

Self-classifications: Of no value without enforcement

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ECHA Enforcement Forum, 5 November 2019



Legal obligation behind self-classification

- Article 31(9) of REACH

“Suppliers shall update the safety data sheet without delay on the following occasions:

(a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available; [...]”



- Article 15(1) and (4) of CLP

“Manufacturers, importers and downstream users shall take all reasonable steps available to them to make themselves aware of new scientific or technical information that may affect the classification of the substances or mixtures they place on the market. [...]”

“Manufacturers, importers and downstream users shall adapt the classification of the substance or the mixture in accordance with the results of the new evaluation except where there are harmonised hazard classes or differentiations for substances included in Part 3 of Annex VI.”

Approach towards classification & supply chain communication

1. Apply classification endpoints harmonized in Annex VI of CLP
2. Investigate (other) hazard profile of substance and derive 'self-classification' based on:
 - Relevant and reliable data on substance, and
 - Relevant and reliable data on similar substances, via read-across
3. Where 1. or 2. lead to CLP classification, produce SDS and communicate self-classification and related safety measures in SDS



C&L Inventory, New information and Enforcement

- C&L Inventory: different classifications for the same substance
- Helpful during extended registration deadline, need to tidy up conflicting information
- Enforcement of Art. 31(9) of REACH and Art. 15(1) and (4) of CLP should be given same weight as that of harmonized classifications...
- ...especially after the last REACH registration deadline
- “New information” for registered substances should now be available
- Priority should be given to C&L derived from joint efforts by industry
- Following informal exchanges with Member States Competent Authorities, it appears that enforcement of self-classification is:
 - Not foreseen/planned
 - Not practically possible



Classifications as competitive (dis)advantage

- Classification triggers safe use requirements, labeling and packaging obligations for manufacturers and downstream users → €€€
- In some (most competitive) sectors, some suppliers (intentionally) apply a no-classification or a less severe classification
 - No or simpler safe use, labeling, packaging and transport obligations result in lower manufacturing costs
 - More attractive to customers: No classification – no comprehensive and expensive risk management measures have to be implemented for the substance / mixture
 - No communication of a hazard to different DUs in the supply chain
- Market/Compliance impact:
 - Anti-competitive behaviour
 - Unsafe handling and use



Example 1: Antimony trisulfide (ATS)



- EC number: 215-713-4 / CAS Number: 1345-04-6
- Molecular formula: S_3Sb_2
- Can be naturally occurring and intentionally manufactured from Sb metal



(N.B.: 100% of Sb is sourced outside EU, 80% is sourced from China)

- Supplied as black powder
- Mainly used in brake pads, friction materials, and primer in ammunitions
- REACH registered in 2013, regularly updated since (last: 2019)
- Undergoing REACH Evaluation with BAuA, probably followed up by CLH
- Lead Registrant: Tribotecc GmbH (Austria); only 1 additional co-registrant in UK
- Other 3 main suppliers in EU of natural ATS

Example 1: Antimony trisulfide (ATS)

Registrants /Suppliers of the substance open all close all

-“ Registrants / Suppliers - ACTIVE

Registrant / Supplier details	Latest dossier received										
	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
● Tribotecc GmbH Industriestrasse 23 A-9601 Arnoldstein Austria											
Wogen Resources Ltd 4, The Sanctuary Westminster SW1P 3JS London United Kingdom											

Intentionally manufactured: 2 REACH registrations (100-1000 t/a), with joint classification: Carc. 2 (inhalation), and STOT RE 2 (lung)

Naturally occurring: exempted from REACH Registration, subject to CLP notification, classification notified: ‘no-classification’

163 C&L notifications in total (cf. next slide)

Example 1: Antimony trisulfide (ATS)

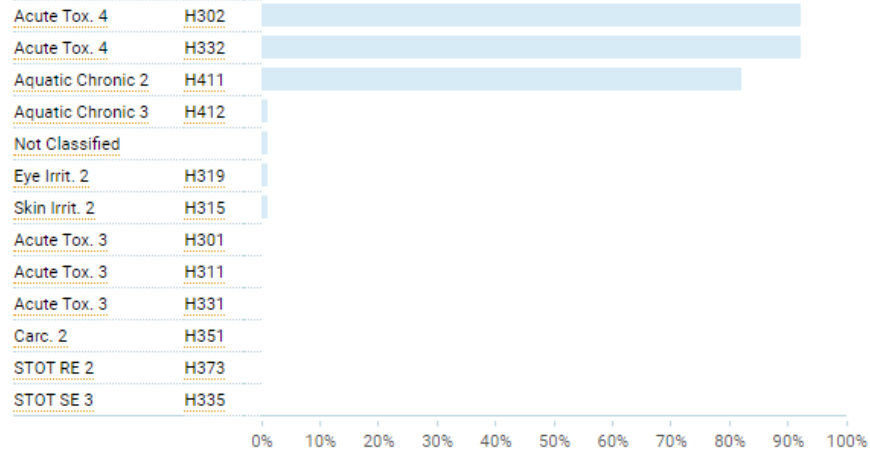
Hazard classification & labelling



Warning! According to the classification provided by companies to ECHA in **CLP notifications** this substance is toxic to aquatic life with long lasting effects, is harmful if swallowed and is harmful if inhaled.

Most relevant endpoints not even visible in brief profile...

Breakdown of all 163 C&L notifications submitted to ECHA



Harmonised Classification
 REACH registration dossiers notifications
 CLP notifications

At least one notifier has indicated that an impurity or an additive present in the substance impacts the notified classification.

- Most of the notified C&L are against CLP Annex VI indications

Index No	International Chemical Identification	EC No	CAS No	Classification		Pictogram, Signal Word Code(s)	Labelling
				Hazard Class and Category Code(s)	Hazard Statement Code(s)		
051-003-00-9	antimony compounds, with the exception of the tetroxide (Sb ₂ O ₄), pentoxide (Sb ₂ O ₅), trisulphide (Sb ₂ S ₃), pentasulphide (Sb ₂ S ₅) and those specified elsewhere in this Annex			Acute Tox. 4 * Acute Tox. 4 * Aquatic Chronic 2	H332 H302 H411	GHS07 GHS09 Wng	H332 H302 H411

Example 1: Antimony trisulfide (ATS)

• Market impacts

- ATS available as non-classified, incorrectly classified, and adequately classified
- Customers unaware, not knowledgeable, rely on supplier/cheapest 'version' of the same substance
- Responsible suppliers unable to influence either other supplier or customer
- **Responsible suppliers lose market (while responsibly responding to Evaluation requirements)!**

• Safety impacts

- ATS supplied without (proper) SDS and classification
- Customers who receive material without classification/SDS are unaware of lung toxicity and applicable precautions, and handle ATS as any other substance
- **Customers may be exposed to unacceptable levels of ATS and develop lung toxicity effects (long-term)!**

Precautionary statements

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P260: Do not breathe dust/fume/gas/mist/vapours/spray.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313: IF exposed or concerned: Get medical advice/attention.

P314: Get medical advice/attention if you feel unwell.

P405: Store locked up.

P501: Dispose of contents/container toin accordance with local/regional/national/international regulations (to be specified). Manufacturer/supplier or the competent authority to specify whether disposal requirements apply to contents, container or both.

in accordance with local regulation (because good practice)

Example 2: Borates

- Boric acid, Sodium borate, Boric oxide... “refined” borates
- Classified as Repr. 1B in CLP Annex VI (2009)
- Heavily scrutinized over the past 10 years from the regulatory side:
 - SVHC, failed industry initiative to re-classify, prioritization, removal of SCLs...
- Wide number of different applications, some uses are essential
 - Micro-nutrient for fertilizers, neutron absorption in nuclear power plants, effective insulation materials leading to CO₂ reduction...
 - Glass, ceramics, flame retardants, industrial fluids...
 - Hundreds of users in multiple supply chains
- Well-defined inorganic materials (sodium/non-sodium borate salts)

Example 2: Borates

- Borate minerals introduced at very high volumes in EU - >100,000 tpa
- Calcium borates (colemanite) / calcium-sodium borates (ulexite)
- Self-classification in EU: No classification
- Natural minerals – no REACH registration dossier available
- It is well established that all inorganic borates dissociate into boric acid
 - Read-across principles should apply! Instead, no data=no C&L
 - Australia: NICNAS-IMAP classification of all borate minerals as Repr. 1B
 - Ulexite listed in REACH Annex III (C&L Inventory), no practical impact
- (Regrettable?) Substitution in many applications is already occurring
 - Suppliers of refined borates impacted - No level playing field
 - Industry committed with compliance, this issue undermines confidence

Summary – key messages

- There are references to enhancing competitiveness in REACH and CLP - difficult to achieve without enforcement on C&L
- Incorrect C&L may lead to unnoticed exposure to harmful chemicals
- Priority should be given to C&L coming from Joint Submissions, when conflicting information is found in the inventory
- Registration exemption for minerals + lack of C&L enforcement results in switch of paradigm “No data – no market” to “No data – no problem”
- Industry should not act as Industry’s police
- Potential negative “perception” in the market for companies pursuing that substances should be correctly classified
- Compliant companies should not be the bad guys – those that have been (presumably) non-compliant for many years should!



Eurometaux' request

1. Consider a REF project looking at how Articles 15 of CLP and 31(9) of REACH are implemented and enforced, and report the outcome to enable future improvements
2. Ensure that the implementation of Articles 15 of CLP and 31(9) of REACH are given the same weight during inspections as other CLP and REACH obligations
3. Consider the set-up of a system/tool (at ECHA or national level) through which companies can inform enforcement authorities about likely cases of non-compliance with classification, packaging and labelling obligations, in order to facilitate targeted inspections and improve environmental and human health protection

THANK YOU

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