

Form 2d, Declaration – Colourants (pigment/dye)

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 for colourants (pigment/dyes).

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 (pigment/dye):

Name of the producer of the colourant (pigment/dye):

Colourant is a generic term including pigments, which are insoluble in the medium (the vehicle or the binder), or dyes, which are soluble in the medium.

O7 Colourant, classification		
Is the colourant (pigment/dye) classified with any of the hazards listed in the Table below?	<input type="checkbox"/> Yes	<input type="checkbox"/> 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	H400
	Aquatic Chronic 1-4	H410, H411, H412 H413
Carcinogenicity	Carc. 1A or 1B	H350
	Carc. 2	H351*
Germ cell mutagenicity	Muta. 1A or 1B	H340
	Muta. 2	H341
Reproductive toxicity	Repr. 1A or 1B	H360
	Repr. 2	H361
	Lact.	H362
Respiratory or skin sensitisation	Resp. Sens. 1, 1A or 1B	H334
	Skin Sens. 1, 1A or 1B	H317
Acute toxicity	Acute Tox. (oral) 1, 2	H330, H310, H300
	Acute Tox. 3	H331, H301, H311
	Acute Tox. 4	H332, H312, H302
Specific target organ toxicity	STOT SE 1	H370
	STOT SE 2	H371
	STOT RE 1	H372
	STOT RE 2	H373
Aspiration hazard	Asp. Tox 1	H304
Skin corrosion/irritation	Skin Corr 1A/B/C	H314
Endocrine disruption for human health**	ED HH 1	EUH380
	ED HH 2	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

*Titanium dioxide (CAS 13463-67-7) is exempted from the requirement when used as a pigment. It cannot be used in powder or spray form.

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

<p>If Yes to any question O7 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.</p>

O15 Specific requirements to the colourant (pigment/dye)		
<p>Is the colourant (pigment/dye) based on* the following metals: aluminium, silver, arsenic, barium, cadmium, cobalt, chromium, copper, mercury, manganese, nickel, lead, selenium, antimony, tin or zinc?</p> <p>If yes, please specify the metal(s):</p> <hr/> <p>Exemptions: Copper in phthalocyanine pigment/dyes and aluminium in aluminosilicates are allowed.</p> <p><i>**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.</i></p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the colourant (pigment/dye) contain fluorinated substances?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the colourant (pigment/dye) 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)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
One of the following must be fulfilled:		
<p>If the colourant (pigment/dye) is used to colour plastic materials:</p> <p>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"?</p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>If the colourant (pigment/dye) is used to colour cellulose materials:</p> <p>Does the colourant (pigment/dye) comply with the BfR's recommendation XXXVI. Paper and board for food contact, from February 2023 or later versions?</p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Please attach safety data sheet for the colourant (pigment/dye).

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 colourant (pigment/dye):
Responsible person:	Signature, responsible person: