

## Appendix 3      Plasticisers, other additives and adhesives

For requirements O5, O6 and O7

Filled out by:

Manufacturer of the ecolabelled product: ☐

Material supplier: ☐

Chemical supplier: ☐

Name of the chemical and purpose of use:

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The requirements (O6 and O7) apply to all ingoing substances in the chemical product (plasticisers, other additives and adhesives), 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).

O5 Chemical product - classification

Is the plasticiser, additive or adhesive classified according to the table below?

Classification under CLP Regulation (EC) No 1272/2008				
Hazard class	Category	Hazard code	Yes	No
Hazardous to the aquatic environment*. ***	Aquatic Acute 1	H400		
	Aquatic Chronic 1	H410		
	Aquatic Chronic 2	H411		
	Aquatic Chronic 3	H412		
	Aquatic Chronic 4	H413		
Carcinogenic	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		
Acute toxicity	Acute Tox 1 or 2	H300		
	Acute Tox 1 or 2	H310		
	Acute Tox 1 or 2	H330		
	Acute Tox 3	H301		
	Acute Tox 3	H311		
	Acute Tox 3	H331		

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		
Allergenic**, ***	Resp. sens 1, 1A and 1B or Skin sens 1, 1A and 1B	H334 H317		

\* There is an exemption of up to 0.1 % by weight of additives classified as hazardous for the environment. The weight calculation shall be based on the total weight of the materials in the Nordic Swan Ecolabelled product. Any pharmaceutical inside the Nordic Swan Ecolabelled product shall not be included in the weight of the product. Please add a calculation showing that the requirement is fulfilled.

\*\* There is an exemption for the classification H317 for the hardener of 2-component adhesives and for dye products used in components that do not come in contact with the medicinal solution or the patient during treatment.

\*\*\* Exemptions for the classifications "Hazardous to the aquatic environment", H317 and H360 only apply to UV-cured acrylates-based adhesives cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.

\*\*\*\* When required for regulatory reasons to avoid release of n-nitrosamine from polyisoprene parts, exemption is given to antioxidants classified as toxic to reproduction cat 2 (H361) as additive in the part at maximum 0.5 % and assessed as safe and not detectable in an ISO 10993 evaluation.

Please state the name of the hardener: \_\_\_\_\_

## O6 Chemical substances - CMR

Are ingoing substances (apart from impurities) in the plasticiser, additive or adhesive classified as carcinogenic (Carc.), mutagenic (Muta.) and/or toxic for reproduction (Repr.) according to CLP Regulation (EC) No 1272/2008 (see table below):

### Classification of CMR substances

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

\* Exemption is given for 2-component adhesives with isocyanates (classified H351, if the workers are not exposed during the production of the product) and the isocyanates are cured in the finished product. Legislation for working environment must be fulfilled.

\*\* Exemption is given to photoinitiators classified as H360 and/or H361 in UV-cured acrylates-based adhesives if the chemical product is cured in a closed production system where there is no direct contact/exposure between worker and the chemical product.

\*\*\* When required for regulatory reasons to avoid release of n-nitrosamine from polyisoprene parts, exemption is given to antioxidants classified as toxic to reproduction cat 2 (H361) as additive in the part at maximum 0.5 % and assessed as safe and not detectable in an ISO 10993 evaluation.

Exemptions apply to:

- Titanium dioxide (CAS No. 13463-67-7) classified as H351.

- 1,1,1-Trimethylolpropane (TMP, CAS No. 77-99-6) classified as H361.

### **O7 Chemical substances – other excluded substances**

Are ingoing substances (apart from impurities) in the plasticiser, additive and adhesive from the list below:

Substances on the Candidate List\*

☐ Yes ☐ No

*For D4, D5 and D6 in silicone polymers, see O4.*

Substances that have been evaluated 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

\* *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/pdf/final\\_report\\_2007.pdf](http://ec.europa.eu/environment/chemicals/endocrine/pdf/final_report_2007.pdf), see appendix L*

\*\*\*\* *Esters of phthalic acid (orthophthalic acid / phthalic acid /1,2-benzenedicarboxylic acid). The prohibition does not include polyethylene terephthalate (PET).*

### **Signature**

Date and place:	Name of company:
Responsible person:	Signature of responsible person: