

Appendix 6 Declaration from the manufacturer/supplier of adhesive or surface treatment

To be submitted with an application for a Nordic Swan Ecolabel licence.

This declaration is based on the best available knowledge at the time of the application, including test results. If new information or scientific findings become available, please inform Nordic Ecolabelling and submit an updated declaration.

For suppliers: If you do not have knowledge about the complete composition of the raw material/ingredient, you are obliged to obtain this information from the manufacturer.

Manufacturer/supplier:
Trade name of the adhesive or surface treatment:

The requirements in the criteria document and accompanying appendices apply to all ingoing substances in the adhesive or surface treatment. Impurities are not regarded as ingoing substances and are exempt from the requirements. Ingoing substances and impurities are defined as below, unless stated otherwise in the requirements.

Ingoing substances: All substances* in the adhesive or surface treatment regardless of amount in the raw materials. Substances released from ingoing substances (e.g., biocidal active substances generated by preservatives, such as formaldehyde) are also regarded as ingoing substances.

** N.B. the difference from the definition of substances in the REACH Regulation (EC) No 1907/2006. Whereas a REACH substance encompasses a chemical element or compound as well as its stabilising additives and process impurities, a substance here refers to each of the constituents separately. The constituents of a UVCB substance (Unknown or Variable composition, Complex reaction products or of biological materials) are also regarded separately, and all known constituents must be regarded.*

Impurities: Trace levels of pollutants, contaminants and residues from production, incl. production of raw materials, that remain in the chemical product or additive in concentrations ≤ 100 ppm (≤ 0.0100 w%). For formaldehyde other than as a biocidal active substance and for arylamine, the corresponding concentration is ≤ 25 ppm (≤ 0.0025 w%).

Impurities in the raw materials in concentrations ≥ 1000 ppm (≥ 0.1000 w%) are always regarded as ingoing substances, regardless of the concentration in the chemical product or additive.

Examples of impurities: Background environmental pollutants from feedstock, as well as contaminants and residues from production such as reactants (incl. monomers), reagents, catalysts, by-products, scavengers, detergents for production equipment, carry-over from other or previous production lines.

Additional information concerning definitions of ingoing substances and impurities:

Limit values: The limit for excluded ingoing substances is 0 ppm (unless otherwise stated), while there's a specific defined limit for impurities. The impurity limit applies separately to each individual excluded substance, from each individual raw material. Concentrations of different impurities with the same excluded classification or substance group characteristics shall not be summed up to meet the impurity limit in the labelled product. Also, concentrations of an individual impurity, originating from different raw materials, shall not be summed.

UVCB substances: UVCB substances (Unknown or Variable composition, Complex reaction products or of biological materials) have a composition of constituents that is not completely known or is variable from time to time. For substances registered under REACH as UVCBs, all constituents are considered individually and are subject to the chemical requirements, including for instance those on excluded substances and excluded classifications.

If the adhesive or surface treatment contain ingoing substances or impurities that are listed under excluded substances or has any of the classifications mentioned in this appendix, write the amount in the box at the end of the appendix. The manufacturer of the Nordic Swan Ecolabelled product is responsible for calculating compliance with the requirements of the criteria.

Type of adhesive/surface treatment	YES	NO
UV-cured acrylates-based adhesive		
UV-cured surface treatment		
2-component adhesive		
Other: (please state)		

O11 Classifications of the adhesive or surface treatment (according to CLP regulation 1272/2008)		
Is the adhesive or surface treatment classified with any of the hazard codes below? Including all classification variants (e.g. H350 also includes H350i).	YES	NO
H400 – Aquatic Acute 1		
H410 – Aquatic Chronic 1		
H411 – Aquatic Chronic 2		
H412 – Aquatic Chronic 3		
H413 – Aquatic Chronic 4		
H420 – Ozone		
H300 – Acute Tox. 1 or 2		

