Form 4c Declaration – Colourants/printing inks

Form for requirement O13, O14, O15 and O19.

Name of dye/ink and area of use:_____

Name of manufacturer of the dye/ink product: _____

These requirements apply to all ingoing substances in the chemical product, but not to impurities unless otherwise stated in the specific requirement. 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, arylamine, in situ-generated preservatives) are also regarded as ingoing substances.

Impurities: residuals, pollutants, contaminants etc. from production, incl. production of raw materials that remain in the raw material/ingredient and/or 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, scavengers, and detergents for production equipment and carry-over from other or previous production lines.

O13 Chemical products, classification

Is the colourant/printing ink classified in accordance with the table below? ☐ Yes ☐ No

Table S4: Classification of chemical products

Classification under CLP Regulation (EC) No 1272/2008		
Hazard class	**Category**	**Hazard code**
Hazardous to the aquatic environment	Aquatic Acute 1 Aquatic Chronic 1-4	H400 H410, H411, H412
Acute toxicity	Acute Tox. 1, 2 Acute Tox. 3	H330, H310, H300 H331, H301, H311
Specific target organ toxicity	STOT SE 1 STOT RE 1	H370 H372
Allergenic	Resp. Sens. 1 or Skin Sens 1	H334 H317
Carcinogenic	Carc. 1A/1B Carc. 2	H350 H351
Germ cell mutagenicity	Muta. 1A/B Muta. 2	H340 H341
Reproductive toxicity	Repr. 1A/1B Repr. 2	H360, H361 H362

O14 Classification of ingoing substances

Does the chemical product contain substances that have a classification as listed in the table below? ☐ Yes ☐ No

Table S5: Classification of CMR substances

Classification under CLP Regulation (EC) No 1272/2008		
Hazard class	**Category**	**Hazard code**
Carcinogenic	Carc. 1A/1B Carc. 2	H350 H351
Germ cell mutagenicity	Muta. 1A/BMuta. 2	H340 H341
Reproductive toxicity	Repr. 1A/1B Repr. 2	H360, H361 H362

O15 Chemical substances – prohibition list

Are any of the following ingoing substances in the colourant/printing ink?

- Substances on the Candidate List* ☐ Yes ☐ No
- 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
- Phthalates**** ☐ Yes ☐ No
- APEO – alkylphenol ethoxylates and alkylphenol derivatives (substances that release alkylphenols on degradation) ☐ Yes ☐ No
- BHT - butylhydroxytoluene ☐ Yes ☐ No

  There is an exemption for BHT up to 2 ppm in water-repelling coatings used on articles made from board. Please note that a plastic layer on the product is not considered a coating. The exemption expires if the substance fulfils one of the following during the validity of the criteria:

  - *The substance is included on the EU Candidate list* or List 1 on the website www.edlist.org.*
  - *ECHA Endocrine Disruptor Expert Group assesses the substance and considers it an endocrine disruptor http://echa.europe.ej/sv/ed-assessment*

- *The substance is included on List 3 on the website www.edlist.org*

- Bisfenol A, F og S ☐ Yes ☐ No
- Halogenated organic compounds[1] ☐ Yes ☐ No
- Antibacterial agents (e.g. nanosilver)***** ☐ 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*

***** The prohibition does not include polyethylene terephthalate (PET).*

****** 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.*

[1] 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.

O19 Colourants for printing and dyeing

Halogenated organic pigments must meet the European Council's "Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food". Is this fulfilled?	☐ Yes ☐ No
Do the colourants meet BfR's (Federal Institute for Risk Assessment) recommendations: "IX. Colorants for Plastics and other Polymers Used in Commodities"* or Swiss Ordinance 817.023.21 Annex 2 and 10?	☐ Yes ☐ No
Do the colourants used for dyeing and/or shading of paper/paperboard/cardboard meet BfR's recommendation XXXVI. Paper and board for food contact, from July 2015 or more recent versions?	☐ Yes ☐ No

** In case of colourants used in paper/paperboard/cardboard, condensation products of aromatic sulfonic acids with formaldehyde are exempted from the requirement in BfR IX, but must fulfil the requirements in BfRs XXXVI.*

If relevant, do the colourants meet the requirements to condensation products of aromatic sulfonic acids with formaldehyde in BfR XXXVI? ☐ Yes ☐ No

Attach safety data sheet.

In the event of any changes to the composition of the chemical product, a new declaration of compliance with the requirements must be submitted to Nordic Ecolabelling.

Place and date:	Colourant manufacturer's name:
Responsible person:	Signature of responsible person: