

The 2.1 update of the SIN List

The technical 2.1 update of the SIN List mainly builds on an important source of information that has only recently become available: the REACH registration dossiers. This information has revealed a number of chemicals, all of them classified as carcinogenic, mutagenic or toxic to reproduction (CMR substances), that are registered and used in a way that puts them in the scope for regulation under REACH. The 2.1 update also includes newly classified CMRs as well as substances recently agreed by EU member states as Substances of Very High Concern. This update of 249 substances and substance groups¹ now results in a SIN List of 626 entries.²

In addition, more information obtained from the REACH registration dossiers has been added to the SIN List database, describing, for example, how the SIN List chemicals are used and in which quantities they are produced.

WHY A 2.1 UPDATE?

The previous update of the SIN List, the 2.0 update in May 2011, built on new reviews of scientific research identifying endocrine disrupting chemicals as Substances of Very High Concern according to the “equivalent level of concern” category in REACH.

The 2.1 update, on the other hand, is rather a technical update building on the implementation of REACH in terms of registration information and the development of the Candidate List, as well as new EU classification data.

REACH REGISTRATIONS PROVIDES NEW INFORMATION

REACH requires companies to provide information about substances produced or imported in the EU market. The first deadline for registration of this information was in November 2010. However the dissemination of this information has only been

made publicly available bit by bit.³ Information that was disseminated by the end of December 2012 has been used for the SIN List 2.1 update.

- 1. Chemicals on the SIN List are added using the group approach from the CLP regulation. One entry on the SIN List may therefore consist of several similar chemicals, with different CAS numbers. For the 2.1 update 292 individual CAS numbers have been added.*
- 2. Since the group approach in the CLP regulation has been used, two substances on the SIN List 2.0 (with 378 entries) have been grouped together resulting in a total of 626 entries on SIN List 2.1.*
- 3. echa.europa.eu/information-on-chemicals/registered-substance*

SPECIFICS FOR SELECTION OF CHEMICALS FOR THE SIN 2.1 UPDATE

Information from REACH registration dossiers

1. The first category of new substances on the SIN List 2.1 are substances which, according to the CLP (Classification, Labelling and Packaging of substances and mixtures) regulation, are defined as complex hydrocarbon distillates (found in table 3.1 of Annex VI of the CLP regulation with all entries from index numbers 648-xxx-xx-x and 649-xxx-xx-x). In earlier versions of the SIN List these substances were exempted, since it was estimated that the vast majority of them were only used as intermediates. However, according to the REACH registration data, many of these substances are fully registered and thus are used also in other applications. Therefore these substances are within the scope of REACH authorisation and when classified as CMR category 1A or 1B these are relevant for the SIN List.

»» In total, 225 new entries from this category have been added to the SIN List 2.1.

2. The second category of new substances added to the SIN List 2.1 includes substances belonging to a chemical group for which the whole group has a CMR classification according to the CLP regulation. Since the CLP regulation gives no indication of which individual substances may be covered by such an entry, the REACH registration dossiers have been used to investigate which such substances have been registered and thus are on the market and in use. Again, only such substances classified as CMR 1A or 1B have been included in the SIN List. Substances found relevant for inclusion were found in the following categories: lead compounds, chromium compounds, hydrazine compounds and arsenic compounds.

»» In total, 5 new entries from this category have been added to the SIN List 2.1.

Recently classified CMRs

3. The third category of new substances on the SIN List 2.1 includes minor corrections to earlier versions and updates to the CLP regulation covering a total of four substances classified as CMRs in the CLP regulation.

The last update of the CLP regulation entered into force in July 2012 (ATP03), and this update classified two new substances as being CMR 1A or 1B, so these have now been included on the

SIN List 2.1. Due to an earlier inaccuracy in the classification data published by the European Commission (the ATP01 update), it has been noticed that another two substances, classified as CMR 1A, qualify for inclusion in the SIN List and those substances have therefore also been added.

»» In total, 4 new entries from this category have been added to the SIN List 2.1.

Officially identified SVHCs from the REACH Candidate List

4. The SIN List identifies substances that are relevant for the REACH Candidate list, and so far the SIN List has closely predicted the substances included on the Candidate List. However, the 2.1 update of the SIN List also includes substances that have already been included on the Candidate List. The differences between the lists originate from the strict methodology and the principles of the SIN List compared to the Candidate List, in which substances are included on a case-by-case basis. Substances that have recently been added to the Candidate List but have not previously been included on the SIN List include substances that are in fact mixtures, substances without a CAS number and substances added under the equivalent level of concern category as sensitisers. As these substances have now been officially recognised to meet the criteria of being Substances of Very High Concern by EU authorities, they have been included in the 2.1 update of the SIN List.

The following entries have been added (with the reason why these have not been picked up by the SIN methodology in brackets):

8 CMRs (including substances without a CAS number, reaction products and mixtures).

4 vPvBs (previously not identified by the EU PBT Working Group but new data provided in the REACH Annex XV dossiers has shown these to meet vPvB criteria).

3 equivalent level of concern substances, (information from the REACH Annex XV dossiers supports the identification of these sensitisers as SVHCs).

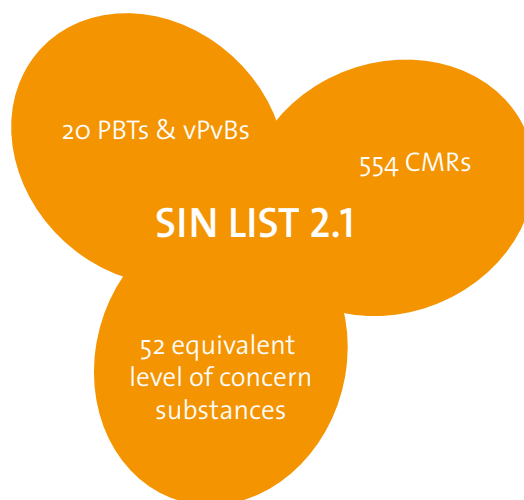
»» In total, 15 new entries from this category have been added to the SIN List 2.1.

UPDATED AND EXTENDED SUBSTANCE INFORMATION IN THE SIN LIST DATABASE

As part of the SIN 2.1 update, more information about the SIN List substances has been added to the publicly available SIN List database (www.sinlist.org). This includes information from the REACH registration dossiers about how these substances are used, as well as the quantities in which they are produced (tonnage bands). This now makes it easier to filter substances in the SIN List database by how they are used.

It is now also possible to de-select substances that have not been registered in the EU, since not all substances on the SIN List, or on the Candidate List, have been registered as being used or produced within the EU.⁴

As earlier, the SIN List database also includes additional information about the SIN List substances, such as classifications, technical functions, and assessment for inclusion on the SIN List.



Candidate List	A list of substances within REACH meeting the criteria of Substances of Very High Concern, and proposed by either the European Commission or the EU member states. All member states must then unanimously decide that these substances are indeed SVHCs. These substances are candidates for authorisation under REACH.
CAS	Chemical Abstracts Services registration number, a system assigning unique substance identification numbers to all chemicals.
CLP regulation	Classification, labelling and packaging of substances and mixtures – CLP Regulation (EC) No 1272/2008.
CMR	Substances that are Carcinogenic, Mutagenic or toxic to Reproduction.
Equivalent level of concern	Substances that are of equivalent level of concern as CMRs, PBTs or vPvB in terms of the potential damage they may cause.
PBT	Substances that are Persistent, Bioaccumulative and Toxic.
REACH	REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is the broad EU chemicals regulation that entered into force in 2007.
SIN List	The "Substitute It Now" List lists substances identified by ChemSec as fulfilling the criteria for Substances of Very High Concern as defined in the REACH regulation. A ChemSec project aiming to speed up the REACH implementation process and provide a substitution tool for companies.
SVHC	Substances of Very High Concern are the most hazardous substances according to article 57 of REACH. These are CMR, PBT and vPvB substances, as well as substances of equivalent level of concern.
vPvB	Substances that are very Persistent and very Bioaccumulative.

4. The first REACH registration deadline in December 2010 only applied for substances manufactured or imported above 1,000 tonnes per year, substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (manufactured or imported in quantities above 100 tonnes per year), as well as substances classified as CMR category 1A or 1B (manufactured or imported above 1 tonne per year). There are CMR substances that were not registered by the end of 2010, even though they were produced in quantities subject to registration earlier during 2010, and enforcement action has been taken by European authorities to look into this matter.