BASTA

Properties criteria - BASTA

- according to Regulation (EC) No. 1272/2008 (CLP)

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Introduction

The aim of the BASTA system is to phase out substances with particularly hazardous properties from construction products. Products that are registered in the BASTA system may not contain substances with properties according to agreed criteria, at concentrations equal to or above specified limits.

The criteria are based on the European Chemicals Legislation REACH, where substances of very high concern are specified. All substances covered by the criteria on REACHs candidates list have particularly hazardous properties.

The criteria have been based on the Regulation **(EC) No. 1272/2008 o**n classification, labelling and packaging of substances[1)] and mixtures[2)] (CLP).
http://echa.europa.eu/documents/10162/13562/clp_labelling_en.pdf

If a metabolite/degradation product is classified with a certain property, then the parent substance should be classified with the same property.

See in particular Annex 1. If the classification of a mixture/preparation[2)], due to its properties differ from the included substances[1)] respective classification, it is the classification of the preparations that applies if this is the way the product is delivered to the construction site (or equivalent).

Concentrations are to be considered 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 not stated otherwise the assessment shall be made considering the total concentration of different substances with the same property.

If different substances have similar properties a summation of the concentrations shall be done, if it says yes in the column for summation in the table for properties criteria shown below. The summation shall be done according to the footnote in this column. It is not always a matter of simple addition.

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** (see note 13).

The properties criteria describe the substance properties which the BASTA-system aims to phase out. The accepted concentration limit normally allowed in the product is shown. (NOTE: It happens in some cases that other concentration limits are specially specified , see note 1). It is shown in the table below if a summation of different substances with similar properties shall be done. In addition there are footnotes with additional information. There is also a list of risk phrases used in this document.

N.B.

The above criteria will be reviewed at regular intervals with the aim to have substances with above properties to be totally phased out. Revisions may be made to adapt them to new knowledge, requirements in the world around and objectives in the area of chemicals.

Properties criteria in the BASTA-register

Properties (substances)		Definition	Concentration limit (by weight) (if specific limits not are specified) [3), 13)]	Summation[14)]
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 with properties according to hazard class of: may cause harm to breastfed children (H362) [4)]	0.3%	—
5. Endocrine disrupting		The criterion will cover the substances which will receive the overall assessment Cat 1 or Cat 2 in EU's - EDC Database[6)].	0.1%	—
6. Persistent, bio accumulative and toxic organic compound [7)] (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 [7] (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
9. Mercury (Hg)		Mercury or compounds of mercury	Total Ban [8)]	Yes
10. Cadmium (Cd)		Cadmium or compounds of cadmium	0,01%	Yes
11. Dangerous to the ozone layer		Substances with Ozon Depletion Potential (ODP) > 0 (EUH 059, H420) [9)]	0,1%	—
12. Sensitising	a)	Substances with properties according to hazard class of causing respiratory sensitisation (H334) [4)]	0,2%	—
	b)	Substances with prperties according to hazard class of causing skin sensitisation (H317) [4)]	1%	—

Substance Properties	Definition	Concentration limit (by weight) (if specific limits not are specified) [3), 13)]	Summation[14)]
13. Acute toxic	Substances with properties according to hazard class of Acute toxicity in category 1, 2 och 3. (H300, H310, H330, H301, H311 or H331)	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**	(H300, H301)	ATE ≤ 300	
- **Dermal**	(H310, H311)	ATE ≤1000	
- **Inhalation**	(H330 or H331)	For gases ATE ≤ 2500 For vapours ATE ≤ 10 For dust/mist ATE ≤ 1,0	
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)]	—
15.Specific target organ toxicity after repeated exposure a)	Substances with properties according to hazard class of Causes damage to organs through prolonged or repeated exposure (STOT-RE) in category 1 (H372)[4)]	1%	—
b)	Substances with properties according to hazard class of Causes damage to organs through prolonged or repeated exposure (STOT-RE) in category 2 (H373)[4)]	10%	—
16. Volatile organic compounds [10)]	Substances with an initial boiling point <250 ^{O}C measured at a standard pressure of 101,3 kPa and has properties according to any of the hazard classes: Fatal, Toxic and Harmful if inhaled (H330, H331, H332) May cause drowsiness or dizziness (H336) May cause damage to organs (H371) or May cause damage to organs through prolonged or repeated exposure (H373).	10% [11)]	Yes
17. Environmentally hazardous a)	Substances with properties according to hazard class of Very toxic to aquatic life in acute category 1 (H400) [4)]	25% only if M=1 [12)]	Yes
b)	Substances with properties according to hazard class of Very toxic to aquatic life in conical category 2 (H411) (also including substances with conical category 1 (H410)) [4)]	2.5% for just H410 substances M=1 [12)] 25% for just H411 substances [12)]	Yes

NOTES

1) Substances: means chemical elements and their compounds as they occur in the natural state or as produced by industry.

