Nordic Ecolabelling of

Dishwasher detergents for professional use



Version 2.4 • 21 June 2010 – 31 March 2016



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080 Dishwasher detergents for professional use, version 2.4, 15 May 2013

This document is a translation of an original in Swedish. In case of dispute, the original document should be taken as authoritative.

Addresses

In 1989, the Nordic Council of Ministers decided to introduce a voluntary official ecolabel, the Swan. These organisations/companies operate the Nordic ecolabelling system on behalf of their own country's government. For more information, see the websites.

Denmark

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What is a Nordic Ecolabelled dishwasher detergent?

A Nordic Ecolabelled dishwasher detergent for professional use, or multicomponent system, is one of the least environmentally harmful options available in its product group. The dishwasher detergent fulfils stringent requirements on the health and environmental characteristics of its ingredients as well as performance and efficiency.

Nordic Ecolabelled dishwasher detergents for professional use:

- Contain limited amounts of environmentally hazardous and harmful substances.
- Contain readily biodegradable substances.
- Perform equally or better than equivalent products designed for the same function.
- Have an optimal dosage, which is checked during customer visits

Dirty dishwater is treated and released into nature. It is therefore vital that all constituent substances are readily biodegradable. The dishwasher detergent must not contain bioaccumulating or toxic substances that can upset the ecosystem.

Many fragrances are allergenic and ecotoxic. Some preservatives bioaccumulate while others are more environmentally suitable. Accordingly, Nordic Ecolabelling prohibits the use of fragrances and limits the use of preservatives.

An important Nordic Ecolabel requirement is that dishwasher detergents for professional use shall perform on a par or better than established products.

In comparative testing, the results at the recommended dosage must be satisfactory. This is also checked through regular inspection visits.

Why choose the Nordic Ecolabel?

- The producer may use the Swan trademark for marketing purposes. The Nordic Ecolabel, the Swan, is a very well-known and well-reputed trademark in the Nordic region.
- The Nordic Ecolabel is a cost-effective and simple way of communicating environmental work and commitment to customers and suppliers.
- Reducing environmental impact often creates scope for lowering costs, such as by cutting the consumption of energy and reducing amounts of packaging and waste.
- Environmental issues are complex. It can take a long time and extensive resources to gain an understanding of a specific area. The Nordic Ecolabel can be seen as an aid in this work.
- The Nordic Ecolabel not only covers environmental issues but also quality requirements, since the environment and quality often go hand in hand. This means that a Swan licence can also be seen as a mark of quality.

What can carry the Nordic Ecolabel?

These criteria apply to single and multi-component dishwasher detergents, rinse aids and presoaks for professional use within institutions and catering centres. The criteria also covers products that are used in washer-disinfectors destined for instrument maintenance in health care. Products that are designed for a wash cycle of less than 20 minutes are considered professional products, ie also including products for hybride/semi-professional machines. The maximal length of the wash cycle within health care is 30 minutes. The maximal time does not concern presoaks. Dishwasher detergents for special machines used in food production, dairies, etc., are not included. The criteria also include routines for customer visits.

How to apply

Each requirement is marked with the letter R (requirement) and a number. All requirements must be fulfilled for the award of a licence.

Icons in the text

The text describes how the applicant shall demonstrate fulfilment of each requirement. There are also icons in the text to make this clearer. These icons are:

🖾 Enclose

 $\boldsymbol{\rho}$ Requirement checked on site

Application

The application shall be sent to Nordic Ecolabelling in the country in which the dishwasher detergent, rinse aid or presoak is sold/the applicant carries on activities. See page 2 for addresses. The documents required for application are an application form and documentation demonstrating fulfilment of the requirements (specified under each requirement).

Further information and assistance may be available. Visit the Web site of the national ecolabelling body for more information.

On-site inspection

During the application process, Nordic Ecolabelling performs an on-site inspection to ensure adherence to the requirements. For this inspection, data used for calculations, original copies of submitted certificates, test records, purchase statistics, and similar documents that support the application must be available for examination.

Costs

An application fee is charged to companies applying for a licence. There is an additional annual fee based on the turnover of the Nordic Ecolabelled product.

Enquiries

Please contact Nordic Ecolabelling if you have any queries or require further information. See page 2 for addresses.

What are the requirements for the Nordic Ecolabel?

To be awarded a Nordic Ecolabel licence, all requirements must be fulfilled. Regarding multi-component systems, calculations shall be based on the entire system. The requirements in Section 1.1 mean that each individual component must also fulfil the requirement. A multi-component system must at a minimum comprise the components required to pass the performance tests.

1 Environmental requirements

The environmental criteria are divided into two sections: Section 1.1 contains general requirements that apply to all products and all components in a multicomponent system.

Section 1.2 specifies requirements that apply to a single component detergent or an entire multi-component system. The requirements in Section 1 apply to all constituent substances unless specified otherwise.

The term constituent substance refers to all substances in the ingredients including additives (such as preservatives and stabilisers) but does not include impurities from primary production. Even known substances released from constituent ingredients are considered as constituent ingredients. Impurities are defined as residual products from primary production that can be found in the dishwasher detergent, rinse aid or presoak in concentrations below 0.01%. Substances that are added intentionally to an ingredient are not considered impurities irrespective of their concentration.

The requirements in Section 1.1 and 1.2 are based on the highest recommended dosage in grams of product per litre water.

1.1 General requirements (applies to all products including all components of multi-component systems)

R1 Description of the product

The applicant must provide a detailed description of the dishwasher detergent, rinse aid or presoak for which the Nordic Ecolabel is sought. The description shall contain:

- Descriptions of the products forming part of a multi-component system.
- Documents supporting that the product is a professional product, with reference to "What can carry the Nordic Ecolabel?" above.
- Specification complying with the above.

Are the requirements met?

Yes	No	
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Appendix no.

R2 Recipe

The Complete recipe for the product/products of the dishwasher detergent, rinse aid or presoak shall be submitted as well as the highest recommended dosage. If the application is for a multi-component system, details must be provided of all the components. The recipe shall clearly state all constituent substances with name and possible CAS number, as well as their function and their proportion as a percentage. In cases where an ingredient comprises several substances, what the particular ingredient contains shall be declared. All of the following parameters must be evident from the submitted information:

- Producer
- Trade name
- Function of each ingredient
- Chemical name
- CAS no.
- DID no. (for substances that can be placed on the list)
- Quantity of each ingredient and constituent substances (including and excluding water)
- Classification according to Council Directive 67/548/EEC and Council Directive 1999/45/EC with amendments.

The DID number is the number assigned to the ingredient on the DID list, which is used for the evaluation of chemical requirements. The DID list is available from Nordic Ecolabelling. See page 2 for addresses.

DID list: "Detergent Ingredient Database" list. See Appendix 4 for further information.

- Complete recipe for the product/products as specified above.
- Material safety data sheet/product data sheet complying with applicable legislation in the country of application such as Annex II of REACH (Council Regulation 1907/2006/EEC) and later additions and changes thereto for each ingredient.

R3 Classification of the product

Products must not be classified according to current regulations in the Nordic countries or the European Dangerous Substances Directive 67/548/EEC with amendments and/or CLP Regulation 1272/2008 with amendments, as specified in Table 1. During a transition period, i.e. until 1 June 2015, cam classification according to European Dangerous Substances Directive 67/548/EEC or the CLP regulation can be used. Following the transition period, classification must comply with Annex VII of the CLP regulation (see Table 1).

Yes No

Appendix no.

Appendix no. ____

Yes No

Table 1	Product	classification
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Classification	Hazard symbol and risk phrase / Hazard category and statement			
	Dangerous Substances Directive 67/548/EEC	CLP Regulation 1272/2008		
Dangerous for the environment	N with R50, R50/53 or R51/53. R52, R53 or R52/53 without N	Hazardous to the aquatic environment Category Acute 1 H400; Category Chronic 1 H410; Category Chronic 2 H411; Category Chronic 3 H412; Category Chronic 4 H413		
Very toxic	Tx (T+ in Norway) with R26, R27, R28 and/or R39	Acute toxicity, Category 1 and 2		
Toxic	T with R23, R24, R25, R39 and/or R48	Acute toxicity, Category 3		
Harmful	Xn with R20, R21, R22, R48, R65 and/or R68. (Exceptions: Classifications R20, R21 and/or R22 are permit- ted if the packaging is so designed that the user does not come into con- tact with the product)	Acute toxicity, Category 4 (Exceptions: Classifications R20, R21 and/or R22 are permitted if the packaging is so designed that the user does not come into contact with the product)		
Corrosive*	C with R34 and R35	Skin corrosion/irritation, Category 1A, 1B and 1C H314		
Sensitizing	Xn with R42 or Xi with R43	Respiratory sensitisation, Category 1 with H334 or Skin sensitisation Category 1 with H317		
Carcinogenic	T with R45 and/or R49 Carc 1 or Carc 2 or Xn with R 40 Carc 3	Carc 1A/1B/2 with H350, H350i and/or H351		
Mutagenic	T with R46, Mut 1 or Mut 2 or Xn with R68 Mut 3	Mut 1B/2 with H340 and/or H341		
Reproductive toxic	T with R60, R61, R64 and/ or R33, Rep 1 or Rep 2 or Xn with R62, R63, R64 and/or R33. Repr 3	Repr 1A/1B/2 with H360, H361, H362		

*Exemption for automatically dosed product and manually dosed presoaks where the inuse-solution is not classified as corrosive at the highest recommended dosage. Corrosive manually dosed presoaks have to be sold with a pump for dosing or be connected to via product hose to a water source mixing the product to an "in-use-solution". The pump needs to be designed to provide correct dosage at the same time as it is minimizing the risk of exposure.

Products in containers smaller than 1 litre do not need to be sold together with a pump if the packaging has a childproof closure in accordance with ISO 9327:2004

Further information on risk phrases can be found in Appendix 6.

Please note that the manufacturer is responsible for the correct classification.

Material safety data sheet for the product complying with applicable legislation in the country of application such as Annex II of REACH (Council Regulation 1907/2006/EEC) and later additions and changes thereto. Appendix no. ____

Yes No

R4 Classification of constituent substances

Substances in the product or in the ingredients must not be classified in accordance with table 2 below, in accordance with the European Dangerous Substances Directive 67/548/EEC with amendments and/or the CLP (Classification, labelling and packaging) directive 1272/2008 as specified in Table 2.

During the transition period, ie until June 1st 2015, the classification according to the European Dangerous Substande Directive or the CLP directive can be used. After the transition period the products have to be classified according to the CLP directive.

Classification	Hazard symbol and risk phrase / Hazard category and statement		
	Dangerous Substances Directive 67/548/EEC	CLP Regulation 1272/2008	
Sensitizing*	Xn with R42 or Xi with R43	Resp. sens. 1 with H334 or Skin sens 1 with H317	
Carcinogenic	T with R45 and/or R49, Carc 1or Carc 2 or Xn with R40, Carc 3.	Carc 1A/1B/2 with H350, H350i and/or H351	
Mutagenic	T with R46, Mut 1 or Mut 2 or Xn with R68, Mut 3.	Mut 1B/2 with H340 and/ or H341	
Reproductive toxic	T with R60, R61, R64 and/or R33, Repr 1 or Rep 2 oe Xn with R62, R63, R64 and/or R33, Repr 3	Repr 1A/1B/2 with H360, H361 and/or H362	

Table 2 Classification of constituent substances

* Enzymes and preservatives are exempted from this – See separate requirements R6 and R8 on enzymes and preservatives.

- Material safety data sheet complying with applicable legislation in the country of application such as Annex II of REACH (Council Regulation 1907/2006/EEC) for each ingredient.
- Appendix 2 and 3 duly completed and signed, or equivalent signed declarations.

R5 Surfactants

All surfactants (irrespective of function) must display ready biodegradability under aerobic conditions in accordance with OECD Guidelines for the Testing of Chemicals, test no. 301 A F, or other equivalent scientifically proven test method. This is also a legal requirement for this category of products.

All surfactants must display biodegradability under anaerobic conditions according to ISO 11734, ECETOC no. 28 or equivalent test method. Documentation shall primarily refer to the DID list of 2007 or later. For surfactants not covered by the DID list, other documentation such as test reports and literature references may be submitted.

