Appendix 4 Declaration chemicals

To be used in conjunction with an application for a licence for the Nordic Swan Ecolabelling of Packaging for Liquid Foods.

This declaration must be used to document Nordic Ecolabelling's requirements of chemicals and is intended for chemical manufacturers/suppliers.

Requirements O15, O16 and O17 apply to all chemical products (part A) used in the production/assembly (conversion*) of primary packaging.

Requirement O18, O20 and O21 are specific for certain chemical types (part B) that are used in production of pulp and paper and in the assembly (conversion) and finishing of primary packaging. Requirement O19 applies to adhesives. Requirement O21 is applied to D4, D5 and D6 in silicone polymers.

Complete the relevant parts of the declaration. Also enclose the safety data sheet for the chemical product, in accordance with applicable European legislation.

Nordic Ecolabelling's requirements concerning chemicals primarily concern chemical products and constituent substances in chemical products such as **adhesives and printing inks, and which are used in the production/assembly (conversion) of the packaging.*

The form must be completed and signed by the chemicals producer, based on the knowledge held at the relevant time, according to information from raw materials producers/suppliers, recipes and available knowledge of the chemical product, with reservation for development and new knowledge. Should such new knowledge arise, the undersigned is obliged to submit an updated declaration to Nordic Ecolabelling.

Name of the chemical product
Manufacturer
Type of chemical product (e.g. adhesive, printing ink)

The requirements apply to all constituent substances, but not to contaminants, unless otherwise specified in the individual requirements. Constituent substances and contaminants are defined below.

***Constituent substances**: all substances in the chemical product, including additives (e.g. preservatives and stabilisers) from the raw materials. Known degradation products from constituent substances (e.g. formaldehyde and arylamine) are also considered to be constituent substances.*

***Contaminants**: residual substances from production, including raw materials production, which are found in a raw material or the final chemical product, equivalent to concentrations ≤100 ppm (≤0.01% by weight, ≤100 mg/kg) in the chemical product. Examples of what is considered to be contaminants are residual concentrations of the*

following: reagents including monomers, catalysts, by-products, "scavengers" (i.e. chemicals used to eliminate/minimise adverse substances), cleaning agents for production equipment, and "carry-over" from other or previous production lines.

Part A, requirements **O15, O16** and **O17** for all chemical products

O15 Chemical products, classification

Is the chemical product classified in accordance with the table below? ☐ Yes ☐ No

If yes, which classifications?

_____

Classification under CLP Regulation (EC) No 1272/2008		
Hazard class	**Category**	**Hazard code**
Hazardous to the aquatic environment	Aquatic Acute 1 Aquatic Chronic 1-2	H400 H410, H411
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

The classifications in the Table concern all classification variants. For example, H350 also covers classification H350i.

O16 CMR substances

Does the product include substances, classified in accordance with below? The classifications in the table concern all classification variants. For example, H350 also covers classification H350i.		
Carc. 1A or 1B H350	☐ Yes	☐ No
Carc. 2 H351	☐ Yes	☐ No
Muta. 1A or 1B H340	☐ Yes	☐ No
Muta. 2 H341	☐ Yes	☐ No
Repr. 1A or 1B H360	☐ Yes	☐ No
Repr 2 H361	☐ Yes	☐ No
H362 (Reprotoxic, effects on or via breastfeeding, supplementary category)	☐ Yes	☐ No

O17 Other substances excluded from use

Does the product contain any of the following substances?		
Substances on the EU Candidate list, see the ECHAs website: http://echa.europa.eu/candidate-list-table)	☐ Yes	☐ No
Substances evaluated by the EU to be PBT (persistent, bioaccumulative and toxic) or vPvB substances (very persistent and very bioaccumulative), in accordance with the criteria in Appendix XIII of REACH and substances that have not yet been evaluated but which meet these criteria.	☐ 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: http://ec.europa.eu/environment/chemicals/endocrine/strategy/being_en.htm	☐ Yes	☐ No
Phthalates. The prohibition does not include polyethylene terephthalate (PET).	☐ Yes	☐ No
Alkylphenol ethoxylates (APEO) and other alkylphenol derivatives (substances that release alkylphenols on degradation), excluding 2,4,6-tri-tert-butylphenol derivatives but not 2,4,6-tri-tert-butylphenol itself.	☐ 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.	☐ Yes	☐ No
Butylhydroxytoluene BHT (CAS 128-37-0) *There is an exemption for BHT up to 0.10% in solvent-based inks. The exemption ceases to exist 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 https://echa.europa.eu/sv/ed-assessment* *- The substance is included in List 3 on the website www.edlist.org*	☐ Yes	☐ No
Bisphenol A, bisphenol F and bisphenol S	☐ Yes	☐ No
Antimicrobial agents (e.g. nano silver), substances that are added to create an antimicrobial or disinfectant effect in the packaging. An antimicrobial chemical is a chemical which prevents or stops the growth of microorganisms such as bacteria, mould or protozoa (unicellular organisms).	☐ Yes	☐ No
MIT (CAS 2682-20-4), CMIT / MIT (CAS 26172-55-4, 2682-20-4), an exception is made for MIT in concentrations below 100 ppm in e.g. printing inks.	☐ Yes	☐ No

