

Dissemination filter rules

Dissemination & confidentiality claims

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ECHA



Introduction

- What are dissemination filter rules?
- Basic filter rules
- Conditional filter rules
- Feedback from ECHA

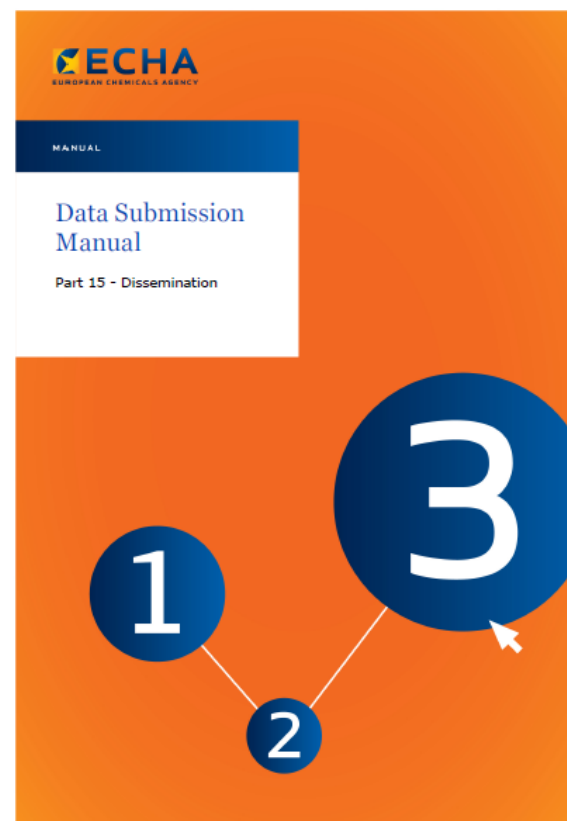
Dissemination filter rules

- A filter rule is assigned for each IUCLID field, enabling the filter tool to automatically determine if the content of the field is disseminated or not

Filter rule set	
IUCLID Field	Assigned filter rule
EC No	Substance
IUPAC Name	IUPAC name
Tonnage Band	Tonnage Band
Toxicology result	Publish

Dissemination filter rules

- The technical annexes to the “Data Submission Manual 15 – Dissemination” explain the rules for the standard dissemination of REACH registration dossiers.
- NONS will initially be disseminated with a reduced set of information.



Basic filter rules



is **not** automatically disseminated



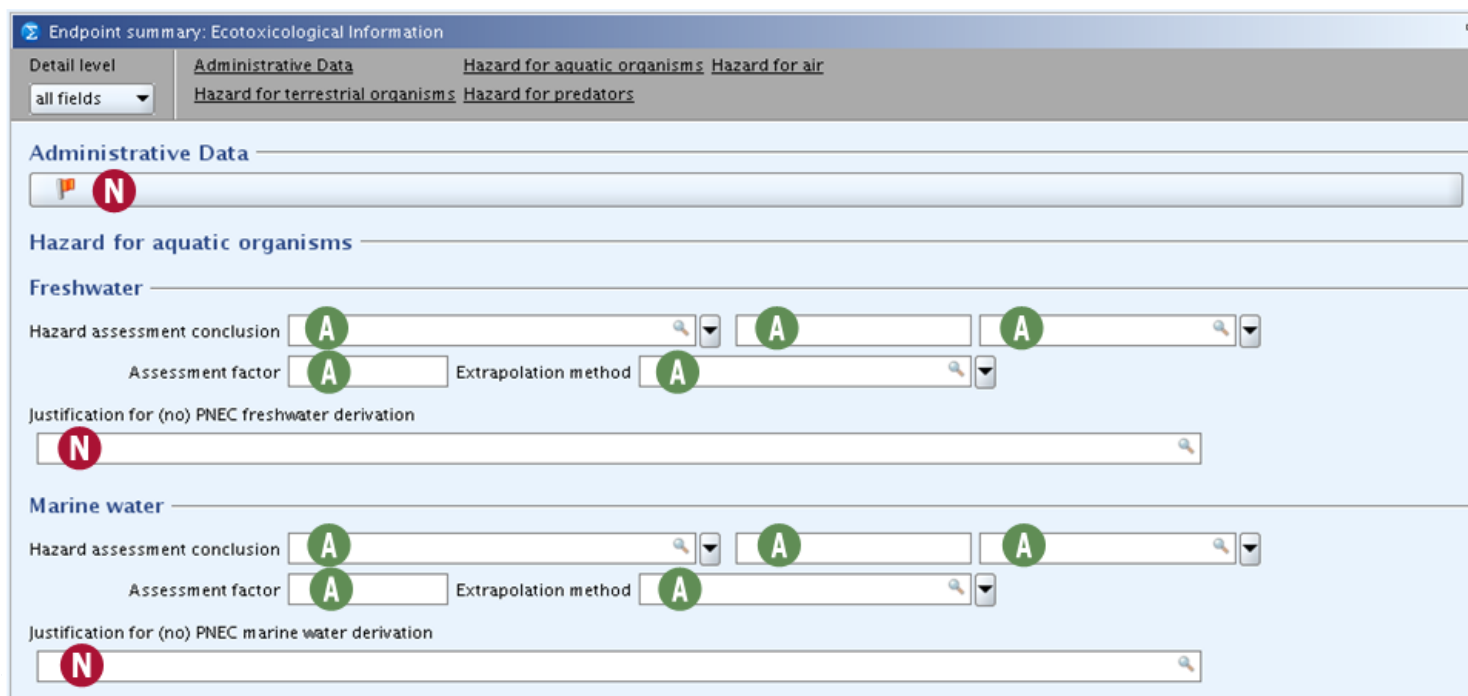
is automatically disseminated unless **confidentiality** has been claimed for this section