H310 – Acute Tox. 1 or 2		
H330 – Acute Tox. 1 or 2		
H301 – Acute Tox. 3		
H311 – Acute Tox. 3		
H331 – Acute Tox. 3		
H370 – STOT SE 1		
H371 – STOT SE 2		
H372 – STOT SE 3		
H373 – STOT SE 4		
H334 – Resp. Sens. 1, 1A or 1B		
H317 – Skin Sens. 1, 1A or 1B <i>If yes because of UV-cured acrylates-based adhesives or the hardener in 2-component adhesives, see below.</i>		
H350 – Carc. 1A or 1B		
H351 – Carc. 2		
H340 – Muta. 1A or 1B		
H341 – Muta. 2		
H360 – Repr. 1A or 1B		
H361 – Repr 2		
H362 – Lact.		
EUH380 – ED HH 1		
EUH381 – ED HH 2		
EUH430 – ED ENV 1		
EUH431 – ED ENV 2		
EUH440 – PBT		
EUH441 – vPvB		
EUH450 – PMT		
EUH451 – vPvM		

<i>For UV-cured acrylates-based adhesives with any classifications above are exempted if the UV-cured acrylates-based adhesives are cured in a closed production system where there is no direct contact/exposure between worker and the chemical product. This must be declared by the applicant of the ecolabelled product.</i>		
<i>H317 is exempted for the hardener in 2-component adhesives and UV-cured acrylates-based adhesives that do not come into contact with the medicinal solution or the patient during treatment. This must be declared by the applicant of the ecolabelled product.</i>		
O12 Classifications of ingoing substances in adhesive and surface treatment (according to CLP regulation 1272/2008)		
Does the adhesive or surface treatment contain ingoing substances or impurities classified with any of the hazard codes below? Including all classification variants (e.g. H350 also includes H350i).	Yes	No
<i>If yes to any classifications below because of photoinitiators in UV-cured acrylates-based adhesives or in UV-cured surface treatment, see below.</i>		
H420 – Ozone		
H372 – STOT RE 1		
H334 – Resp. Sens. 1, 1A or 1B <i>If yes because the hardener in 2-component adhesives, see below.</i>		
H317 – Skin Sens. 1, 1A or 1B <i>If yes because of UV-cured acrylates-based adhesives or the hardener in 2-component adhesives, see below.</i>		
H350 – Carc. 1A or 1B		
H351 – Carc. 2 <i>If yes because of 2-component adhesives with isocyanates, see below.</i>		
H340 – Muta. 1A or 1B		
H341 – Muta. 2		
H360 – Repr. 1A or 1B		
H361 – Repr 2 .		
H362 – Lact.		
EUH380 – ED HH 1		
EUH381 – ED HH 2		
EUH430 – ED ENV 1		
EUH431 – ED ENV 2		
EUH440 – PBT		
EUH441 – vPvB		
EUH450 – PMT		
EUH451 – vPvM		
For UV-cured acrylates-based adhesives or UV-cured surface treatment with any classifications above: Are the classifications due to photoinitiators?		

