October 2021

IUCLID features:Validation assistant – current status and discussion on development

DATA

Trusted science for safe food

European Food Safety Authority

Existing rules

Published in the IUCID PPP manuals and documentation

European Food Safety Authority (EFSA). (2021). IUCLID for PPP Filter rules (2.0). Zenodo. https://doi.org/10.5281/zenodo.5118638

Validation rules

Summary	Issue Type	Message	Target documents	Checked field reference
QLT_PPP_001: Endpoint must be indicated	Quality rules/Warning	'Administrative data' is not complete. The 'Endpoint' addressed by the study record must be indicated.	All endpoint study records	Administrative data – common block
QLT_PPP_002: Data waiving must be justified	Quality rules/Warning	'Administrative data' is not complete. If you want to submit a data waiving then	All endpoint study records	Administrative data – common block

European Food Safety Authority. (2021). IUCLID submission rules for PPP dossiers (1.0). Zenodo. https://doi.org/10.5281/zenodo.5141357

Updated rules: Data source

- QLT_PPP 004/009/010/027/047

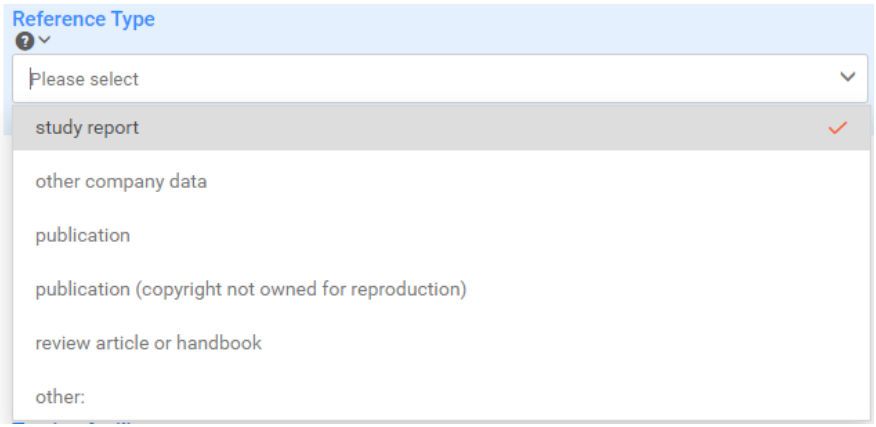
Updated to reflect the changes in the Literature Reference entity and resolve issues with multiple literature reference entities in a data source

Other study identifier(s) + New item | Import file

#	Study ID type	Study ID	Remarks	Action
1	Notification of Studies (NoS) ID	EFSA-2021-12345678	*None*	

Attachments + New item | Import file

#	Attachment type	Attached confidential ...	Attached (sanitised) d...	Action
1	full study report	Full original study report (1).pdf	Sanitised Study Report.pdf	



Updated rules: Data requirements

- QLT_PPP 011/13/15/17

Checks presence of Endpoint Study Records

ENDPOINT_STUDY_RECORD.OtherDistributionData	7.2 Mobility	
ENDPOINT_STUDY_RECORD.ToxicityToBirds	8.1 Effects on birds	
ENDPOINT_STUDY_RECORD.ShortTermToxicityToFish	8.2.1.1 Short-term toxicity testing on fish	x
ENDPOINT_STUDY_RECORD.LongTermToxToFish	8.2.1.2 Long-term toxicity testing on fish	
ENDPOINT_STUDY_RECORD.ShortTermToxicityToAquaInv	8.2.2.1 Short-term toxicity testing on aquatic invertebr	x
ENDPOINT_STUDY_RECORD.LongTermToxicityToAquaInv	8.2.2.2 Long-term toxicity testing on aquatic invertebrates	
ENDPOINT_STUDY_RECORD.ToxicityToAquaticAlgae	8.2.3 Effects on algae growth	x
ENDPOINT_STUDY_RECORD.ToxicityToAquaticPlant	8.2.4 Effects on plants other than algae	x
ENDPOINT_STUDY_RECORD.ToxicityToMicroorganisms	8.2.5 Inhibition of microbial activity	x
ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialArthropods	8.3 Effects on bees	
ENDPOINT_STUDY_RECORD.ToxicityToSoilMacroorganismsExceptA	8.5 Effects on earthworms	
ENDPOINT_STUDY_RECORD.ToxicityToSoilMicroorganisms	8.6 Effects on non-target soil microorganisms	
ENDPOINT_STUDY_RECORD.AdditionalEcotoxicologicalInformatio	8.7 Further studies	x
ENDPOINT_STUDY_RECORD.ToxicityToTerrestrialPlants	8.7.1 Terrestrial plants	x

New rules: Confidentiality and Attachments

- QLT_PPP_037

If in a Data Protection block, in the field is checked, then the field 'Justification' must not be empty and if in a Data Protection block, the field 'Justification' is not empty, the flag must be checked

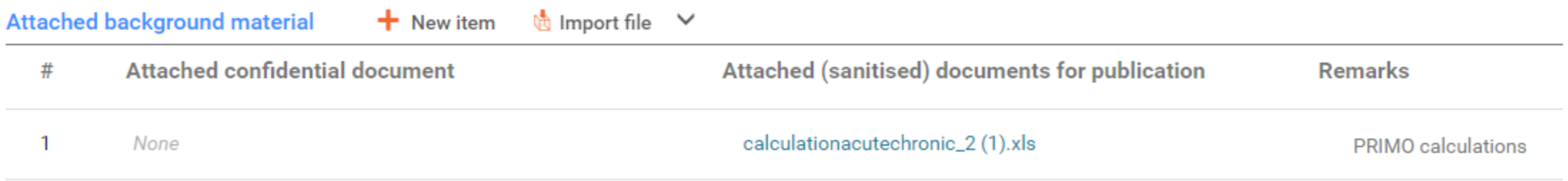
- QLT_PPP 047/041/040/042/043/044/049/045/046

Example: The rule checks all EU_PPP endpoint study records in the Mixture and linked under mixture composition Substance datasets.

The rule passed if at least one of the following conditions is met:

The field '*Attached (confidential) document*' is **empty**

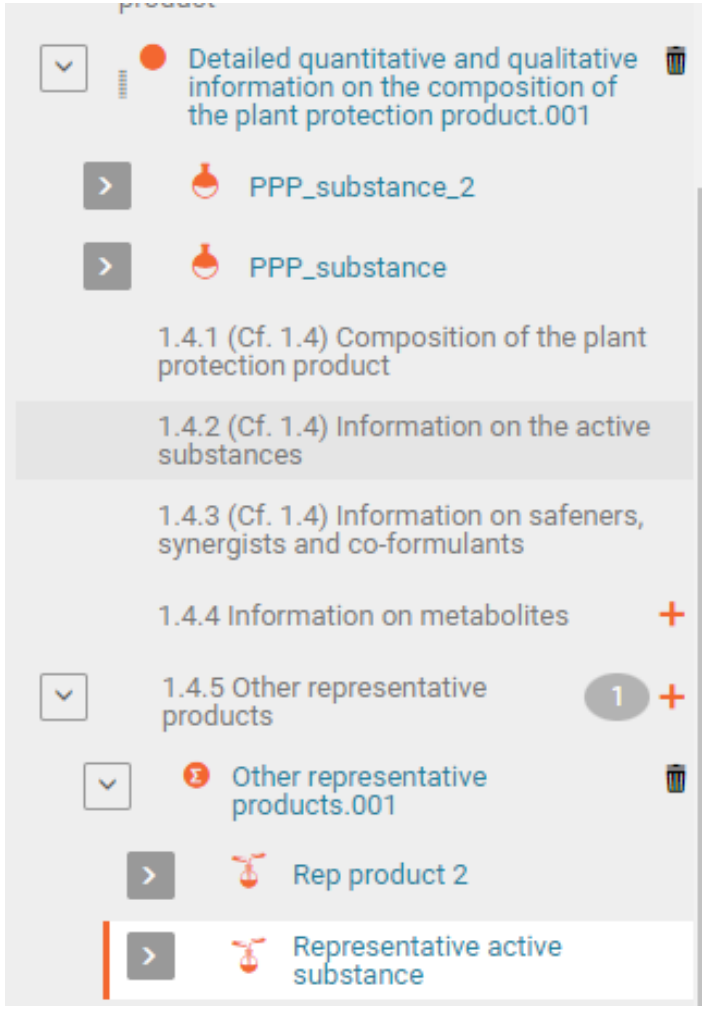
The fields *'Attached (confidential) document'* AND *'Attached (sanitised) documents for publication' have an attachment.*



New rules: Multiple product

- QLT_PPP_050:

Other representative product is incomplete. The Mixture composition must include one linked substance which has the Function = 'active substance'. This substance must be the same in the Main product mixture and in the Other Representative products



