

Form 2d, Declaration - Colourants for dyeing of incontinence products

For requirement O3, O4, O5, O11

Name of the colourant:

Name of the producer of the colourant:

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, including additives (e.g. preservatives and stabilisers) in the raw materials. Substances known to be released from ingoing substances (e.g. formaldehyde and arylamine) are also regarded as ingoing substances.

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.

O3 Is the colourant classified according to the table below? Yes No

Table A3: Classification of chemical products

Classification under CLP Regulation (EC) No 1272/2008	
Hazard class and category	H phrases (Code)
<u>Toxic to aquatic organisms</u> Aquatic Acute 1 Aquatic chronic 1-4	H400 H410, H411, H412, H413
<u>Acute toxicity</u> Acute Tox 1, 2 Acute Tox 3 Acute Tox 4	H330, H310, H300 H331, H301, H311 H332, H312, H302
<u>Specific target organ toxicity</u> STOT SE 1 STOT SE 2 STOT RE 1 STOT RE 2	H370 H371 H372 H373
<u>Aspiration hazard</u> Asp. Tox 1	H304
<u>Skin corrosion/irritation</u> Skin Corr. 1A/B/C	H314

<u>Allergenic</u> Resp. sens 1 or Skin sens 1	H334 H317
<u>Carcinogenic</u> Carc 1A/1B Carc. 2*	H350 H351
<u>Mutagenic</u> Muta. 1A/B Muta. 2	H340 H341
<u>Toxic for reproduction</u> Repr 1A/1B Repr 2	H360, H361 H362

*An exemption is made for titanium dioxide (CAS no. 13463-67-7).

O4 Chemical substances, CMR

Does the colourant contain substances that are or may degrade into substances that are classified according to the table below?

Yes No

Table F3-2: Classification of CMR substances

Classification in line with CLP Regulation (EC) No 1272/2008	
Hazard class and category	H phrases (Code)
<u>Carcinogenic</u> Carc. 1A/1B Carc. 2*	H350 H351
<u>Mutagenic</u> Muta. 1A/B Muta. 2	H340 H341
<u>Toxic for reproduction</u> Repr. 1A/1B Repr. 2	H360, H361 H362

*An exemption is made for titanium dioxide (CAS no. 13463-67-7).

O5 Other excluded substances

Does the colourant contain any of the substances from the list below?

Substances on the Candidate List*

Yes No

D4, D5 and D6 in silicone polymer have an own requirement, see O6

Organotin compounds

Yes No

Phthalates

Yes No

APEO – alkylphenol ethoxylates and alkylphenol derivatives (substances that release alkylphenols on degradation). An exception is made for:

Yes No

- sterically hindered phenolic antioxidants with molecular weight (MW) >600 g/mole

If yes, is the substance a sterically hindered phenolic antioxidant with a molecular weight >600 g/mole? Yes No

State CAS no. _____

Flame retardants Yes No

Halogenated organic compounds. An exception is made for: Yes No

- 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

- the preservative CMIT (CAS no. 26172-55-4)

Substances that have been judged in the EU to be PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative)** Yes No

Substances considered to be potential endocrine disruptors in category 1 or 2 on the EU's priority list of substances that are to be investigated further for endocrine disruptive effects*** Yes No

Preservatives which are bioaccumulating (BCF >500/log Kow >4) Yes No

Antibacterial agents (e.g. nanosilver and triclosan)**** Yes No

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

** PBT and vPvB in accordance with the criteria in Annex XIII of REACH

*** Substances considered to be potential endocrine disruptors in category 1 or 2, see following link:

http://ec.europa.eu/environment/chemicals/endocrine/strategy/being_en.htm

**** 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.

Does the colourant fulfil the requirements in the European Council's "Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food"?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<p>For dyeing of polymer material:</p> <p>Does the colourant fulfil</p> <p>- BfR's (Federal Institute for Risk Assessment) recommendations: "IX. Colorants for Plastics and other Polymers Used in Commodities" or</p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

<p>- Swiss Ordinance 817.023.21 Annex 2 and 10.</p> <p>If yes, please state if the colourant fulfils BfRs recommendations or the requirements in the Swiss Ordinance:</p> <hr/>		
<p>For dyeing of cellulose material:</p> <p>Does the colourant fulfil BfR's recommendation XXXVI. Paper and board for food contact, from July 2015 or later versions?</p>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Requirements in the chemical module for paper products

Either the requirements in the chemical module for paper products, version 2 or version 3 must be fulfilled.

The requirements in version 2

The declarations below concern the requirements R9-R12 in the Chemical module for paper products, version 2 (requirement R9-R12 in the chemical module are given in appendix 5 in these criteria).

