Guideline – Criteria:
”Properties 5 – Endocrine disrupting”

Intro

According to the BASTA-systems criteria: ”Properties 5 – Endocrine disrupting”, substances with endocrine disrupting properties must not be included in higher levels equal to or higher than 0.1%.

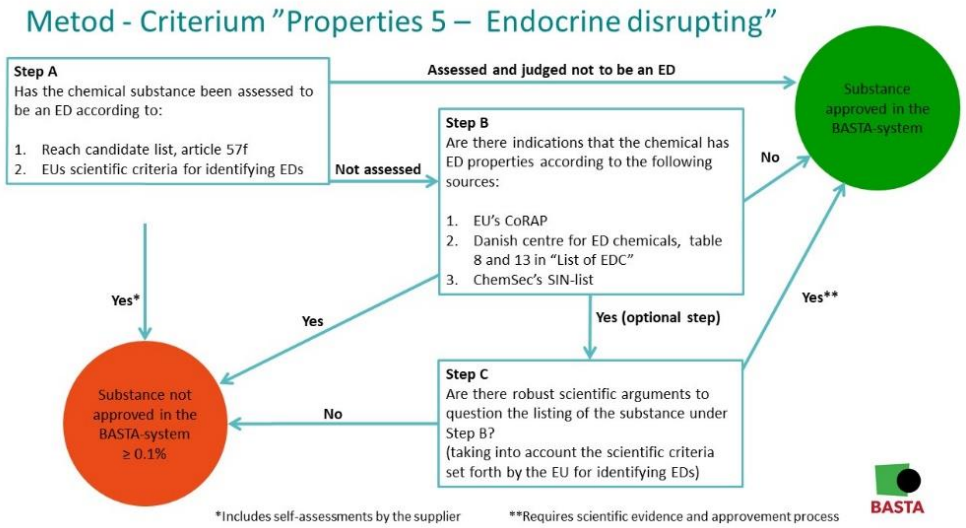
Procedures for the assessment of endocrine disruptors in the BASTA system are based since the 1/1 2020 on a methodology described in the report “Guidance document for handling criteria for endocrine disruptors in the construction industry” (IVL report B2369, 2020).

A transition period was applied during the period 1/1 2020 to 1/7 2020 to adapt to the new criterion. The EDS database, which has so far been the basis for criterion ”Properties 5 – Endocrine disrupting”, continued to apply until 1/7 2020, but thereafter the EDS database will only be included in the BASTA-system in the form of an information requirement.

The method for evaluation is based on three steps:

A. Substances assessed as endocrine disruptors as defined by the EU*
B. Substances that are listed on three selected lists and where there are indications that the substances are endocrine disruptors or alternatively that they are being investigated within the EU.
C. The possibility of questioning the substances listed under B if there are scientifically robust arguments. Mandatory documentation requirements and approval process.

The method for assessing substances with endocrine disrupting properties in Basta is schematically described in the figure below. This guide describes how to interpret and use the decision tree.



See criteria's and more information on https://www.bastaonline.se

*) 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

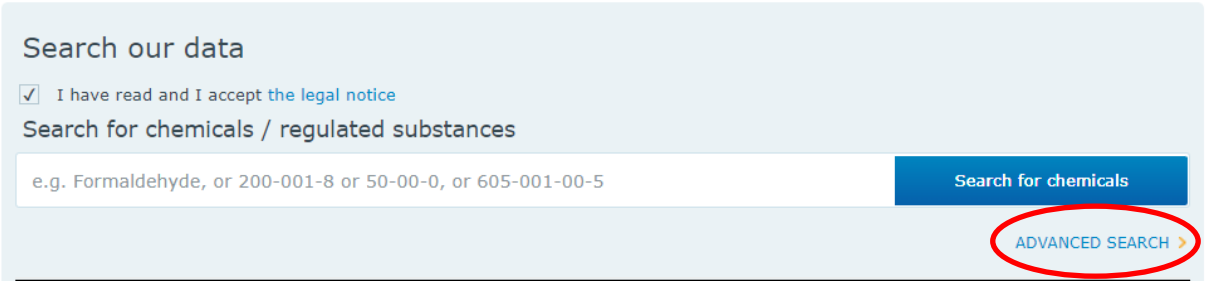
b) it has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system

c) the adverse effect is a consequence of the endocrine mode of action

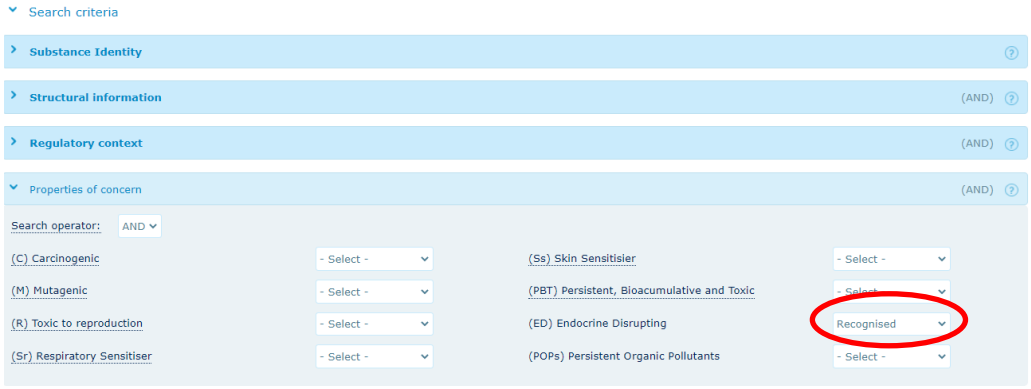
Step A. Is the substance assessed as an endocrine disruptor?

The basis for assessing whether the substance is an endocrine disruptor is either based on the supplier's information (i.e. the supplier's self-classification), or whether the substance is assessed as an endocrine disruptor under EU's chemicals legislation. If the substance is assessed as endocrine disruptors by the EU, this is shown in ECHA's database (www.echa.eu), recommended search path:

1. Select the "Advanced search" function on www.echa.eu.



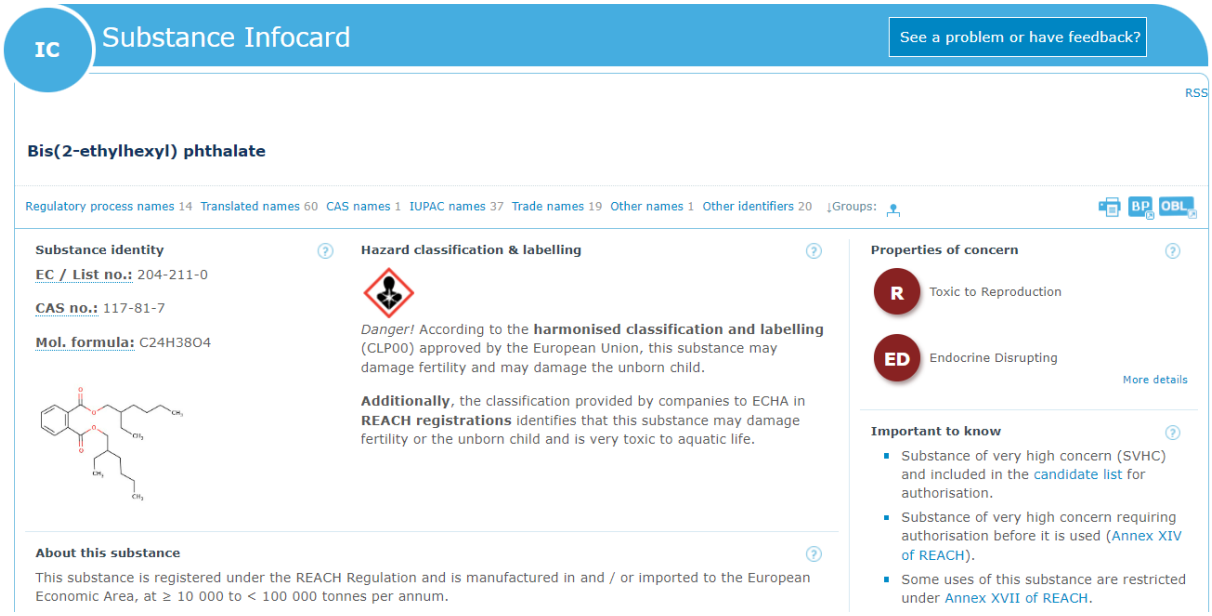
2. Then select "Properties of concern", followed by "Endocrine Disrupting" and finally "Recognized".



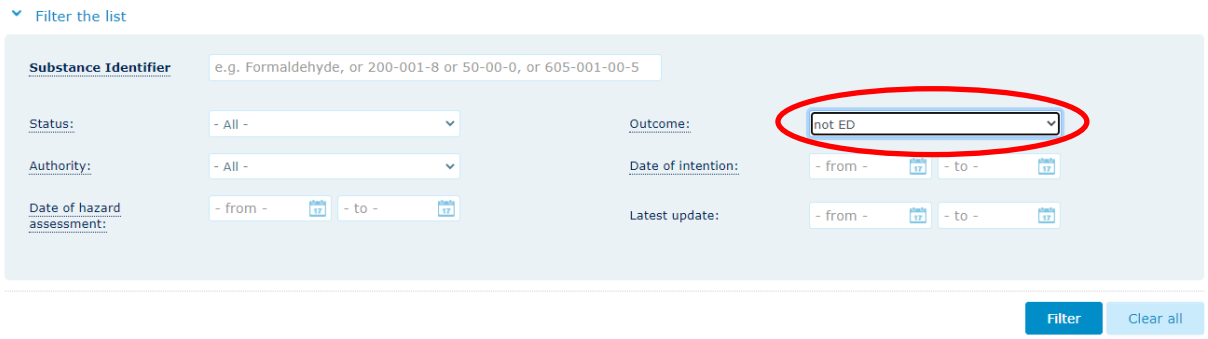
The listed substances are not allowed in products registered in the Basta database if the concentration level is equal to or exceeds 0,1%.

One option is to search directly for a specific substance with a CAS number in ECHA's database on www.echa.eu.

If the substance has been deemed to have endocrine disrupting properties, this is indicated with a dark red econ "ED" under the heading "Properties of concern", see example below:



If the substance is assessed in the EU with the result "not ED", it is allowed in Basta-registered products without further assessment. To get an overview of which substances that have been assessed with the result "not ED" a search of the EU assessment list for endocrine disruptors (https://echa.europa.eu/ed-assessment) is recommended. The search should filter the list on "not ED".



The Substances not captured in Step A according to any of the above methods are further evaluated in Step B.

Step B. Are there indications that the substance has endocrine disrupting properties?

During Step B, it is checked whether there are other indications that the substance has endocrine disrupting properties.

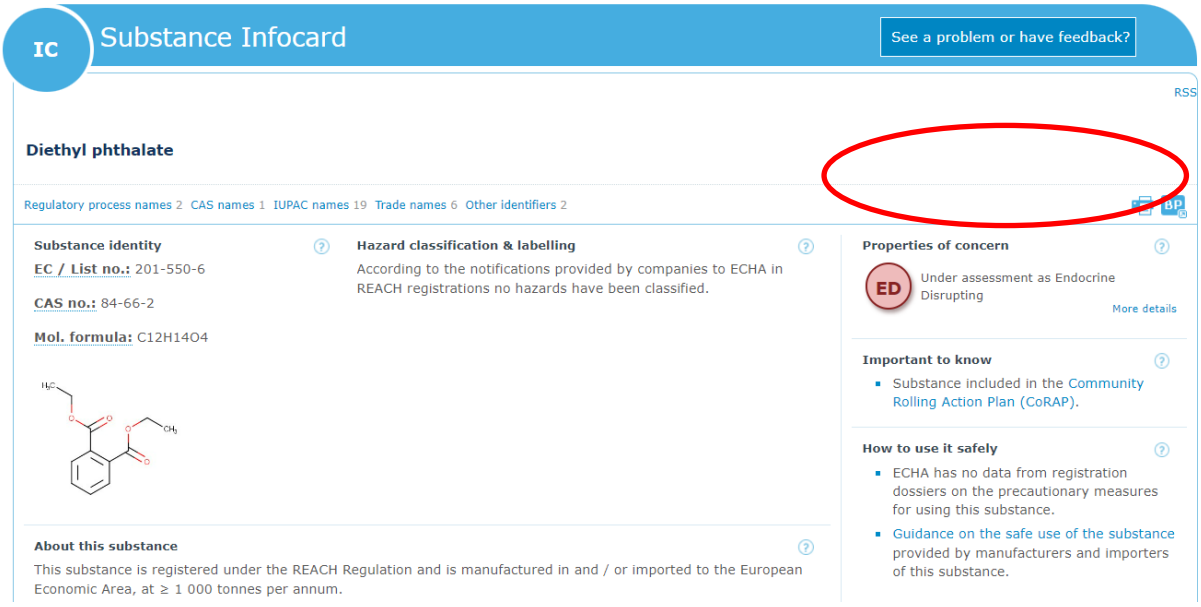
An indication is if the substance is included on one or more of the following lists:

- CoRAP,
- Danish centre for endocrine disrupting properties, table 8 and 13 in the report ”List of Endocrine Disrupting Chemicals”
- the SIN-list.

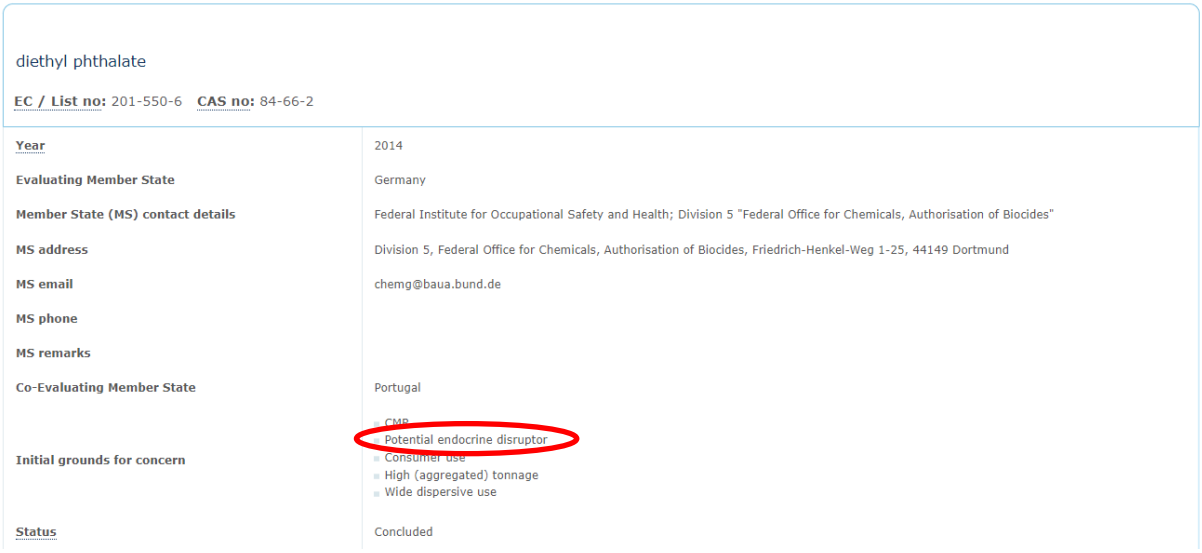
An overview list is available on BASTAS webpage under documents. The lista is named ”Substance list Basta”.

1. The CoRAP-list

A search of ECHAs chemical database at www.echa.eu shows if the substance is listed on CoRAP (Community Rolling Action Plan.) Both substances that will be evaluated, and the substances with completed evaluations should be included. One option is to search directly for a specific substance by stating the CAS-number. It will then be listed under the heading “Important to know”.

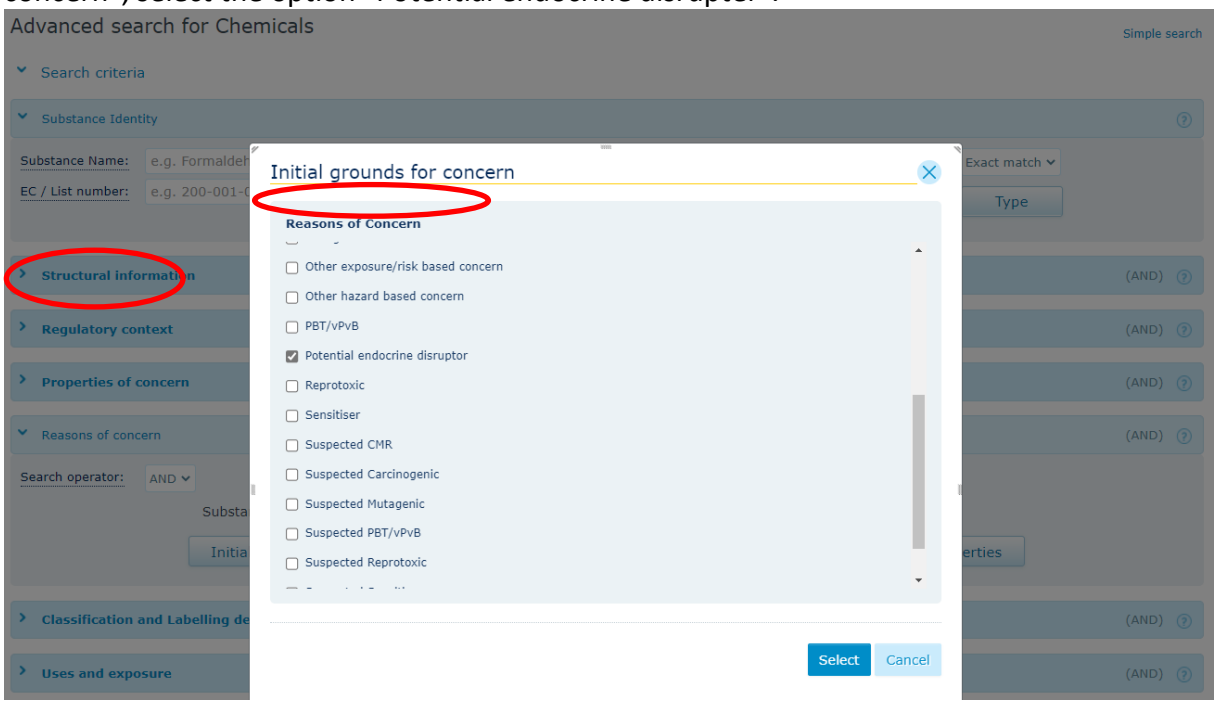


Follow the link "Community Rolling Action Plan (CoRAP)" to get information if the substance is included due to being a suspected endocrine disruptor.



You can also get a list of all substances that are listed on CoRAP by going directly to CoRAP on the website https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table.

Alternatively search CoRAP via the ECHA website by selecting "Advanced Search". Subsequently, select "Reasons of concern" and "Initial grounds for concern", which are under the heading "Substance evaluation - CoRAP". In the box "Initial grounds for concern", select the option "Potential endocrine disrupter".



2. *Danish center for endocrine disruptors*

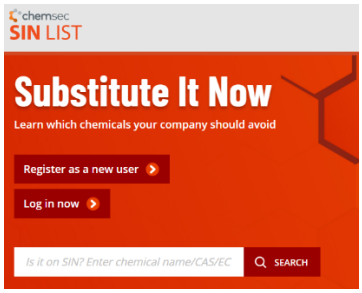
Substances assessed as endocrine disruptors by the Danish centre for endocrine disruptors are listed in the report http://www.cend.dk/files/DK_ED-list-final_2018.pdf.

