

Properties criteria - BASTA

VERSION 2020:A1

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Introduction

ABOUT THE BASTA SYSTEM

The aim of the BASTA system is to phase out substances with particularly hazardous properties from building- and construction products. With products, BASTA refers to both articles and chemical products. The core of the BASTA-systems is an transparent and scientifically based criteria and quality is ensured through follow-up audits. To achieve comparable and relevant requirement levels, BASTA's properties criteria are based on the European chemicals legislations REACH and CLP¹¹. The BASTA system is founded on the legislation, to the extent that the limits of BASTAs criteria comply with specified classification limits. However, the BASTA system goes further than the legislation: where the legislation sets the limit for classifications, the BASTA system sets the limit for acceptable content. Where the legislation only covers chemical products, the BASTA system covers both chemical products and articles.

THE BASTA CRITERION

Table 1 describes the substance properties covered by the BASTA criterion. Products that are registered in the BASTA system may not contain substances with the properties listed in the table, at concentrations equal to or above specified concentration limits. When a specific concentration limit is specified for a substance with regards to any property ⁴), it applies instead of the one given in Table 1, the third column. All substances included in the so-called candidate list ⁷⁾ to REACH is subject to the criteria. The table contains footnotes that clarify or describe how the criteria should be interpreted and used. As the last entry to the document we find a list of the used hazard statements.

In addition to limiting the content of substances with specific properties, BASTA also has information requirements. Table 2 describes the information requirements that apply to products registered in the BASTA register.

Furthermore, BASTA has a requirement, entailing that registered companies must allow audits of the assessments that form the basis for the companies' article registration, as well as that suppliers can demonstrate that they have working methods, knowledge and documentation, which enable that the criteria can be followed over time. These requirements are stated in the agreement signed between the company and BASTA. BASTAs criteria are constantly evolving. A notification of any Criteria Changes that entails stricter criteria are announced at least 6 months before implementation.

BASIS FOR CALCULATIONS

The constituent substances content levels are to be calculated for the product in the form it is delivered to a building site or equivalent. Chemicals that have been used in manufacturing but are not present in the delivered product do not need to be considered.

If several substances have similar properties, their contents should be combined if it says "yes" in the fourth column in table 1, in order to obtain the total contribution in the assessment for the current hazard. More information on how the calculation is made can be found in footnote 12.

If the classification of a chemical product that is a preparation²⁾, due to its properties differ from the included substances respective classification, it is the classification of the mixture that applies.

For complex articles³⁾ that consist of several parts, the basis for calculations should be the weight of the individual part that contains the substance, i.e the assessment should not be based on the content of the complex article. It is the individual concentration of

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Table 1. Properties criteria in the BASTA-register

Products that are registered in the BASTA system may not contain substances with the properties listed in the table, at concentrations equal to or above specified concentration limits. In some cases, specific content limits must be considered⁴⁾.

Properties (substances)		Definition	Concentration limit (by weight-%) (if specific limits not are specified) 4)	Summation 12)
1. Carcinogenic	a)	Substances with properties according to hazard class of carcinogenic in category 1A or 1B (H350) ⁴⁾	0.1%	_
	b)	Substances with properties according to hazard class of carcinogenic in category 2 (H351) 4)	1%	_
2. Mutagenic	a)	Substances with properties according to hazard class of mutagenic in category 1A or 1B (H340) ⁴⁾	0.1%	_
	b)	Substances with properties according to hazard class of mutagenic in category 2 (H341) 4)	1%	-
3. Toxic to reproduction	a)	Substances with properties according to hazard class of toxic to reproduction in category 1A or 1B (H360) ⁴⁾	0.3%	_
	b)	Substances with properties according to hazard class of toxic to reproduction in category 2 (H361) ⁴⁾	3%	_
4. Effect during lactation		Substances that meet the hazard class Reproductive toxicity, category Effects on or via breastfeeding (H362) ⁴⁾	0.3%	-
5. Endocrine disrupting	a)	Substances that are considered endocrine disrupters in accordance with the EU definition of endocrine disrupting substances ¹⁵⁾ . See BASTA's guide on restriction of endocrine disruptors ¹⁶⁾ .	0.1%	-
	b)	Substances that receive the overall assessment Cat 1 or Cat 2 in EU's - EDS Database ⁶⁾	0.1%	-
6. Persistent, bio accumulative and toxic organic compound (PBT)		Substances with 1) a half-life > 60 days in marine water or > 40 days in fresh- or estuarine water or > 180 days in marine sediment or > 120 days in fresh- or estuarine sediment or > 120 days in soil and 2) BCF (Bio Concentration Factor) > 2000 l/kg (wet weight) and 3) Toxicity NOEC or EC10 < 0.01mg/l or CMR - Carcinogenic 1A, 1B (H350). Germcell Mutagenic 1A, 1B (H340). Toxic for reproduction 1A, 1B, 2 (H360 and H361) or classified H372 or H373	0.1%	_
7. Very persistent and very bio accumulative organic compound (vPvB)		Substances with 1) a half-life	0.1%	-
8. Lead (Pb)		Lead or compounds of lead	0.1%	Yes 12)
9. Mercury (Hg)		Mercury or compounds of mercury	Total Ban ⁸⁾	Yes 12)
10. Cadmium (Cd)		Cadmium or compounds of cadmium	0.01%	Yes 12)
11. Dangerous to the ozone layer		Substances meeting the criteria for the hazard class Hazardous to the ozone layer (EUH 059, H420) and all substances listed in the Annex to Regulation (EC) No 1005/20099) 9)	0,1%	-



