contact applications and compliant with EU 10/2011 (as amended):

- Such masterbatches do not contain recycled plastics that fall within the scope of Regulation EC 282/2008.
- Such masterbatches do not contain active and intelligent materials that fall within the scope of Regulation EC 450/2009.
- Compliance with EU 10/2011 is an implicit statement (through the Declaration of Compliance) that only chemical substances mentioned in the legislation (Annex I or Article 6) are used in such masterbatches. Other chemical substances, not mentioned in the legislation, are excluded from use in food contact

applications. Therefore, the Declaration of Compliance should be interpreted as an implicit confirmation of absence of non-allowable chemical substances.

Allowable chemical substances from EU 10/2011 that have a restriction (e.g. SML-substances) have to be explicitly listed in the DoC. Absence of such a substance under the Restricted Substances section of the DoC should therefore also be interpreted as an implicit statement that the particular restricted substance is not used in the masterbatch.

Final remarks

This document does not imply that our masterbatches are non-compliant with legislation not mentioned. In cases of other legislation, further queries or unclarities, do not hesitate to contact us.

Ultimately customers must make their own determination that their use of our products is safe, compliant with applicable legislation and technically suitable in their intended applications. Because of possible changes in legislation, we recommend that customers continuing to use our products verify the Regulatory status on a regular basis (for instance every 12 or 18 months, or when a customer is aware of a major change in legislation).

For further questions we are at your disposal at any time and remain

With kind regards

Color - Service GmbH & Co. KG

Karlstein / Bayern

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product safety

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