Workshop on substance identity and substance sameness:
FR MNI experience

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Substance ID : The issue

Join submission of« a » substance

ECHA compliance checks the Lead dossier (SID)
OR eMSCA evaluate « the » substance

Clear indications: many compositions or forms or substances

ECHA

eMSCA:

responsibility of the registrants within the Joint Submission to have the same substance

SONC

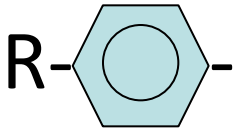
enforcement

Accurate evaluation

Worst case scenario?

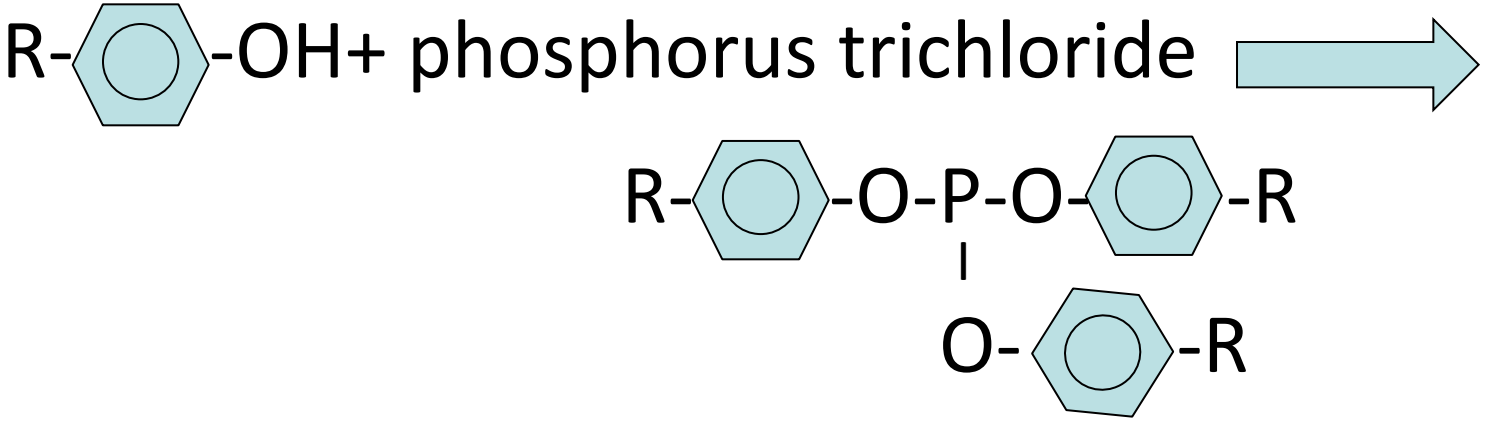
SAME substance??

Isomeric issues



R is an alkyl

→ exists as various isomers (o-, m- and p-)



Mixture of (o-, m- and p-) isomers→ mixture of decade of isomers .

Even more complex with ramification of the alkyls!!

Isomeric issues (2)

- Included lately in CoRAP following on-going evaluation under EU Regulation 793/93.

- Its CAS number covers various isomers, having various stabilities → ≠ impurities → **different toxicity (eg. Neurotoxicity)** .

- FR proposal in SEv DD : Request information on the hazards (ENV, e-fate (solubility)) **of the composition or forms as put on the market**.

- ECHA recommendation in SEv DD : first to challenge the SID, only for LR.

- ECHA said FR should not send requests before having ascertain SID, because "it would be uncertain what substance would actually be tested and whether the tests would reflect on properties of the registered substance"

- FR proposed to take advantage of SID for gaining knowledge on a purer process claimed by one of the registrant.

→Which composition or form (to test) tested? Worst case scenario?

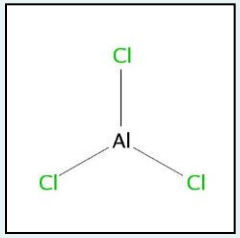
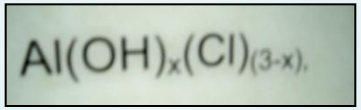
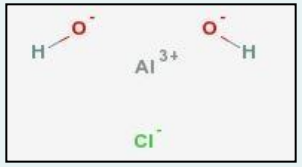
→This is registrants responsibility to prove data (to be) provided by lead is applicable to the other composition or forms (part of SEv)

→Clarify which data for which composition or form

→Perform SID before any evaluation

Substance ID : ex. of Aluminium chloride issues (1)

• Registration dossiers for 2 substances included in 2014 in the CoRAP for evaluation in 2015

Aluminium chloride CAS: 7446-70-0	Aluminium chloride, basic CAS: 1327-41-9
	  
Reactive form; Al^{3+} $(Cl^-)_3$ in acid solutions	Hydroxylated form that can be polymerised
Uses: reactive process agent in inorganic and organic syntheses; use in laboratory	Trade names: polyaluminium chloride Uses: use in synthesis as process chemical; use as flocculant or a coagulant in water and waste water treatment; use in laboratory
-> information consistent	-> inconsistent information within and between RD on identity of the substance based on formula, names and uses

Substance ID : ex. of Aluminium chloride issues (2)

- **Our issue**: to avoid evaluation of a substance for which registration dossier covers various non-characterised substances and includes data that are potentially not on the relevant substance.

- SID CCH performed by ECHA:
  - ❖ request of SID clarification for the basic AlCl
  - ❖ but only LR evaluated for CCH and other registrants not informed
  - ❖ no emphasis on the need to clarify also SID for test substance and its relevance to the registered substance.

- In literature, CAS 1327-41-9 =aluminium chlorohydrate basic
  - ❖ ≠ with the general formula given in the dossiers.
  - ❖ what use for which composition/form. Is there any polymers covered (excluded from REACh, what is not)

Specific compositions/ forms of certain substance have specific properties leading to specific uses. Its should be understood that these properties may lead to specific side-effects!

➢Clarify which data for which composition/form, which uses.

Mono or multi-constituent??

•**Monoconstituent** (>= 99.9% w/w) for Lead Registrant

• Different **manufacturing processes** exist → lead to different impurity profiles and different classifications of the substance.

• Nine different compositions (grades) are provided by six registrants. **Four groups have been identified based on the purity and the impurity profile** which are differently classified:

1- Purity > 99% with a typical at 99.9% (**5 dossiers**) with no relevant impurities for the classification

2- Purity > 99.1% with a typical at 99.5% (**1 dossier**), with no information on the impurity profile

3- Purity > 85% with a typical at 97.5% for one and 90% for the second (**2 dossiers**). One impurity is relevant for the classification of the substance.

4- Purity between 38 and 99.9%, with two other constituents which could be present at a content upper than 10% → should not be considered as a mono-constituent but as a **multi-constituent** of 3 constituents. **This dossier was excluded of the evaluation performed (as stated in SEv report).**

Mono or Multi : lessons learned

- an awkward situation: **This excluded dossier = pure case of enforcement and this dossier should be excluded from the SIEF.**

➢ **Strong collaboration between the different players is required**

MNI

Enforcement from other MSs

- **However, the data produced in the framework of SEv should, partially , be used by the registrant of the multi-constituent substance (if he decided to evaluate of a mixture??)**
- **OR ideally, should perform a separated evaluation**

Substance ID : critical issues

• For ECHA, CCH mostly on Lead registrant's substance

• Multiplier letters sent to raise awareness among Members of a Joint submission together with SID decision on LR

• ECHA does not challenge the SIEF nor the composition of a susbtance: cf Board of Appeal decision 008-2012: 02/04/2014

• SIEF has the responsability of « *sameness* »

• FR wonders :

→ How SID can be clarified when challenging the LR only (LR not responsible of the others composition)?

→ How to ensure that all SIEF members are aware there is a potential issue with the SIEF definition?

→Reverse the burden of proof should give the registrants the responsibility in defining in detail the tested substance for each test and to show this is the worst case scenario.

Conclusions

•Same CAS does not necessary mean same substance or composition.

•Good indication is that when the uses are different, it means that the commercial properties are different: raises the question if the “adverse” effects could be different.
•Need to clarify sameness issues before SEv (Delay in SEv when SID is not challenged, who has to be informed, who is responsible of the choice the registered substance…): Sameness is a key issue

→ Strong messages need to be sent to REG with technical SID CCH:

- **SID problems = critical point that challenges the validity of the registration**
- **when SID issue with 1 REG in a JS → all REG in the JS to be informed of potential need for clarification/confirmation that substances are the same.**
- **need to check that registered and test substances are relevant and appropriate or that relevance/read-across is justified.**