

Appendix 5 Declaration of additive used in plastic, silicone or rubber

Filled out by:

Manufacturer/supplier of additive:	
Manufacturer/supplier of plastic, silicone or rubber:	

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 additives in the polymer material, you are obliged to obtain this information from the manufacturer.

Manufacturer/supplier:
(When declaration is filled out by manufacturer/supplier of additive) Trade name of the additive:
(When declaration is filled out by manufacturer/supplier of additive) Type of additive (e.g. plasticisers, colourants/pigments, antioxidants):
(When declaration is filled out by manufacturer/supplier of plastic, silicone or rubber) Trade name of the polymer material:
(When declaration is filled out by manufacturer/supplier of plastic, silicone or rubber) Type of polymer material (e.g. PP, PET, TPE, silicone):

This appendix covers requirements to additives, e.g., plasticisers, colourants/pigments and antioxidants, added to the masterbatch or compound. The requirement does not include the polymer production itself.

The requirements in this section and accompanying appendices apply to **all ingoing substances in the additives**. 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 chemical product/additive regardless of amount, including additives (e.g., preservatives and stabilizers) 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 additives** 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.

O9 Classifications of ingoing substances in additives (according to CLP regulation 1272/2008)		
Do the additives 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
H420 – Ozone		
H370 – STOT SE 1		
H371 – STOT SE 2		
H372 – STOT RE 1		

H373 – STOT RE 2		
H350 – Carc. 1A or 1B		
H351 – Carc. 2		
H340 – Muta. 1A or 1B		
H341 – Muta. 2		
H360 – Repr. 1A or 1B		
H361 – Repr 2 <i>If yes because of polyisoprene parts with H361, the following documentation must be attached:</i> <ul style="list-style-type: none"> • Data from licensee confirming that a replacement is required for regulatory reasons due to release of n-nitrosamine impurities from polyisoprene part(s). • Data from supplier showing that the level of such antioxidant does not exceed 0.5% in the polyisoprene material. • An evaluation according to ISO 10993 concluding that the use of an antioxidant (classified as above) in the polyisoprene part is safe, and that the antioxidant is not released in detectable amounts from the medicinal product and medical device. 		
H362 – Lact.		
H334 – Resp. Sens. 1, 1A or 1B		
H317 – Skin Sens. 1, 1A or 1B		
EUH380 – ED HH 1		
EUH381 – ED HH 2		
EUH430 – ED ENV 1		
EUH431 – ED ENV 2		
EUH440 – PBT		
EUH441 – vPvB		
EUH450 – PMT		
EUH451 – vPvM		
O10 Excluded substances in additives		
Do the additives contain any of the following as ingoing substances or impurities?	Yes	No
Substances on the REACH Candidate list of SVHC substances https://www.echa.europa.eu/candidate-list-table For D4, D5 and D6 in silicone polymers, use Appendix 3.		
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))		
Azo dyes that may release aromatic amines with carcinogenic, reproductive toxicity or mutagenic properties listed in Regulation (EC) No 1907/2006, Annex XVII, Appendix 8		
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>		
Per- and polyfluoroalkyl substances (PFAS) <i>PFAS is defined as any substance that contains at least one fully fluorinated methyl (CF₃-) or methylene (-CF₂-) carbon atom (without any H/Cl/Br/I attached to it)</i>		
Halogenated organic compounds <i>Exemption for: Pigments that meet the EU's requirement concerning colourants in food packaging under Resolution AP (89) point 2.5. Please note: Per- and polyfluoroalkyl substances (PFAS) are covered by their own bullet and are not included in the exemption.</i>		
Metals and metalloids: Mercury (Hg), chromium VI (Cr), cobalt (Co), copper (Cu), nickel (Ni), cadmium (Cd), lead (Pb), arsenic (As), antimony (Sb)		

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.

--

If the additives composition change, 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