For 2-component adhesives with classifications H317 and/or H334: Are the classifications due to hardener?		
<i>H317 and H334 are exempted for the hardener in 2-component adhesives that do not come into contact with the medicinal solution or the patient during treatment. This must be declared by the applicant of the Ecolabelled product.</i>		
<i>Isocyanates classified H351 is exempted in 2-component adhesives 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. This must be declared by the applicant of the Ecolabelled product.</i>		
<i>Photoinitiators classified with any above are exempted in UV-cured acrylates-based adhesives and in UV-cured surface treatment if adhesives/surface treatment are cured in a closed production system where there is no direct contact/exposure between worker and the chemical product. This must be declared by the applicant of the Ecolabelled product.</i>		
<i>H317 is exempted in UV-cured acrylates-based adhesives if it is cured in a closed production system where there is no direct contact/exposure between worker and the chemical product. This must be declared by the applicant of the Ecolabelled product</i>		
O13 Excluded substances in adhesive and surface treatment		
Does the adhesive or surface treatment contain any of the following as ingoing substances?	Yes	No
Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate-list-table <i>For D4, D5 and D6 in silicone polymers, see below under O14.</i>		
PBT and vPvB as defined in REACH Annex XIII, including those under ECHA PBT assessment https://echa.europa.eu/da/pbt		
Potential or identified endocrine disruptors, listed in any of the following "Endocrine Disruptor Lists" List I; II and III		
Phthalates (Esters of 1,2-benzenedicarboxylic acid (orthophthalic acid, CAS NO. 88-99-3))		
Alkylphenols (AP) (e.g. butylated hydroxy anisole (BHA, CAS NO. 25013-16-5), butylated hydroxytoluene (BHT, CAS NO. 128-37-0), alkylphenol ethoxylates (APEOs) and other alkylphenol derivates (APD)		
Per- and polyfluoroalkyl substances (PFAS) PFAS is defined as any substance that contains at least one fully fluorinated methyl (CF ₃ -) or methylene (-CF ₂ -) carbon atom (without any H/Cl/Br/I attached to it)		
Halogenated organic compounds		
Metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)		
Bisphenols and bisphenol derivatives, defined as 34 bisphenols identified by ECHA for further EU regulatory risk management due to known or potential endocrine disruption or reproductive toxicity. <i>EC/List No. 201-245-8 (BPA), 201-025-1 (BPB), 401-720-1 (4,4'-Isobutylethylidenediphenol), 216-036-7 (BPAF) and its 8 salts (278-305-5; 425-060-9; 443-330-4; 468-740-0; 469-080-6; 479-100-5; 943-265-6; 947-368-7), 201-250-5 (BPS), 201-240-0 (BPC), 204-279-1 (TBMD), 201-618-5 (6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol), 242-895-2, 248-607-1, 405-520-5 (D8), 217-121-1 (DAB), 227-033-5 (TMBPA), 210-658-2 (BPF), 411-570-9, 277-962-5 (contains BPS), 500-086-4 (contains BPA), 500-263-6 (contains BPA), 500-607-5 (contains BPA), 701-362-9, 904-653-0 (contains BPA), 908-912-9 (contains BPF), 926-571-4 (contains BPA), 931-252-8 (contains BPA), 941-992-3 (contains BPS), 943-503-9 (contains BPA)</i>		
Quaternary ammonium compounds, which are not readily aerobic biodegradable such as DTDMAC (CAS NO. 61789-80-8), DSDMAC (CAS NO. 107-64-2), DHTDMAC (CAS NO. 61789-72-8) and DADMAC (CAS NO. 7398-69-8)		
Volatile aromatic compounds (VAC) (volatile organic compounds containing one or more benzene rings)		
Nanomaterials/-particles* <i>* Nanomaterials/-particles are defined according to the EU Commission Recommendation on the Definition of Nanomaterial (2022/C 229/01)10: "Nanomaterial" means a natural, incidental or manufactured material consisting of solid particles that are present, either on their own or as identifiable constituent particles in aggregates or agglomerates, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions: (a) one or more external dimensions of the particle are in the size range 1 nm to 100 nm; (b) the particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm; (c) the</i>		

<i>particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.</i>		
O14 Silicone in adhesive and surface treatment	YES	NO
Does the adhesive or surface treatment contain silicone or siloxanes? <i>If yes, fill out below.</i>		
Are D4, D5 or D6 a part of the adhesive and surface treatment?		
Please state number of impurities* of D4, D5 and D6 in the silicone fluids: <i>D4: Octamethylcyclotetrasiloxane, (CAS NO.556-67-2)</i> <i>D5: Decamethylcyclopenta-siloxane, (CAS NO.541-02-6)</i> <i>D6: Dodecamethylcyclohexasiloxane, (CAS NO.540-97-6)</i> D4: _____ ppm D5: _____ ppm D6: _____ ppm <i>* Impurities of D4, D5 and D6 are defined as residual products from the raw material production that can be found in the silicone material.</i>		
Is test report showing the amount of D4, D5 and D6 in the silicone fluids according to test method for silicone fluids from CES-Silicones Europe* or any ISO/IEC 17025-validated GC-MS method achieving LOQs at or below 100 ppm attached? <i>* Quantification-of-residual-amounts-of-Volatile-Siloxanes-in-silicone-products_final.pdf</i>		
Is documentation for the analysis laboratory fulfils the general requirements of standard EN ISO/IEC 17025 or have official GLP status attached?		

If the answer to any of the above questions regarding ingoing substances or impurities is Yes, please provide the following information for each relevant substance: CAS NO. (where possible), chemical name, concentration (in ppm, % by weight or mg/kg). Also state whether the substance is present as an ingoing substance or impurity.

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If the adhesive or surface treatment composition changes, a new declaration confirming compliance with the requirements must be submitted to Nordic Ecolabelling.

Place and date	Company name
Responsible person	Signature of responsible person
Telephone	Email