New Rules: Dossier header

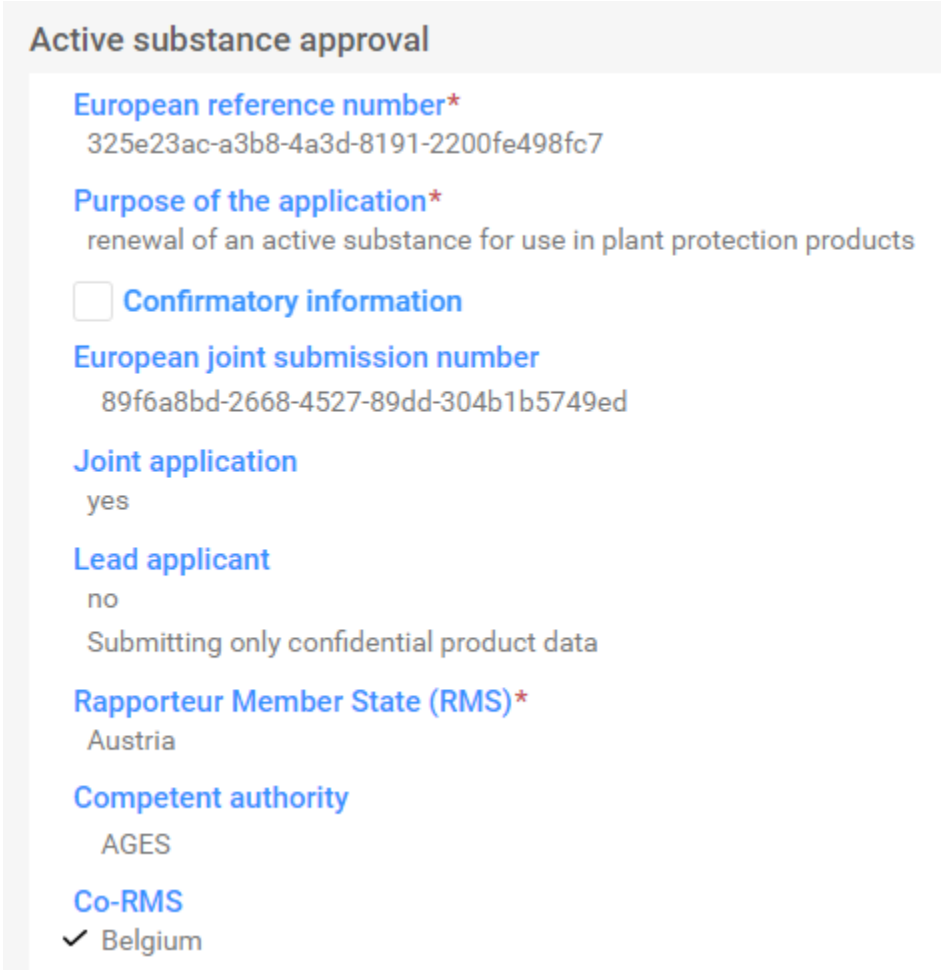
- BR_PPP_038/051

For renewals *'European joint submission number' field in UUID format must be completed*

- *BR_PPP_039/52*

For renewals - a selection must be done in the Lead applicant field if the selection is 'no' the Remarks field must not be empty.

Offers the potential for refinement of rules applied based on the selections in these fields



Enhancements: Endpoint_Summary checks

QLT_PPP 012 / 014 / 016 / 018

Currently all summaries are required

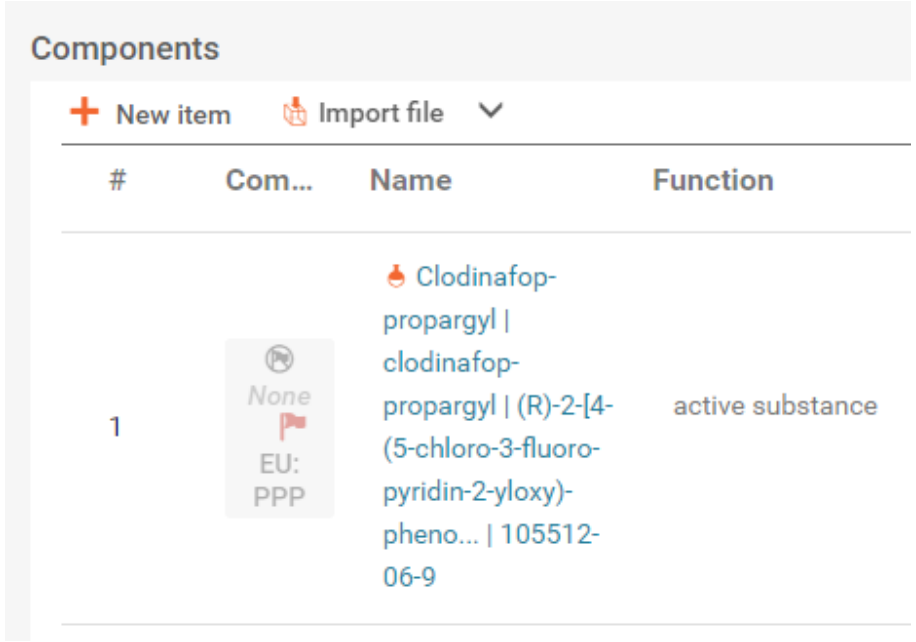
Need for document completion to allow the compilation of endpoint lists

