



**FEEDBACK FROM MEMBER STATES
IUCLID PSN MEETING
29 FEBRUARY 2024**

FEEDBACK FROM [FR]

Needs and proposed improvements for RMS related to the report generator: feedback from France:

- - general
- - related to physchem and analytical methods



FEEDBACK FROM [FR]

Needs and proposed improvements for RMS related to the report generator: feedback from France – General

What are the possibilities to adapt the report generator (RG) in case of a AS dossier with several applicants who are NOT in a task force ?

- ❑ Currently the RMS can generate reports via IUCLID only for each dossier separately.
=> the RMS merges these documents manually when producing the RAR.

- ❑ **But** it could be very useful if the RG could merge the reports from the different dossiers, for example for :
 - ❖ Generating the list of studies
 - ❖ documents M
 - ❖ Others...

⇒ What is the opinion of the other MSs ?
⇒ Would it be technically possible to create such merged reports?



FEEDBACK FROM [FR]

Needs and proposed improvements for RMS related to the report generator: feedback from France – physchem and analytical methods

1/ MRL application report in IUCLID / document M - analytical methods part

Currently, the report generator does not work correctly because in lots of cases the dossier is not completed correctly regarding the analytical methods part of the IUCLID dossier.

Indeed, in most cases, all data are copy-past in a free-text box where additionnal data without any format can be added.

- What:** details of validation data (recovery, repeatability ...) are not completed in the correct boxes and the report generator does not recognise them => they are not reported in the generated report
- Why?** It seems that the work to add the validation data manually in each box is too time consuming for companies.
- Request:** the template of the analytical methods part of the IUCLID should be redesigned in order to simplify the work of applicants and of MS.

The same observation was made for physical chemical properties.

User manual indicates how to prepare the analytical part correctly.



FEEDBACK FROM [FR]

Example on validation data for analytical methods:

OFTEN: Validation data are not filled in the right place in IUCLID but somewhere else

- RMS does not know where the information will be in the automatic generated report
- (or at least **if** the information will be reported in any case!)

=> Is the information reported?

- If no, how to extract the information from IUCLID ?
- If yes, where can it be found ?

How RMS knows if we can trust the automatic report and have access to all the information available in IUCLID via this report?

- RMS cannot do this check
- Validation assistant report is not sufficiently precise and/or explicit to obtain this information

In IUCLID: 5 boxes are present to fill in 5 recoveries

In the dossier: the 5 results are presented in a table in the first box with a summary text

⇒ The report generator does not recognise the 5 individual values, no certainty the table is recognised or not

prothioconazole MRL dossier : the information was present but not at the right place

=> Efsa has provided assistance to extract the information, RMS not autonomous



FEEDBACK FROM [FR]

Example on physchem properties:

The same issues are observed, e.g. melting point, solubility:

Dashboard > Mixtures / Products > BCP222H_repr. formulation of Metobr...

Metobromuron AIR 5_update 5
a4917f91-119d-4ab2-8ece-df155c1125f6

View Dossiers Validate ... ?

Type at least 3 characters

UUID: 39587350-b84a-45df-b494-64002abc8e78

Hide empty fields ...

...

BCP222H_repr. formulation of Metobromur

Metobromuron

1 Identity of the active substance and applicant 27

2 Physical and chemical properties of the active substance 38

Physical and chemical properties of the active substance.001

2.1 Melting point and boiling point 5

2.1.1 Melting point 2

Melting point.001

2010_Melting point_01

2.1.2 Boiling point 3

2.2 Vapour pressure, volatility 5

2.3 Appearance (physical state, colour) 2

2.4 Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity 1

2.5 Solubility in water 3

Administrative data Link to relevant study record(s) Description of key information Key value for chemical safety assessment Additional information

Link to relevant study record(s)

Link to relevant study record(s)

2010_Melting point_01 | experimental study | 1 (reliable without restriction) | capillary method | 95.6 97.5 °C

Description of key information ① ^

Mean melting point = 96.4 °C

Key value for chemical safety assessment

Melting / freezing point at the pressure of 101325 Pa

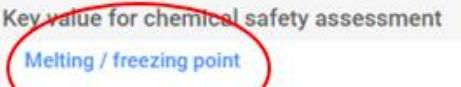
Additional information

Attached background material

| # | Attached confidential document | Attached (sanitised) documents for pu... | Remarks | Actions |
|---|--------------------------------|--|---------|---------|
| | | | | |

...

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FEEDBACK FOMR [FR]

Metobromuron AIR 5_update 5
a4917f91-119d-4ab2-8ece-df155c1125f6

2 Physical and chemical properties 38

Physical and chemical properties of the active substance

Physical and chemical properties of the active substance.001

2.1 Melting point and boiling point 5

2.1.1 Melting point 2

 Melting point.001

 2010_Melting point_01

2.1.2 Boiling point 3

2.2 Vapour pressure, volatility 5

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2.4 Spectra (UV/VIS, IR, NMR, MS), molar extinction at relevant wavelengths, optical purity 1

2.5 Solubility in water 3

 Solubility in water.001

 2010_Solubility in water_01

 2020_Solubility in water_02

2.6 Solubility in organic solvents 2

2.7 Partition coefficient n-octanol/water 3

UUID: af7059ce-b60a-4acd-b4f5-2f8892e5b822

EU: PPP

Administrative data Link to relevant study record(s) Description of key information Key value for chemical safety assessment Additional information

Link to relevant study record(s)

Link to relevant study record(s)

2020_Solubility in water_02 | experimental study | 1 (reliable without restriction) | flask method | 0.2478 g/L | 20 °C | 7.3 | mean of 6 determinations

Description of key information

At pH 7.3, the mean solubility of metobromuron in water was found to be 274.8 mg/L at 20 ± 0.3 °C. (RSD 0.8%, 6 determinations)

Key value for chemical safety assessment

Water solubility at the temperature of

Additional Information

Attached background material

| # | Attached confidential document | Attached (sanitised) documents for pu... | Remarks | Actions |
|---|--------------------------------|--|---------|---------|
|---|--------------------------------|--|---------|---------|

Hide empty fields

View Dossiers Validate ...

...

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FEEDBACK FROM [FR]

Needs and proposed improvements for RMS related to the report generator: feedback from France – physchem and analytical methods

2/ Validation data of analytical methods in all sections

- ❑ Validation data of analytical methods (AM) concern all sections for RA.
- ❑ In IUCLID, all validation data for AM should be provided for monitoring and pre-registration methods, sorted by section and for each matrix, **within the dedicated section for analytical methods** (and **not** in each section for RA e.g. fate, residues,...).
- ❑ **Warning:** please avoid including this information in the general analytical methods part, without sorting hem section by section => *no business rule exists for this*
- ❑ **Consequence for the RMS:** need to open every study report to see to which section the method corresponds ; no overview per section / matrix available => **not workable for the experts as too much time consuming**

➤ FR identifies the need of a business rule:

The methods should be included in the AM part of IUCLID and sorted out by section and by⁸ matrix within a section



FEEDBACK FROM [FR]

In a nutshell :

- ❑ *It seems too much timeconsuming for the applicant to copy every item in a specific box for AM and physchem properties*
- ❑ *Applicants prefer filling as much information as possible in one free text box, sometimes in presented in tables*
- ❑ *For the experts : no specific interest in having all the information in separate boxes, and in theory, could use the data as they are currently provided (even though not filled in as described in the user manual)*
- ❑ *However, unfortunately currently the RMS cannot export this information through the report generator and thus cannot use this compiled information provided by the applicants in IUCLID*

- We cannot use the report generator for doc M or MRL application report as the data are not reported: **no trust in the automatic generated report – loss of information**
- **We continue to ask for 'manually prepared' doc M and MRL application reports** in order to have all the information that we need
- This **questions** also the future planned **deletion of doc J in IUCLID** – FR volunteers by participating in a WS on this issue if Efsa plans one.



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