

Form 2e, Declaration – Colourant formulation

To be used in conjunction with an application for a licence for the Nordic Ecolabelling for hygiene products, generation 7. For requirement O7, O8, O9 and O15.

The manufacturer declares, to the best of their knowledge at the time, based on information from raw material suppliers, the product formulation, and available knowledge of the chemical product. This declaration is made with reservations for new scientific advances and knowledge. If such new information becomes available, the undersigned commits to providing an updated declaration to Nordic Ecolabelling.

Name of the colourant formulation and purpose of use:

Name of the producer of the colourant formulation:

Colourant formulation is chemical mix that includes at least one colourant. Product sold by manufacturer that is used for printing, dyeing, shading or colouring of materials.

O7 Chemical products, classification		
Is the colour formulation classified with any of the hazards listed in the table below?	☐ Yes	☐ No

Table A3. Excluded hazards.

Classification in line with CLP Regulation (EC) No 1272/2008		
Hazard class	Hazard class and category	Hazard code
Hazardous to aquatic environment	Aquatic Acute 1 Aquatic Chronic 1-4	H400 H410, H411, H412 H413
Carcinogenicity	Carc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity	Muta. 1A or 1B Muta. 2	H340 H341
Reproductive toxicity	Repr. 1A or 1B Repr. 2 Lact.	H360 H361 H362
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B Skin Sens. 1, 1A or 1B	H334 H317
Acute toxicity	Acute Tox. (oral) 1, 2 Acute Tox. 3 Acute Tox. 4	H330, H310, H300 H331, H301, H311 H332, H312, H302

Specific target organ toxicity	STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
Aspiration hazard	Asp. Tox 1	H304
Skin corrosion/irritation	Skin Corr 1A/B/C	H314
Endocrine disruption for human health*	ED HH 1 ED HH 2	EUH380 EUH381
Endocrine disruption for the environment*	ED ENV 1 ED ENV 2	EUH430 EUH431
Persistent, Bioaccumulative and Toxic properties* Very Persistent, Very Bioaccumulative properties*	PBT vPvB	EUH440 EUH441
Persistent, Mobile, and Toxic properties Very Persistent, Very Mobile properties	PMT vPvM	EUH450 EUH451

*See also O9 Other excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances.

O8 Chemical substances classification		
Does the colourant formulation contain chemical substances that are or may degrade into substances that are classified with any of the hazards listed in the table below?	☐ Yes	☐ No

The requirements apply to all ingoing substances in the chemical product, but not impurities unless stated otherwise in the requirements. Ingoing substances and impurities are defined below:

Ingoing substances: All substances in the chemical product regardless of amount, including additives (e.g. preservatives and stabilisers) in the raw materials of the chemical product. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine, in situ-generated preservatives) are also regarded as ingoing substances.

N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance are also regarded separately. UVCB stands for unknown or variable composition, complex reaction products or of biological materials.

Impurities: Residuals, pollutants, contaminants etc. from production, incl. production of raw materials that remain in the chemical product in concentrations less than 100 ppm (0,0100 w-%, 100 mg/kg). Examples of impurities are residues of the following: residues or reagents incl. residues of monomers, catalysts, by-products and detergents for production equipment and carry-over from other or previous production lines.

Additional information

Limit values: The limit for excluded ingoing substances is 0 ppm (unless otherwise stated), while there's a specific defined limit for impurities. The impurity limit applies separately to each individual excluded substance, from each individual raw material. Concentrations of different impurities with the same excluded classification or substance group characteristics shall not be summed up to meet the impurity limit in the labelled product. Also, concentrations of an individual impurity, originating from different raw materials, shall not be summed.

UVCB substances: UVCB substances (Unknown or Variable composition, Complex reaction products or of Biological materials) have a composition of constituents that is not completely known or is variable from time to time. For UVCB substances, all constituents that are known must be considered individually and are subject to the chemical requirements, including for instance those on excluded substances and excluded classifications.

Table A4. Excluded hazards.

Classification in line with CLP Regulation (EC) No 1272/2008		
Hazard class	Hazard class and category	Hazard code
Carcinogenicity	Carc. 1A or 1B Carc. 2	H350 H351
Germ cell mutagenicity	Muta. 1A or 1B Muta. 2	H340 H341
Reproductive toxicity	Repr. 1A or 1B Repr. 2 Lact.	H360 H361 H362
Endocrine disruption for human health*	ED HH 1 ED HH 2	EUH380 EUH381
Endocrine disruption for the environment*	ED ENV 1 ED ENV 2	EUH430 EUH431
Persistent, Bioaccumulative and Toxic properties* Very Persistent, Very Bioaccumulative properties*	PBT vPvB	EUH440 EUH441
Persistent, Mobile, and Toxic properties Very Persistent, Very Mobile properties	PMT vPvM	EUH450 EUH451

*See also O9 Other excluded substances for additional requirements for potential or identified endocrine disruptors and PBT/vPvB substances.