Need for a failure: Active substance

- QLT_PPP_021

Mixture composition is incomplete. At least one Mixture composition must be present in the dossier function. This must include a linked substance which has the Function = 'active substance'.

Need for refinement in case of confirmatory data?



Reasons

1) No substance information available for notifications that a dossier has been submitted
2) Resubmission with substance added will results in a submission failure

Development: Flexible record checks

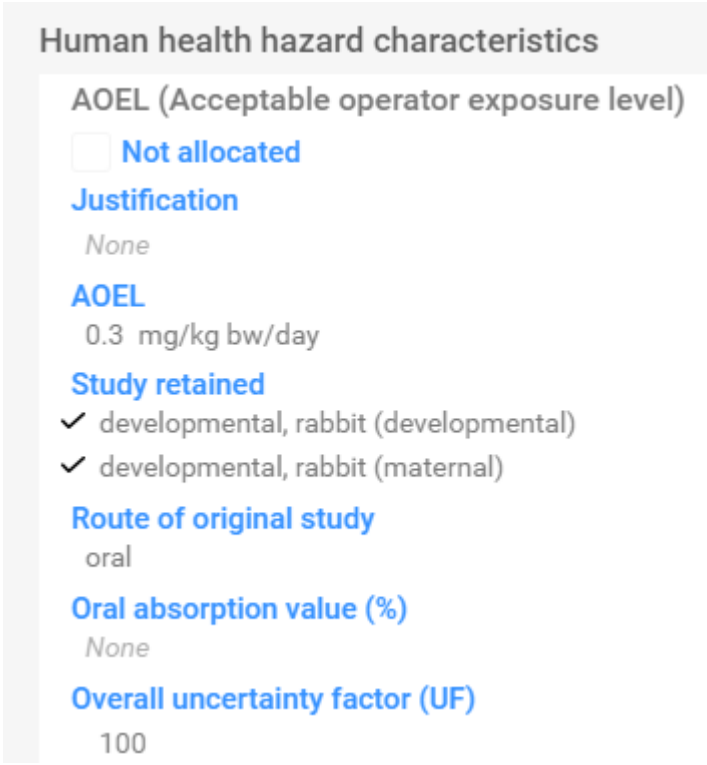
- **Example Requirement**
  summary: FLEXIBLE_SUMMARY.ToxRefValues is complete

The rule fails if any of the following is not true
The rule checks each *Toxicological reference values* (FLEXIBLE_SUMMARY.ToxRefValues) document for completeness.

Complete means: at least one of the following set of conditions (1 or 2) must be fulfilled, otherwise the rule fails for the document:

IF *'Not allocated'* under the AOEL (Acceptable operator exposure level*) header is **not** selected, THEN *'AOEL', 'Study retained'*, *Route of original study*, 'Oral absorption value (%)', *'Overall uncertainty factor (UF)'* **must have an entry**

IF 'Not allocated' **is** selected, THEN a *'Justification'* field **must have an entry.**

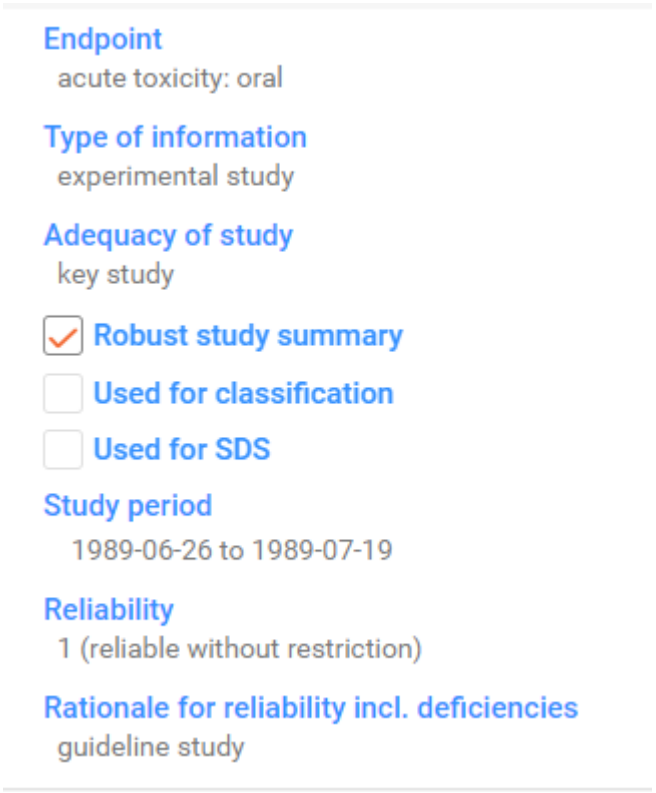


Backlog item 1782 – Added to Hypercare rules backlog

Development: Rules for ‘Other’ dataset

- QLT_PPP 001 - 009

Apply the checks on the administrative data to the ‘Other substance’ and ‘Other mixture’ datasets



Backlog item 1782 – Added to Hypercare rules backlog

Development: Reuse of results table checks

- Example: Results and discussion' is not complete. For each endpoint study record marked as 'key study' or 'weight of evidence', under 'Effect concentrations' heading, the fields 'Duration', 'Dose descriptor', 'Effect conc.' and 'Basis for effect' must be filled in, with unit. If 'other:' was selected in any of the picklists, the below field must be filled in. Each created entry must be complete.

  If a quantitative result was not determined, an explanation must be provided in the field 'Remarks on result'. If none of the available picklist values apply, select 'other:' and provide the reason for not determining a quantitative result in the below field.

Effect concentrations + New item Import file

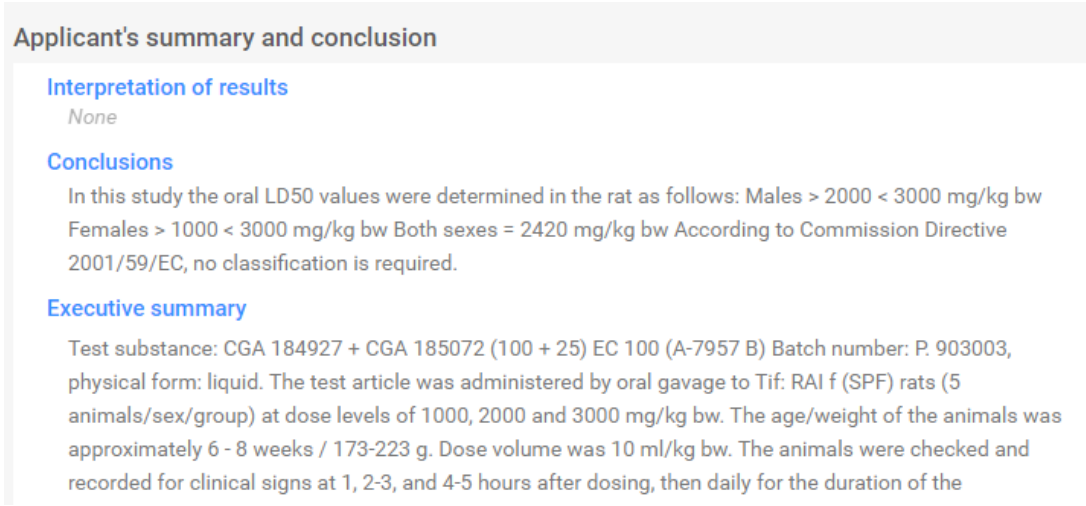
#	Key result	Duration	Dose descriptor	Effect conc.	95% CI	Nominal / meas...	Conc. based on	Basis for effect
1	☐	48 h	LD50 oral toxicity	17.8 µg per animal	*None*	nominal	act. ingr.	mortality
2	☐	48 h	LD50 contact toxicity	40.9 µg per animal	*None*	nominal	act. ingr.	mortality

Development: Applicants summary

Require fields in the applicants summary to be mandatory

All fields?