3 (9)

Substance Properties	Definition	Concentration limit (by weight-%) (if specific limits not are specified) ⁴⁾	Summation 12)
12. Sensitising a)	Substances with properties according to hazard class of causing respiratory sensitisation (H334) 4)	0.2%	-
b)	Substances with properties according to hazard class of causing skin sensitisation (H317) 4)	1%	-
13. Acute toxic	Substances with properties according to hazard class of Acute toxicity in category 1, 2 and 3.	The ATE-values that would at least classify the mixture as Acute toxicity, category 3 ⁴⁾	Yes, and it should be performed for each relevant exposure route
- Oral - Dermal - Inhalation	(H300, H301) (H310, H311) (H330 or H331)	ATE ≤ 300 ATE ≤1000 For gases ATE ≤ 2500 For vapours ATE ≤ 10 For dust/mist ATE ≤ 1.0	
14. Specific target a) organ toxicity after single exposure	Substances with properties according to hazard class of Causes damage to organs after single exposure (STOT-SE) in category 1. (H370) 4)	1%	-
b)	Substances with properties according to hazard class of Causes damage to organs after single exposure (STOT-SE) in category 2 (H371) ⁴⁾	10%	-
с)	Chemical products with properties according to the classification Aspiration toxicity in category 1 (H304) ⁵⁾	Refers to the product's classification 5)	-
15. Specific target a) organ toxicity after repeated exposure	Substances with properties according to hazard class of Causes Specific damage to organs through repeated exposure (STOT-RE) in category 1 (H372) ⁴⁾	1%	-
b)	Substances with properties according to hazard class of Causes Specific damage to organs through repeated exposure (STOT-RE) in category 2 (H373) ⁴⁾	10%	-
16. Volatile organic compounds	Substances with an initial boiling point <250 °C measured at a standard pressure of 101,3 kPa and has properties according to any of the hazard classes:	10% 10)	Yes
	Fatal, Toxic and Harmful if inhaled (H330, H331, H332) May cause drowsiness or dizziness (H336) May cause damage to organs (H371) May cause damage to organs through prolonged or repeated exposure (H373).		
17. Environmentally hazardous a)	Substances meeting the criteria for the hazard class Very toxic to aquatic life, acute category 1 (H400) 4)	25% if M=1 ¹¹⁾	Yes
b)	Substances with properties according to hazard class Very toxic to aquatic life, category chronic 1 (H410) and 2 (H411) $^{\rm 4)}$	2.5% for H410 - substances M=1 ¹¹⁾ 25% for H411- substances ¹¹⁾	Yes
c)	Substances meeting the criteria for the hazard class Very toxic to aquatic life, category chronic 4 (H413) ⁴⁾ . Summation is made for mixtures that do not meet the criteria for chronic 1, 2 or 3. The summation also includes substances classified as chronic 1 (H410), chronic 2 (H411), chronic 3 (H412) chronic 4 (H413).	25% ¹¹⁾	Yes





Table 2. Information requirements in the BASTA-register

Information requirements	Definition	Information-limits (weight-%)
A. Substances on the Candidates list	The chemical name, CAS number and substance level shall be stated for substances found on the Candidates List. Enter the information into the description field in the system registration view. The text must contain the phrase "Contains substances on the Candidate list."	0,1 % ¹⁴⁾
B. Information requirement linked to Criteria 5 Edocrine disrupters ¹⁷⁾	The chemical name, CAS number and substance level shall be stated for substances covered by the information requirement in step C. The information is entered into the designated field in the registration view. See current substances covered by the information requirement at https://www.bastaonline.se/how-it-works/endocrine-disrupting-substances/?lang=en/ .	0,1 % ¹⁷⁾

NOTES

1) CLP, Regulation **(EC) no 1272/2008** on the classification, labeling and packaging of substances and mixtures, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20181201&rid=2

REACH, Regulation **(EC) no 1907/2006** on the Registration, Evaluation, Authorization and Restriction of Chemicals (Reach), https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20150601&from=EN

2) Chemical element and its compounds in natural or prepared form, including additives necessary to product stability and any impurities from the production process, but excluding solvents which may be separated without affecting the stability of the substance or changing its composition.