The DID list (Detergents Ingredients Database) is available on the Nordic Ecolabelling webpages (addresses page 2). The list can also be found on: http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/pdf/did_list/didlist_part_a_en.pdf

The documentation of the surfactants shall primarily refer to the DID list dated January 2007 or later. For surfactants not found on the DID list, other documentation such as test reports and literature references may be submitted (see Appendix 4). Appendix no. _____

Yes 📃 No 📃

Appendix no. ____

R6	Enzymes Enzymes must be in liquid form or dust-free granulate. Enzymes must be free from micro-organism remnants from manufacture. Products in spray bottles or designed for use in spray bottles or equivalent must not contain enzymes.	Yes No 📃
	The producer of the dishwasher detergent, rinse aid or presoak must take precautionary measures to ensure that users are not exposed to enzymes. Special protective equipment shall protect against high levels of exposure.	
\bowtie	Specification from the enzyme producer or details on the MSDS/product data sheet in accordance with the requirement.	Appendix no
\bowtie	Description of measures and methods to protect users.	Appendix no
R7	Prohibited substances The following constituent substances are prohibited from use in the product and ingredients:	Yes No 📃
	 Fragrances Reactive chlorine compounds Borates and perborates APEO (Alkyl phenol ethoxylates) APD (Alkylphenol derivatives) NTA (MGDA and GLDA complexing agents may however contain NTA contaminants in concentrations < 1.0%, as long as the concentration in the final product is < 0.10%) EDTA and associated salts Substances with potential for endocrine disruption of Category 1 or 2 in accordance with official EU lists. The EU report on endocrine disrupters can be read in full at http://ec.europa.eu/environment/endocrine/index_en.htm Nanomaterials/particles (size <100 nm) based on metal, carbon and/or fluorine compounds Substances that have been evaluated in the EU to be PBT or vPvB (see http://ecb.jrc.ec.europa.eu/esis/index.php?PGM=pbt) LAS (Linear alkylbenzene sulphonates) DADMAC (Diallyl dimethyl ammonium chloride) 	
\bowtie	Complete recipe for the product/products, as in requirement 2.	Appendix no
\bowtie	Appendix 2 and 3 duly completed and signed, or equivalent signed declaration.	Appendix no
R8	Preservatives The product may contain preservatives provide that the preservatives are not bioaccumulating. A preservative is not considered bioaccumulating if BCF < 500 or logK _{ow} < 4.0. If both BCF and logK _{ow} values are available, the highest measured BCF value shall be used. The concentration of every single substance classified as sensitizing, shall be	Yes 📄 No 📄
	< 0,10 %.	
\bowtie	Documentation of BCF or logK _{ow} .	Appendix no
\bowtie	Complete recipe for the product/products- see K2.	Appendix no
R9	Colouring agents Colouring agents must not be considered bioaccumulating. A colouring agent is not considered bioaccumulating if BCF < 500 or $\log K_{ow}$ < 4.0. If both BCF and $\log K_{ow}$ values are available, the highest measured BCF value shall be used. Colouring agents approved for use in foodstuffs can be approved.	Yes No 🗌
\bowtie	Documentation of BCF or logK _{ow} or specification of E-number for the colouring agent.	Appendix no

1.2 Total content of chemicals

The following section applies to a single component system of dishwasher detergent, rinse aid and presoak for professional use or the total quantity in the components of a multi-component system.

All components of a multi-component system for which the Nordic Ecolabel is sought must be included in the calculations. The calculations shall be based on the highest recommended dosage if the instructions specify different intervals. The limits in the criteria are set in (m)g / litre water, referring to (m)g / litre in-use-solution and (m)g / litre water in the dishwasher. All limit values exclude water.

R10 Environmentally hazardous substances

Substances that are classified as environmentally hazardous are permitted in limited quantities in single component dishwasher detergents and in multicomponent dishwasher detergent systems.

The inclusion of substances that are classified with any of the risk phrases R50/53, R51/53 or R52/53, alternatively are classified as Hazardous to the aquatic environment Category Chronic 1 H410, Category Chronic 2 H411 or Category Chronic 3 H412 is limited as specified below.

100 *A_{\tiny R50/53} + 10* A_{\tiny R51/53} + A_{\tiny R52/53} \leq 0,40mg/ litre water or:

100 *A_{{\rm H410}} + 10* A_{{\rm H411}} + A_{{\rm H412}} \leq 0,40mg/ litre water

At the highest recommended dose:

A_{R50/53} / H410 is the quantity of substances assigned R50/53 or H410 classification in milligrams per litre water.

A_{R51/53} / H411 is the quantity of substances assigned R51/53 or H411 classification in milligrams per litre water.

A_{R52/53} / H412 is the quantity of substances assigned R52/53 or H412 classification in milligrams per litre water.

Surfactants classified with H412 are exempted from the requirement, provided that they are readily degradable* and anaerobically degradable**.

* In accordance to the DID-list or test method No. 301 A-F or No. 310 in OECD guidelines for testing of chemicals or other equivalent test methods.

** In accordance to the DID-list or ISO 11734, ECETOC No. 28 (June 1988) or other equivalent test methods, where a minimum of 60% degradability under anaerobic conditions is achieved.

If no details of a substance's environmental properties are available it is considered environmentally hazardous with classification R50/53 / H410.

- Declaration of surfactants that are exempted from the requirement (quantity, classification, degradability).
- Summary of the content of substances and preparations classified as R50/53, R51/53 or R52/53 / H410, H411 or H412 in the products in milligrams per litre water.
- Calculations demonstrating the fulfilment of the requirement.
- Material safety data sheet for each ingredient in accordance with current regulations in the country of application, such as Annex II of REACH (Council Regulation 1907/2006/EEC) and later additions and changes thereto with an account of the substance's environmental hazard (acute aquatic toxicity, degradability and/or bioaccumulating properties).

Are the requirements met?

Yes No

Appendix no. _____

Appendix no.

Appendix no. _____

Appendix no.

R11 **Critical Dilution Volume (CDV)**

The critical dilution volume of a single or multi-component system must not exceed the limit values (at the highest recommended dose) in table 3. Acute values (CDV_{acute}) or for chronic (CDV_{chronic}) values may be used.

Parameter	Symbol (unit)	Dishwasher deter- gents and presoaks	Rinse aids	
Critical	CDV _{acute} (litre/litre water)	5000	8000	
Dilution Volume	CDV _{chronic} (litre/litre water)	1900	3000	

Documentation shall primarily refer to the DID list of 2007 or later. For substances not covered by this list, other documentation such as test reports and literature references may be submitted.

The DID list can be found on the Nordic Ecolabelling webpages (addresses page 2). The list can also be found on: http://ec.europa.eu/environment/ ecolabel/ecolabelled products/categories/did list en.htm

A worksheet for this calculation is available from Nordic Ecolabelling and can be downloaded from the Swedish and Danish Web sites:

http://www.ecolabel.dk/producenter/kriterier/kriterieliste/kriteriedetaljer?m aerke=Svanen&produktgruppe=80

http://www.svanen.se/en/Svanenmarka/Kriterier/Criteria/?productGroupID=76001

The calculation formula for CDV can be found in Appendix 4. The parameter and calculation formula are found in Section B of the guidelines to the DID list.

Calculation of CDV for the single or multi-component system demonstrating \bowtie compliance with the requirement. Specify whether the values are for CDVacute or CDV chronic. Documentation of each substance shall be refered to the DIDlist of 2007 or later. For substances that are not present on the list part B of the DID-list shall be used.

Aerobic Non-Biodegradable Organics (aNBO) and Anaerobic R12 Non-Biodegradable Organics (anNBO)

The total quantity of organic substances that are aerobic non-biodegradable or anaerobic non-biodegradable in the single or multi-component system for professional use (at the highest recommended dosage) must not exceed the limit values specified in the following table.

Note that special requirements apply for surfactants (see R5).

Table 4 Limit values for aerobic and anaerobic biodegradability at the highest recommended dosage

Parameter	Symbol (unit)	Dishwasher deter- gents and presoaks	Rinse aids
Aerobic non- biode- gradable organics	aNBO (g/l water)	0.4	0.04
Anaerobic non- bio- degradable organics	anNBO (g/l water)	0.4*	0.04*

*Iminodisuccinate (IDS) and cumene sulphonate are exempted from the requirements on anaerobic biodegradability.

Calculation of aNBO and anNBO. The parameters and formulas required to document this requirement can be found in Appendix 4.

A worksheet is available from Nordic Ecolabelling.

Appendix no.

Yes 📃 No 📃

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R13 **Phosphorous**

The total quantity of phosphates and other phosphorous compounds must not exceed the limit values specified in table 5, calculated in grams of phosphorous per litre water. The highest recommended dosage shall be used for the phosphorous calculations.

Table 5 Limit values for elementary phosphorous

Parameter	Symbol (unit)	Dishwasher detergents and presoaks	Rinse aids
Quantity of phosphorous	P (g /litre water)	0.08	0.04

Calculation of the total quantity of elementary phosphorous in g/l dishwater. \bowtie

R14 Phosphonates/phosphonic acids

The content of phosphonates/phosphonic acids must not exceed the limits specified in Table 6, calculated in grams per litre of dishwater. Dishwater refers to the in-use solution in the dishwasher. The highest recommended dosage shall be used for the calculations.

Table 6 Limit values for the content of phosphonates/phosphonic acids

Parameter	Symbol (unit)	Dishwasher deter- gents and presoaks	Rinse aids
Phosphonates/ phosphonic	Phosphonates/ phosphonic acids	0.01	0.006
acids	(g/litre water)		

Calculation of the total quantity of phosphonates/phosphonic acids in g/l water. \bowtie

1.3 **Dosage and packaging**

R15	Dosage The product must be easily dispensed using an automatic dosage system. If the product is dispensed manually, clear dosage instructions shall be provided.	Yes		No	
	Description of how dosage is normally performed. A dosing instruction for manually dosed products is required.	Арре	endix no	o	
R16	Plastic packaging and marking of packaging PVC and other halogenated plastics must not be used for packaging and labels. Plastic materials shall be marked in accordance with DIN 6120 part 2 or equivalent. Small parts (< 5g) are exempted from requirement about marking of packaging.	Yes		No	
	Product sheet or description demonstrating what types of plastic the packaging and label contain.	Арр	endix n	0	
	Documentation of primary packaging demonstrating that marking complies with DIN 6120 or equivalent marking regulations.	Арр	endix n	0	

Yes	No	

Yes

No 🔲

Appendix no.

Appendix no. _

Are the requirements met?

1.4	Mandatory information and declaration of ingredients	Are the require- ments met?
R17	Declaration of ingredients The declaration of ingredients shall comply with EU detergent regulation 648/2004/EC.	Yes No
	Material safety data sheet, technical product data sheet or copy of the label displaying the declaration of ingredients.	Appendix no
R18	Mandatory information Instructions for use stating the recommended dosage (g/l water) for app- ropriate water hardness values must be specified on the packaging or a product data sheet.	Yes No
\bowtie	Technical product data sheet or copy of the product label.	Appendix no
R19	User instructions and environmental advice User instructions with the following or equivalent text must found on the product data sheet or product label:	Yes No
	 Attempt to wash full machines whenever possible Avoid under or over dosing the detergent Wash at the lowest temperature possible resulting in hygienic dishes Information on disposal of empty packaging 	
	A printable version of user instructions shall be available (for example on the web).	
	Please contact the Nordic Ecolabelling body in the appropriate country for the texts applicable in the local language	
\bowtie	Copy of the product label or product data sheet demonstrating compliance with the requirement.	Appendix no
	Copy of the user instruction or link to the webpage where the information can be downloaded demonstrating compliance with the requirement.	Appendix no
1.5	Performance and user test	Are the require- ments met?
	erformance of the single or multi-component system must be satisfactory recommended dosage with soft water.	
R20	Performance and user test	Yes 📄 No 📄

The performance and efficiency of the product must be satisfactory. The product must satisfy the requirements for the user test in accordance with Appendix 5.

The results from tests from at least 8 test locations shall be submitted along with a report summarising these results and specifying the number and position of respondents.

Dosing must agree with the producer's recommendations. The test period must last for at least four weeks. At least 80% of test locations must assess the product as offering satisfactory or excellent performance on all accounts (see Appendix 5). Respondents must also be satisfied or very satisfied with the customer visit agreement. If products that are destined for use in instrumental maintenance within health care (as defined in the product group definition) are tested according to the standard ISO 15883 no user tests are required. In case a test report from a certified laboratory (see appendix 4, point 1) showing that the tests have been carried out according to the standard with satisfying results shall be included as documentation.

All complete, signed and submitted test reports. Use Appendix 5 or equivalent.

A report summarising the test results and specifying the number and position of respondents.