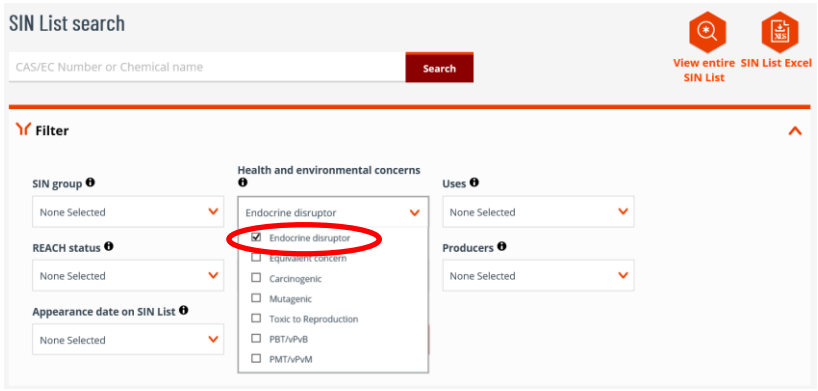
Check the substance against Table 8 and Table 13. Detailed documentation for topics can be obtained from the report's appendix http://www.cend.dk/files/DK_ED-list-final_appendix1_2018.pdf

The full reports can also be found at https://www.bastaonline.se/how-it-works/endocrine-disrupting-substances/?lang=en

3. The SIN-list

Substances listed on the SIN list due to endocrine disrupting properties are listed on the SIN list's database at https://sinlist.chemsec.org. You can search directly by using CAS numbers or substance names as well as filter the search results that have endocrine disrupting properties.





Substances listed as endocrine disruptors on any of the above lists due to endocrine disrupting properties are not allowed according to Basta's criteria at levels equal to or greater than 0.1%. Exceptions may be granted in Step C.

Steg C. Assessment - are there reasons that indications in Step B can be called into question?

It is possible to question the reason why the substance is included in the lists found under B. This is done by demonstrating scientific documentation and arguments showing that the listing cannot be said to meet criteria for endocrine disrupting in accordance with EU's scientific criteria. If this is the case, a dossier must be compiled and sent to Basta for

evaluation and approval before products containing the substance in question can be registered.

The dossier must contain a compilation of all the relevant information and arguments as to why the listing of the substance as an endocrine disruptor should not be considered as accurate. The basis for the assessment should be based on the EU's scientific criteria for endocrine disruptors and it should be specific about why the listing should not be considered as accurate. The documentation must be clear and verifiable, i.e. Basta's auditors should be able to check the information in the dossier in question.

The dossier shall contain:

- A summary that clarifies the substance, CAS number, in which construction products the substance is included and reasons why the substance should not be considered endocrine disruptor. Basta reserves the right to publish this summary on Basta's website.
- A justification that addresses all arguments as to why the topic is included in one or more of the lists in step B and why these arguments are considered incorrect.
- Scientific evidence, including references to literature studies and tests, when reference is made to studies

The dossier must be sent to: Bastaonline AB, Box 210 60, 100 31 Stockholm or by email to bastaonline@ivl.se.

Basta uses expert support for evaluation of the documentation, and the cost of the evaluation is paid by the applicant – Basta provides price information on request. When requested, the substance (CAS number and chemical name), which building products the substance is included in, as well as the organization number and invoice address shall be included. See more information on page www.bastaonline.se.

If necessary, Basta's auditors may require supplementation and clarification of the documentation in order to be able to evaluate the documentation.

In a positive assessment, i.e. that the reviewer accepts the applicant's argument, the substance can be used in products registered in the Basta system. However, an information requirement applies to these substances which means that the name, CAS number and concentration (weight%) must be stated and made publicly searchable. Location for registering this information can be found in the database's registration view from March 2020. If the submitted documentation is deemed insufficient, the substance is not allowed at concentration levels equal to or exceeding 0.1% in accordance with Basta's criteria.

Basta shows the substances whose data have been evaluated and approved on bastas webpage. The listing can be used as a basis for all companies that register their products in the system. For all registered products containing a substance listed, the information requirements stated above apply.