Preparations: means mixtures or solutions composed of two or more substances.

3) For more information regarding the definition of an "article", or "complex article", see KEMI's fact sheet on substances in articles. https://www.kemi.se/global/broschyrer/guidance-for-suppliers-of-articles.pdf

To determine if the article meets the BASTA criteria need the substance content in the article needs to be checked against the criteria limits. For complex articles that consist of several parts, the basis for calculations should be the weight of the individual part that contains the substance, not the total weight of the complex article. The concentration, which is compared to the BASTA defined concentration limit, should therefore be calculated on each part of a complex article which itself meets the definition of an "article" in article 3.3 in the REACH regulation:

"Article: An article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition". An object that in a certain step in its life cycle has become an article, will normally remain an article until it eventually becomes waste after end use ("once an article, always an article").

VERSION 2020:A1 5 (9)



- 4) For information about H-phrases, concentration limits and specific classification limits: see ECHA's classification database "C & L Inventory," https://echa.europa.eu/information-on-chemicals/cl-inventory-database In those cases where there are specific classification limits for individual substance content, that is, higher or lower than the content limits specified under each criterion, these apply. This applies to both substances with harmonized classification and non-harmonized (self-classification).
 - For PAHs in plastic or rubber components covered by Commission Regulation (EC) No 1272/2013 and where exposure can be by skin or mouth, the content limits apply in accordance with EC 1907/2006 (Annex XVII, paragraph 50 of the REACH Regulation).
- 5) The criteria are not a substance criterion but apply to chemical products with the classification H304.
- 6) An extract of the EDS database in its entirety can be found at https://www.bastaonline.se/document/?lang=en
- 7) Substances listed on the Candidate List: https://www.echa.europa.eu/web/guest/candidate-list-table
- 8) In accordance with criteria 9 there is a ban on mercury. The ban applies to articles 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.
- 9) According to "Guidance on the Application of the CLP Criteria", a substance is defined as ozone depleting if ODP (Ozone Depletion Potential) is equal to or greater than 0.005. These known substances are listed in Annex I to Regulation (EC) No 1005/2009. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1005
- 10) The initial boiling point is set in accordance with **directive 2004/42/EG** with the concentration limit in agreement with the paint, adhesive and sealants trade. In cases where a lower concentration limits is specified in **KIFS 2008:2** or **2004/42/EG** with current changes for paints and lacquers, those apply.
- 11) If no environmentally hazardous substances have specifically lower concentration limits such as specified in Regulation (EC) No 1272/2008 (CLP), the following applies:
 - Criteria 17a: If the containing substances, which are classified H400, all have M=1, then a summation of their concentrations can/shall be done, and the concentration limit will then be 25%.
 - Criteria 17b: If all the containing substances that fall under this criterion only are classified H410, all have M=1, then a summation of their concentration can/shall be done, and the concentration limit then will be 2.5%. If no substances are classified H410, then a summation of the concentration of the containing substances classified H411 can/shall be done, and the concentration limit will then be 25%.
 - Criteria 17 c: If all the containing substances that fall under this criterion only are classified H412. A summation of the concentration of the containing substances can/shall be done and the concentration limit is then 25%. If no substances are classified H412, then a summation of the concentration of the containing substances classified H413 can/shall be done, and the concentration limit will then be 25%.
 - In cases where substances with different hazard categories are represented the above does not apply and for substances with other M-values the concentration limits are according to the **table 4.1.3**, **Annex 1**, according to CLP (with current changes). The summation of substances with different M-values shall be performed in accordance with the Method of calculation for BASTA, https://www.bastaonline.se/document/?lang=en
- 12) When there is a "yes" listed in the column for summation, the following applies:

 In cases, where concentration limits are not specified in (EC) No. 1272/2008) (CLP), and where all

VERSION 2020:A1 6 (9)



substances with the same hazard class belongs to the same hazard category, the summation is done by adding the concentrations of these substances. When these conditions do not apply, how to do the summation is described in "BASTA's Methods for calculation", https://www.bastaonline.se/document/?lang=en

In criteria 8-10 the summantion shall include the total concentration levels of lead, mercury and cadmium.

The concentration limit set in criterion 13 is based on the mixtures ATE-value (Acute Toxicity Estimate). If the toxicity of a mixture is not measured, an estimate can be based on the toxicity of the chemical content (Acute Toxicity Estimate), The approach and the various ATE-values for different paths of exposure are stated For criterion 16 a simple summation is used to calculate the concentration of the substance properties covered by the criteria, even if they do not belong to the same hazard class or if they belong to the same hazard class but belong to a different hazard category, e.g. Toxic or Harmful if inhaled.