1.6 Customer visits and visit reports

R21 Customer visits and visit reports

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Customer visits shall be made during the licence period in accordance with the supplier's procedures and agreement with each customer. The manufacturer/ supplier must have a standard procedure for customer visits. In exceptional cases, a customer visit may be waived for occasional customers if the distance and method of delivery makes the visit impractical and difficult. The customer visit may be performed by a third party, such as a test institute or consultancy firm. The visit report shall be the supplier's standard visit report and contain the following items:

- Check that users have access to care instructions for the dishwasher.
- Measurement of water hardness or certificate from the water supplier (does not have to be measured every time, but water hardness needs to be documented at all customers).
- Dosage recommendation at the particular water hardness.
- Current dosage.
- Offer to provide an environmental advice poster* free of charge.
- * At least the following environmental advice must be included:
- Attempt to wash full machines whenever
- Do not leave the dishwasher on for extended periods when not in use
- Wash at the lowest temperature possible, resulting in hygienic dishes

Please contact the Nordic Ecolabelling body in the appropriate country for the texts applicable in the local language.

The Nordic Ecolabelling shall on request, in connection to a random inspection, have access to signed and completed visit reports. All visit reports shall be saved during the whole time that the license is valid.

- Copies of dated, signed and completed visit reports, containing the items listed above, from the at least eight customer visits that have been made to fulfil the performance requirements under Section 1.5.
- Written report specifying the general procedures for customer visits and information on who conducts the visits, how often visits are made and which customers are visited. If some customers are not visited a description of them and the reasoning for not visiting them is required.
- Routine for storing visit reports throughout the validity of the license.

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2	Quality and regulatory requirements	Are the require- ments met?
procedu system i procedu	are that Nordic Ecolabelling requirements are fulfilled, the following ares must be implemented. If the company's environmental management is certified to ISO 14 001, EMAS or equivalent, where the following ares are applied, it is sufficient if the accredited auditor reports that the ments are implemented.	
R22	Laws and regulations The licensee must guarantee adherence to safety regulations, working environment legislation, environmental legislation and conditions/conces- sions specific to the operations at all sites where the Nordic Ecolabelled dishwasher detergent is manufactured.	Yes 📄 No 📄
\bowtie	Signed application form.	Appendix no
R23	Licence administrators The company shall appoint a contact person responsible for ensuring the fulfilment of Nordic Ecolabel requirements.	Yes No 📃
	A chart of the company's organizational structure detailing the responsible contacts.	Appendix no
R24	Documentation The licensee must be able to present a copy of the application and factual and calculation data supporting the documents submitted on application (including test reports, documents from suppliers and suchlike).	Yes No 🗌
۶	Checked on site.	
R25	Quality of the dishwasher detergent The licensee must guarantee that the production quality of the Nordic Ecolabelled dishwasher detergent (single or multi-component system), rinse aid or presoak is maintained throughout the validity period of the licence.	Yes No
	Procedures for collating and, where necessary, dealing with claims and complaints regarding the quality of the Nordic Ecolabelled rinse aid, presoak or dishwasher detergent for professional use.	Appendix no
R26	Changes and nonconformities Written notice must be given to Nordic Ecolabelling of planned changes and unforeseen nonconformities that have a bearing on Nordic Ecolabel requirements.	Yes No 📃
\bowtie	Procedures detailing how changes and nonconformities are handled.	Appendix no
R27	Traceability The licensee must have a traceability system for the production of the Nordic Ecolabelled product.	Yes No 📃
\bowtie	Description of/procedures for the fulfilment of the requirement.	Appendix no

3	Take back system and marketing	Are the require- ments met?
R28	Take-back system National regulations, legislation and/or agreements within the sector regarding the recycling systems for products and packaging shall be met in the Nordic countries in which the company markets its dishwasher detergent.	Yes No 🗌
	Copies of agreements from the applicant demonstrating adherence to existing recycling/take-back agreements.	Appendix no
R29	Marketing Marketing of the Nordic Ecolabelled dishwasher detergent shall comply with "Regulations for the Nordic Ecolabelling of products" of 22 June 2011 or later version.	Yes No
\bowtie	Appendix 1 duly completed.	Appendix no

Marketing

The Nordic Ecolabel, the Swan, is a very well-known and well-reputed trademark in the Nordic region. Nordic Ecolabelled rinse aid, presoak or dishwasher detergent for professional use may be marketed using the Nordic Ecolabel as long as the associated licence is valid.

The label must be positioned so that there is no doubt as to what the label refers and so that it is clear that the rinse aid, presoak or dishwasher detergent for professional use is ecolabelled.

More information on marketing can be found in "Regulations for the Nordic Ecolabelling of products" of 22 June 2011 or later version.

Design of the Nordic Ecolabel

Design of the Nordic Ecolabel:



Each licence has a unique, six-digit licence number that must be displayed along with the label.

More information on the design of the label can be found in "Regulations for the Nordic Ecolabelling of products" of 22 June 2011 or later version.

Sales in other Nordic countries

Registering a licence in another Nordic country allows the Nordic Ecolabel to be used on a larger market. The following must be submitted to Nordic Ecolabelling:

- Application form for registration or original Nordic Ecolabel application*.
- Copy of licence.
- Copy of the product label and material safety data sheet.
- Documentation demonstrating the fulfilment of national regulations concerning the phosphorus concentration in the product takes precedence in the country of registration.
- Product turnover in the country of registration.
- Documentation regarding affiliation to a take-back system.
- Any marketing material for the country of registration.
- Description of procedures for customer visits in the country of registration.
- The supplier/distributor in the country of registration if other than the licensee.

* If the applicant specifies in the original application that the product should be registered in a further Nordic country, this is sufficient. Nordic Ecolabelling then collates and forwards the documentation to the country or countries in question.

Registration is free of charge but an annual fee shall be paid in accordance with the national regulations.

Follow-up inspections

Nordic Ecolabelling may decide to check whether the rinse aid, presoak or dishwasher detergent for professional use fulfils Nordic Ecolabelling requirements during the licence period. This may involve a site visit, random sampling or similar test.

The licence may be revoked if it is evident that the rinse aid, presoak or dishwasher detergent for professional use does not meet the requirements.

Random samples may also be taken from trade sources and analysed by an independent laboratory. If the requirements are not met, Nordic Ecolabelling may charge the analysis costs to the licensee.

