

# Confidentiality and filtering rules

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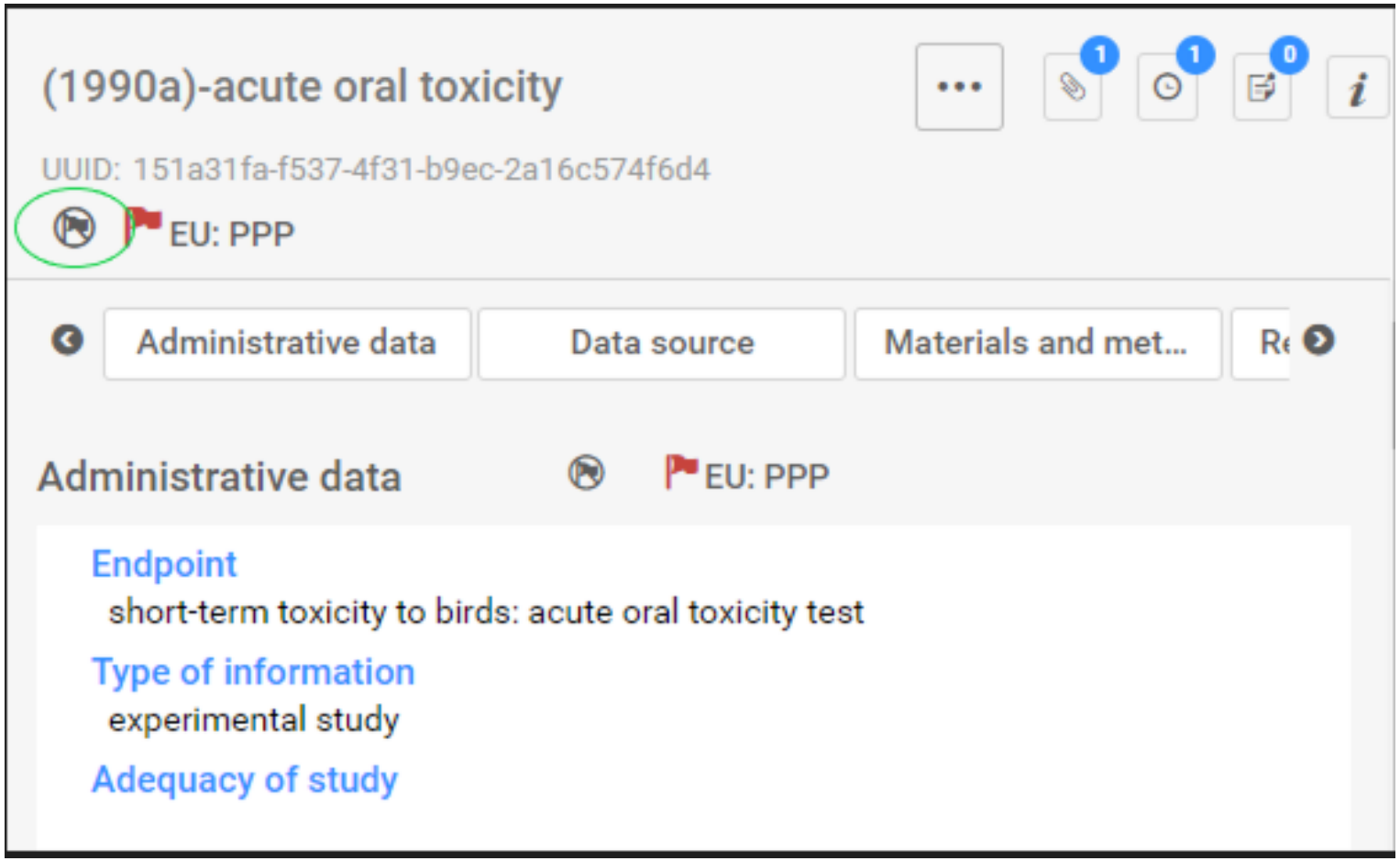
# Confidentiality – NEW approach to personal data in IUCLID

- A new approach to handling **confidentiality requests** for **personal data** ('PD') **only** in IUCLID was presented to the IUCLID PSN sub-group in May and subsequently endorsed
- The new approach to PD entails that, if the applicant considers that **only PD** but **no confidential business information** ('CBI') is present in an **attachment** (e.g. full study report), confidential treatment needs to be requested by:
  - not selecting any value from the confidentiality picklist,
  - but only filling in the justification box identifying the nature and location of the personal data concerned in the attachment

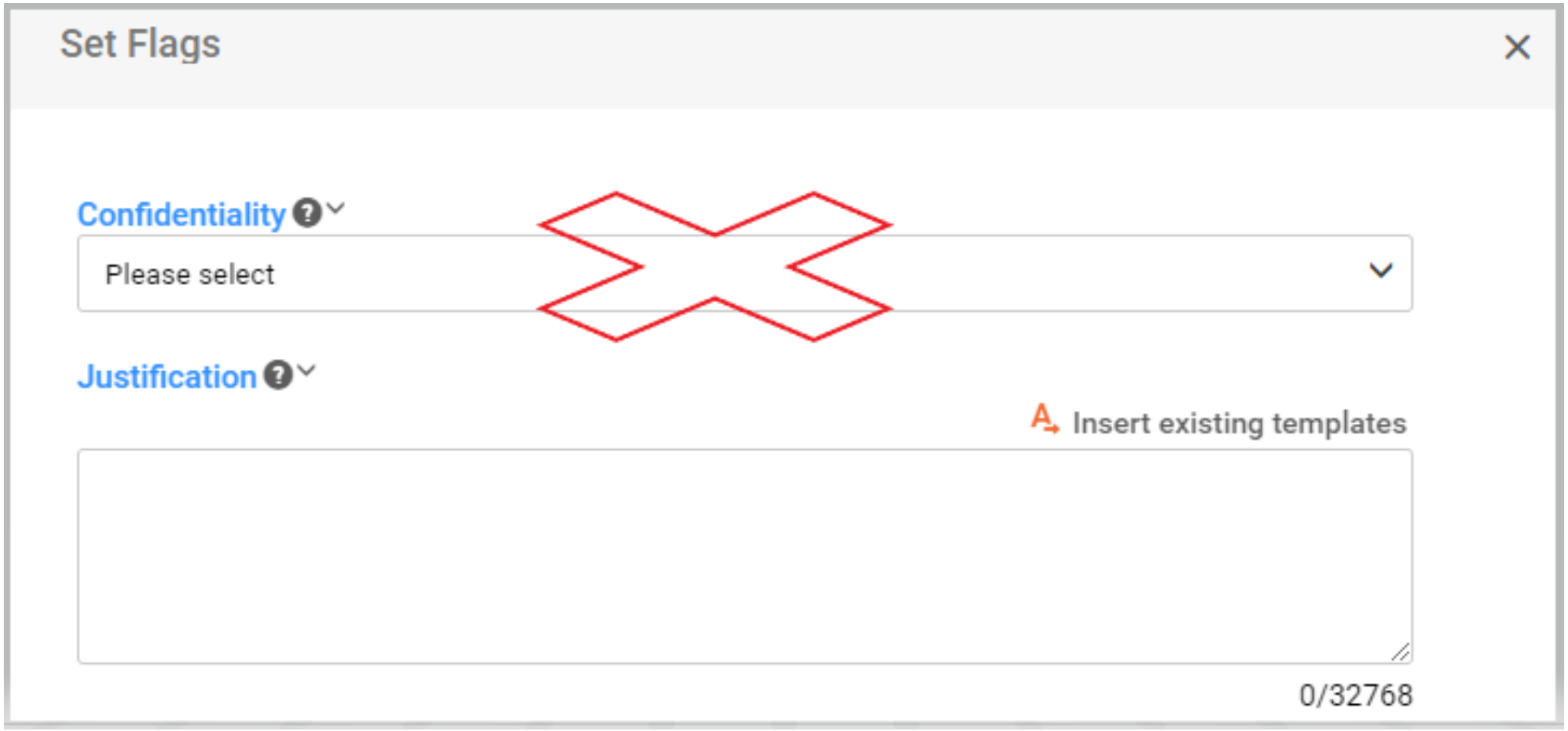
# NEW approach to PD in practice - 1

1) Applicant clicks on the "*Set Flags*" field applicable to the IUCLID attachment concerned, e.g. for an attachment in the form of a study report the relevant flag to be selected is the one on top of the endpoint study record linked to the study report in question:



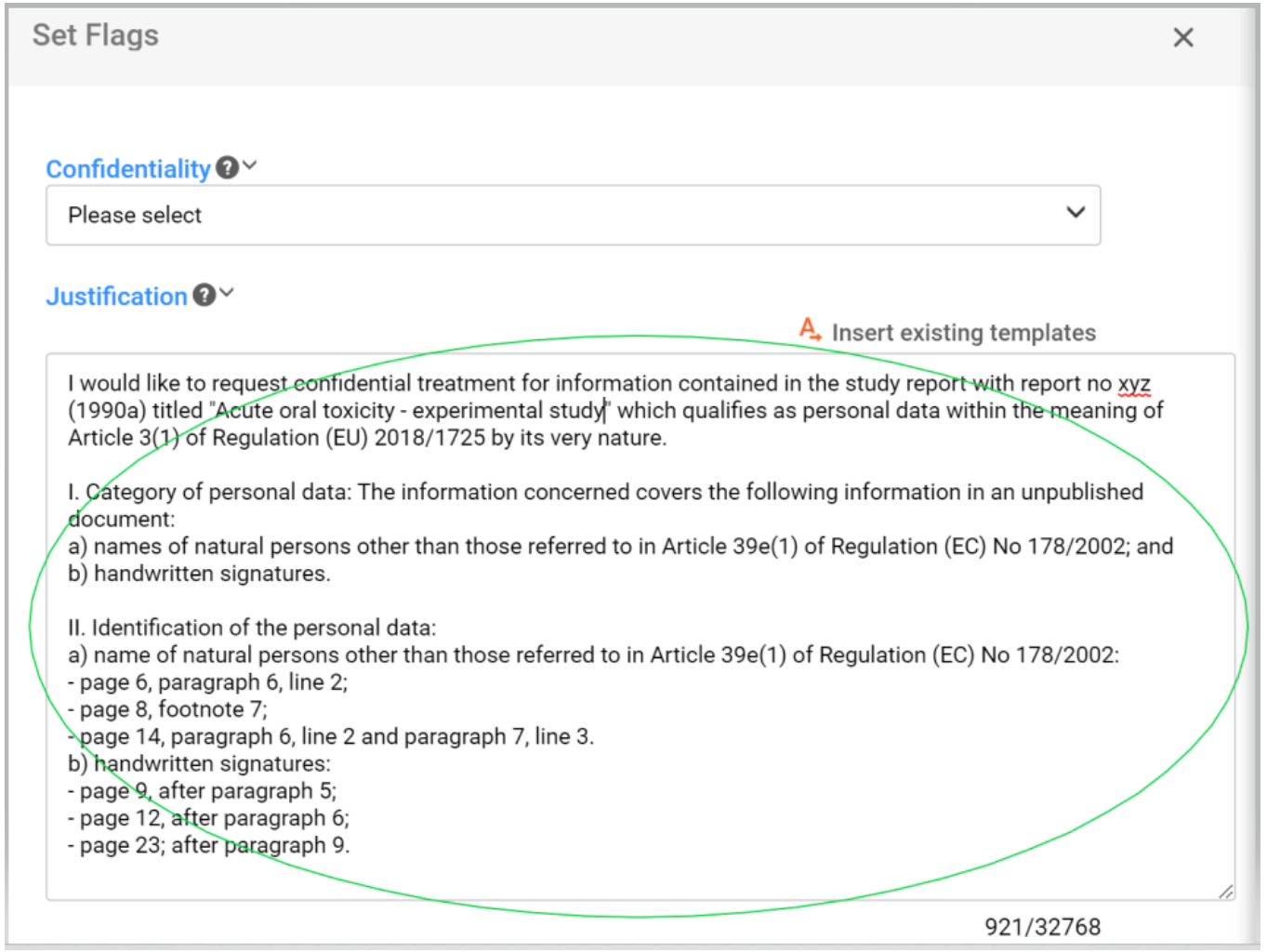
# NEW approach to PD in practice - 2

**2) no value** is selected form the confidentiality picklist:



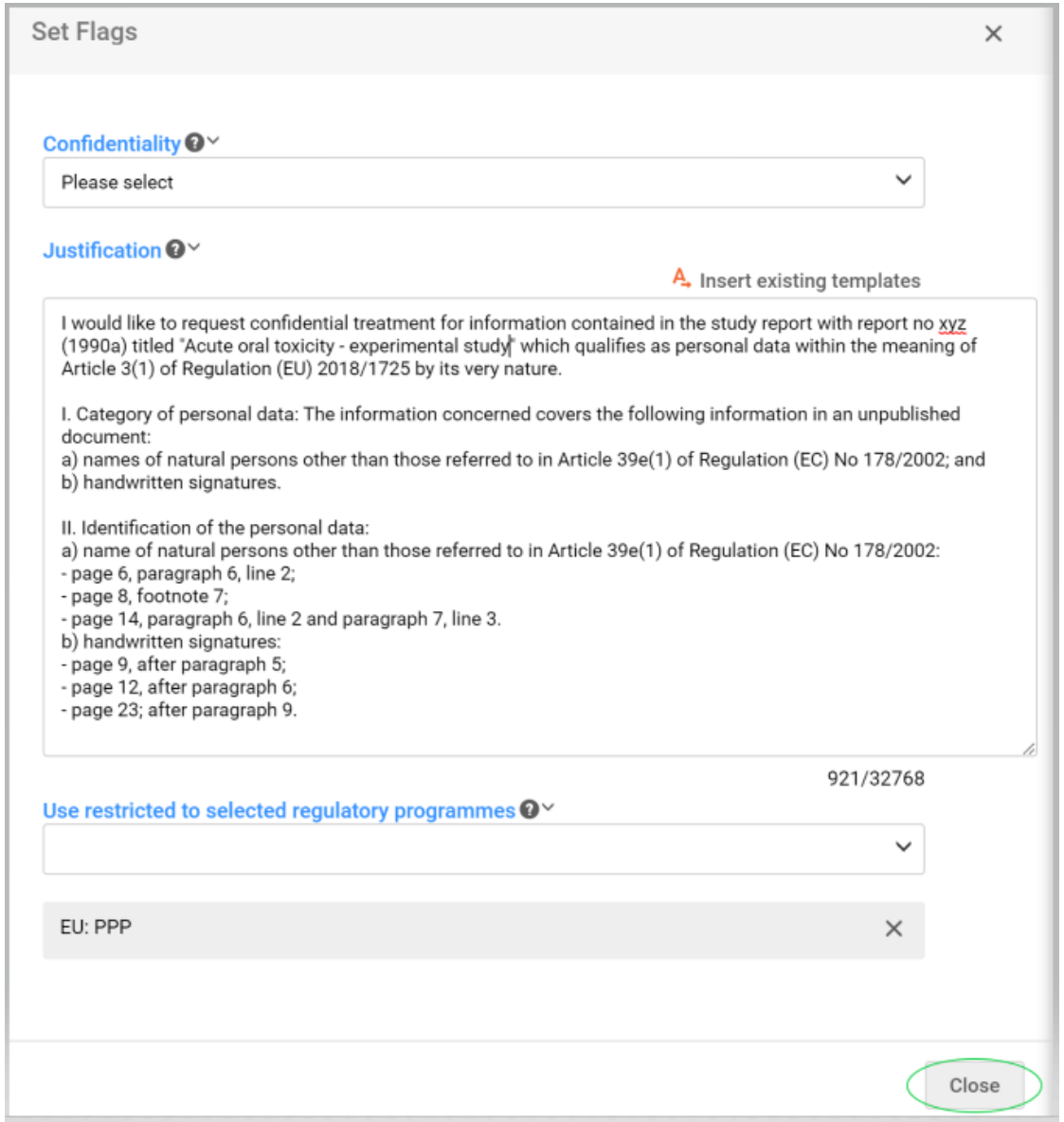
# NEW approach to PD in practice - 3

3) **justification box is filled in** having regard to the relevant PD justification templates and examples available on electronic pp. 36-37 in the EFSA User Guide on Confidentiality (**nota bene**: the new approach to PD is not yet reflected in the EFSA User Guide on Confidentiality but the document will be updated shortly to account for the changed requirements):



# NEW approach to PD in practice - 4

4) upon having filled in the justification box your confidentiality request on PD only is complete; **click "*Close*"** and your confidentiality request on PD only is **automatically saved and reflected in the new confidentiality report** titled "*List of Confidentiality Claims (incl. PD claims)*" that can be generated via the "*Generate report*" function under "*Uploaded IUCLID reports*":



# NEW approach to PD vs approach for CBI claims & mixed CBI/PD claims

- For confidentiality requests regarding **CBI <u>only</u>** and **confidentiality requests concerning CBI and PD** in the same attachment ('mixed CBI/PD claims') **nothing changes**:
  - Pure CBI and mixed CBI/PD claims need to be submitted by selecting the "*CBI*" value from the confidentiality picklist and by inserting the justification in the justification box having due regard to the justification templates and examples available on electronic pp. 33-37 in the EFSA User Guide on Confidentiality.