R9 Do dyes for use in printing and colouring contain substances classified as environmentally hazardous (H400, H411, H412, EUH 059)*? Yes No

If yes, state the unambiguous chemical name, the CAS number and the concentration:

_____ %
 _____ %
 _____ %

Exception to the requirement are dyes where dyestuffs are fixed to fibres >98%. The degree of fixation is calculated as the total retention of dyestuffs on the fibres during the process.

and

where the constituent substances are not found in Restricted Substances Database (Sweden), List of undesirable substances, Environmental Review³ or The Priority List⁴, (State of the Environment, Norway)

Is the exception for dyes applied? Yes No

³ <https://mst.dk/kemi/kemikalier/stoflister-og-databaser/listen-over-uoenskede-stoffer-kortlaegning-strategi-og-implementering/revideret-liste-over-uoenskede-stoffer/>

⁴ <https://www.miljostatus.no/tema/kjemikalier/prioritetslisten/>

If yes, specify how the requirements for exception are met (e.g. fixing to fibres >98%):

R10 Are heavy metals, aluminium and copper, or impurities* of heavy metals, present in dyestuffs or pigments?

Yes No

If yes, please specify the metal: _____

* Impurities:

- We hereby declare that total lead, cadmium, mercury and chromium impurities do not exceed 100 ppm in the dye or pigment.

- We hereby declare that the lead content does not exceed 100 ppm, mercury 4 ppm, cadmium 20 ppm and chromium 100 in direct dyes.

- We hereby declare that the lead content does not exceed 100 ppm, mercury 25 ppm, cadmium 50 ppm, chromium 100 ppm in the pigment dyes.

R11 Does the dye formulation contain dyes that can decompose to form any of the amines in the table below?

Yes No

Amin	CAS number
4-amino-bifenyl	92-67-1
Bensidin	92-87-5
4-klor-o-toluidin	95-69-2
2-naftylamin	91-59-8
o-aminoazo-toluol	97-56-3
2-amino-4-nitro-toluol	99-55-8
p-klor-anilin	106-47-8
2,4-diamino-anisol	615-05-4
2,4'-diamino-difenylmetan	101-77-9
3,3'-diklorbensidin	91-94-1
3,3'-dimetoxi-bensidin	119-90-4

3,3'-dimetyl-bensidin	119-93-7
3,3'-dimetyl-4,4'-diamino-difenylmetan	838-88-0
p-kresidin	120-71-8
4,4'-metylen-bis(2-klor-anilin)	101-14-4
4,4'-oxi-dianilin	101-80-4
4,4'-tio-dianilin	139-65-1
o-toluidin	95-53-4
2,4-toluylendiamin	95-80-7
2,4,5-trimetyl-anilin	137-17-7
0-anisidin 2-methoxyanilin	90-04-0
2,4-xyloidin	95-68-1
4,6-xyloidin	87-62-7
4-aminoazobenzen	60-09-3

R12 Do dye formulations contain phthalates?

Yes No

Please attach safety data sheet for the dye/pigment.

The requirements in version 3

The declarations below concern the requirements O10-O11 in the Chemical module for paper products, version 3 (the requirements O10-O11 in the chemical module are given in appendix 5 in these criteria).

Paper colourants, Metals (O9)

Are dyes or pigments in paper colourants based on aluminium, silver, arsenic, barium, cadmium, cobalt, chromium, copper, mercury, manganese, nickel, lead, selenium, antimony, tin or zinc?	<input type="checkbox"/> Yes <input type="checkbox"/> No
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If yes, please specify the metal(s)?: _____

Copper in phthalocyanine pigment and aluminium in aluminosilicates are exempted from this requirement.

Ionic impurities (O9)

Do the levels of ionic impurities in the paper colourants exceed the following limits?

Antimony: 50 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Arsenic: 50 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Barium: 100 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Cadmium: 20 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Chromium: 100 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Cobalt: 500 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Copper: 250 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Lead: 100 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Mercury: 4 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Nickel: 200 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Selenium: 20 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Silver: 100 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Tin: 250 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Zinc: 1 500 ppm	<input type="checkbox"/> Yes	<input type="checkbox"/> No

Amines and phthalates (O10)

Does the dye formulation contain dyes that can decompose to form any of the aromatic amines listed in Regulation (EC) No 1907/2006 Annex XVII, Appendix 8?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Does the paper colourant contain phthalates?	<input type="checkbox"/> Yes	<input type="checkbox"/> No

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 dye/printing ink:
Responsible person:	Signature, responsible person: