

SUBSTANCE IDENTITY FOR PESTICIDE CHEMICALS - ALIGNMENT WITH RULES FOR IDENTIFICATION AND NAMING OF SUBSTANCES UNDER REACH AND CLP

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OUTLINE

- Chemical Strategy for Sustainability: 1S1A and EU CDPC
- Experience in the SID alignment among PPP and CLH
- ECHA Guidance for Substance Identification and Naming
- Application of the ECHA SID Guidance in other Legislations
- Benefits
- Next Steps



CHEMICAL STRATEGY FOR SUSTAINABILITY: 1S1A AND EU CDPC

Within the Chemical Strategy for Sustainability (CSS), the Commission defined a series of actions among which:

- the 'one substance, one assessment' (1S1A) process which aims at improving efficiency and coherence of the safety assessment of chemicals across legislations;
- the development of a common open data platform on chemicals (EU-CDPC) to facilitate the sharing, access and re-use of information on chemicals coming from all sources.

In consideration of above, a common way for identifying and naming substances across EU is recognised as essential step to enable a meaningful **CDPC creation** and the practical implementation of the **1S1A project**.



This would be possible with the alignment to the **ECHA Guidance on Substance identification and naming**



EXPERIENCE IN THE SID ALIGNMENT AMONG PPP AND CLH

Since Spring 2022, ECHA and EFSA decided to undertake a systematic SID check at the intake phase, at AR/CLH dossier submission to EFSA and ECHA.

The combined AR/CLH template was developed to enable parallel submission. Moreover, Reg (EU) No 2020/1740 introduces a more stringent obligation for MSs to submit a CLH proposal to ECHA (latest) at the time of submission of the RAR.

The SID check was introduced to ensure harmonization and consistency between the EFSA-ECHA naming convention for substances in parallel in the two processes (same name/identifiers in background docs and website).

The experience so far has enabled to clarify inconsistencies/issues on the name or on identifiers used. However, the absence of common agreed rules has prompted EFSA to do a case-by-case internal verification of the names proposed by ECHA.

→ the alignment to the ECHA SID Guidance will set basic principles, bring a systematic procedure in handling cases and ensure consistency.



ECHA GUIDANCE FOR SUBSTANCE IDENTIFICATION AND NAMING



GUIDANCE

Guidance for identification and naming of substances under REACH and CLP

GUIDANCE IN A NUTSHELL

Identification and naming of substances under REACH and CLP

The document aims to explain in simple terms the main principles behind the identification and naming of substances

Guidance: https://echa.europa.eu/view-article/-/journal_content/title/guidance-for-identification-and-naming-of-substances-under-reach-and-clp

Substance identification: <https://echa.europa.eu/regulations/reach/substance-identity>



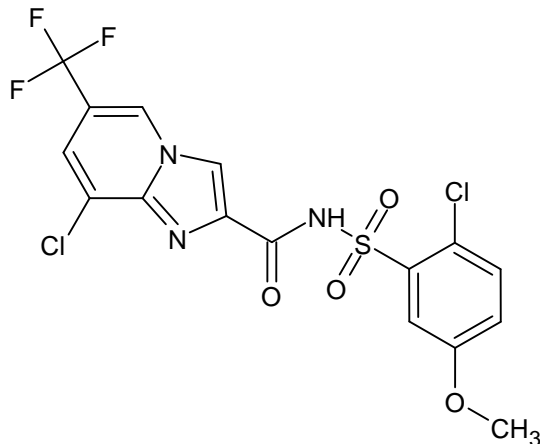
ECHA GUIDANCE FOR SUBSTANCE IDENTIFICATION AND NAMING – APPLICATION OF THE RULES TO PESTICIDE

NAMING AND SUBSTANCE TYPES: WELL-DEFINED vs UVCB

- **WELL DEFINED SUBSTANCES** have a CLEAR QUALITATIVE and QUANTITATIVE COMPOSITION

◇ MONO-CONSTITUENT SUBSTANCE

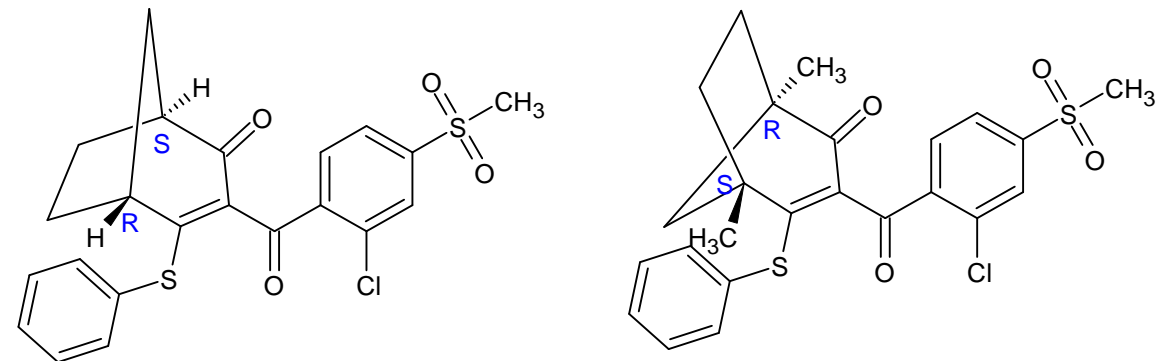
One main constituent typically $\geq 80\%$ w/w.