How long is a licence valid?

Nordic Ecolabelling adopted version 2 of the criteria for dishwasher detergents for professional use on 21 June 2010. The criteria are valid until 30 June 2014.

The Secretariat Managers Meeting decided on 16 February 2011 to change R13 Phosphorus and to make an adjustment in the chapter "Sales in other Nordic countries". The new version is called 2.1.

The Secretariat Managers Meeting decided on 15 December 2011 to adjust the product group definition in order to clarify that also products destined for use in washer-disinfectors in instrument maintenance within health-care are covered by this criteria. Annexes 2 and 3 were adjusted and a couple of other minor corrections were made. The new version is called 2.2.

On 12 December 2012 the Nordic Ecolabelling Board adopted a change in R10. The new version is called 2.3.

The Secretariat Managers Meeting decided on 15 May 2013 to prolong the validity of the criteria document with 21 months. The new version is called 2.4 and it is valid until 31 March 2016.

An ecolabel licence is valid providing the criteria are fulfilled and until the criteria expire. The validity period of the criteria may be extended or adjusted, in which case the licence is automatically extended and the licensee informed.

Revised criteria shall be published at least one year prior to the expiry of the present criteria. The licensee is then offered the opportunity to renew their licence.

New criteria

The criteria for phosphorous will be reviewed and the possibility to forbid phosphate or phosphonates will be evaluated.

The possibility to impose energy requirements will be investigated.

The possibility to omit the exemption for IDS regarding anaerobic biodegradability will be re-evaluated.

Evaluate if CDV values for only chronic CDV can be used.

Evaluate the possibility to give credit (by scoring points or similar) to low water flow in the final rinse to lower the consumption of water. Evaluate the possibility to include requirements on other factors concerning for example problems with the machine.

Appendix 1 Marketing of Nordic Ecolabelled dishwasher detergents, rinse aids and presoaks

We hereby certify that we are well acquainted with the regulations governing the use of the Nordic Ecolabel, as detailed in "Regulations for the Nordic Ecolabelling of products" of 22 June 2011 or later version. We agree to follow these regulations when marketing the Nordic Ecolabelled product.

Further, we confirm that we are familiar with the criteria document regarding the Nordic Ecolabelling of dishwasher detergent for professional use.

We undertake to advise those individuals within the company involved in marketing the Nordic Ecolabelled dishwasher detergent for professional use of the criteria for the Nordic Ecolabelling of dishwasher detergent for professional use and "Regulations for the Nordic Ecolabelling of products" of 22 June 2011 or later version.

Location and date	Company
Signature, contact person	
Name in block capitals	Phone
Signature, marketing manager	
Name in block capitals	Phone

In case of a change in personnel, a new declaration must be submitted to Nordic Ecolabelling.

Appendix 2 Declaration from the manufacturer of dishwasher detergent for professional use

Use this appendix when applying for a Nordic Ecolabel licence for dishwasher detergent for professional use.

Constituent substances include all substances in the product, including additives in the ingredients (such as preservatives and stabilisers) but do not include impurities from primary production. Impurity refers to residues from primary production which may be found in the product at concentrations below 0.01% (100 ppm) provided the impurity has not been actively added for a particular purpose.

Even known substances released (such as formaldehyde and arylamines) from constituent ingredients are considered as constituent ingredients.

Product name:		
Type of product:		
Does the product contain fragrances?	Yes	No 📃
Does the product contain reactive chlorine compounds?	Yes	No 📃
Does the product contain borates or perborates?	Yes	No 📃
Does the product contain APEO?	Yes	No 📃
Does the product contain APD?	Yes	No 📃
Does the product contain NTA? If yes, indicate amount in product:	Yes 📃	No 📃
If yes, is NTA present as an impurity from MGDA or GLDA?	Yes	No 📃
Does the product contain EDTA?	Yes	No 📃
Does the product contain substances with potential for endocrine disruption of Category 1 or 2 in accordance with official EU lists? (See http://ec.europa.eu/envi-ronment/endocrine/documents/final_report_2007.pdf)	Yes 📃	No 📃
Does the product contain nanoparticles (< 100 nm) based on metal, coal and/or fluoride compounds?	Yes 📃	No 📃
Does the product contain substances that are evaluated by the EU as PBT or vPvB? (See http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)	Yes 📃	No 📃
Does the product contain LAS?	Yes	No 📃
Does the product contain DADMAC?	Yes	No 📃
Does the product contain colouring agent(s)? If yes, specify the E-number, BCF or logKow value:	Yes 📃	No 📃

Are there any substances classified with the following risk phrases in the product?

Xn with R42 or Xi med R43 / Resp. sens 1 with H334 or Skin sens 1 with H317 If yes, indicate concentration:	Yes 📃	No 📃
T with R45 and/or R49 (Carc 1 or Carc 2) or Xn med R40(Carc 3) /Carc 1A/1B/2 with H359, H350i and/or H351 If yes, indicate concentration:	Yes 📃	No 📃
T with R46 (Mut 1 or Mut 2) or Xn with R68 (Mut 3) / Mut 1B/2 with H340 and/or H341 If yes, indicate concentration:	Yes 📃	No 📃
T with R60, R61, R64 and/or R33 (Repr 1 or Repr 2) or Xn with R62, R63, R64 and/or R33 (Repr3) / Repr 1A/1B/2 with H360, H361 and/or H362 If yes, indicate concentration:	Yes 📃	No 🗌
If yes to any of the above question, please explain:		

In case new information gives reason to change the declaration, a new declaration shall be sent to Nordic Ecolabelling.

Date:	Company name:
Signature (person responsible):	<u> </u>
Name in block capitals:	E-mail/Phone:

Appendix 3 Declaration from the ingredient manufacturer

Use this appendix when applying for a Nordic Ecolabel licence for dishwasher detergent for professional use.

Constituent substances include all substances in the product, including additives in the ingredients (such as preservatives and stabilisers) but do not include impurities from primary production. Impurity refers to residues from primary production which may be found in the product at concentrations below 0.01% (100 ppm) provided the impurity has not been actively added for a particular purpose.

Even known substances released (such as formaldehyde and arylamines) from constituent ingredients are considered as constituent ingredients.

Ingredient name:		
Function of ingredient:		
Does the ingredient contain fragrances? If yes, indicate concentration:	Yes 📃	No 🗌
Does the ingredient contain reactive chlorine compounds? If yes, indicate concentration:	Yes	No 🗌
Does the ingredient contain borates or perborates? If yes, indicate concentration:	Yes	No
Does the ingredient contain APEO? If yes, indicate concentration:	Yes 📃	No 📃
Does the ingredient contain APD? If yes, indicate concentration:	Yes 📃	No 📃
Does the ingredient NTA? If yes, indicate concentration:	Yes	No
Does the ingredient contain EDTA? If yes, indicate concentration:	Yes	No 📃
Does the ingredient contain substances with potential for endocrine disruption of Category 1 or 2 in accordance with official EU lists? (See http://ec.europa.eu/ environment/endocrine/documents/final_report_2007.pdf) If yes, indicate concentration:	Yes 📃	No 📃
Does the ingredient nanoparticles (< 100 nm) based on metal, coal and/or fluoride compounds?	Yes	No 📃
If yes, indicate concentration: Does the ingredient contain substances that are evaluated by the EU as PBT or vPvB? (See http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp) If yes, indicate concentration:	Yes 📃	No 📃
Does the ingredient contain LAS? If yes, indicate concentration:	Yes	No 🗌
Does the ingredient contain DADMAC? If yes, indicate concentration:	Yes	No 📃
Does the ingredient contain colouring agent(s)? If yes, specify the E-number, BCF or logKow value:	Yes	No 📃

Are there any substances classified with the following risk phrases in the ingredient?

Xn with R42 or Xi med R43 / Resp. sens 1 with H334 or Skin sens 1 with H317* If yes, indicate concentration:	Yes	No 📃
T with R45 and/or R49 (Carc 1 or Carc 2) or Xn med R40(Carc 3) /Carc 1A/1B/2 with H359, H350i and/or H351 If yes, indicate concentration:	Yes 📃	No 📃
T with R46 (Mut 1 or Mut 2) or Xn with R68 (Mut 3) / Mut 1B/2 with H340 and/or H341 If yes, indicate concentration:	Yes 📃	No 📃
T with R60, R61, R64 and/or R33 (Repr 1 or Repr 2) or Xn with R62, R63, R64 and/or R33 (Repr3) / Repr 1A/1B/2 with H360, H361 and/or H362 If yes, indicate concentration:	Yes 📃	No 🗌
If yes to any of the above, please explain:		

* Enzymes and preservatives are excepted from the requirements for the sensitizing classifications (see requirement R4). Any addition of enzyme and preservatives shall be reported in this declaration despite the exemption.

In case new information gives reason to change the declaration, a new declaration shall be sent to Nordic Ecolabelling.

Date:	Company name:
Signature (person responsible):	
Name in block capitals:	E-mail/Phone:

Appendix 4 Test methods and equations

1 Requirements on the analysis laboratory

The analysis laboratory used shall fulfil the general requirements of standard EN ISO 17025 or have official GLP status.

The applicant's own analysis laboratory/test procedure may be approved for analysis and testing if:

- the analyses and tests are monitored by the authorities, or if
- the manufacturer has a quality management system encompassing sampling and analysis and has been certified to ISO 9001 or ISO 9002, or
- the manufacturer can demonstrate that it is consistent with the initial analysis/ testing performed as a parallel analysis/test by an accredited laboratory and the manufacturer's own laboratory and that the manufacturer takes samples in accordance with a predetermined sampling programme.

2 Ecotoxicological test methods

International test methods (OECD Guidelines for Testing of Chemicals, ISBN 92 64 1222144) or similar methods must be used. If equivalent methods are used, these must be evaluated by an independent body to ensure that the test results are equivalent. The test methods to be used are specified below.

3 Acute aquatic toxicity

Use test methods 201, 202 and 203 in the OECD Guidelines for the Testing of Chemicals (ISBN 92 64 1222144), or equivalent method to test aquatic acute toxicity.

4 Bioaccumulation

A substance is considered bioaccumulating if tested for bioaccumulation on fish according to method OECD 305 A E and its bioconcentration factor (BCF) is >500. If no BCF value has been determined, a substance is considered bioaccumulating if its logK_{ow} value \geq 4.0 according to method 107, 117 or 123 in the OECD Guidelines for the Testing of Chemicals (ISBN 92 64 1222144) or equivalent method, unless proven otherwise. If highest measured BCF \leq 500, the substance is not considered bioaccumulating even if logK_{ow} \geq 4.0.

OECDs test method 107 cannot be used for surface-active substances, which are both fat and water soluble. Based on current knowledge, for such substances it must be shown to a high degree of certainty that the substance itself and its decomposition products do not pose a long-term hazard to aquatic organisms.

Computer models (such as BIOWIN) are permitted but if the results of an approximation are close to the set limit values or if Nordic Ecolabelling holds contradictory information, more reliable information is required.

5 Aerobic biodegradability

Test methods 301 (A to F) or 310 in the OECD Guidelines for the Testing of Chemicals (ISBN 92 64 1222144) should be used to test aerobic biodegradability.

Other scientifically accepted test methods may also be used. The test results of such equivalent methods must be evaluated by an independent body.

6 Anaerobic degradability

Use ISO 11734, ECOTOC no. 28 (June 1988) or equivalent test method to determine anaerobic biodegradability. For a substance to be considered to biodegrade anaerobically, a mineralisation of >60% within 60 days is required (equivalent to >60% ThOD/ThCO₂ or >70% DOC reduction).

Substances, other than surfactants, that are not found on the DID list may be exempted from the requirement on anaerobic biodegradability if the substance displays:

- Ready aerobic biodegradability and low adsorption (A < 25%), or
- Ready aerobic biodegradability and high desorption (D < 25%), or
- Ready aerobic biodegradability and no potential to bioaccumulate.

Test method 106 in the OECD Guidelines or ISO CD 18749 "Water quality – Adsorption of substances on activated sludge" is used to establish adsorption/ desorption values.

7 DID list

The DID list is common to the European ecolabel and Nordic Ecolabelling. The list has been established in collaboration with stakeholders from industry and consumer and environmental organisations. The list contains information on the toxicity and biodegradability of substances that may be used in chemical/ technical products. The DID list does not show which substances can be used in ecolabelled products.

The DID list cannot be used to document the toxicity of individual substances for classification purposes. For this purpose, MSDS, pertinent literature and information from the ingredient supplier shall be used.

The DID list is available from the ecolabelling body or via the national ecolabel website (see page 2 for addresses).

Valid to these criteria is the DID list dated January 2007 or later.

8 CDV calculation

Critical dilution volume, CDV_{acute} and CDV_{chronic}, is calculated as follows:

 $CDV_{acute} = \sum CDV(i) = 1000 \sum dosage(i) \times DF(i) / TF_{acute}(i)$, or

 $CDV_{chronic} = \sum CDV(i) = 1000 \sum dosage(i) \ge DF(i) / TF_{chronic}(i)$

Dosage(i) = Dosage of ingredient(i), expressed in g/l

DF(i) = Degradation factor of ingredient (i), as specified on DID list.

 $TF_{acute}(i) = Acute toxicity factor of ingredient (i), as specified on DID list.$

 $TF_{chronic}(i) = Chronic toxicity factor of ingredient (i), as specified on DID list.$ DF and TF shall where possible be taken from the DID list dated January 2007 or later. The DID-list can be found on the Nordic Ecolabelling webpages (addresses page 2).

The list can also be found on:

http://ec.europa.eu/environment/ecolabel/ecolabelled_products/categories/pdf/did_list/didlist_ part_b_en.pdf

If an ingredient is not found on the DID list, the factors shall be set as follows:

DF (see also Part B of the DID list):

- 0.05 for organic substances that are readily biodegradable according to Appendix 2.
- 0.15 for organic substances that are readily biodegradable according to Appendix 2 but for which the 10-day window is not met (excluding surfactants).
- 0.5 for organic substances that are inherently biodegradable according to Appendix 2.
- 1.0 for persistent organic substances.

TF (see also Part B of the DID list):

TF = toxicity/SF,

where the toxicity is the lowest found acute LC50/EC50/IC50 value, and SF is determined according to the following.

SFacute (see also Part B of the DID list):

- 1 000 Substances with acute toxicity data for each of three trophic levels.
- 5 000 Substances with acute toxicity data for two trophic levels.
- 10 000 Substances with acute toxicity data for only one trophic level.

SFchronic (see also Part B of the DID list):

- 10 Substance with thee long-term NOEC from at least three species representing three trophic levels.
- 50 Substance with two long-term NOEC from at least two species representing two trophic levels.
- 100 Substances with one long-term NOEC (fish or crustaceans).

Appendix 5 User test

- 1. Responses must be gained from at least eight test locations representing a random selection of customers.
- 2. The procedure and dosing must be in accordance with the producer's recommendations.
- 3. The test period must last for at least four weeks.
- 4. Each test location shall evaluate the performance of the product by assessing the following areas:
 - The product's ability to remove soiling from the dishes.
 - The product's ability to dry the dishes.
 - The products ability to prevent mineral deposits on the dishes and dishwasher.
 - The respondent's satisfaction with the agreement on customer visits.
- 5. The answers must be assessed on a scale with at least three levels. E.g. "poor performance", "satisfactory performance" and "excellent performance". As regards the test location's satisfaction with the agreement on customer visits, the categories should be "not satisfied", "satisfied" and "very satisfied".
- 6. All returned and signed reports shall be sent in. The results from at least 8 test locations must submitted. At least 80% of test locations must assess the product as offering satisfactory performance or excellent performance on all accounts (see Item 4). Respondents must also be satisfied or very satisfied with the customer visit agreement.
- 7. All raw data from the test must be presented.
- 8. The test procedure must be presented in detail.
- 9. If products that are destined for use in instrumental maintenance within health care (as defined in the product group definition) are tested according to the standard ISO 15883 no user tests are required. In case a test report from a certified laboratory (see appendix 4, point 1) showing that the tests have been carried out according to the standard with satisfying results shall be included as documentation.

User test (dishwasher detergent, rinse aid and presoak for professional use)

Customer and test location (including address)

Name, function and producer of each product:

Recommended dosage ______ at _____ dH (water hardness) Actual dosage ______ at _____ dH (water hardness) Water temperature ______ °C

	Poor performance	Satisfactory performance	Excellent performance
Ability of the dishwasher detergent to remove soiling			
Ability of the rinse aid to dry the dishes			
The product's ability to prevent mineral deposits on the dishes			
The product's ability to prevent mineral deposits on the dishwasher			
How satisfied are you with the imple- mentation of the customer visits?			

Comments:

Description of the test procedure:

What is the test location's primary activity (e.g. hotel, restaurant or school)?

What type of soiling was most difficult to remove and from what type of goods?

How often are dishes rewashed?	
Other comments:	
Contact details of test location	
Contact person:	
E-mail:	
Phone:	

Name

Date, location

(Signature of contact person at the test location)

Appendix 6 Information on classifications (R3)

Dangerous for the environment

- R50: Very toxic to aquatic organisms
- R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
- R51/53: Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
- R52: Harmful to aquatic organisms
- R53: May cause long-term adverse effects in the aquatic environment
- R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
- H410: Very toxic to aquatic life with long lasting effects
- H411: Toxic to aquatic life with long lasting effects.
- H412: Harmful to aquatic life with long lasting effects
- H413: May cause long lasting harmful effects to aquatic life

Inhalation, oral, dermal

- R20: Harmful by inhalation
- R21: Harmful by contact with skin
- R22: Harmful if swallowed
- H332: Harmful if inhaled
- H312: Harmful in contact with skin
- H302: Harmful if swallowed

Corrosive

- R34: Causes burns
- R35: Causes severe burns
- H314: Causes severe skin burns and eye damage

Sensitization

- R42: May cause sensitization by inhalation
- R43: May cause sensitization by skin contact
- H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H317: May cause an allergic skin reaction

Cancer, teratogenic

R40:	Possible risk of cancer
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- R45: May cause cancer
- R49: May cause cancer by inhalation
- R46: May cause heritable genetic damage
- R60: May impair fertility
- R61: May cause featal damage
- R62: May cause risk for damage of fertility
- R63 Possible risk of harm to the unborn child
- R64: May harm children who are breastfeeding
- R68: My cause long lasting health effects
- H350: May cause cancer
- H351: Suspected to cause cancer
- H340: May cause genetic damage
- H341: May cause genetic defects
- H360: May harm fertility or the unborn baby
- H361: Suspected to harm fertility or the unborn baby.
- H362: May harm babies being breastfed