

BASTA

Properties criteria - BASTA

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Introduction

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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 CLP¹⁾. The BASTA system is founded on the legislation, to the extent that the limits of BASTA's 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. BASTA's 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. The full content of all constituent substances included in a product or subcomponent with a general content level $\geq 0.1\%$ are included. Note that some substances require declaration at lower content limits. This applies to substances with lower content limits in BASTA's properties criteria, substances that are aggregated and substances with specific lower concentration limits for classification according to CLP. Note that these content limits apply to intentionally added substances, reaction products and possible impurities/contaminants.

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 each individual component that shall be evaluated against BASTA criterions concentration limits. See the definition of an "article" in **article 33 in the REACH regulation¹⁾**.

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	Substances that are considered endocrine disrupters in accordance with the EU definition of endocrine disrupting substances ¹⁵⁾ . See Substance-list-Basta and BASTA's guide on restriction of endocrine disruptors ¹⁶⁾ .	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 > 60 days in marine-, fresh- or estuarine water or > 180 days in marine-, fresh- or estuarine sediment or > 180 days in soil and 2) BCF (Bio Concentration Factor) >5000 l/kg (wet weight)	0.1%	—
8. Lead (Pb)	Lead or compounds of lead	0.1%	Yes ¹²⁾

Substance Properties	Definition	Concentration limit (by weight-%) (if specific limits not are specified) ⁴⁾	Summation 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 1005/2009 ⁹⁾	0,1%	—
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 - Oral - Dermal - Inhalation	Substances with properties according to hazard class of Acute toxicity in category 1, 2 and 3. (H300, H301) (H310, H311) (H330 or H331)	The ATE-values that would at least classify the mixture as Acute toxicity, category 3 ⁴⁾ ATE ≤ 300 ATE ≤ 1000 For gases ATE ≤ 2500 For vapours ATE ≤ 10 For dust/mist ATE ≤ 1.0	Yes, and it should be performed for each relevant exposure route
14. Specific target organ toxicity after single exposure	a) 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%	—
	c) 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 organ toxicity after repeated exposure	a) 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 both an initial boiling point <250 °C measured at a standard pressure of 101,3 kPa and with properties according to any of the hazard classes: Fatal, Toxic or 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).	10% ¹⁰⁾	Yes

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) 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. Affiliated suppliers can contact Basta for a consolidated total list of all substances covered by the information requirement.

Information requirements	Definition	Information-limits (weight-%)
I. Substances on the Candidates list⁹⁾: substances of very high concern (SVHC)	The chemical name, CAS number and substance level shall be stated for substances found on the Candidates List that have a harmonized classification limit > 0.1%. The substance is registered under "Information requirements for chemical substances" in the system's article registration.	0.1 % ¹³⁾
II. Information requirement linked to exceptions to Criteria 5 Endocrine disrupters¹⁷⁾	The chemical name, CAS number and substance level shall be stated for substances covered by the information requirement in step C. The substance is registered under "Information requirements for chemical substances" in the system's article registration. See current substances covered by the information requirement at https://www.bastaonline.se/how-it-works/endocrine-disrupting-substances/?lang=en/ .	0.1 % ¹⁷⁾
III. Substances listed in the EDS database⁶⁾ as a selection of suspected endocrine disruptors.	The chemical name, CAS number and substance level shall be stated for substances which receives the overall assessment Cat 1 or Cat 2 in the EU EDS Database ⁶⁾ . The substance is registered under "Information requirements for chemical substances" in the system's article registration.	0.1 %
IV. Potentially persistent, bio accumulative and toxic organic compound (PBT) and potentially very persistent and very bio accumulative organic compound (vPvB)	The chemical name, CAS number and substance level shall be stated for substances found on CoRAP ¹⁷⁾ to be evaluated or evaluated as potentially persistent, bio accumulative and toxic organic compound (PBT) and potentially very persistent and very bio accumulative organic compound. The substance is registered under "Information requirements for chemical substances" in the system's article registration.	0.1 %

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/broschyer/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”).

- 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> These substances have been identified as SVHC substances, i.e. substances of very high concern and have one of the following hazardous properties:
 - Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B in accordance with the CLP Regulation.
 - Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII.
 - Substances on a case-by-case basis, that cause an equivalent level of concern as CMR or PBT/vPvB substances.
- 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)**, (classifications and M-factors can also be found in ECHA's database, see footnote 4), 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%.

Cbe 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 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%.

Criterion 17c: This is a collection criterion made for products that do not meet the criteria for chronic 1 (H410), chronic 2 (H411) or chronic 3 (H412). A summation includes substances classified chronic 1 (H410), chronic 2 (H411), chronic 3 (H412), chronic 4 (H413). To meet the requirement the sum of the containing substances must be below 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)** (classifications and specific substance levels can also be found in ECHA's database, see footnote 4); and where all 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 summation shall include the total concentration levels of lead, mercury and respectively cadmium. In the case of compounds, it is only the content of lead, mercury and cadmium that needs to be considered or counted.

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

13) The information limit applies even if the specific classification limit differs.

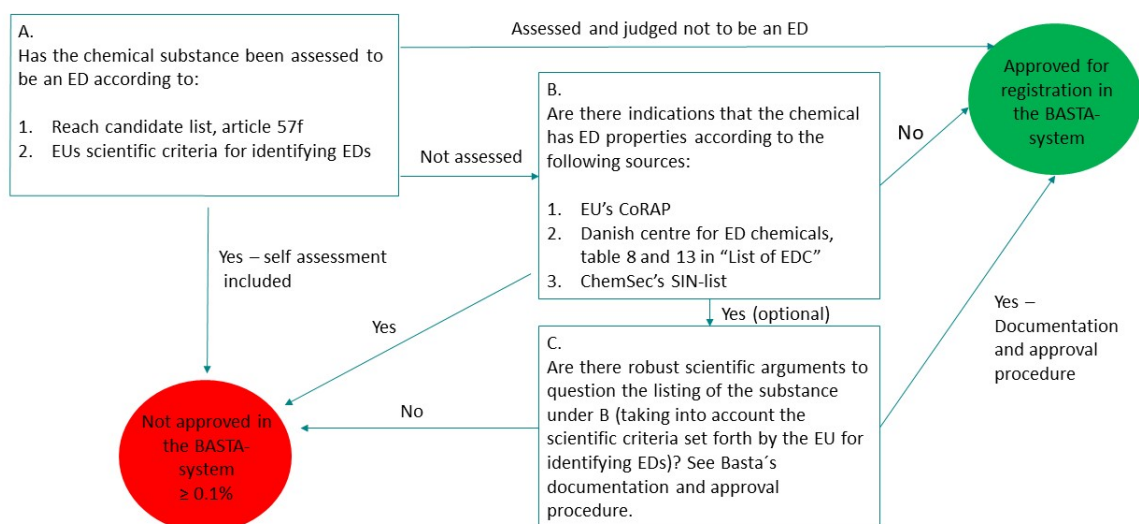
14) Basta's criterion for endocrine disruptors is based on the scientific criteria applied under EU chemicals legislation: "Commission delegated regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012" as well as the "Commission regulation (EU) 2018/605 of 19 April 2018 amending Annex II substances with the same hazard class belongs to the same hazard category, the summation

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.
- 15) 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 BASTA Substance-list-Basta and 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:



- 16) Information requirements linked to exemption from 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 15) 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>. An excel list of all substances covered by the information requirement is available for affiliated companies and partners of Basta on request to bastaonline@ivl.se
- 17) CoRAP, the Community rolling action plan, can be found on the European Chemicals Agency (ECHAS) website: <https://echa.europa.eu/en/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>. The list contains substances that have been evaluated or that are to be evaluated

within ECHA. The list can be filtered to find substances that are included in the list for their potential persistent, bioaccumulative and toxic organic substances (PBTs), and potentially very persistent and very bioaccumulative (vPvB). An excel list of all substances covered by the information requirement is available for affiliated companies and partners of Basta on request to bastaonline@ivl.se

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	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
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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