O9 Prohibited substances		
Does the colour formulation contain any of the substances from the list below?	☐ Yes	☐ No
Substances on the REACH Candidate list of SVHC* D4, D5 and D6 in silicone polymer have an own requirement, see O10.	☐ Yes ☐ No	
Organotin compounds	☐ Yes ☐ No	
Phthalates	☐ Yes ☐ No	
Alkylphenols, alkylphenol ethoxylates (APEO) and alkylphenol derivatives (APD). Alkylphenol derivatives are defined as substances that release alkylphenols when they break down. An exception is made for: - sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole.	☐ Yes ☐ No	
Halogenated organic compounds. An exception** is made for: - halogenated organic pigments that meet the European Council's "Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food", point 2.5. - CMIT C(M)IT/MIT (3:1), CAS No. 55965-84-9 CAS No. 26172-55-4 in water-based inks where it must not exceed 15 ppm in the ink	☐ Yes ☐ No	
Perfluorinated and polyfluorinated alkylated substances (PFAS)	☐ Yes ☐ No	
Flame retardants	☐ Yes ☐ No	
Volatile aromatic carbons (VAC)	☐ Yes ☐ No	
Ethylenediamine tetraacetate (EDTA, CAS No. 6381-92-6) and its salts and Diethylenetriamine pentaacetate (DTPA, CAS No. 67-43-6) and its salts	☐ Yes ☐ No	
34 bisphenols that have been identified by ECHA for further EU regulatory risk management that are known or potential endocrine disruptors for the environment or for human health, or that can be identified as toxic for reproduction. <i>Assessment of regulatory needs: Bisphenols. ECHA – 16 December 2021: Section 2.1: Bisphenols for which further EU RRM is proposed – restriction</i> https://echa.europa.eu/documents/10162/c2a8b29d-0e2d-7df8-dac1-2433e2477b02	☐ Yes ☐ No	
Nanomaterials*** -An exemption is made for pigments.	☐ Yes ☐ No	

Substances evaluated by the EU to be Persistent, Bioaccumulative, and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB), in accordance with the criteria in Annex XIII of REACH and substances that have not yet been investigated, but which meet these criteria. Endocrine disruptors: Substances on the EU member state initiative "Endocrine Disruptor Lists", List I, II and III, see the following links: - https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu - https://edlists.org/the-ed-lists/list-ii-substances-under-eu-investigation-endocrine-disruption - https://edlists.org/the-ed-lists/list-iii-substances-identified-as-endocrine-disruptors-by-participating-national-authorities A substance which is transferred to one of the corresponding sub lists called "Substances no longer on list", and no longer appears on any of List I-III, is no longer excluded. The exception is those substances on sub list II which were evaluated under a regulation or directive which doesn't have provisions for identifying EDs (e.g., the Cosmetics Regulation, etc.). For those substances, ED properties may still have been confirmed or suspected. Nordic Ecolabelling will evaluate the circumstances case-by-case, based on the background information indicated on sub list II."	☐ Yes ☐ No
Preservatives that are bioaccumulative in accordance with Appendix 2 (BCF >500 / logKow >4).	☐ Yes ☐ No
Antibacterial agents (e.g. nanosilver and triclosan)****	☐ Yes ☐ No

* The Candidate List can be found on the ECHA website: <https://echa.europa.eu/candidate-list-table>

** Perfluorinated and polyfluorinated alkyl substances are covered by their own bulletin and are not included in the exemption.

*** Nanomaterials/-particles are defined according to the EU Commission Recommendation on the Definition of Nanomaterial (2022/C 229/01).2: 'Nanomaterial' means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; (c) the particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.

**** An antibacterial agent is a chemical/product that inhibits or stops growth of microorganisms such as bacteria, fungi or protozoa (single-celled organisms). The requirement does not apply to preservatives used to preserve the chemical product, so-called in-can preservatives.

If Yes to any question O7-O9 above, please state the chemical name/Cas nr., concentration (in ppm, w% or mg/kg) and whether the substance is contained in the form of an impurity or an ingoing substance.

O16 Specific requirements for the colourant formulation		
Is the colourant (pigment/dye) used in the colour formulation based on* the following metals: aluminium, silver, arsenic, barium, cadmium, cobalt, chromium, copper, mercury, manganese, nickel, lead, selenium, antimony, tin or zinc. If yes, please specify the metal(s):	☐ Yes	☐ No
Exemptions: Copper in phthalocyanine pigment/dyes and aluminium in aluminosilicates are allowed. **Based on" refers to cases where the metal is covalently bound to the other constituents/elements of the pigment/dye and is not regarded as an impurity.		
Does the colour formulation contain substances that may release one or more of the aromatic amines listed in Regulation (EC) No 1907/2006 Annex XVII, Appendix 8, (E.g. Azo dyes, which by reductive cleavage of one or more azo groups)	☐ Yes	☐ No

Does the level of ionic impurities in the colour formulation exceed the following limits? Antimony: 50 ppm Arsenic: 50 ppm Barium: 100 ppm Cadmium: 20 ppm Chromium: 100 ppm Cobalt: 500 ppm Copper: 250 ppm Lead: 100 ppm Mercury: 4 ppm Nickel: 200 ppm Selenium: 20 ppm Silver, 100 ppm Tin: 250 ppm Zinc: 1 500 ppm	☐ Yes	☐ No
One of the following must be fulfilled:		
<i>If the colourant (pigment/dye) is used to colour plastic materials:</i> Does the colourant (pigment/dye) comply with the BfR's (Federal Institute for Risk Assessment) recommendations: "IX. Colorants for Plastics and other Polymers Used in Commodities"?	☐ Yes	☐ No
<i>If the colourant (pigment/dye) is used to colour cellulose materials:</i> Does the colourant (pigment/dye) comply with the BfR's recommendation XXXVI. Paper and board for food contact, from February 2023 or later versions?	☐ Yes	☐ No

Please attach safety data sheet for the colour formulation.

If there are changes in product composition, a new declaration of compliance with the requirements must be submitted to Nordic Ecolabelling.

Date and place:	Name of the producer of the printing ink:
Responsible person:	Signature, responsible person: