CRITERIA DOCUMENT – BASTA SYSTEM

VERSION 35.1

If differences occur between the English and Swedish version of the criteria document, the Swedish version is always superior to the English version.

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INTRODUCTION

ABOUT THE BASTA SYSTEM

The BASTA system's vision is that construction products are free of hazardous substances, they are based on renewable resources and can be circulated. BASTA supports the construction industry's sustainability work by defining requirements, spreading knowledge, and making information and tools available to facilitate conscious product choices.

The BASTA system provides support for sustainable product choices in several aspects – such as chemical content linked to health and environmental hazards, circularity, renewability, and environmental effects.

The BASTA system is an open system that gives anyone who wants to make conscious product choices access to quality-assured assessments of products. The products registered in the BASTA system receive a grade based on the criteria met. The different grades are a good guide for making sustainable product choices.

The criteria in the system are transparent and scientifically based and harmonised with European chemicals legislation, Regulation ((EG) 1907/2006) of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Regulation ((EG) 1272/2008) on Classification, Labelling and Packaging of substances and mixtures (CLP) and the Swedish Chemicals Agency's PRIO tool.

The BASTA system's criteria go beyond the legislation but never against:

- The BASTA system's concentration limits are set based on the legal limits for classification
- Where the legislation only covers chemical products, the BASTA system also covers articles
- The BASTA system has concentration limits or information requirements for substances
- > The BASTA system has criteria that cover the registering company and ensure that they have sufficient competence and procedures to maintain assessments and registrations over time
- BASTA performs audits of companies where the organization's and products' criteria fulfilment are examined

JOIN THE BASTA SYSTEM AND REGISTER PRODUCTS

The following section describes the process of joining the BASTA system and how to assess and register products.

1. READ THE CRITERIA DOCUMENT AND CONTRACT TERMS TO JOIN THE BASTA SYSTEM

Before a company joins the BASTA system and register its products, it is important to read the criteria document and the terms for registering products, which are contained in the agreement concluded between the company that wants to register products and BASTAonline AB.

2. ASSESSMENT AND DOCUMENTATION

It is the company's obligation to assess whether products to be registered meet the system's criteria and to save assessments along with the documents used. To register a product in the BASTA system, the company must meet the criteria described under the criteria area "<u>Organisation</u>" and the product must be assessed against all criteria under the criteria area "<u>Health and environmental hazards</u>". When registering, it must be stated which of the criteria the product meets, and which it does not. In order to make the assessment, the company must have complete documentation that shows whether the content of the product meet the criteria. How assessment is to be carried out and how assessment data is to be handled is described in criteria V35.O2: "<u>Assessment and documentation</u>" in the criteria area "<u>Organisation</u>".

3. CONNECT THE COMPANY TO THE BASTA SYSTEM

When the assessment is made and documentation has been compiled, the company can join the BASTA system. This is done through the following steps:

- 1. Create a personal user account at BASTAonline, via www.bastaonline.se/en
- 2. Log in to the user account
 - a. If the company has already joined the BASTA system, select "Connect to a company". This sends a request to connect to your company's existing users
 - b. If the company has not joined the BASTA system, select "Register new company" to create a new company. The company is activated when the agreement to join the BASTA system has been signed by the company and BASTAonline AB. The agreement contains the conditions that must be followed to be connected to the BASTA system

4. REGISTER PRODUCTS

When the company is activated on BASTAonline, users linked to the company can register products. Products must be registered at the article level, which means that each unique product must be registered as its own article. Example: if a product is available in three sizes, 1 litre, 5 litres and 10 litres, they should be registered as 3 articles.

A company can have multiple users registering and managing registered products. Registration can be done via manual entry or via an import file. All products registered shall be assessed and documented according to criteria V35.02: "Assessment and documentation" in the criteria area "Organisation".

5. UPDATING REGISTERED PRODUCTS

The company is obliged to ensure that assessments are updated if the composition of the product changes, the constituent substances get a changed classification or if the BASTA system's criteria are updated. See criteria V35.O3: "Update of assessment in case of changes" in the criteria area "Organisation".

6. AUDIT

Companies that have joined the BASTA system must approve that BASTAonline AB has audits carried out to check that assessments and documentation are correct. The audits also cover the company's subcontractors. See criteria V35.04: "BASTA audit" in the criteria area "<u>Organisation</u>".

CRITERIA AREAS

The BASTA system's criteria are divided into different criteria areas. To register a product in the BASTA system, it is mandatory to assess and declare whether the product meets the criteria in the criteria area "<u>Health and environmental hazards</u>". Companies registering products must also meet the criteria in the criteria area "Organisation".



Health and environmental hazards



effects

Organisation

Emissions

and tests

For the following criteria areas, it is optional to assess and declare criteria fulfilment:



CRITERIA AREA:

HEALTH AND ENVIRONMENTAL HAZARDS (MANDATORY)



This criteria area is the basis of the BASTA system and limits substances with different health and environmentally hazardous properties. The criteria area comprises 38 criteria which are divided into 11 areas.

When registering a product in the BASTA system, it is mandatory to assess and declare which of the criteria are met and which are not. Depending on the criteria met in this criteria area, the registered product receives a specific grade.

GRADES

In order for a product to receive a certain grade, specific criteria must be met, this is described under each criterion and in the summary of the criteria for health and environmental hazards. The rating levels provide guidance on a product's health and environmental performance without the need to check which individual criteria the product meets in order to make a sustainable product choice.

The BASTA system's grades are:

Grade BASTA



The BASTA grade is the highest level in the system. Products that meet this level meet criteria that limits phase-out substances and risk reduction substances according to the Swedish Chemicals Agency's "PRIO tool".

Grade BETA



The BETA grade is the second highest level in the system. Products that meet this level meet criteria that limits phase-out substances according to the Swedish Chemicals Agency's "PRIO tool".

Grade DEKLARERAD



Products registered with this grade do not meet all criteria to reach the BASTA or BETA grade. In order to register a product as DECLARED, full knowledge of the product's content and what criteria are fulfilled or not is required. For products registered as DECLARED, information is displayed about which criteria are met or not met. This provides the person making the product selection with information to be able to evaluate whether the product should be used or not.

Grade BETA to BASTA



This grade only applies to chemical products that are chemically altered when used, for example via curing or drying. The grade means that the product meets the grade BETA upon delivery, but that in its built-in stage meets the grade BASTA.

Grade DECLARED tO BASTA



This grade only applies to chemical products that are chemically altered when used, for example via curing or drying. The grade means that the product meets the grade DECLARED on delivery, but that in its built-in stage it meets the grade BASTA.

PRODUCT GROUP

ELECTRONICS

Products that contain components where complete content information is missing cannot be registered in any of the BASTA system's grades as this requires complete content information.

Not having complete content information is common for construction products that contain electronics and/ or electronic components. For this type of product to be registered, there is the product group ELECTRONICS. The purpose of the product group is to provide the opportunity for simplified declaration where the proportion of the product that meets different levels is reported. Products registered in this product group must comply with the RoHS directive.

When registering, the weight proportion of the product that meets the respective level is declared in the order listed below:

Grade: BASTA

Describe the proportion (by weight-%) of the product that meets the grade BASTA

Grade: BETA

Describe the proportion (by weight-%) of the product, in addition to the proportion that meets the BAS-TA grade, that meets the grade BETA

Grade: DECLARED

Describe the proportion (by weight-%) of the product, in addition to the proportion that meets the BAS-TA and BETA grade, that meets the grade DECLARED

RoHS

Describe the proportion (by weight-%) of the product, in addition to the proportion that meets any of the grades above, that meets the RoHS Directive

> Unknown

Please describe the proportion (by weight-%) of the product that does not meet any of the above levels

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METHODOLOGY FOR ASSESSMENT

Assessment and documentation

In order to assess whether the criteria are met, the joined company needs complete knowledge of the product's constituent substances, meaning 100% of the content. The company can ensure this by having full knowledge of the content itself or by obtaining guarantees from its sub suppliers via the sub supplier declaration.

To facilitate assessment and documentation, BASTA has developed an assessment template that can be found under Templates at <u>BASTAonline/Documents</u>. This can be used to document the constituent substances in the product, which criteria are met, and which documentation that has been used for the assessment. It is possible to make your own assessment documentation as long as it contains information about the constituent substances and which criteria that are met.

How an assessment is to be carried out and how assessment data is to be handled is described in criterion V34.02: "<u>Assessment and documentation</u>" in the criteria area "<u>Organisation</u>".

Calculation of the concentration of a substance

The concentrations of constituent substances are calculated based on the content of the product, as it is delivered to the construction site or equivalent. Chemicals that have been used in the manufacture but are not retained in the delivered product shall not be taken into account. If the product also contains propellant, such as in aerosols that is released by means of a propellant in sprays, it is the application that determines whether the propellant is to be included or not. BASTA follows how propellant gas is handled within CLP, see guidance regarding this (FAQ) on BASTA's website.

With product we mean any of the three options below.

1. Chemical products

A chemical product consists of a substance or mixture consisting of two or more substances. For chemical products, the content of constituent substances in the product is calculated based on the content of the product when it is delivered to the construction site.

2. Articles

An article is, according to the definition of REACH, Chapter 2 Article 3, an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. For articles, the content of constituent substances in the article is calculated based on the content of the article when it is delivered to the construction site.

3. Assembled articles

An assembled article is an article that has been assembled together by two or more articles, see definition of an article. For assembled articles, the assessment of compliance with the criteria shall be based on the content of the substance(s) in each individual article. The assessment of compliance shall not be based on the content of the assembled article, unless expressed under an individual criterion.

Two- (or multi-) component products are handled as follows:

Case 1: If the two components are sold together as ONE product, these should be handled as an assembled article. The product is registered as ONE article in BASTA. The assessment shall be based on the concentration of substances in the individual components, i.e. that is, the assessment should NOT be based on the total content of constituent substances in the assembled article. When registering the product, the criteria that are not met are reported.

Case 2: If the two components are sold separately as DIFFERENT products, these should be handled as two separate products. They must be registered as two separate articles in BASTA. The assessments shall be based on the concentration of substances in each article.

Concentration limit

All criteria in the criteria area "<u>Health and environmental hazards</u>" have concentration limits. If a substance (or summation of substances for certain criteria) exceeds a concentration limit, see "<u>Calculation of the</u> <u>concentration of a substance</u>" above, the criterion is not met. The concentration limits in the BASTA system refer to individual substances unless otherwise specified for the individual criterion.

The concentration limits are, where possible, based on concentration limits for classification of substances in the chemical legislation CLP. When summarising substances in mixtures, classification rules are applied to mixtures according to CLP. Where CLP specifies a limit value for classification of the product, the BASTA system applies that limit value as a concentration limit for constituent substances. The concentration limit applies to intentionally added substances as well as reaction products and impurities, unless otherwise specified under the specific criterion.

In cases where the classification of a chemical product that is a mixture differs from the individual classification of the constituent substances, the classification of the mixture applies.

Concentration limit for substances with specific concentration limits

CLP sets specific concentration limits for certain substances. This means that these substances have a different classification limit than the general classification limits.

In line with CLP, these specific concentration limits are also applied in the BASTA system. This means that if a substance has a specific concentration limit for classification, the specific concentration limit is used as the concentration limit for the relevant criterion in the BASTA system. This applies both to substances with harmonised classification and non-harmonised classification (self-classification) as well as substances to be summarised. If a summation is to take place, it is noted in the respective criterion. For a more detailed description, see "Calculation and summation rules".

Information on substances and any specific concentration limits can be found in CLP Annex VI and is searchable via <u>echa.europa.eu/</u> under information on classification and labelling "C&L". For products that have a safety data sheet, information on constituent substances is provided in section 3.

Example of substances with specific concentration limits:

Substance "2-methylisothiazolin-3(2H)-one" with CAS No 2682-20-4 has a specific concentration limit.

In ECHA's database <u>echa.europa.eu/</u>, you can view the following information via the "C&L Inventory":

Classification		Labelling			Specific Concentration limits,	Notes
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supple- mentary Hazard Statement Code(s)	Pictograms, Signal Word Code(s)	M-Factors, Acute Toxicity Estimates (ATE)	
Acute Tox. 3	H301	H301	EUH071	GHS09	Skin Sens. 1A; H317: C≥ 0.0015%	
Acute Tox. 3	H311	H311		GHS05		
Skin Corr, 1B	H314	H314		GHS06		
Eye Dam. 1	H318			Dgr	M=10	
Skin Sens. 1A	H317	H317		- 0.	M(Chronic)=1	
Acute Tox. 2	H330	H330				
Aquatic Acute 1	H400					
Aquatic Chronic 1	H410	H410				

The table above shows that there is a specific concentration limit for the hazard class skin sensitiser category 1A H317, "Skin Sens. 1A; H317", which applies from a concentration greater than or equal to 0.0015% (15 ppm).

This means that the specific concentration limit of 15 ppm replaces the concentration limit for the criterion V35.H7.C: Skin sensitiser – Category 1A (H317) for this substance, which must therefore not be present above 15 ppm if the product is to fulfil this criterion.

Classification of chemical products through testing

If a chemical product has been tested according to CLP for a classification that is covered by the BASTA system's criteria and the test result has led to a classification other than that based on the classification of constituent substances, it is the result of the test classification that should be compared with the relevant criteria.

Calculation and summation rules

If substances are to be summarised for a criterion, this means that the substances in the product covered by the criterion are to be added together and that it is the total concentration that is to be compared with the concentration limit.

The calculation and summation rules applied in the BASTA system are based on the rules in the CLP Regulation, (EG) No 1272/2008. For a better understanding of these rules, please read the "Guidance on the Application of the CLP Criteria" available for download here: <u>echa.europa.eu/guidance-documents/</u><u>guidance-on-clp</u>.

Declaration levels

There are two Declaration levels, which level to apply is described under each criterion.

The declaration levels are:



Declaration (R)

Declaration of whether or not the criterion is met

i Declaration with information requirements (i)

Declaration of whether or not the criterion is met. If the criterion is not met, information shall also be provided on the substance or substances causing the non-compliance with the criterion. This information shall include:

- Name of the substance(s)
- CAS or EC number of the substance(s) (If CAS or EC number exists for the substance)
- Weight-% range of substance(s)

The background to the two different levels of declaration is that for certain criteria it is considered particularly relevant to provide users with more information about which substances exceed the concentration limit. This may be because declaration of these substances is required for environmental certifications, or that there is reason for special monitoring of substances that are under investigation as substances of very high concern and are deemed to be subject to future restrictions in the legislation.

SUMMARY OF THE CRITERIA FOR HEALTH AND ENVIRONMENTAL **HAZARDS PART 1**

Areas CMR

Endocrine

disrupting

PBT/PMT

Particularly

hazardous

Hazardous to

Fluorinated

greenhouse gases Sensitising

Toxicity

the ozone layer

metals

(R) Declaration of whether concentration limit respective grade the criterion is met in CLP, this applies instead of the Declaration of whether concentration limit the criterion is met. If below) the criterion is not met and the substance or DECLARED substances causing the non-compliance with BASTA **SETA** the criterion Concentration Declaration **ASTA NSTA ASTA** Criteria limit (weight %) level Summation V35.H1.A Carcinogenicity - Category 1A or 1B (H350) 0.1% -R V35.H1.B Carcinogenicity - Category 2 (H351) 1% (R)V35.H1.C Germ cell mutagenicity - Category 1A or 1B 0.1% (R)(H340) Germ cell mutagenicity - Category 2 (H341) 1% V35.H1.D (R)Reproductive toxicity - Category 1A or 1B 0.3% V35.H1.E 8 (R)(H360)V35.H1.F Reproductive toxicity- Category 1A or 1B 0.1% 8 Ξ (R)(H360) (Requirement in the EU taxonomy) V35.H1.G Reproductive toxicity - Additional category 3% 8 (R)for effects on or via lactation (H361) V35.H1.H Reproductive toxicity - Additional category 0.3% R for effects on or via lactation (H362) Endocrine disruptors - Category 1 (EUH380 0.1% V35.H2.A Ø (R)and EUH430) V35.H2.B Endocrine disruptors - Category 2 (EUH381 1% (R)and EUH431) Substances excluded from "Criteria H2.A" 0.1% V35.H2.C 8 V35.H3.A Persistent, bio accumulative and toxic 0.1% 8 (R)substances (PBT) (EUH440) Very persistent and very bio accumulative 01% V35.H3.B (R)substances (vPvB) (EUH441) V35.H3.C Potentially PBT or vPvB 0.1% 6 V35.H3.D PFAS 0.1% Ø 8 V35.H3.E Persistent, mobile and toxic substances 0.1% \bigcirc (R)(PMT) - (EUH450) Very persistent and mobile substances 0.1% V35.H3.F (R)(vPvM) - (EUH451) Lead or compounds of lead (Pb) 0.1% V35.H4.A (R)Yes Lead or compounds of lead (Pb) + exemption 0.1 % + V35.H4.B (R)Yes for moving parts of machine steel 0.35% V35.H4.C Mercury or compounds of mercury (Hg) Total Ban (R)Ø Yes V35.H4.D Cadmium or compounds of cadmium (Cd) 0.01% Ø (R)Yes V35.H5.A Hazardous to the ozone layer – Category 1 0.1% (R)(H420) or regulation ((EG) 1005/2009) V35.H6.A Fluorinated greenhouse gases - F-gases 0.1% (R)Ø Ø V35.H7.A Respiratory sensitisers - Category 1A (H334) 0.1% (R)V35.H7.B Respiratory sensitisers - Category 1 and 1B 0.2% gases (H334) (R)1% solid-/liquid phase V35.H7.C Skin sensitisers – Category 1A (H317) 0.1% (R)Skin sensitisers - Category 1 and 1B (H317) 1% V35.H7.D (R)Acute toxicity - Category 1, 2 or 3 V35.H8.A Refers to the 1. Oral (H300, H301) (R)product's \sim Yes 2. Dermal (H310, H311) classification 3. Inhalation (H330, H331) V35.H8.B Specific target organ toxicity (single 1% (R)exposure) - Category 1 (H370)

(If a substance

has a specific

Criteria that must

be met to reach the

Declaration level

SUMM/ CRITE		F THE DR HEALTH	(If a substance has a specific concentration limit in CLP, this applies	Criteria that must be met to reach the respective grade			 Declaration level Declaration of whether the criterion is met Declaration of whether the criterion is met. If the criterion is not met and the substance or substances causing the non-compliance with the criterion 	
AND ENVIRONMENTAL HAZARDS PART 2			instead of the concentration limit below)	BASTA	BETA			
Areas	Criteria		Concentration limit (weight %)			BASTA D	Declaration level	Summation
<i>Continuation</i> Toxicity	<u>V35.H8.C</u>	Specific target organ toxicity (single exposure) – Category 2 (H371)	10%	Ø	-	-	R	
	<u>V35.H8.D</u>	Aspiration toxicity – Category 1 (H304) – Applies only to chemical products	Refers to the product's classification	Ø	-	-	R	Yes
	<u>V35.H8.E</u>	Specific target organ toxicity (repeated exposure) – Category 1 (H372)	1%	Ø	•	-	R	
	<u>V35.H8.F</u>	Specific target organ toxicity (repeated exposure) – Category 2 (H373)	10%	Ø	-	-	R	
VOC	<u>V35.H9.A</u>	Volatile organic compounds (VOC)	10%	Ø	•	-	R	Yes
Environ mentally hazardous	<u>V35.H10.A</u>	Hazardous to the aquatic environment – Category Acute 1 (H400)	Refers to the product's classification	Ø	-	-	R	Yes
	<u>V35.H10.B</u>	Hazardous to the aquatic environment – Category Chronic 1 or 2, (H410) or (H411)	Refers to the product's classification	Ø	-		R	Yes
	<u>V35.H10.C</u>	Hazardous to the aquatic environment – Category Chronic 3 (H412)	1%	-	-	-	R	
	<u>V35.H10.D</u>	Hazardous to the aquatic environment – Category Chronic 4 (H413)	Refers to the product's classification	Ø	-	-	R	Yes
Candidate List	<u>V35.H11.A</u>	Substances on the Candidate List	0.1%	-	-		0	

CRITERIA:

HEALTH AND ENVIRONMENTAL HAZARDS



Which criteria that needs to be fulfilled for each grade are specified under each criterion below, two options are available:

🕑 Must be fulfilled – Means that the criteria must be fulfilled for the product to pass the grade

Must be declared – Means that the criteria do not have to be fulfilled for the product to pass the grade, but criteria fulfilment must be reported at registration

H1: CMR – Carcinogenic, mutagenic or toxic to reproduction

ID: V35.H1.A Criterion: Carcinogenicity – Category 1A or 1B (H350) Concentration limit Declaration level Substances to be summarised Grade 0.1% ® Declaration No Image: Substance summarised Image: Substance summarised

Criteria fulfilment:

Substances meeting the criteria for the hazard class 'Carcinogenicity – Category 1A or 1B' (H350 – May cause cancer) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for phase-out substances.

ID: V35.H1.B	Criterion: Carcinogenicity – Category 2 (H351)					
	Concentration limit	Declaration level	Substances to be summarised	Grade		
	1%	R Declaration	No	🛇 🔜 BASTA — 🔜 BETA — 🔜 DECLARED		

Criteria fulfilment:

Substances meeting the criteria for the hazard class "Carcinogenicity – Category 2" (H351 – Suspected of causing cancer) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

ID:		
V35	.H1	.c

H1.C	Criterion: Germ cell mutagenicity – Category 1A or 1B (H340)					
	Concentration limit	Declaration level	Substances to be summarised	Grade		
	0.1%	R Declaration	No	오 🔜 BASTA 📀 🔜 BETA 😑 🔜 DECLARED		

Substances meeting the criteria for the hazard class "Germ cell mutagenicity – Category 1A or 1B" (H340 – May cause genetic defects) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for phase-out substances.

ID: V35.H1.D	Criterion: Germ	Criterion: Germ cell mutagenicity – Category 2 (H341)					
	Concentration limit	Declaration level	Substances to be summarised	Grade			
	1%	R Declaration	No	🕑 🔜 BASTA — 🔜 BETA — 🔜 DECLARED			

Criteria fulfilment:

Substances meeting the criteria for the hazard class "Germ cell mutagenicity – Category 2" (H341 – Suspected of causing genetic defects) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration</u> <u>limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for risk-reduction substances.

ID: V35.H1.E	Criterion: Repro	Criterion: Reproductive toxicity – Category 1A or 1B (H360)					
	Concentration limit		Substances to be summarised	Grade			
		R Declaration	No	🛇 🔜 BASTA 🛇 🔜 BETA — 🔜 DECLARED			

Criteria fulfilment:

Substances meeting the criteria for the hazard class 'Reproductive toxicity – Category 1A or 1B' (H360 – May damage fertility or the unborn child) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

H1.F	Criterion: Reproductive toxicity – Category 1A or 1B (H360) (requirement in the EU taxonomy)					
	Concentration limit	Declaration level	Substances to be summarised	Grade		
	0.1%	R Declaration	No	- ER BASTA - ER BETA - ER DECLARED		

Substances meeting the criteria for the hazard class 'Reproductive toxicity – Category 1A or 1B' (H360 – May damage fertility or the unborn child) are not present at concentrations equal to or above the concentration limit.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for phase-out substances.

Background:

This criterion has been added as the EU taxonomy has introduced a requirement, in "Appendix C" in The DNSH criteria for the environmental goal "Prevention and control of pollution". The requirement has a lower concentration limit than that in V35.H1.E. This requirement will be used to show if an article fulfils the chemical requirements in the taxonomy.

ID: V35.H1.G	Criterion: Repro	Criterion: Reproductive toxicity – Category 2 (H361)					
	Concentration limit	Declaration level	Substances to be summarised	Grade			
	3%	R Declaration	No	🛇 🔜 BASTA — 🔜 BETA — 🔜 DECLARED			

Criteria fulfilment:

Substances meeting the criteria for the hazard class 'Reproductive toxicity – Category 2' (H361 – Suspected of damaging fertility or the unborn child) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration</u> <u>limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for risk-reduction substances.

ID: V35.H1.H	Criterion: Repro	ductive toxicity	– Additional category for e	ffects on or via lactation (H362)
	Concentration limit	Declaration level	Substances to be summarised	Grade
	0.3%	R Declaration	No	🛇 🔜 BASTA — 🔜 BETA — 🔜 DECLARED

Criteria fulfilment:

Substances meeting the criteria for the hazard class "Reproductive toxicity – Additional category for effects on or via lactation" (H362 – May cause harm to breast-fed children) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

H2: Endocrine disrupting

ID: V35.H2.A		Criterion: Endocrine disruptors – Category 1 (EUH380 and EUH430) and substances covered by BASTAs methodology Step A and B				
	Concentration limit	Declaration level	Substances to be summarised	Grade		
	0.1%	R Declaration	No	🛇 🔜 BASTA 🛇 🔜 BETA 🚽 🔜 DECLARED		

Criteria fulfilment:

Substances meeting the criteria for being endocrine disrupting according to BASTAs methodology, are not present at concentrations equal to or above the concentration limit.

The methodology consists of three steps: A, B and C. In each step, substances that are endocrine disruptors are identified according to BASTA's methodology. To facilitate identification of these substances, all topics are summarized in BASTA's document "Substance list – Ämneslista" (Documents/Supporting documents at <u>www.bastaonline.se/en/document</u>), see more information under the section "Verification of criteria fulfilment" below.

Step A – Evaluation according to EU criteria

If a substance has been assessed as an endocrine disruptor according to Step A, the substance must not be present in a concentration equal to or above the concentration limit to meet this criterion (V35.H2.A). Substances are covered by Step A if any of the following criteria are met:

1. The substance is on the "Candidate List" of the REACH legislation due to endocrine disrupting properties (Article 57f)

2. The substance meets the criteria for any of the hazard classes below:

- 'Endocrine disruption for human health Category 1' (EUH380 May cause endocrine disruption in humans)
- 'Endocrine disruption for the environment Category 1' (EUH430 May cause endocrine disruption in the environment)

Definition of endocrine disruptors according to CLP: Commission delegated regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008.

Summary of criteria for endocrine disruptors (criteria 1, 2 and 3 to be met):

- 1. The substance has endocrine activity
- 2. It causes an adverse effect in an intact organism or its offspring or future generations
- 3. There is a biologically plausible link between the endocrine activity and the adverse effect.

If a substance has been evaluated by the EU and assessed as 'non-endocrine disruptor' according to the EU definition of endocrine disruptors, the substance is not covered by Step B or Step C.

Step B - Substances are listed on specific lists

If a substance is not covered by Step A, the substance shall be assessed according to Step B.

N.B. If the substance is classified with EUH381 "Suspected of causing endocrine disruption in humans" or EUH431 "Suspected of causing endocrine disruption in the environment", criterion V35.H2.B applies. For these substances no check against lists according to step B needs to be performed.

If a substance falls under Step B, the substance must not be present in a concentration above the concentration limit to meet this criterion (V35.H2.A). Substances are covered by step B if any of the following criteria are met:

- 1. The substance is listed on CoRAP (Community Rolling Action Plan) for endocrine disrupting properties. The list can be accessed from ECHA's website: www.echa.eu. Both substances that are included in CoRAP for evaluation, as well as substances that have been evaluated with a positive outcome, are covered
- 2. The substance is listed in the Danish Centre for Endocrine Disruptors' list, tables 8 and 13 in the "List of EDC". See <u>www.cend.dk</u> for more information
- 3. The substance is included on ChemSec's SIN list due to endocrine disrupting properties. See <u>www.sinlist.chemsec.org</u> for more information

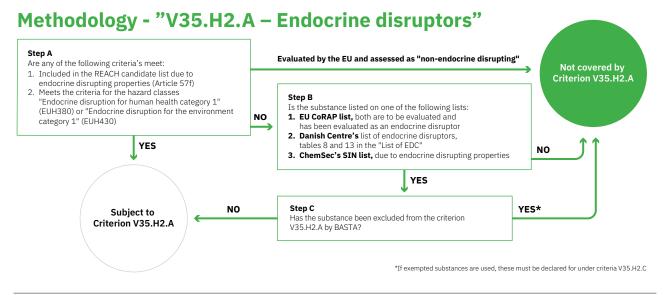
Step C – The exception of BASTA

If a substance is covered by Step B, the substance must be checked against BASTA's exemption list which is available on BASTA's website and in BASTA's document "Substance list – Ämneslista", see more under "Verification of criteria fulfilment" below.

If the substance is on the exclusion list, the substance is not covered by this criterion (V35.H2.A). However, the presence of the exempted substance shall be reported according to criterion V35.H2.C. No other supporting material needs to be submitted to BASTA if the substance has already been evaluated and included in the exemption list.

For new exemptions to be approved, documentation must be submitted to BASTAonline AB that allows an assessment to be made. More about this process is described on BASTA's website.

Visualization of the methodology



Background:

The methodology described above was developed in collaborative projects with the industry against the background that endocrine disruptors previously was not covered by classification and labelling according to CLP. The methodology is described in detail in the report: "Guidance document for handling criteria for endocrine disruptors in the construction industry" (IVL report B2369, 2020). Since the 20th of April 2023 there are new hazard classes for endocrine disruptors in place in CLP. During the transition period until 1st of May 2025, BASTA's methodology are applied for those substances that have not yet been assessed according to the new hazard classes.

CoRAP

A list of all substances listed on CoRAP can be found on the website: echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

Danish Centre for Endocrine Disruptors

Substances evaluated as endocrine disruptors by the Danish Centre for Endocrine Disruptors are included in the report <u>cend.dk/files/DK_ED-list-final_2018.pdf</u>.

Check the substance against Table 8 and Table 13. Detailed documentation on topics can be found in the annex to the report cend.dk/files/DK_ED-list-final_appendix1_2018.pdf.

SIN list

Substances on the SIN list due to endocrine disrupting properties are shown in the SIN list database at sinlist.chemsec.org.

It is possible to search directly by CAS number, EC number or substance name and to filter the search results with endocrine disrupting properties.

Verification of criteria fulfilment:

Use ECHA:s database C&L Inventory to see substance classifications, which contain information on substances' EUH phrases and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Also check substances against BASTA's document "Substance list – Ämneslista" (Documents/Supporting documents) which is published on <u>www.bastaonline.se/en/document</u>. Criteria fulfilment can also be checked against each list/organization's own databases, see links above. The sources databases are always superior to BASTA's substance list.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for phase-out substances.

Please note that BASTA's criteria is more extensive than the PRIO tool.

ID:	
V35.H2.B	Criterion: Endo

5.H2.B	Criterion: Endoc	rine disruptors	– Category 2 (EUH381 and	EUH431)
	Concentration limit	Declaration level	Substances to be summarised	Grade
	1%	R Declaration	No	🕑 🔜 BASTA — 🔜 BETA — 🔜 DECLARED

Substances meeting the criteria for any of the hazard classes below:

- 'Endocrine disruption for human health Category 2' (EUH381 Suspected of causing endocrine disruption in humans)
- 'Endocrine disruption for the environment Category 2' (EUH431 Suspected of causing endocrine disruption in the environment) are not present in concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "Concentration limits for substances with specific concentration limits" for more information.

Definition of suspected endocrine disruptors according to CLP: Commission delegated regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008.

A Substance shall be classified in Category 2 where all the following criteria are fulfilled:

1. There is evidence of:

- a. an endocrine activity and
- b. an adverse effect in an intact organism or it offspring or future generations
- 2. The evidence referred to in point (a) is not sufficiently convincing to classify the substance in Category 1
- 3. There is evidence of a biologically plausible link between the endocrine activity and the adverse effect

Background:

Previously, the subjects concerned were covered by the criterion H2.A. With the new hazard classification for endocrine disruptor Category 2, criterion H2.A is now divided into V35.H2.A and V35.H2.B. Definition of suspected endocrine disruptor is taken from Commission Delegated Regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008.

Verification of criteria fulfilment:

Use ECHA:s database C&L Inventory to see substance classifications, which contain information on substances' EUH phrases and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for risk-reduction substances.

ID: V35.H2.C	Criterion: Subst	ances excluded	from criteria V34.H2.A	
	Concentration limit	Declaration level	Substances to be summarised	Grade
	0.1%	Declaration with information requirements	No	- 🔜 BASTA - 🔜 BETA - 🔜 DECLARED

Criteria fulfilment:

Substances exempted under Step C in criteria "V35.H2.A - Endocrine disrupting" are not present at concentrations equal to or above the concentration limit.

Substances present at concentrations equal to or above the concentration limit shall be declared at registration.

Verification of criteria fulfilment:

Check substances against BASTA's document "Substance list – Ämneslista" (Documents/Supporting documents) which is published on www.bastaonline.se/en/document.

Current substances covered by the exemption are also available at (FAQ).

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion are not covered by the PRIO tool.

H3: PBT/PMT – Persistent, bio accumulative, toxic or mobile

ID: V35.H3.A	Criterion: Persis	tent, bioaccum	ulative and toxic substance	es (PBT) – (EUH440)
	Concentration limit		Substances to be summarised	Grade
	0.1%	R Declaration		📀 🔜 BASTA 📀 🔜 BETA — 🔜 DECLARED

Criteria fulfilment:

Substances meeting the criteria for PBT: persistent, bioaccumulative and toxic substances (EUH440 Accumulates in the environment and living organisms including in humans) are not present at concentrations equal to or above the concentration limit.

PBT substances are those meeting the criteria in point 1, 2 and 3 below.

- 1. Persistence: Half-life according to one of the following:
 - > 60 days in marine water
 - > 40 days in fresh- or estuarine water
 - > 180 days in marine sediment
 - > 120 days in fresh- or estuarine sediment
 - > 120 days in soil
- 2. Bioaccumulation: BCF (Bioconcentration Factor) > 2000 l/kg (wet weight)
- 3. Toxicity: According to a or b:
 - a. NOEC or EC10 < 0.01 mg/l
 - b. Classified according to one of the following:
 - i. Carcinogenicity category 1A or 1B (H350)
 - ii. Germ cell mutagenicity category 1A or 1B (H340)
 - iii. Reproductive toxicity category 1A, 1B or 2 (H360 or H361)
 - iv. Specific target organ toxicity (repeated exposure) category 1 or 2 (H372 or H373)
 - v. Endocrine disrupting for human or the environment, category 1 (EUH380 or EUH430)

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. Use ECHA's database and look under the substance's "Substance infocard" to find information about PBT properties. For chemical products, this information can also be found in the product's safety data sheet.

Background:

The definition is taken from is taken from Commission Delegated Regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008.

Connection to the Swedish Chemicals Agency's PRIO tool:

ID:	
V35.H3.B	Criteri

3	Criterion: Very p	ersistent and v	ery bioaccumulative substa	ances (vPvB) – (EUH441)
	Concentration limit	Declaration level	Substances to be summarised	Grade
	0.1%	R Declaration	No	🕑 🔜 BASTA 🕑 🔜 BETA 😑 🔜 DECLARED

Substances meeting the criteria for vPvB: very persistent and very bioaccumulative substances (EUH441 Strongly accumulates in the environment and living organisms including humans) are not present at concentrations equal to or above the concentration limit.

vPvB substances are those meeting the criteria in point 1 and 2 below.

1. Very persistent: Half-life according to one of the following

- > 60 days in marine-, fresh- or estuarine water
- > 180 days in marine-, fresh- or estuarine sediment
- > 180 days in soil
- 2. Very bioaccumulative: BCF (Bioconcentration Factor) > 5000 l/kg (wet weight)

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. Use ECHA's database and look under the substance's "Substance infocard" to find information about vPvB properties. For chemical products, this information can also be found in the product's safety data sheet.

Background:

The definition is taken from is taken from Commission Delegated Regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for phase-out substances.

ID: V35.H3.C	Criterion: Potent	tially PBT or vP\	/B	
	Concentration limit	Declaration level	Substances to be summarised	Grade
	0.1%	Declaration with information requirements	No	🛇 🔜 BASTA — 🔜 BETA — 🔜 DECLARED

Criteria fulfilment:

Substances listed in PRIO which are either :

• Potentially persistent, bioaccumulative and toxic (PBT)

and/or

• Potentially very persistent and very bioaccumulative (vPvB)

Are not present at concentrations equal to or above the concentration limit.

Substances present at concentrations equal to or above the concentration limit shall be declared at registration.

Verification of criteria fulfilment:

Check substances against the PRIO tool on KEMI:s webpage: https://www.kemi.se/prioguiden/english/start.

Connection to the Swedish Chemicals Agency's PRIO tool:

ID: V35.H3.D	Criterion: PFAS			
	Concentration limit	Declaration level		Grade
	0.1%	Declaration with information requirements	No	CO DECLARED

PFAS, according to the definition below, are not present at concentrations equal to or above the concentration limit.

Substances present at concentrations equal to or above the concentration limit shall be declared at registration.

Definition of PFAS:

PFAS is defined as fluorinated substances containing at least one complete fluorinated methyl- or methylene carbon atom (without any H/Cl/Br/I-atom attached to it), i.e., with a few noted exceptions, any chemicals with at least one perfluorinated methyl group (-CF3) or one perfluorinated methylene group (-CF2-) is a PFAS.

Background:

This distinction follows the OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoralkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris.

PFAS substances are very difficult to break down and some PFAS can have harmful effects, both for humans and the environment. The Swedish Chemicals Agency, together with four other European authorities, has developed a broad limitation proposal for PFAS in the EU. The proposal is currently being evaluated by the European Chemicals Agency, ECHA. A broad restriction of PFAS is expected to enter into force in 2025 at the earliest.

As PFAS are highly effective, only low concentrations are often needed to achieve the desired effect in the product. BASTA's current limit for PFAS is therefore relatively high in relation to the concentration expected to occur in construction products.

Substitution tools to identify alternatives: <u>The Substitution Centre</u> and <u>the Substitution Guide</u>, <u>the PRIO tool</u>, <u>the Chemsec Marketplace</u>, <u>The Alternative Assessment Database to PFAS</u>.

Verification of criteria fulfilment:

See the Swedish Chemicals Agency's PRIO tool with searchable database for substances classified as PFAS, www.kemi.se/prioguiden.

Connection to the Swedish Chemicals Agency's PRIO tool:

ID: V35.H3.E	Criterion: Persis	tent, mobile an	d toxic substances (PMT) –	(EUH450)
	Concentration limit	Declaration level	Substances to be summarised	Grade
	0.1%	R Declaration	No	🕑 🔜 BASTA 🕑 🔜 BETA 🚽 🔜 DECLARED

Substances meeting the criteria for PMT: persistent, mobile and toxic substances (EUH450 Can cause long-lasting and diffuse contamination of water resources) are not present at concentrations equal to or above the concentration limit.

PMT substances are those meeting the criteria in point 1, 2 and 3 below.

- 1. Persistence: Half-life according to one of the following:
 - > 60 days in marine water
 - > 40 days in fresh- or estuarine water
 - > 180 days in marine sediment
 - > 120 days in fresh- or estuarine sediment
 - > 120 days in soil
- Mobility: A substance shall be considered to fulfil the mobility criterion (M) when the log K_{oc} is less than 3. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest log K_{oc} value for pH between 4 and 9 is less than 3.
- 3. Toxicity: According to a or b:
 - a. NOEC or EC10 < 0.01 mg/l
 - b. Classified according to one of the following:
 - i. Carcinogenicity category 1A or 1B (H350)
 - ii. Germ cell mutagenicity category 1A or 1B (H340)
 - iii. Reproductive toxicity category 1A, 1B or 2 (H360 or H361)
 - iv. Specific target organ toxicity (repeated exposure) category 1 or 2 (H372 or H373)
 - v. Endocrine disrupting for human or the environment, category 1 (EUH380 or EUH430)

Background:

The definition is taken from is taken from Commission Delegated Regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Concentration limit Declaration level Substances to be summarised Grade	ID: V35.H3.F Crite	erion: Very persistent	and very mobile substances (v	PvM) – (EUH451)
	••••••		n level Substances to be summarised	l Grade
0.1% R Declaration No REBASTA RETA - R DECLA			ation No	🛇 🔜 BASTA 🛇 🔜 BETA 😑 🔜 DECLARED

Substances meeting the criteria for vPvM: very persistent and very mobile substances (EUH451 Can cause very long-lasting and diffuse contamination of water resources) are not present at concentrations equal to or above the concentration limit.

vPvM substances are those meeting the criteria in point 1 and 2 below.

- 1. Very persistence: Half-life according to one of the following:
 - > 60 days in marine water
 - > 60 days in fresh- or estuarine water
 - > 180 days in marine sediment
 - > 180 days in fresh- or estuarine sediment
 - > 180 days in soil
- 2. Very mobile: A substance shall be considered to fulfil the mobility criterion (vM) when the log Koc is less than 2. For an ionisable substance, the mobility criterion shall be considered fulfilled when the lowest log Koc value for pH between 4 and 9 is less than 2.

Background:

The definition is taken from is taken from Commission Delegated Regulation (EU) 2023/707 amending Regulation (EC) No 1272/2008.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for phase-out substances.

H4: Particularly hazardous metals

Criterion: Lead o	or compounds of	f lead (Pb)	
Concentration limit	Declaration level		Grade
0.1%	R Declaration	Yes	🗸 🔙 BASTA – 🔜 BETA – 🔜 DECLARED

Criteria fulfilment:

Lead or compounds of lead are not present at concentrations equal to or above the concentration limit.

If the criterion is not met, it is also needed to consider V35.H4.B.

Calculation and summation rules:

Summation of the total content of lead; In the case of lead compounds, only the content of lead needs to be counted.

Verification of criteria fulfilment:

Control of substances in the product, information can be found in safety data sheets (for chemical products) or in product declarations (for articles). If there is no complete content, the sub supplier declaration must be used.

Connection to the Swedish Chemicals Agency's PRIO tool:

ID:

Criterion: Lead or compounds of lead (Pb) + exemption for moving parts of machine steel

Concentration limit			Grade
0.1% and 0.35%	R Declaration	Yes	🛇 🔜 BASTA 🛇 🔜 BETA 🚽 🔜 DECLARED

If criterion H4.A is fulfilled, this criterion is fulfilled automatically.

Criteria fulfilment:

Non-moving parts:

Lead or compounds of lead are not present at concentrations equal to or above the concentration limit 0.1%. (Same criterion as H4.A).

Moving parts (Exceptions):

Lead or compounds of lead are not present at concentrations equal to or above the concentration limit 0.35% for components included in moving parts of the machine steel where fatigue resistance is required, e.g. espagnolettes.

Please note that espagnolettes are considered as an assembled product where the criterion must be met for each component. The total lead content of an assembled article, in which the sub-component is incorporated, must be less than 0.1%.

Products:

Lead or compounds of lead are not present in concentrations equal to or above 0.1% in the product.

Calculation and summation rules:

Summation of the total content of lead in the component; In the case of lead compounds, only the content of lead needs to be counted.

Verification of criteria fulfilment:

Control of substances in the product, information can be found in safety data sheets (for chemical products) or in product declarations (for articles). If there is no complete content, the sub supplier declaration must be used.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for phase-out substances.

Criteria fulfilment:

Mercury or mercury compounds are not to be present in the product, regardless of content. The ban applies to products where mercury has been used or added.

*Low concentrations of mercury that are not intentionally added in any stage thus fall outside the prohibition, but such traces/ contamination of mercury should not exceed 2.5 mg/kg. Deviations exceeding 2.5 mg/kg are permitted in cases where they stem from natural occurrence in coal, ore or ore concentrate.

Calculation and summation rules:

Summation of the total mercury content. In the case of mercury compounds, only the content of mercury needs to be counted.

Background:

The specified content of 2.5 mg/kg is based on The Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944), 20 § in which it is stated that agricultural sludge may not contain more mercury than 2.5 mg/kg dry matter.

Verification of criteria fulfilment:

Control of substances in the product, information can be found in safety data sheets (for chemical products) or in product declarations (for articles). If there is no complete content, the sub supplier declaration must be used.

Connection to the Swedish Chemicals Agency's PRIO tool:

Criterion: Cadmium or compounds of cadmium (Cd) Concentration limit Declaration level Substances to be summarised Grade 0.01% Poclaration Yes Poclaration Poc

Criteria fulfilment:

Cadmium or compounds of cadmium are not present at concentrations equal to or above the concentration limit.

Calculation and summation rules:

Summation of the total cadmium content. In the case of cadmium compounds, only the content of cadmium needs to be counted.

Verification of criteria fulfilment:

Control of substances in the product, information can be found in safety data sheets (for chemical products) or in product declarations (for articles). If there is no complete content, the sub supplier declaration must be used.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for phase-out substances.

H5: Hazardous to the ozone layer

ID.		
V35.	H5.A	

τь.

Criterion: Hazaro	Criterion: Hazardous to the ozone layer – Category 1 (H420) or regulation ((EG) 1005/2009)				
Concentration limit	Declaration level	Substances to be summarised	Grade		
0.1%	R Declaration	No	🛇 🔜 BASTA 🔗 🔜 BETA 🚽 🔜 DECLARED		

Criteria fulfilment:

Substances meeting the criteria listed in 1 or 2 below are not present at concentrations equal to or above the concentration limit:

- 1. Hazardous to the ozone layer Category 1" (H420 Harms public health and the environment by destroying ozone in the upper atmosphere)
- 2. Listed in Annex I or II to Regulation (EG) No 1005/2009 of the European Parliament and of the Council)

Background:

According to the "Guidance on the Application of the CLP Criteria", a substance is defined as ozone-depleting if the ODP (Ozone Depletion Potential) is equal to or greater than 0.005.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances. For chemical products, this information can also be found in the product's safety data sheet.

Check substances against BASTA's document "Substance list – Ämneslista" (<u>Documents/BASTAonline</u>) which is published on <u>www.bastaonline.se</u>. Verification of criteria fulfilment can also be checked directly in Annexes I and II to Regulation (EG) No 1005/2009 of the European Parliament and of the Council: <u>eur-lex.europa.eu/legal-content/SV/TXT/PDF/?uri=CELEX:02009R1005-20170419&qid=1622549998711&from=SV</u>. The council's regulation is always superior to BASTAs list.

Connection to the Swedish Chemicals Agency's PRIO tool:

H6: Fluorinated greenhouse gases

16.A	Criterion: Fluorinated greenhouse gases – F-gases				
	Concentration limit	Declaration level	Substances to be summarised	Grade	
	0.1%	R Declaration	No	🛇 🔜 BASTA 🛇 🔜 BETA – 🔜 DECLARED	

Criteria fulfilment:

Substances that are Synthetically produced fluorinated gases (F-gases) and listed in Annex I to Regulation (EU) 2024/573 of the European Parliament and of the Council) are not present at concentrations equal to or above the concentration limit.

Background:

Fluorinated greenhouse gases (F-gases) are a group of gases most commonly used to replace substances that can deplete the ozone layer.

They do not destroy the ozone layer but are very potent greenhouse gases that are thousands of times more powerful than carbon dioxide and contribute to global warming. Fluorinated greenhouse gases include hydrofluorocarbons (HFCs), perfluorocarbons (PFCs) and sulphur hexafluoride (SF6).

Verification of criteria fulfilment:

Check substances against BASTA's document "Substance list – Ämneslista" (Documents/BASTAonline) which is published on <u>www.bastaonline.se/document</u>. Verification of criteria fulfilment can also be checked directly towards the substances contained in Regulation ((EU) 2024/573) Annex I. The council's regulation is always superior to BASTAs list.

Connection to the Swedish Chemicals Agency's PRIO tool:

Some of the substances covered by this criterion meet the PRIO tool's criteria for phase-out substances. For more information, see the PRIO-tool.

H7: Sensitising

ID.
V35.H7.A

Criterion: Respir	Criterion: Respiratory sensitisers – Category 1A (H334)					
Concentration limit	Declaration level	Substances to be summarised	Grade			
0.1%	R Declaration	No	오 🔜 BASTA 📀 🔜 BETA 😑 🔜 DECLARED			

Criteria fulfilment:

Substances meeting the criteria for the hazard class 'Respiratory sensitisers – Category 1A' (H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion are covered by the PRIO tool.

ID: V35.H7.B	Criterion: Respiratory sensitisers – Category 1 and 1B (H334)			
	Concentration limit	Declaration level	Substances to be summarised	Grade
	0.2% gases	R Declaration	No	🖉 🔜 BASTA 🔮 🔜 BETA 🚽 🔜 DECLARED
	1% solid-/liquid phase			

Substances meeting the criteria for the hazard class "Respiratory sensitisers – Categories 1 and 1B" (H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for phase-out substances.

V35.H7.C	Criterion: Skin sensitisers – Category 1A (H317)			
	Concentration limit	Declaration level	Substances to be summarised	Grade
	0.1%	R Declaration	No	ELEM BASTA V LEM BETA - LAT DECLARED

Criteria fulfilment:

TD.

Substances meeting the criteria for the hazard class "Skin sensitisers – Category 1A" (H317 – May cause an allergic skin reaction) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

In cases where the classification of a chemical product that is a mixture differs from the individual classification of the constituent substances, the classification of the mixture applies.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet. See BASTA's website under questions and answers (FAQ) for clarification on the assessment of allergenic substances as the classification of the product may differ from the classification of the individual substances.

Connection to the Swedish Chemicals Agency's PRIO tool:

V35.H7.D	Criterion: Skin sensitisers – Category 1 and 1B (H317)			
	Concentration limit			Grade
	1%	R Declaration	No	🕑 🔜 BASTA — 🔜 BETA — 🔜 DECLARED

ID:

Substances meeting the criteria for the hazard class "Skin sensitisers – Categories 1 and 1B" (H317 – May cause an allergic skin reaction) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

In cases where the classification of a chemical product that is a mixture differs from the individual classification of the constituent substances, the classification of the mixture applies.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet. See BASTA's website under questions and answers (FAQ) for clarification on the assessment of allergenic substances as the classification of the product may differ from the classification of the individual substances.

Connection to the Swedish Chemicals Agency's PRIO tool:

H8: Toxicity

.A	Criterion: Acute toxicity – Category 1, 2 or 3					
	Concentration limit	Declaration level	Substances to be summarised	Grade		
	The product must not meet the criteria for the hazard class "Acute toxicity – Category 1, 2 or 3"	(R) Declaration	Yes, and it shall be carried out for each relevant route of exposure	🕐 🔜 BASTA — 🔜 BETA — 🔜 DECLARED		

Criteria fulfilment:

The ATE_{RI} value of the product, according to the summation rules below, must not result in a value equal to or less than specified limits:

- 1. Oral ATE_{BI}: 300
- 2. Dermal ATE_{BI}: 1000
- 3. Inhalation
 - a. Gas ATE_{RI}: 2500
 - b. Vapor ATE_{BI}: 10
 - c. Mist/ dust ATE_{BI}: 1.0

A product with an ATE_{BI}-value less than specified limits is classified in category 1, 2 or 3.

In the case of inhalation, calculations shall be performed for each relevant form substances may have in the air (gas, vapor, mist / dust).

The ATE of the product shall be calculated for all relevant routes of exposure, as determined by the classification of the constituent substances. Calculation of ATE_B-value for criteria control is not required for chemical products since that information can be obtained from the product's safety data sheet section 2. A product without substances classified as acutely toxic automatically meets this criterion.

Example: A chemical product containing one substance classified acute toxic dermal and oral, and another substance classified acute toxic dermal means that the ATE value of the product must be calculated for oral and dermal exposure. Inhalation in this case is not considered a relevant route of exposure.

Calculation shall be made based on substances meeting the criteria for the hazard class "Acute toxicity – Category 1, 2 or 3":

- 1. Oral (H300 Fatal if swallowed or H301 Toxic if swallowed)
- 2. Dermal (H310 Fatal in contact with skin or H311 Toxic in contact with skin)
- 3. Inhalation (H330 Fatal if inhaled or H331 Toxic if inhaled)

Calculation and summation rules:

ATE value of the mixture

If the toxicity of a mixture is not tested, it can be estimated from the toxicity of the constituent substances by calculating the ATE of the mixture.

This is done by adding the ATE values of the constituent substances (often LD50 or LC50 depending on the route of exposure) and their constituent concentrations in the product together according to the formula below. A description of how this is to be done can be found in: "Guidance on the Application of the CLP Criteria" Part 1: General Principles for Classification and Labelling, Section 1.6 : <u>echa.europa.</u> <u>eu/guidance-documents/guidance-on-clp</u>".

$$\frac{100}{ATE_{Bl}} = \sum_{i=1}^{N} \frac{C_i}{ATE_i}$$

Where:

Ν	is the number of substances which are classified as acute toxicity in category 1, 2 and 3 (H300, H310, H330, H301, H311 or H331)
i	represent each such substance

- C is the concentration in weight-% of each such substance (i) in the product
- ATE, is the acute toxicity for each substance (i) in the product
- $\mathsf{ATE}_{_{\mathsf{RI}}}$ is the calculated acute toxicity of the mixture

Summation by route of exposure

Summation shall be performed for each relevant route of exposure for which the substances show toxicity – oral, dermal and inhalation. Furthermore, in the case of inhalation, calculations shall be performed for each relevant form substances may have in the air (gas, vapor, mist/ dust).

Data missing

If the product contains substances that lack acute toxicity data (i.e. LD50 or LC50 values), further guidance may be provided in: "Guidance on the Application of the CLP Criteria", Section 3.1.

Point estimate

Table 3.1.2 of Annex I to CLP Regulation (EG) No 1272/2008, sets out the point estimates that can be used for the calculation of ATE_{BI} for each classification category and for each route of exposure.

Exposure routes	Classification Category	Converted acute toxicity point estimate, ATE,
Oral (mg/kg body weight)	Category 1	0.5
	Category 2	5
	Category 3	100
Dermal (mg/kg body weight)	Category 1	5
	Category 2	50
	Category 3	300
Inhalation of gases (ppmV)	Category 1	10
	Category 2	100
	Category 3	700
Inhalation of vapours (mg/l)	Category 1	0.05
	Category 2	0.5
	Category 3	3
Inhalation of dust/mist (mg/l)	Category 1	0.005
	Category 2	0.05
	Category 3	0.5

Verification of criteria fulfilment:

Criteria control for chemical products is done against its safety data sheet section 2.

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits.

See the assessment template for a calculation tool and examples at Documents/Supporting documents published at www.bastaonline.se/document.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for risk-reduction substances.

ID: V35.H8.B	Criterion: Specific target organ toxicity (single exposure) – Category 1 (H370)				
	Concentration limit	Declaration level	Substances to be summarised	Grade	
	1%	R Declaration	No	🛇 🔜 BASTA — 🔜 BETA — 🔜 DECLARED	

Criteria fulfilment:

Substances meeting the criteria for the hazard class 'Specific target organ toxicity (single exposure) – Category 1' (H370 – Causes damage to organs) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration</u> limits for substances with specific concentration limits" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

V35.H8.C	Criterion: Specific target organ toxicity (single exposure) – Category 2 (H371)				
	Concentration limit	Declaration level	Substances to be summarised	Grade	
	10%	R Declaration	No	🕑 🔜 BASTA — 🔜 BETA — 🔜 DECLARED	

Substances meeting the criteria for the hazard class 'Specific target organ toxicity (single exposure) - Category 2' (H371 - May cause damage to organs) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "Concentration limits for substances with specific concentration limits" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion are not covered by the PRIO tool.

1D: V35.H8.D	Criterion: Aspiration toxicity – Category 1 (H304) – Applies only to chemical products				
	Concentration limit	Declaration level	Substances to be summarised	Grade	
	The product must not meet the criteria for the hazard class "Aspiration Toxicity – Category 1" (H304)	(R) Declaration	Yes	EXAMPLE ASTA - MAR BETA - MAR DECLARED	

Criteria fulfilment:

The product (only applies to chemical products) does not meet the criteria for the hazard class "Aspiration Toxicity – Category 1" (H304 – May be fatal if swallowed and enters airways).

Calculation and summation rules:

The product's summarised concentration of substances that meets the criteria for the hazard class:

"Aspiration Toxicity – Category 1" (H304 – May be fatal if swallowed and enters airways) is not equal to or greater than 10% and the mixture has a kinematic viscosity lower than or equal to 20.5 mm²/s, measured at 40°C.

Summation rules come from CLP and in the case of interpretations, it is the rules in CLP that apply.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion are not covered by the PRIO tool.

ID: V35.H8.E	Criterion: Specific target organ toxicity (repeated exposure) – Category 1 (H372)				
	Concentration limit	Declaration level	Substances to be summarised	Grade	
	1%	R Declaration	No	🕑 🔜 BASTA — 🔜 BETA — 🔜 DECLARED	

Criteria fulfilment:

ID:

Substances meeting the criteria for the hazard class Specific target organ toxicity (repeated exposure) – Category 1' (H372 – Causes damage to organs through prolonged or repeated exposure) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "Concentration limits for substances with specific concentration limits" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for risk-reduction substances.

V35.H8.F	Criterion: Specific target organ toxicity (repeated exposure) – Category 2 (H373)					
	Concentration limit	Declaration level		Grade		
	10%	R Declaration	No	📀 🔜 BASTA — 🔜 BETA — 🔜 DECLARED		

Criteria fulfilment:

Substances meeting the criteria for the hazard class Specific target organ toxicity (repeated exposure) – Category 2' (H373 – May cause damage to organs through prolonged or repeated exposure) are not present at concentrations equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the concentration limit. See "<u>Concentration limits for substances with specific concentration limits</u>" for more information.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances and any specific concentration limits. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion are not covered by the PRIO tool.

H9: VOC – Volatile organic compounds

TD.

Criterion: Volatile organic compounds (VOC)					
Concentration limit	Declaration level	Substances to be summarised	Grade		
10%	R Declaration	Yes	🛇 🔜 BASTA — 🔜 BETA — 🔜 DECLARED		

Criteria fulfilment:

Substances meeting the criteria listed in 1 and 2 below shall be added together. The total content shall not be equal to or higher than the concentration limit.

- 1. Organic substances initial boiling point < 250°C measured at a standard pressure of 101.3
- 2. Organic substances meeting the criteria for any of the following hazard statements:
 - Acute toxicity Category 1 or 2 (H330 Fatal if inhaled)
 - Acute toxicity Category 3 (H331 Toxic if inhaled)
 - Acute toxicity Category 4 (H332 Harmful if inhaled)
 - Specific target organ toxicity (single exposure) Category 2 (H371 May cause damage to organs)
 - Specific target organ toxicity (single exposure) Category 3 (H336 May cause drowsiness or dizziness)
 - Specific target organ toxicity (repeated exposure) Category 2 (H373 May cause damage to organs through prolonged or repeated exposure)

Calculation and summation rules:

Summation of substances meeting criteria 1 and 2 above.

Background:

The initial boiling point is set on the basis of EU Directive on the limitation of emissions of volatile organic compounds <u>2004/42/EC</u>. The concentration limit has been set based on industry agreements for paints, varnishes, and adhesives. The hazard statements selected in this criterion concern only properties hazardous to health.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, which provides information on the H-phrases of substances. For chemical products, this information can also be found in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion are not covered by the PRIO tool.

H10: Environmentally hazardous

Criterion: Hazardous to the aquatic environment – Category Acute 1 (H400)

Concentration limit	Declaration level	Substances to be summarised	Grade
The product must not meet the criteria for the hazard class "Hazardous to the aquatic environment – Category Acute 1" (H400)	(R) Declaration	Yes	EASTA - RETA - RECLARED

Criteria fulfilment:

The summarised concentration of substances of the product, according to the summation rules below, is not equal to or greater than 25%.

The summation is based on concentration of and M-factor for substances meeting the criteria for the hazard class:

• "Hazardous to the aquatic environment - Category: Acute 1" (H400 - Very toxic to aquatic life)

Calculation and summation rules:

The summation shall be based on substances meeting the criteria for the hazard class – "Hazardous to the aquatic environment – Category: Acute 1" (H400) if its concentration is greater than or equal to 0.1 divided by its M-factor (defined according to CLP), see below for further explanation.

- M-factor = 1 means that H400 substances should be included if their concentration $\geq 0.1\%$
- M-factor = 10 means that H400 substances should be included if their concentration $\ge 0.01\%$
- M-factor = 100 means that H400 substances should be included if their concentration ≥ 0.001%

The criterion is not met if the summation according to the equation below is equal to or greater than 25%.

$$\sum_{i}^{N} (C_i * M_i) \ge 25\%$$

Where:

- N is the number of substances to be taken into account in summation
- i represents each such substances
- C_i is the concentration by weight-% of each such substance (i)
- M_i is the multiplying factor, which is often found in the substance's REACH dossier, C&L inventory or supplier's safety data sheet. If this is not the case, use the table below to determine the M-factor of substance (i)

L(E)C ₅₀ value (mg/l)	M-factor
$0.1 < L(E)C_{50} \le 1$	M = 1
$0.01 < L(E)C_{50} \le 0.1$	M = 10
$0.001 < L(E)C_{50} \le 0.01$	M = 100
0.0001 < L(E)C ₅₀ ≤ 0.001	M = 1 000

Continue in factor 10 intervals

Example:

A product contains, among other things, the substances below:

- Substance 1 is classified H400 with M = 1 and a concentration of 10%
- Substance 2 is classified H400 with M = 10 and a concentration of 1%
- Substance 3 is classified H400 with M = 1 and a concentration of 0.01%

In order to know whether substances 1, 2 and 3 should be included into account, the concentration of H400 substances shall be equal to or greater than the ratio of 0.1/M:

- Substance 1: 0.1/1 = 0.1 means that the substance should be included because 10% > 0.1
- Substance 2: 0.1/10 = 0.01 means that the substance should be included because 1% > 0.01
- Substance 3: 0.1/1 = 0.1 means that the substance should not be included because 0.01% < 0.1

$$\sum_{i}^{N} (C_{i} * M_{i}) = (C_{\text{ämne 1}} * M_{1}) + (C_{\text{ämne 2}} * M_{2}) = (10 * 1) + (1 * 10) = 10 + 10 = 20 < 25\%$$

The summarised content is less than 25%, which means that the criterion is met.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database or the substance's REACH dossier to see its classification and M-factor. For chemical products, this information can also be found in the product's safety data sheet. See BASTA's assessment template for calculation support and examples at Document/Supporting documents published at <u>www.bastaonline.se/documents</u>.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion are not covered by the PRIO tool.

ID: V35.H10.B	Criterion: Hazardous to the aquatic environment – Category Chronic 1 or 2, (H410) or (H411)					
	Concentration limit	Declaration level	Substances to be summarised	Grade		
	The product must not meet the criteria for the hazard class "Hazardous to the aquatic environment: Chronic 1 or 2" (H410) or (H411)	R Declaration	Yes	EX BASTA - REFA - RECLARED		

Criteria fulfilment:

The summarised concentration of substances of the product, according to the summation rules below, is not equal to or greater than 25%.

The summation is based on concentration of and M-factor for substances meeting the criteria for the hazard classes:

- "Hazardous to the aquatic environment Category: Chronic 1" (H410 Very toxic to aquatic life with long lasting effects)
- "Hazardous to the aquatic environment Category: Chronic 2" (H411 Toxic to aquatic life with long lasting effects)

Calculation and summation rules:

The summation shall be based on substances meeting the criteria for the hazard class "Hazardous to the aquatic environment – Category: Chronic 1 or 2" (H410 or H411).

Substances classified H410 should be considered if their concentration is greater than or equal to 0.1 divided by its M-factor (defined according to CLP), see below for further explanation. Substances classified H411 shall be considered if their concentration is equal to or greater than 1%.

- M-factor = 1 means that H410 substances should be included if their concentration ≥ 0.1%
- M-factor = 10 means that H410 substances should be included if their concentration ≥ 0.01%
- M-factor = 100 means that H410 substances should be included if their concentration $\ge 0.001\%$

The criterion is not met if the summation according to the equation below is equal to or greater than 25%.

$$\sum_{j=1}^{S} M_i * C_j * 10 + \sum_{k=1}^{T} C_k \ge 25\%$$

Where:

- S is the number of substances meeting the criteria for the hazard class "Hazardous to the aquatic environment Category: Chronic 1" (H410)
- T is the number of substances meeting the criteria for the hazard class "Hazardous to the aquatic environment Category: Chronic 2" (H411)
- j represents each H410 substance in the product
- k represents each H411 substance in the product
- C, is the concentration by weight-% of each H410 substance in the product
- C_k is the concentration by weight-% of each H411 substance in the product
- M_i is the multiplying factor, which is often found in the substance's REACH dossier, C&L inventory or supplier's safety data sheet. If this is not the case, use the table below to determine the M-factor of substance (i)

NOEC-value (mg/l)	M-factor (Non-rapidly degradable)	M-factor (Rapidly degradable)
$0.01 < (NOEC eller EC_{10}) \le 0.1$	M = 1	-
$0.001 < (\text{NOEC eller EC}_{10}) \le 0.01$	M = 10	M = 1
$0.0001 < (NOEC eller EC_{10}) \le 0.001$	M = 100	M = 10
$0.00001 < (NOEC eller EC_{10}) \le 0.0001$	M = 1 000	M = 100
$0.000001 < (NOEC eller EC_{10}) \le 0.00001$	M = 10 000	M = 1 000

Continue in factor 10 intervals

Example:

A product contains, among other things, the substances below:

- Substance 1 is classified H410 with M = 1 and a concentration of 10%
- Substance 2 is classified H410 with M = 1 and a concentration of 0.01%
- Substance 3 is classified H411 with a concentration of 1%

In order to know whether substances 1 and 2 are to be included, the concentration of H410 substances shall be equal to or greater than the ratio of 0.1/M:

• Substance 1: 0.1/1=0.1 means that the substance should be included because 10% > 0.1

- Substance 2: 0.1/1=0.1 means that the substance should not be included because 0.01% < 0.1

In order to know whether substance 3 should be included, its concentration should be \geq 1%:

• Substance 3: Concentration is 1%, which means that the substance should be included

$$\sum_{j=1}^{S} M_i * C_j * 10 + \sum_{k=1}^{T} C_k = (C_{amne_1} * M_1 * 10) + C_{amne_3} = (10 * 1 * 10) + 1 = 100 + 1 = 101 > 25\%$$

The summarised content exceeds 25%, which means that the criterion is not met.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database or the substance's REACH dossier to see its classification and M-factor. For chemical products, this information can also be found in the product's safety data sheet.

See BASTA's assessment template for calculation support and examples at Document/Supporting documents published at www.bastaonline.se/documents.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion meet the PRIO tool's criteria for risk-reduction substances.

ID: V35.H10.C	Criterion: Hazardous to the aquatic environment – Category Chronic 3 (H412)			
	Concentration limit	Declaration level	Substances to be summarised	Grade
	1%	R Declaration	No	- 🔜 BASTA - 🔜 BETA - 🔜 DECLARED

Criteria fulfilment:

Substances meeting the criteria for the hazard class "Hazardous to the aquatic environment – Category: Chronic 3 (H412)" are not present at levels equal to or above the concentration limit.

For substances with specific concentration limits in CLP, these shall be applied instead of the general concentration limit. See "Content limit for substances with specific concentration limits" for more information.

Background:

This criterion has been added as the CSRD Directive has requirements of SoCs (substances of concern) in the ESRS E2 pollution standard (<u>09 Draft ESRS E2 Pollution November 2022.pdf</u>). The remaining requirements for SoC substances are addressed in other criteria within BASTA. This requirement will be used to demonstrate whether an article meets the chemical requirements of the CSRD Directive.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database to view substance classifications, where information on the H-phrases of substances and any specific concentration limits can be found. For chemical products, this information is also available in the product's safety data sheet.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion are not covered by the PRIO tool.

H10.D	Criterion: Hazardous to the aquatic environment – Category Chronic 4 (H413)			
	Concentration limit	Declaration level	Substances to be summarised	Grade
	The product must not meet the criteria for the hazard class "Hazardous to the aquatic environment: Chronic 4 (H413)	(R) Declaration	Yes	E BASTA – E BETA – E DECLARED

Criteria fulfilment:

The summarised concentration of substances of the product, according to the summation rules below, is not equal to or greater than 25%.

The summation is based on concentration of substances meeting the criteria for the hazard class:

- "Hazardous to the aquatic environment Category: Chronic 1" (H410 Very toxic to aquatic life with long lasting effects)
- "Hazardous to the aquatic environment Category: Chronic 2" (H411 Toxic to aquatic life with long lasting effects)
- "Hazardous to the aquatic environment Category: Chronic 3" (H412 Harmful to aquatic life with long lasting effects)
- "Hazardous to the aquatic environment Category: Chronic 4"(H413 May cause long lasting harmful effects to aquatic life)

Calculation and summation rules:

The summarised concentration of substances meeting the criteria for the hazard class "Hazardous to the aquatic environment – Category: Chronic 1, 2, 3 or 4" (H410, H411, H412 or H413).

Example:

A product contains, among other things, the substances below:

- Substance 1 is classified H410 with a concentration of 10%
- Substance 2 is classified H411 with a concentration of 1%
- Substance 3 is classified H412 with a concentration of 0.1%
- Substance 4 is classified H413 with a concentration of 10%

Substance 1 + Substance 2 + Substance 3 + Substance 4 = 10 + 1 + 0.1 + 10 = 21.1 < 25%.

The summarised content is less than 25%, which means that the criterion is met.

Verification of criteria fulfilment:

Use ECHA's C&L Inventory database or the substance's REACH dossier to see its classification. For chemical products, this information can also be found in the product's safety data sheet. See BASTA's assessment template for calculation support and examples at Document/Supporting documents published at <u>www.bastaonline.se/documents</u>.

Connection to the Swedish Chemicals Agency's PRIO tool:

Some substances covered by this criterion meet the PRIO tool's criteria for risk-reduction substances.

H11: Candidate List

ID: V35.H11.A	Criterion: Candie	date List		
	Concentration limit	Declaration level		Grade
	0.1%	Declaration with information requirements	No	- 🔜 BASTA - 🔜 BETA - 🔜 DECLARED

Criteria fulfilment:

Substances on the Candidate List (substances of very high concern (SVHC)) are not present at concentrations equal to or above the concentration limit.

Substances present at concentrations equal to or above the concentration limit shall be declared at registration.

Background:

Substances on the Candidate List, <u>www.echa.europa.eu/sv/candidate-list-table</u>, have been identified as SVHCs, i.e. substances of very high concern. Examples of properties that make a substance eligible for the candidate list are CMR-substances, PBT-substances, vPvB-substances, endocrine disruptors, allergenic substances, and specific organ toxicity. Substances with these properties are covered by the other BASTA criteria, but the substances may nevertheless be present in registered articles at concentrations above 0.1% depending on the concentration limit for each criterion.

Substances on the Candidate List risk ending up in REACH Annex 14 or 17, which means that they may be subject to authorisation requirements or restrictions.

Verification of criteria fulfilment:

Check substances against BASTA's document "Substance list – Ämneslista" which is published on <u>BASTAonline/Documents/Supporting</u> <u>documents/</u>.

Compliance with the criteria can also be checked directly against the Candidate List. The Candidate List is always superior to BASTA's substance list.

Connection to the Swedish Chemicals Agency's PRIO tool:

Substances covered by this criterion are not covered by the PRIO tool.

ORGANISATION (MANDATORY)



V35.01 Criterion: Responsibility list and competence

Criteria fulfilment:

ID:

ID:

Persons within the company or contracted consultants, who carry out assessments of products, handle documentation and/or are responsible for registration in the BASTA system must have competence according to the list below:

- 1. Adequate knowledge of the substance content of the products in question
- 2. Adequate knowledge of the BASTA system's criteria
- 3. Adequate knowledge of health and environmental assessment of chemical substances and products
- 4. Adequate knowledge of REACH, the European regulatory system for chemicals control
- 5. Adequate knowledge of classification and labelling of chemical substances according to CLP

The competence must be documented in a responsibility list together with name, title and contact information. In the event of an audit, competence must be proven by presenting a transcript of education, CV or similar.

The company shall ensure that the responsibility list is updated in the event of personnel changes and that BASTAonline always has updated contact information for those responsible for registered products.

Verification of criteria fulfilment:

The responsibility list must be filled in before the registration of products and the company must be able to present the responsibility list in the event of an audit.

V35.02 Criterion: Assessment and documentation

Criteria fulfilment:

Assessment of criteria fulfilment and assessment basis shall be documented in an assessment overview. Assessment overview and assessment documentation must be archived and available as long as the company is connected to the BASTA system.

An assessment overview must be prepared in accordance with BASTAonline AB designated Assessment template (<u>BASTAonline/</u><u>Documents</u>) or equivalent.

The assessment overview shall contain the following information:

- 1. Constituent chemical substances in raw materials/materials/articles
- 2. CAS number or equivalent identification of substances
- 3. Concentration by weight of substances in the product (for assembled articles, the proportion by weight in each article must be reported and assessed)
- 4. Compliance with the criteria for each constituent substance
- 5. What assessment documentation the assessment is based on
- 6. Reference to assessment documentation and where it is stored

Exceptions for reporting CAS numbers can be made for unmodified naturally occurring raw materials such as minerals, wood and the like whose chemical properties are judged by the registrant to be irrelevant for the criteria fulfilment.

Assessment documentation

The documentation for the assessment may take the following form:

1. Full knowledge of content

For products where the company itself has full knowledge of the content, such as a full content declaration, this is a sufficient basis for assessment.

2. Safety Data Sheet

If there are safety data sheets issued in accordance with Annex IV of Regulation (EC) No 1907/2006 (REACH) for the product or constituent substances, they can provide a basis for assessment, but additional information may be needed.

If it is not clear from the safety data sheet that the product meets the criteria, for example because the reported substance content is not complete, the person who performs the registration shall request a separate "Sub supplier declaration" according to a template specified by BASTAonline AB or equivalent, which shows that the product meets the criteria. The person who registers products in the BASTA system must also ensure that the sub supplier can answer questions about the product during a BASTA audit.

3. Construction product declaration (eBVD)

If a construction product declaration (eBVD) exists for the product or constituent substances, it can serve as a basis for assessment. However, additional information may be needed.

If it is not clear from the construction product declaration that the product fulfils the criteria, for example because the reported substance content is not complete, the registrant must request a separate "Sub supplier declaration" from his subcontractor according to the template provided by BASTAonline AB or equivalent, which shows that the product fulfils the criteria. The person registering in the BASTA system must also ensure that the subcontractor can answer questions about the product in a BASTA audit.

4. Sub supplier declaration

For registration of products that the company does not manufacture itself and where the manufacturer does not provide complete accounting of content, the person registering must have a signed "Sub supplier declaration", according to a template specified by BASTAonline AB or equivalent. The person who registers in the BASTA system must also ensure that the declaration received meets BASTA's criteria and that the subcontractor can answer questions about their declaration during a BASTA audit.

5. Already registered product

If a product, or subcomponent of a product, already is registered in the BASTA system, reference to the registration can be used as a basis for assessment. However, the person who re-registers the product must obtain written confirmation from the company that originally registered the product which includes the following:

- That the registered product is the same as the one to be registered
- That if the registration status/criteria fulfilment changes for the registered product, this must be notified to the person who further registers the product

Curing/drying products

For chemical products that are chemically changed from manufacturing to use, such as hardening or drying products can be registered as "BETA to BASTA" and "DECLARED to BASTA". For products registered as "BETA to BASTA" and "DECLARED to BASTA", documentation must credibly demonstrate that the product undergoes a curing process/drying under the conditions that can be expected on a construction site and that it has a chemical content that meets the BASTA criterion in its built-in position. The documentation should be made in three steps:

- 1. Assessment of the delivered product
- 2. Theoretical discussion and possibly analysis
- 3. Assessment for the built-in product

The analysis result can as for example be a monomer certificate. In the assessment template (BASTAonline/Documents) there is a separate folder for BETA/DECLARED to BASTA with the three steps.

Circulated raw material

If the product contains recycled or reused raw material where the complete content is not known, expert judgement is required in combination with selected tests:

- Expert assessment based on BASTA's criterion area "Health and environmental hazardous properties" and for each criterion indicates whether substances covered by the criterion are deemed to be present in the recycled/reused raw material or not. The expert must have good knowledge of the substances that may occur in the specific product type. BASTA can assist with contacts to recommended experts in the field.
- Based on the results of the expert assessment, supplementation is needed with selected tests recommended by the expert to check whether the substances are included and at what level. The aim is to be able to evaluate whether BASTA's criteria are met or not. Depending on the nature of the raw material, the origin of the raw material and whether the content is likely to vary in different batches, repeated sampling may be required.
- Expert assessment including information on who performed the assessment and their qualifications, selection of tests and test results should be sent to BASTA and approved before registration.

Verification of criteria fulfilment:

Assessment overview and assessment documents, must be available before registration of products and must be presented during an audit.

ID: V35.03 Criterion: Update of assessment in case of changes

Criteria fulfilment:

The Company shall update its assessment and registration of products if any of the following occurs:

- 1. The composition of the product changes
- 2. Constituent substances are reclassified
- 3. The BASTA system's criteria are updated

BASTAonline AB has the right to update the BASTA system's criteria continuously. Changes that entail stricter criteria must be notified in writing at least six (6) months before they become mandatory. Companies that have joined the BASTA system are obliged to keep up to date on new criteria and to update assessments and registrations within six (6) months of updated criteria being announced.

Verification of criteria fulfilment:

During audits, it is checked that there is a written procedure that ensures that the criteria is met.

V35.04 Criterion: BASTA audit

ID:

ID:

Criteria fulfilment:

Companies that join the BASTA system and register products must allow audits according to the BASTA system.

During an audit, assessment and assessment documentation for a selection of registered products, responsibility list and competence as well as procedures for BASTA registrations are checked. Documentation from sub suppliers used in assessment is also covered in an audit.

Verification of criteria fulfilment:

Allowing auditing when the company is selected for audit.

V35.05 Criterion: Marketing

Criteria fulfilment:

Companies connected to the BASTA system have the right to show that they are part of the BASTA-system and also referring to their registered products meets one of the BASTA system's grades or product groups (ELECTRONIC) in:

- · Product documentation and catalogues
- Direct connection to the product (for example, on shelf edges or in the web shop)
- · Annual report of the company
- In other types of media as for example ads in magazines, newsletters or social media).

Companies that have joined the BASTA system have the right to use BASTAonline AB's trademarks, for the BASTA system, grades, and product groups, in accordance with <u>BASTA's graphic profile</u>.

If the company is advertised as being connected to the BASTA-system, one of the following must be met:

- The logotype of BASTA-system and a link to the company page at BASTAonline
- · Sticker with a QR-code to the company page at BASTAonline
- In text is written:

The company is connected to the BASTA-system and has registered products, see BASTAonline.se for current declaration status

If products are marketed as registered in the BASTA system, one of the following formulations must be used:

- Grade logotype and link to the article page at BASTAonline
- Grade logotype and QR-code to the article page at BASTAonline
- In text is written:

"Product name" is registered in the BASTA-system and fulfils the grade XXXX, see <u>BASTAonline.se</u> for the product's current registration status.

If the trademarks are misused, the following action will be taken:

• Correction of usage will be required within a given timeframe. The length of the time frame will be assessed and set depending on the type of misuse and extent. If not corrected, the company's products will be unpublished.

Verification of criteria fulfilment:

During an audit it is checked whether the company has marketed products registered in the BASTA system and, if so, it is controlled how they have been marketed.

CIRCULARITY (OPTIONAL)



When registering, it is optional to report criteria fulfilment for this criteria area. Reporting of criteria fulfilment within this criteria area does not affect the product's grade.

ID:

Criterion: Circulated material

Criteria fulfilment:

If the product contains circulated material as defined below, the following information may be declared upon registration:

- 1. Share of circulated material expressed as % of total weight of product
- 2. Share of circulated material that is:
- Reused material/raw material in %
- Recycled material/raw material in % (100% of specified "Circulated material" shall be distributed among these items)
- 3. Share of recycled material/raw material originating from:
- Pre-consumer in %
- Post-consumer in % (100% of specified "Recycled material/raw material" shall be distributed among these items)

Definitions:

- · Circulated material: Material circulated by reuse or recycling
- Reuse: A non-waste product or component is used again to fulfil the same function for which it was originally intended. As defined in the Environmental Code, 1998:808 with amendment SFS:2020:601
- Recycled materials: Material from a product or component taken from the waste stream and returned to the production process. Intermediate steps such as collection, handling, purification and more may occur. As defined in ISO 14021:2017
- Pre-consumer recycled: The recycling step has taken place before the consumer stage, such as the collection and return of waste streams from production waste. Please note that the collection and re-introduction of residual material and waste that arises within the same production process shall not be included
- Post-consumer recycled: The recycling step has taken place after the consumer stage, for example through collection/return after a product has been used by the consumer

Verification of criteria fulfilment:

Information on compliance with the criteria shall be included in the assessment overview together with arguments for how this criterion is fulfilled.