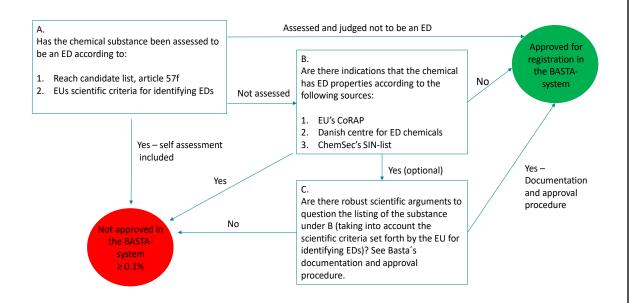
For critirion 17 a sumation is made in accordance with the rules specified in the document "BASTA's Methods for calculation", https://www.bastaonline.se/document/?lang=en

- 13) In the case of compounds, it is only the content of lead, mercury and cadmium that needs to be considered or counted.
- 14) The information limit applies even if the specific classification limit differs.
- 15) Basta's criterion for endocrine disruptors is based on the scientific criteria applied under EU chemicals legislation: "Commission delegated regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012" as well as the "Commission regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties".
 - The criteria means that substances should be considered to have endocrine disrupting properties if they meet all of the following criteria:
- a) it shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which
 is a change in the morphology, physiology, growth, development, reproduction or life span of
 an organism, system or (sub)population that results in an impairment of functional capacity, an
 impairment of the capacity to compensate for additional stress or an increase in susceptibility to
 other influences;
- b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;
- c) the adverse effect is a consequence of the endocrine mode of action.
- 16) For the assessment of which substances that are covered by the above definition, apply Basta's methodology described in the document "Guidance document for handling criteria for endocrine disruptors in the construction industry" (IVL rapport B2369, 2020).

For application in Basta, see the document "Guidance - limitation of endocrine disruptors in Basta Criterion 5", which is available in its entirety on the website https://www.bastaonline.se/how-it-works/endocrine-disrupting-substances/?lang=en. The guide gives practical instructions on which substances are considered endocrine disruptors in the BASTA system by applying the following decision tree:

VERSION 2020:A1 7 (9)





17) Information requirements linked to criterion 5 - Endocrine disruptors. Substances evaluated as permitted in Basta in accordance with Step C of Basta's decision-making tree for the limitation of endocrine disruptors (see note 16) are subject to the information requirement. Substances listed on CoRAP, Danish Center for Endocrine Disruptors or the Chemsecs SIN list are generally not allowed in Basta. An exception is if an evaluation has been carried out which shows that the scientific basis for the list of substances are not compatible with the EU criteria for endocrine disruptors. A current list of assessed and evaluated topics can be found on the page https://www.bastaonline.se/how-it-works/endocrine-disrupting-substances/?lang=en.

Risk phrases used in these criteria

H300	Fatal if swallowed
H301	Toxic if swallowed
H304	May be fatal if swallowed and enters airways
H310	Fatal in contact with skin
H311	Toxic in contact with skin
H317	May cause an allergic skin reaction
H330	Fatal if inhaled
H331	Toxic if inhaled
H332	Harmful if inhaled
H334	$\label{eq:maycause} \mbox{May cause allergy or asthma symptoms or breathing difficulties if inhaled}$
H336	May cause drowsiness or dizziness
H340	May cause genetic defects
H341	Suspected of causing genetic defects
H350	May cause cancer

VERSION 2020:A1 8 (9)



H351	Suspected of causing cancer
H360	May damage fertility or the unborn child
H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children
H370	Causes damage to organs
H371	May cause damage to organs
H372	Causes damage to organs through prolonged or repeated exposure
H373	May cause damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H411	Toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects, category chronic 3
H413	May cause long lasting harmful effects to aquatic life, category chronic 4
H420	Harms public health and the environment by destroying ozone in the upper atmosphere
EUH059	Hazardous to the ozone layer

The links contained in the document are updated outside of BASTA's control. BASTA is not responsible ensuring that the links are updated at all times but refer to the relevant website. The criteria are continuously reviewed to conform and adapt to new legislation, knowledge and objectives in the chemicals field. New versions of the criteria will enter into force on January 1st or alternatively on July the 1st.

Information about construction products that meet the properties criteria are found on the web-site www.bastaonline.se., E-mail address is basta@ivl.se

You can also contact IVL Swedish Environmental Research Institute, Box 21060, SE-100 31 Stockholm, Sweden. Telephone +46 10 788 65 00 for more information



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9 (9)