Technical note: Text box fields can be used more effectively in Report Generator than HTML fields



Applicant's summary and conclusion

Interpretation of results

None

Conclusions

In this study the oral LD50 values were determined in the rat as follows: Males > 2000 < 3000 mg/kg bw Females > 1000 < 3000 mg/kg bw Both sexes = 2420 mg/kg bw According to Commission Directive 2001/59/EC, no classification is required.

Executive summary

Test substance: CGA 184927 + CGA 185072 (100 + 25) EC 100 (A-7957 B) Batch number: P. 903003, physical form: liquid. The test article was administered by oral gavage to Tif: RAI f (SPF) rats (5 animals/sex/group) at dose levels of 1000, 2000 and 3000 mg/kg bw. The age/weight of the animals was approximately 6 - 8 weeks / 173-223 g. Dose volume was 10 ml/kg bw. The animals were checked and recorded for clinical signs at 1, 2-3, and 4-5 hours after dosing, then daily for the duration of the

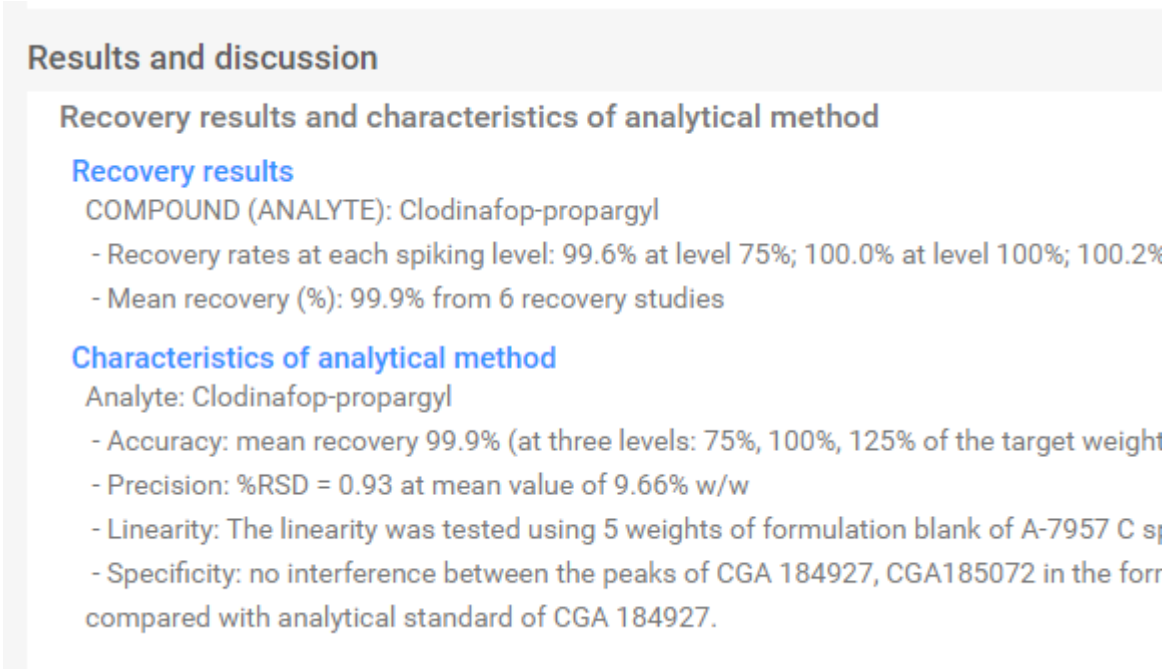
Backlog item 1741 – Added to Hypercare rules backlog

Development: Rules and Document Updates

OHT 57 Analytical methods

Further review needed based on feedback from the OECD consultation

Should rules be defined in conjunctions with document reviews?



Results and discussion

Recovery results and characteristics of analytical method

Recovery results

COMPOUND (ANALYTE): Clodinafop-propargyl

- Recovery rates at each spiking level: 99.6% at level 75%; 100.0% at level 100%; 100.2%
- Mean recovery (%): 99.9% from 6 recovery studies

Characteristics of analytical method

Analyte: Clodinafop-propargyl

- Accuracy: mean recovery 99.9% (at three levels: 75%, 100%, 125% of the target weight
- Precision: %RSD = 0.93 at mean value of 9.66% w/w
- Linearity: The linearity was tested using 5 weights of formulation blank of A-7957 C sp
- Specificity: no interference between the peaks of CGA 184927, CGA185072 in the forr

compared with analytical standard of CGA 184927.

Points for discussion

- Time needed between rule implementation and inclusion in Validation assistant?
- Form of consultation - in writing or meeting?

Most importantly: How can validation assistant support your work in IUCLID?

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