V35.C2 Criterion: Prepared for reuse

Criteria fulfilment:

If the product is prepared to be reused as defined below, the following information may be declared upon registration:

• Share (weight-%) that can be reused

Definition reuse:

A non-waste product or component is used again to fulfil the same function for which it was originally intended. As defined in the Environmental Code, 1998:808 with amendment SFS:2020:601.

Verification of criteria fulfilment:

Information on compliance with the criteria shall be included in the assessment overview together with product information describing how the product can be reused.

ID: V35.C3 Criterion: Prepared for material recycling

Criteria fulfilment:

If the product is prepared to be material recycled as defined below, the following information may be declared upon registration:

• Share (weight-%) that can be material recycled

Definition of material recycling:

Material from a product or component taken from the waste stream and returned to the production process. Intermediate steps such as collection, handling, purification and more may occur. As defined in ISO 14021:2017.

Verification of criteria fulfilment:

Information on compliance with the criteria shall be included in the assessment overview together with product information describing how the product can be material recycled.

ID: V35.C4 Criterion: Circular business models

Criteria fulfilment:

If the company has a circular business model for the product, the following information may be declared upon registration (one or more of the options below can be selected upon registration):

- The product can be disassembled, reassembled
- A circular business model, or similar, exists for the product
- · Other way to support a circularity for the product exists

Verification of criteria fulfilment:

Information on compliance with the criteria shall be included in the assessment overview product information describing the circular business model.

RENEWABILITY (OPTIONAL)



When registering, it is optional to report criteria fulfilment for this criteria area. Reporting of criteria fulfilment within this criteria area does not affect the product's grade.

V35.F1 Criterion: Renewability

ID:

Criteria fulfilment:

If the product contains renewable raw materials/materials as defined below, the following information may be declared upon registration:

• Share (weight-%) of the product that comes from renewable materials/raw materials

Definition renewable raw materials/materials:

Renewable is defined as materials or raw materials that origin from biobased sources that are recreated at least as fast as they are consumed. Examples of renewable raw materials/materials: wood, starch, and cellulose. BASTA does not consider water as a renewable raw material. As defined in the ISO 14021:2017 standard.

Verification of criteria fulfilment:

Information on compliance with the criteria shall be included in the assessment overview together with arguments for how this criterion is fulfilled.

ENVIRONMENTAL EFFECTS (OPTIONAL)



When registering, it is optional to report criteria fulfilment for this criteria area. Reporting of criteria fulfilment within this criteria area does not affect the product's grade.

V35.M1 Criterion: Environmental product declaration – EPD

Criteria fulfilment:

ID:

If a verified/third-party audited EPD (Environmental Product Declaration) in accordance with ISO 14025 (and EN 15804 if applicable) exists for the product, the following information may be declared upon registration:

- If the information comes from a product specific or generic EPD
- Functional unit (weight, volume or other used unit, see the EPD)
- · Amount of the product in the functional unit (as for example the weight of the product)
- Web address to published and verified EPD
- The following values as stated in your EPD. No recalculation needs to be carried out:
 - GWP-f Climate Change fossil
 - For: A1-A3, A4, C1, C2, C3, C4, D
 - ODP
 - For: A1-A3, A4
 - AP
 - For: A1–A3, A4
 - EP-fw Eutrophication aquatic freshwater
 - For: A1–A3, A4
 - POCP
 - For: A1-A3, A4
 - ADPE
 - For: A1-A3, A4
 - ADPF
 - For: A1-A3, A4

Background:

EP-fw: Eutrophication aquatic freshwater according to EN15804+A2 Eutrophication, freshwater [kg P eq]

Verification of criteria fulfilment:

Information on compliance with criteria shall be included in the assessment overview.

EMISSIONS AND TESTS (OPTIONAL)



When registering, it is optional to report criteria fulfilment for this criteria area. Reporting of criteria fulfilment within this criteria area does not affect the product's grade.

ID:	
V35.E1	

ID:

Criterion: Emission – VOC

Criteria fulfilment:

The following information related to volatile organic compound (VOC) emission testing can be provided:

E1.1 Obtained certificate (for instance EMICODE EC1plus/EC1/EC2, Blue Angel, M1/M2 (RTS), GUT, AgBB)

E1.2 Measurement method/standard (for instance ISO 16000–9, ISO 16000–10, ISO 16000–6, ISO 16000–3, EN 16516, EN 717–1, CDPH Standard Method v1.1)

E1.3 Measured content expressed in unit [µg/m³]

E1.4 If the article is exempted from emission measurement due to the fact that it does not contain any organic material

Verification of criteria fulfilment:

Information on criteria fulfilment must be included in the assessment overview and a complete test report must be available as documentation.

V35.E2 Criterion: Emission – Formaldehyde

Criteria fulfilment:

The following information related to formaldehyde emission testing can be provided:

E2.1 Measurement method/standard (for instance ISO 16000–9, ISO 16000–10, ISO 16000–6, ISO 16000–3, EN 16516, EN 717–1, CDPH Standard Method v1.1)

E2.2 Measured content expressed in unit [mg/m³]

E2.3 If the article is exempted from emission measurement due to the fact that it does not contain any organic material

E2.4 If the article is exempted from emission measurement due to the fact that it does not contain any organic material If the measurement method indicated under point 1 an approved measurement method according to the DNSH criteria for the environmental objective "Pollution prevention and control" in the EU taxonomy 2020/852/EU

E2.5 If the article falls within the product types that according to the DNSH criteria for the environmental objective "Pollution prevention and control" in the EU taxonomy must fulfil emission requirements

Background

Within the EU Taxonomy there are requirements for emission measurements to meet the indoor requirements for certain product groups, see Taxonomy info on BASTAonline about requirements. Other certifications also require emission measurements to meet the indoor requirements. In 2026, Annex XVII to Regulation (EC) No 1907/2006 will be amended with regard to emissions of formaldehyde and formaldehyde emitters.

Verification of criteria fulfilment:

Information on criteria fulfilment must be included in the assessment overview and a complete test report must be available as documentation.

ID: V35.E3

Criterion: Emission – Carcinogenic volatile organic compounds

The following information related to emission testing for carcinogenic volatile organic compounds of categories 1A and 1B can be provided:

E3.1 Measurement method/standard (for instance ISO 16000–9, ISO 16000–10, ISO 16000–6, ISO 16000–3, EN 16516, EN 717–1, CDPH Standard Method v1.1)

E3.2 Measured content expressed in unit [mg/m³]

E3.3 If the article is exempted from emission measurement due to the fact that it does not contain any organic material

E3.4 If the measurement method indicated under point 1 an approved measurement method according to the DNSH criteria for the environmental objective "Pollution prevention and control" in the EU taxonomy 2020/852/EU

E3.5 If the article falls within the product types that according to the DNSH criteria for the environmental objective "Pollution prevention and control" in the EU taxonomy must fulfil emission requirements

Background:

Within the EU Taxonomy there are requirements for emission measurements to meet the indoor requirements for certain product groups, see Taxonomy info on BASTAonline about requirements. Other certifications also require emission measurements to meet the indoor requirements.

Verification of criteria fulfilment:

Information on criteria fulfilment must be included in the assessment overview and a complete test report must be available as documentation.

ID: V35.E4 Criterion: Leaching into drinking water – 4MS

Criteria fulfilment:

For products tested according to "4MS - Leaching of lead into drinking water ", the following should be declared upon registration:

E4.1 The product is approved according to 4MS – Leaching of lead into drinking water is less than 5 μg/l.

E4.2 Information on the lead content of the copper alloy in the following ranges:

- The 4MS approved copper alloy contains ≤ 0.25% Lead
- The 4MS approved copper alloy contains > 0.25–0.8% Lead
- The 4MS approved copper alloy contains > 0.8% Lead

E4.3 Results from the 4MS report expressed in unit $[\mu g/l]$

For more information: Approval and Harmonization – 4MS Initiative | Umweltbundesamt.

Verification of criteria fulfilment:

Information on criteria fulfilment must be included in the assessment overview and a complete 4MS-test report must be available as documentation.

DEFINITIONS

Article – According to REACH

According to the definition in REACH, Chapter 2 Article 3, an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. After an object has become an article in its own right during the production process, it will remain an article until it finally becomes waste after finished use.

In order to determine whether an article meets a criterion, the content of the substances contained in the article needs to be reconciled with the criteria.

Article – Registration of articles in the BASTA-system

An item is a specific version of a product, specific article number. For example, it can be a specific size or length. When registering, each individual article must be registered separately.

Assembled articles

An assembled article is an article that has been assembled together by two or more articles.

For assembled articles, the assessment of compliance with the criteria shall be based on the content of the substance(s) in each individual article. The assessment of compliance shall not be based on the content of the assembled article.

For assembled articles, articles consisting of several articles as described above, the assessment of compliance with the criteria shall be based on the concentration of the substance in the individual article containing the substance, i.e. the assessment of compliance with the criteria shall not be based on the content of the assembled article.

For more information about what is an article, alternatively assembled article, see:

- KEMI's website about REACH and articles: <u>www.kemi.se/lagar-och-regler/reach-forordningen/</u> reach-och-varor
- ECHA Short Guide "Requirements for Substances in Articles": <u>echa.europa.eu/documents</u> /10162/23036412/nutshell_guidance_articles2_sv.pdf/16e1cf2a-de07-488b-9bc3-5445ce53e967
- ECHA "Guidance on requirements for substances in articles": <u>echa.europa.eu/documents</u> /10162/23036412/articles_sv.pdf/a4c1ece3-83e2-3d16-0584-5b74a26d97ae

Chemical product

A chemical product is a chemical substance or preparation of chemical substances that is not an article.

CLP

Regulation (EG) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, <u>eur-lex.europa.eu/legal-content/SV/TXT/PDF/</u>?uri=CELEX:02008R1272-20210510&from=sv.

Mixture

Mixture or solution composed of two or more substances.

Product

In the BASTA system, products refer to both articles and chemical products.

REACH

Regulation (EG) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, <u>eur-lex.europa.eu/legal-content/sv/TXT/PDF/</u>?uri=CELEX:02006R1907-20210101.

Substance

Element or compound of elements in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the manufacturing process, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

VERSION HISTORY

The update to this version from version V34.2 has been made through the following changes to the criteria:

V35.H1.H V34.1 No longer requirement for rating BETA, harmonization with PRIO.

V35.H3.C Definition changed from from CoRAP to PRIO.

V35.H6.A Update of regulation.

Added criterion V35.H10.C and former V34.H10.C has become V35.H10.D.

V35.05 has been updated with clearer guidelines on marketing.

As well as clarifications in the criteria V34.H2.B, V34.H3.D, V34.H3.E, V34.H7.C, V34.H7.D and V34.O2.V35. H2.A, V35.H4.A. V35.H4.B, V35.H7.C, V35.H7.D, V35.H8.A, V35.H10.A, V35.H10.B, V35.H11, V35.O2 for curing/drying products and for the voluntary criteria Circularity and Emissions.

CONCLUSION

The links provided in the document may be updated beyond BASTAonline's control. BASTAonline is not responsible for ensuring that the links are updated at all times but refers to the respective source. The criteria are continuously reviewed to adapt to new legislation, knowledge, and objectives.



The BASTA system was started in 2004 through a project supported by the European Commission's LIFE fund LIFE03/ENV/S/00094. The criteria in the BASTA system were then part of the "Kretsloppsrådets" joint action plan. Since 2007, the BASTA system is run by BASTAonline AB, which is owned by IVL Swedish Environmental Research Institute and The Swedish Construction Federation

Information about products that meet the criteria is available in an open database that can be accessed via <u>www.bastaonline.se</u>, BASTA's logbook service or via BASTA's open API. Contact BASTAonline by e-mail to <u>bastaonline@ivl.se</u> or by phone 010-788 65 00 for further information