- Confidentiality requests on (i) **PD only** can be distinguished from (ii) **confidentiality claims on CBI only or mixed CBI/PD claims** in the new confidentiality report titled "*List of Confidentiality Claims (incl. PD claims)*" as follows:
  - **pure CBI** and **mixed CBI/PD claims** come with the **header "*[CBI]*"** in the column "*Claim and Justification*" of the new confidentiality report, and
  - **pure PD claims** come with **no header** in the "*Claim and Justification*" column.

# NEW approach to PD in IUCLID - timeline

- As of **31 October 2022** applicants can voluntarily submit their dossier in accordance with the new approach to PD.
- The new approach to PD will become mandatory as of **01 January 2023**.
- EFSA will publish an **official communication** regarding the new approach to PD on relevant EFSA channels, including the EFSA webpage, shortly providing further details and confirming the envisaged date for its entry into application.

# GENERAL REMINDER: Personal data protection

**Article 39e General Food Law (GFL)**

1. **Public:** name & address applicant, names of authors of published studies
2. **Protection:** Names, addresses, contact details, signatures of authors and other natural persons linked to unpublished studies, in particular insofar as this information relates to natural persons involved in testing on vertebrate studies or in obtaining toxicological info
3. Application of the GDPR and of the EUDPR – **purpose limitation principle** - transparency of the scientific risk assessment

**EFSA PAs transparency and confidentiality**

**Ensure the absence**, sanitisation or anonymisation, as appropriate, **of information relating to identified or identifiable persons from non-confidential versions** of dossiers, information, documents and data

# GENERAL REMINDER: Personal data protection - Responsibility of the applicant

- **Applicant's confidentiality requests include requests to sanitise personal data**

Enables EFSA to formally support requests by adopting a decision accepting the requests & to verify that personal data concerned has been effectively sanitized in the relevant non-confidential version of the document concerned

- **Applicant's confidentiality requests DO NOT include requests to sanitise personal data**

Unblackened personal data remains visible in the non-confidential version published online & applicant may be held accountable for any infringement of the personal data protection rules

# Working party on filter rules

- Composition of the working party
  - 13 members + 1 alternate:
    - (4 + 1) applicants representing CLE, ECCA and IBMA
    - 2 MS (Austria & Poland)
    - 1 ECHA (filter rule expert)
    - 6 EFSA (IUCLID team, legal, pesticide units)
- 4 meetings held so far
- All the material is available in the dedicated PSN Teams folder

# New IUCLID documents

- Preliminary rules defined for the new/amended documents going live in April 2023:
  - Analytical methods
  - Analytical profile of batches
  - Manufacturer

  Conclusion: Additional CBI fields added to the analytical chemistry documents in the repeatable blocks with links to reference substances

# Mixture composition table

- The full mixture composition should be provided in section 1.4 of the dossier and not in Doc J
- Components which are flagged confidential will be removed entirely from the mixture composition table (no empty rows visible)
- New VA warning: **Active substance, active substance (other, not to be assessed), safener & synergist** cannot be claimed confidential
- For the above-mentioned functions, the following fields will always be published

  - Reference
  - Function
  - Typical concentration
  - Concentration Range

| # | Component flag | Name | Function | Typical conc... | Concentrati... |
|---|---|---|---|---|---|
| 1 | | CR UAT active substance \| CR UAT active substance \| IUCPAC NAME \| 134-56-7 | active substance | 67 mg/L | 60 - 72 mg/L |

# UNLESS_CONF review → ongoing

- The legislation foresees a closed list of items (Closed list for confidentiality.docx) which can be claimed confidential – the IUCLID documents which host these items have been identified
- There are **2091** fields with the UNLESS_CONF rule for PPP dossiers but only **149** are found in the closed list
- The aim is to reduce the use of UNLESS_CONF in documents which do not contain information in the closed list, without jeopardising the amount/type of information provided in the IUCLID documents

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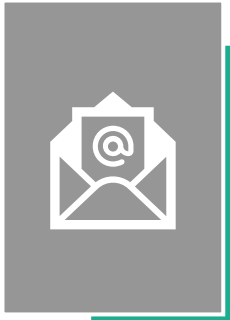

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