

The importance of substance identity in ensuring a successful registration

Ninth Stakeholders' Day

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Key messages



- You need to know the identity of your substance
- You need to be able to express your substance identity in REACH language
 - For authorities
 - For your potential co-registrants
- ECHA provides support
 - Webinars to get basic understanding
 - Documents of varying detail to guide you through your substance identification
 - Validation Assistant to check substance identity information in your dossier
- ECHA takes large-scale actions to improve substance identification in the registrations

Why correct and unambiguous substance identification is important

- What do I manufacture /import?
- What are my obligations under REACH?
- Can two (or more) of my substances be regarded as the same?
- Is there a (pre)SIEF for my substance? Can I register jointly?
- Can I share existing data with other registrants?
- Is my substance concerned by other regulatory processes (e.g. harmonised classification & labelling, Candidate List for substances of very high concern, etc.)?

The information on substance identity must:

- Be submitted individually by each registrant
- Be specific to the substance actually manufactured/imported by the registrant
- Allow unambiguous identification of the substance
- Be supported by qualitative and quantitative analytical data
- Be consistent throughout the registration

How to identify your substance?



Steps to be considered

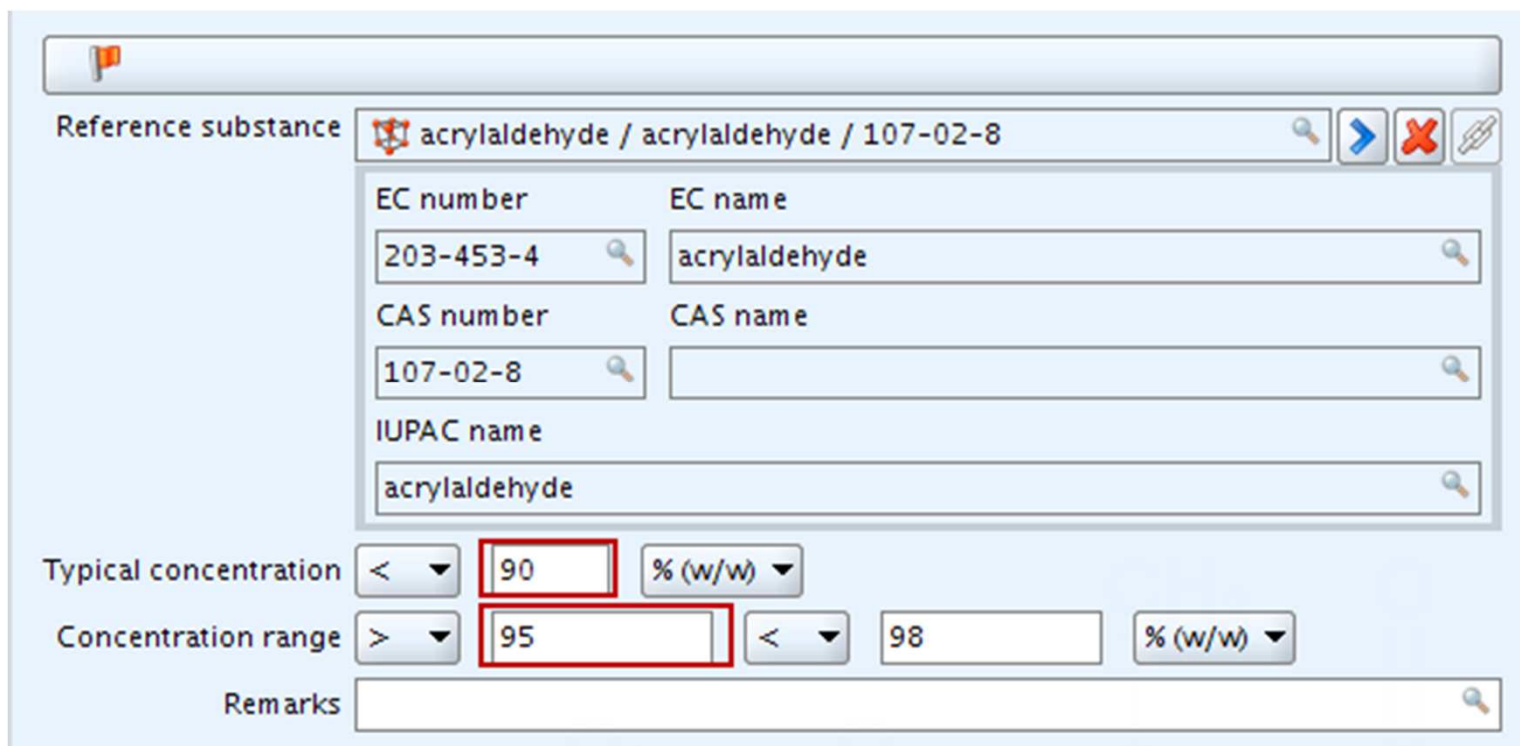
- Identify the type of your substance based on its composition:
 - Well-defined (mono/multiconstituent);
 - Substance of unknown or variable composition, (UVCB);
- Provide all necessary information as defined in Annex VI of REACH:
 - Identifiers: Chemical/IUPAC name, CAS, EC numbers (if available and appropriate) etc.
 - Information on molecular and structural formula
 - Composition
 - Spectral and analytical data, description of methods.