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

3) In cases where a concentration limits differs, higher or lower, from the specified limit found in table **3.1 in Annex VI** to the Council Directive on classification, labeling and packaging of substances and mixtures (CLP) **(Regulation (EC) No. 1272/2008)**, this concentration limit applies instead of the concentration specified within the criterion.
In the event that a product consists of plastic or rubber components that contain any PAHs covered by Commission Regulation **(EC) No 1272/2013** of 6 December 2013 amending **Annex XVII to Regulation (EC) No 1907/2006** of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards polycyclic aromatic hydrocarbons, and any of these parts come into direct and prolonged or short-time repeated contact with the human skin or oral cavity, under normal or reasonably foreseeable conditions of use, the concentration limit under this directive applies.

4) In accordance with Regulation **(EC) No. 1272/2008 (CLP)**. The assessment is to be based on all relevant data on the hazardousness to health and the environment of the product. The criteria are directly applicable when data are obtained from information requirements described in **article 13** to regulation **(EC) no. 1907/2006 (REACH)**. If for a given property that is hazardous to health or the environment, there are data from several studies which, according to the criteria, would lead to differing classification, the data that result in the strictest classification are to be used provided they are of good scientific quality.
The different ATE-values for each relevant exposure route (criteria 13) are presented in Methods of calculation for BASTA.

5) The criteria are not a substance criterion but apply to chemical products.

6) EU's - EDS Database can be downloaded at: **http://ec.europa.eu/environment/chemicals/endocrine/strategy/being_en.htm** To extract the database, please follow these instructions:
1. Download the zipped file to your hard-disk
2. Unzip the file and run the database (by a double-click on the mdb-file).
3. Choose "Categorisation" in order to view the substances that are included in the database.
Minimum requirement: MS Access 2003 or later.
Please note that this also encompasses the other CAS numbers of the substances subject to the EDS database of Cat 1 and Cat 2!

7) There are substances that fulfil the criteria for both PBT and vPvB. They must be tested both according to the criteria 6 and 7, if such substances are present in the product. The criteria for potentially PBT according to PRIO (www.kemi.se) can, in cases where it indicates no potential and where no other data exist, be used as a base for the PBT-classification.

8) In accordance with the Swedish directive **(1998:944)** there is a general Swedish ban on mercury with specified exclusions. Low concentrations of mercury that are not intentionally added in any stage thus fall outside the prohibition. **With low levels of mercury refers in BASTA to a maximum occurring concentration of 2.5 mg per kg**.

9) According to Guidance on the Application of the CLP Criteria (The latest version will be found at:
http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp)
means any substances with ODP (Ozone Depletion Potential) ≥ 0,005. Known substances are listed in **Annex I** to Regulation **(EC) No. 1005/2009**:
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:286:0001:0030:EN:PDF

10) The initial boiling point is set in accordance with **directive 2004/42/EC** with the concentration limit in agreement with the paint, adhesive and sealants trade. The concentration limits are according to **Directive 1999/45/EC Annex II**.

11) In the case that lower concentrations are stipulated for paints and lacquer in Council **Directive 2004/42/EG**, they should apply.

12) If none of the environmentally hazardous substances in the product have any specific lower concentration limit stated in Annex VI, table 3.1 in the Council Directive on classification, labelling and packaging of substances and mixtures **(CLP) (Regulation (EC) No. 1272/2008),** the following applies:

    Criteria 17a: If the containing substances, which are classified H400 (or H410 which also shall be included in the calculation), all have M=1, then a summation of their concentrations shall be done, and the concentration limit will be 25%. 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). For summation of substances with different M-values, it shall be performed according to the Method of calculation for BASTA.

    Criteria 17b: If the containing substances only are classified H410, all have M=1, then a summation of their concentraiton shall be done, and the concentration limit will be 2.5%. If no substances are classified H410, then a summation of the concentration of the containing substances classified H411 shall be done, and the concentration limit is 25%.

13) 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**:

    "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").

    During an industrial process, a chemical product may cease to be a chemical product and become an article. When an undesired substance is found in the chemical product, it is the weight of the new article that is formed in the process where the chemical product becomes an article which is used to calculate the concentration of the undesired substance when applying the BASTA criteria. For example, if two boards are glued together and an undesired substance is present in the adhesive layer, it is the weight of the new articles, i.e. the joined boards, that is used to calculate the concentration of the undesired substance.

    If a board instead is covered with a laminate, which is defined as a separate article by the REACH definition, and there is an undesired substance present in the laminate; it is the weight of the laminate itself that is used to calculate the concentration of the undesired substance.

    <u>Swedish interpretation of the 0.1 % for giving information according to articles 7.2 and 33</u>

    <u>Dissenting views on the guidance on requirements for substances in articles</u>

14) In simple cases, where concentration limits are not specified in **Regulation (EC) No. 1272/2008) (CLP), Annex VI, table 3.1**, 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.

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. The purpose of this kind of summation is to promote a good working environment by minimizing the amount of volatile organic compounds found on constructions sites.

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), see BASTA's "Methods for calculation".

The calculation method for criterion 17 is made in accordance with the rules specified in BASTA's "Methods for calculation".

Risk phrases used in these criteria

H 300	Fatal if swallowed
H301	Toxic if swalled
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 ausing 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 childt

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 lifte with long lasting effects
H411	Toxic to aquatic life with long lasting effects
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.

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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