fluazaindolizine (ISO); 8-chloro-N-[(2-chloro-5-methoxyphenyl)sulfonyl]-6-(trifluoromethyl)imidazo[1,2-a]pyridine-2-carboxamide

◇ MULTI-CONSTITUENT SUBSTANCE

more than one main constituent typically $\geq 10\%$ and $< 80\%$ (w/w)



benzobicyclon (ISO); (1R,5R)-3-[2-chloro-4-(methylsulfonyl)benzoyl]-4-(phenylthio)bicyclo[3.2.1]oct-3-en-2-one

UVCB: Substances of Unknown or Variable Composition, complex reaction products or Biological material



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- **UVCB SUBSTANCES**: Substances of Unknown or Variable Composition, complex reaction products or Biological material
 - Variability of COMPOSITION, number of CONSTITUENTS relatively LARGE, COMPOSITION to a significant extent UNKNOWN
 - Additional information needed for their identification (to the composition) ---> Manufacturing process details

example:

“Paraffin oils”

CAS number: 64742-46-7

EC/Chemical name: “Distillates (petroleum), hydrotreated middle”

A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C11 through C25 and boiling in the range of approximately 205°C to 400°C (401°F to 752°F).



APPLICATION OF THE ECHA SID GUIDANCE IN OTHER LEGISLATIONS

Relevant Substance Identifiers (e.g. CAS/EC nr and name, IUPAC name etc..) are listed in each Regulation while the alignment to the ECHA SID Guidance is recorded in appropriate Guidance documents.

REACH – Listed among the Guidance on REACH

CLP - Guidance on the preparation of dossiers for harmonised classification and labelling, p.11: *“The Guidance is complemented by other supporting documents: [...] Guidance for identification and naming of substances under REACH and CLP”*.

BPR – in March 2007 the ECHA SID Guidance was adopted by the Competent Authorities of the Member States to ensure a consistent identification of substances considering that biocidal active substances are also subject to the CLP Regulation.

Guidance on Biocidal Product Regulation - Identity of the Active Substance, p.13: *“The ECHA Guidance for identification and naming of substances under REACH and CLP, Chapter 4, should be applied for the purpose of identification of the active substances”*.

CLH: https://echa.europa.eu/documents/10162/2324906/clh_en.pdf/36b11f14-01a0-4474-be46-e48dd9b27849?t=1407851738424

BPR: https://echa.europa.eu/documents/10162/2324906/bpr_guidance_vols_i_part_abc_en.pdf/31b245e5-52c2-f0c7-04db-8988683cbc4b?t=1648547577294



BENEFITS

Alignment to the ECHA SID Guidance will

- Bring a systematic procedure in handling cases
- Ensure consistency across legislation (e.g. PPP, CLP, BPR)
- Set basic principles and rules which could be adapted upon need in specific cases – this is already done for biocide active substances
- Ensure the 1S1A (onesubstance-oneassessment) project success
- Enable a meaningful EU-CDPC (common data platform of chemicals) creation



NEXT STEPS

- Today's presentation at the Pesticide Steering Network meeting is to inform on EFSA's intention to align with ECHA SID guidance and to gather feedback on the proposed alignment.
- Possible options for next steps – for discussion
 - Bring the proposal for alignment to the General Expert meeting on physico-chemical properties which is planned on the 22-23 November 2023, for discussion with the experts.
 - Record the alignment to the ECHA SID Guidance in the most appropriate Technical Guidance, similarly to what has been done for Biocides.



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SECTOR SPECIFIC GUIDANCE

Sector-specific support for substance identification:

Oleochemicals

Essential oils

Petroleum products

Hydrocarbon solvents

Complex inorganic coloured pigments

Metals

- ECHA works closely with certain sectors of the chemical industry to develop guidance on how to identify substances for regulatory purposes
- Such sectorial guidance are developed in the framework of the OECD and in collaboration with the relevant Industry Associations
- ECHA SID Guidance principles stems from rules defined at sectorial level