is **always** automatically disseminated

PNEC and DNEL - endpoint summaries

- Justifications for no PNEC derivation, discussion and conclusion on classification are not disseminated.
- All other PNEC information is disseminated, including the assessment factor and the extrapolation method.



Endpoint summary: Ecotoxicological Information

Detail level: Administrative Data | Hazard for aquatic organisms | Hazard for air
all fields | Hazard for terrestrial organisms | Hazard for predators

Administrative Data

Hazard for aquatic organisms

Freshwater

Hazard assessment conclusion: A A A
Assessment factor: A Extrapolation method: A
Justification for (no) PNEC freshwater derivation: N

Marine water



Hazard assessment conclusion: A A A
Assessment factor: A Extrapolation method: A
Justification for (no) PNEC marine water derivation: N

PNEC and DNEL - endpoint summaries

Endpoint summary: Toxicological information

Detail level: Administrative Data Workers - Hazard via inhalation route Workers - Hazard via dermal route
 all fields Workers - Hazard for the eyes General Population - Hazard via inhalation route General Population - Hazard via dermal route
General Population - Hazard via oral route General Population - Hazard for the eyes




Administrative Data



 

Workers - Hazard via inhalation route



Systemic effects


Long term exposure





Hazard assessment conclusion   


Most sensitive endpoint  Route of original study 















DN(M)EL related information


DNEL derivation method  

Overall assessment factor (AF) 

Dose descriptor starting point (after route to route extrapolation)    

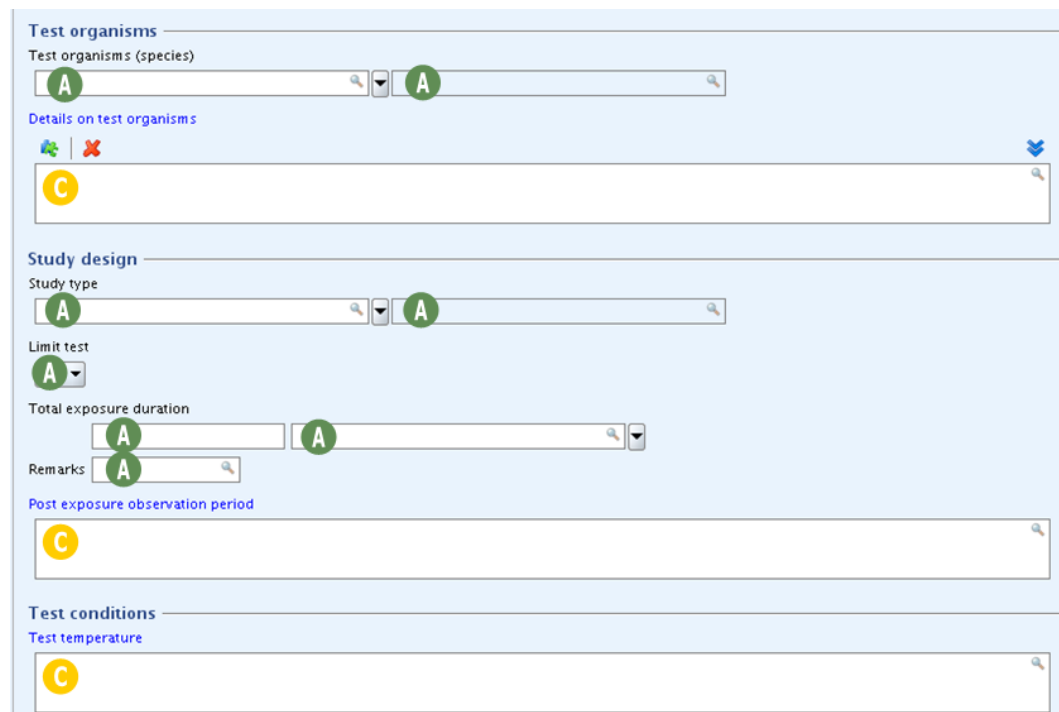
Justification for route to route extrapolation 

AF for dose response relationship		Justification	
AF for differences in duration of exposure		Justification	
AF for interspecies differences (allometric scaling)		Justification	
AF for other interspecies differences		Justification	
AF for intraspecies differences		Justification	
AF for the quality of the whole database		Justification	
AF for remaining uncertainties		Justification	

Justification and comments 

Endpoint study records

- A number of fields in the endpoint study records are always published as part of the study result, even if confidentiality has been claimed on the study.
- These fields are not only under the title "Results and discussion"



The screenshot displays a web form for recording endpoint study data. It is organized into several sections:

- Test organisms:** Contains a field for "Test organisms (species)" with two input boxes, each marked with a green 'A' icon. Below this is a "Details on test organisms" section with a text area marked with a yellow 'C' icon.
- Study design:** Includes a "Study type" field with a green 'A' icon, a "Limit test" dropdown menu with a green 'A' icon, and a "Total exposure duration" field with two input boxes, each marked with a green 'A' icon. A "Remarks" field with a green 'A' icon is also present.
- Post exposure observation period:** A text area marked with a yellow 'C' icon.
- Test conditions:** A "Test temperature" field with a yellow 'C' icon.

Conditional filter rules – Substance identifiers



Filter rules – substance identifiers

Reference substance

General information

Reference substance name **N**

EC inventory

EC number **S EINECS**

EC name **S EINECS**

Molecular formula **S EINECS**

Description **S EINECS**

No EC information available

Justification **N**

Reference substance information

P A

CAS information

CAS number **S IUPAC**

CAS name **N**

IUPAC name

S IUPAC

For substances listed in **EINECS** (EC number starting with 2 or 3) the EINECS name and EC number are always disseminated.

If the substance is not listed in EINECS, the IUPAC name rule is used.

S

EINECS

S

IUPAC

Filter rules – substance identifiers

Substance composition

Name **S IUPAC**

Brief description **S IUPAC**

Composition ID **A**

Constituents

A

Reference substance **S CONST**

Typical concentration **N** **N** **N**

Concentration range **N** **N** **N** **N**




Remarks **N**

S CONST	<p>Unless the IUPAC name (of the section 1.1 dossier reference substance) has been claimed confidential, and provided the section 1.2 constituents have not themselves been claimed confidential, the IUPAC name and associated data for section 1.2 constituents are disseminated.</p>
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IUPAC confidentiality – flag above or in 1.1 ref subs

Dossier submitted

Section 1.1


 1.1 Substance A+B+C   Linked Ref Substance

Section 1.2
Composition X

1.2 Constituent A	 Linked Ref Substance
1.2 Constituent B	 Linked Ref Substance
1.2 Constituent C	 Linked Ref Substance

Dossier disseminated

Section 1.1


 [CONFIDENTIAL]

Section 1.2

IUPAC confidentiality – flag(s) above or in 1.2 constituent ref sub(s)




Dossier submitted


Section 1.1


1.1 Substance A+B+C  Linked Ref Substance

Section 1.2

Composition X


 1.2 Constituent A   Linked Ref Substance

1.2 Constituent B  Linked Ref Substance

1.2 Constituent C  Linked Ref Substance


Dossier disseminated


Section 1.1


 [CONFIDENTIAL]

Section 1.2

Composition X

 [CONFIDENTIAL]

1.2 Constituent B  Linked Ref Substance

1.2 Constituent C  Linked Ref Substance

Filter rules – impurities and additives

Impurities

Reference substance I

Typical concentration N N N

Concentration range N N N N

Remarks N

I this impurity is considered relevant for the classification and labelling of the substance

Additives

Reference substance I

Function N N

Typical concentration N N N

Concentration range N N N N

Remarks N

I this additive is considered relevant for the classification and labelling of the substance

I


















The identity of an **impurity** or additive which is essential for the C&L will be automatically disseminated if the registrant has indicated, using the tick-box, that the impurity or additive is essential for C&L, unless confidentiality has been claimed on this section.

Filter rules – bibliographic references



Data source

Reference

Reference type	Author	Year	Title	Bibliographic s...	Testing laborat...	Report no.	Owner company	Company study...	Report date
									
 Add...	 Edit...	 Delete	 Move up	 Move down	 Select	 Insert			

The **bibliographic references** author, title, and source are disseminated according to the following rule, with the most important criteria listed first:

- not disseminated if the section 1.1 reference substance IUPAC name is claimed confidential;
- not disseminated if the endpoint record is claimed confidential, unless the reference type is publication, review article or handbook;
- not disseminated if the reference type is study report or company data;
- not disseminated if at least one of following is provided: testing lab, report number, owner company or study number.

Filter rules – test material identity



Test materials

Identity of test material same as for substance defined in section 1 (if not read-across)

A

Test material identity

Identifier	Identity
C Material	C Material

Add... Edit... Delete Move up Move down

Test material form

A **A**

The identity of the **test material** in an endpoint study record will be disseminated if (1) the identifier is CAS number, EC number, EC Name or IUPAC name; and (2) the (robust) study summary data in the endpoint study record is not claimed confidential; and (3) the IUPAC name of the substance being registered is not claimed confidential in the dossier.

Other changes made to the dossier

Additionally, there are a few pieces of information in the IUCLID dossier which are also changed by the filter tool:

- UUIDs in the dossiers are replaced by newly generated random UUIDs
- The registrant's dossier modification history is removed

Other changes made to the dossier

- the registrant's endpoint record titles are removed in the filtering and replaced in the aggregation step by standard endpoint titles
- **NAME** = (Source) + Result Type + Purpose Flag + IUCLID Section + Number

For example: *(Member) Exp NS Acute toxicity: oral.007*

Table 1: Endpoint study record result types & purpose flags

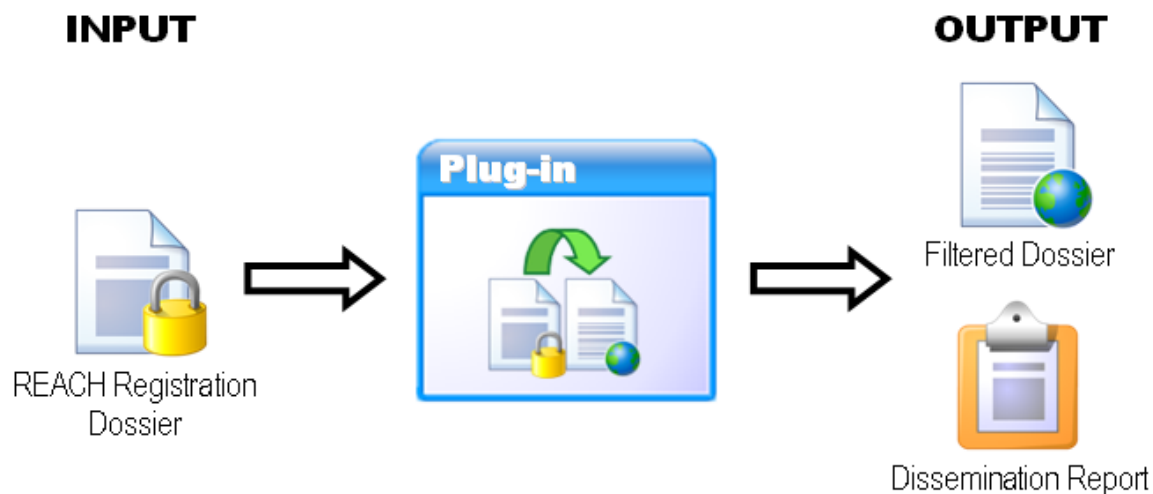
Result Type	Definition
Exp	Experimental result
Planned	Experimental study planned
Calc	Estimated by calculation
Read-across Cat	Read-across based on grouping of substances (category approach)
Read-across Subs	Read-across from supporting substance (structural analogue or surr
QSAR	QSAR

Feedback from ECHA

- IUPAC name claims are triggered if a constituent in IUCLID section 1.2 is flagged confidential. Often, the concern is the typical concentration or the concentration range
→no flag is needed in these cases
- Remember to fill in the checkbox in section 1.2 if an impurity or additive is relevant for the classification and labelling
- Fill in the information in the correct fields
- Avoid referring to attached documents

Tools available for registrants

- IUCLID 5 dissemination plug-in



- Data Submission Manual 15 – Dissemination + technical annexes

Thank you

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