Part B Requirements specifically for certain types of chemicals

O18 Colourants for printing and dyeing

Requirement for colourants for printing and dyeing are applied to all materials (e.g. paper, board, plastic)		
Do the colorants fulfil the recommendations of BfR (Federal Institute for Risk Assessment): "IX. Colorants for Plastics and other Polymers Used in Commodities" or Swiss Ordinance 817.023.21 Annex 2 and 10 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
Halogenated organic pigments		
Does the product contain halogenated organic pigments?	☐ Yes	☐ No
If yes, do halogenated organic pigments fulfil the requirements in the Council of Europe's resolution: "Resolution AP (89) 1 on the use of colourants in plastic materials coming into contact with food".	☐ Yes	☐ No

O19 Adhesives - constituent substances

Adhesives		
Are ethylene glycol ethers included in the adhesives?	☐ Yes	☐ No
Is rosin included in the adhesives? The exception is modified rosin derivatives that are not classified as allergenic.	☐ Yes	☐ No
Formaldehyde		
Is the adhesive hotmelt? Note that hotmelt adhesives are exempted from the requirement to document formaldehyde.	☐ Yes	☐ No
Is the content of formaldehyde generated during the production process maximum 250 ppm (0.0250% by weight) in the adhesive, measured by newly produced polymer dispersion? Measured by the VdL-RL 03 method "In-can concentration of formaldehyde determined by the acetyl-acetone method" or the Merckoquant method (see Annex x to RAL-UZ 102), alternatively another equivalent method.	☐ Yes	☐ No
Is the content of formaldehyde in the hardened adhesive maximum 10 ppm (0,001% by weight)? Measured using the Merckoquant method (see Appendix X of RAL-UZ 102), or some other equivalent method.	☐ Yes	☐ No

Enclose results of analysis of the formaldehyde content of the adhesive.

O21 Coatings and impregnations

Liquid-proof and grease-roof properties in the pulp/paper/board/packaging must not be based on chromium or fluorinated compounds. Does the product used for coating/impregnating/mixing into the pulp/paper/board/packaging contain any of following		
Chromium compounds?	☐ Yes	☐ No
Fluorinated compounds?	☐ Yes	☐ No
Silicone treatment		
Is the product used for silicone treatment of pulp/paper/board/packaging?	☐ Yes	☐ No
If yes, is the product solvent-based?	☐ Yes	☐ No
If yes, are organotin catalysts used in the production of silicone polymers?	☐ Yes	☐ No
If yes, does the product contain octamethylcyclotetrasiloxane, D4, (CAS 556-67-2) and decamethylcyclopentasiloxane, D5, (CAS 541-02-6) and dodecamethylcyclohexasiloxane, D6 (CAS 540-97-6)? *Contaminants of D4*, D5 *and D*6 *included in the final commercial product in concentrations below 800 ppm (0.08% by weight, 800 mg/kg) are exempt from the requirement. The commercial product refers to the silicone emulsion's coating bath.*	☐ Yes	☐ No

If the product contains D4 (CAS 556-67-2) and D5 (CAS 541-02-6) and/or D6 (CAS 540-97-6)

please state volumes of D4:_____

please state volumes of D5:_____

please state volumes of D6:_____

In the event of any change to the composition of the product, a new declaration of fulfilment of the requirements is to be submitted to Nordic Ecolabelling.

Signature of the chemical manufacturer / chemical supplier

Place and date	Company name/stamp
Person responsible	Signature of the person responsible (electronic signature is accepted)
Telephone	E-mail