Validation Assistant

- Two tools in one:
 - Technical Completeness Check, including check of Business Rules
 - Dossier Quality Assistant
- Can be used for verifying dossiers before submission
- Dossier Quality Assistant:
 - Contains substance identification rules in line with the Guidance on substance identification
 - Supports registrants to improve the quality of their registrations
 - Identifies substance identity shortcomings

Validation Assistant - example



The screenshot shows the Validation Assistant interface for the reference substance acrylaldehyde. The interface includes a search bar at the top, a table of substance properties, and input fields for concentration and remarks.

Reference substance	acrylaldehyde / acrylaldehyde / 107-02-8
EC number	203-453-4
EC name	acrylaldehyde
CAS number	107-02-8
CAS name	
IUPAC name	acrylaldehyde

Typical concentration: < 90 % (w/w)

Concentration range: > 95 < 98 % (w/w)

Remarks:

Validation Assistant - example

Validation Assistant

The Dossier Quality Assistant helps registrants to detect technical inconsistencies in the information provided in their dossiers. These inconsistencies are reported as Quality rules and Substance Identity rules. Please note that this tool does not carry out a full assessment of the adequacy of the information provided.

Business Rules (2) (1)
Technical Completeness Check

Dossier Quality Assistant (4)

Filter: Show all with type warning, reminder

Section number	Section name	Document name	Failure description	Type
			concentration ranges must not be lower than the maximum degree of purity.	
Section 1.2	Composition		Warning in Substance Identity Rule SID017	Substance Identity warning
Section 1.2	Composition, Composition (1), Constituent (1)		Section 1.2: The value of the typical concentration of each constituent must be within the specified concentration ranges.	Substance Identity warning
Section 1.4	Analytical information		Warning in Substance Identity Rule SID026	Substance Identity warning
Section 1.4	Analytical		Section 1.4: Information on the optical activity should be	Substance Identity

Support available on the ECHA website

- Webinars
(<http://echa.europa.eu/support/training-material/webinars>)
- Documents
(<http://echa.europa.eu/support>)
 - Guidance for identification and naming of substances under REACH and CLP
 - Data Submission Manual Part 18 – “How to report the substance identity in IUCLID 5 for registration under REACH”
 - Evaluation under REACH - Progress report 2013
- ECHA pages “How to improve your dossier”

**ECHA activities to improve
substance identification
in the registrations**



Substance identification issues need to be tackled in dossier evaluation

- Substance identification is the starting point of the dossier evaluation process
 - Verifies whether only one substance is covered by the registration being evaluated
 - Enables proper assessment of hazard data
 - Allows evaluation of read-across justifications
 - Facilitates effective decision making for further risk management
- Substance identity is a frequent shortcoming observed in registration dossiers
- Decisions on substance identity may affect the joint registration

Letter campaigns

- Systematic screening of all registration dossiers
- Scenarios are based on similar rules as those available in the Dossier Quality Assistant
- Efficient and effective way to address potential substance identification issues
- First step before more severe actions (compliance checks) are taken
- Specific shortcomings are addressed, e.g.
 - Insufficient information
 - Inconsistencies
- Campaign launched in April 2014

Informative letters to the members of joint submissions

- Since 2013, co-registrants are informed whenever a draft decision on substance identification is sent to any member of the joint submission
- To encourage joint submission members to:
 - swiftly contact the lead registrant, and
 - check whether the decision may affect their own registration
- The letter does not specify the aspects covered by the draft decision, but aims to alert the co-registrants

So before you submit...

- Double-check information on the identity of substance(s) you manufacture/import
- Verify whether you are in the right SIEF
- Provide consistent and unambiguous information in your dossier
- Avoid generic identifiers, which do not specifically correspond to your substance
- Make sure that your dossier does not cover multiple substances
- Provide relevant explanations for any information
- Appropriately justify any deviation from standard data requirements
- Run the Validation Assistant before submission

Thank you

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