

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:

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	
Hazardous to the aquatic environment*	Aquatic Acute 1	H400	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Aquatic Chronic 1	H410	
	Aquatic Chronic 2	H411	
	Aquatic Chronic 3	H412	
	Aquatic Chronic 4	H413	
Carcinogenic	Carc. 1A or 1B	H350	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Carc. 2	H351	
Germ cell mutagenicity	Muta. 1A or 1B	H340	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Muta. 2	H341	
Reproductive toxicity****	Repr. 1A or 1B	H360	<input type="checkbox"/> Yes <input type="checkbox"/> No
	Repr. 2	H361	
	Lact.	H362	
Acute toxicity	Acute Tox 1 or 2	H300	<input type="checkbox"/> Yes <input type="checkbox"/> No
	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	<input type="checkbox"/> Yes <input type="checkbox"/> No
Aspiration hazard	Asp. Tox. 1	H304	<input type="checkbox"/> Yes <input type="checkbox"/> No
Allergenic**, ***	Resp. sens 1, 1A and 1B or Skin sens 1, 1A and 1B	H334 H317	<input type="checkbox"/> Yes <input type="checkbox"/> No

* 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" and H317 (Skin sens 1, 1A and 1B) only applies 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)	
Carcinogenic Carc. 1A/1B Carc. 2	H350 H351*	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
Mutagenic Muta. 1A/B Muta. 2	H340 H341	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
Toxic for reproduction Repr. 1A/1B Repr. 2	H360, H361**, *** H362	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No

* 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 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.

07 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, see appendix L*

*****Esters of phtalic 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: