Ministry of Environment of Denmark
Environmental Protection Agency

WORKSHOP 2 ON ASSESSMENT OF PLANT PRODUCTION PRODUCTS

Danish EPA experience in assessing PPPs

Brussels
21 June 2023

Human health risk assessor

1. Identification of co-formulants

Data requirement 1.4.3

Initial check of dossier – co-formulant identity

Data requirement 1.4.3 (Reg. 284/2013)
Information on safeners, synergists and co-formulants

- **Chemical name**
- **Structural formula**
- For **each component**
  - **EC number and Chemical Abstracts Service (CAS) number**,
- For co-formulants which are **mixtures**,
  - **the composition shall be provided**.

Where the information provided does not fully identify the safener, synergist or co-formulant, an appropriate specification shall be provided.

The trade name,
Safety data sheets - shall be **up to date**
Function

Product composition in Part C

Component	CAS no.	Trade name	Function	g/L	% w/w[2]
Active substance 1	xxxxxxxx	x	xxxxxx	xx	**xx**
				xx	**xx**
Polymer xxxxx	xxxxxxxxxx	x	Adjuvant	xx	**xx**
Mixture xxxxx	Mixture Xxxxxxx Xxxxxxxxx Xxxxxxx	x	Emulsifier	xx	**xx**
Substance xxxxxxx	xxxxxx	x	Solvent	xx	**xx**
Reaction mass of xxxx	Mixture not assigned	x	Solvent	xx	**xx**
Polymer xxxxx	Mixture not assigned	x	Antifoam	xx	xx

+ alternative co-formulants

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Often 10-20 co-formulants to collect information on

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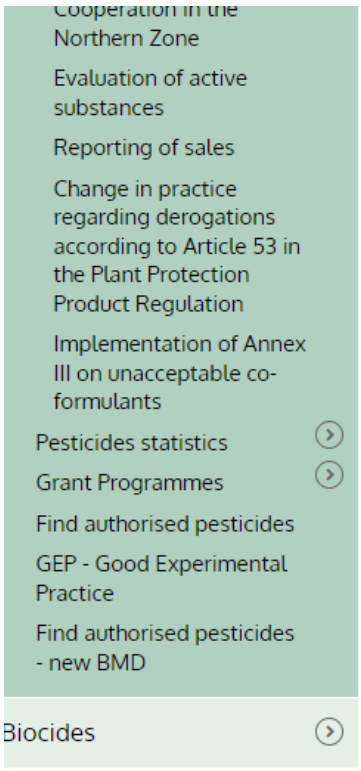
Guiding applicants to submit sufficient information



submitted in the dRR format from 2015. Download dRR format (version 2015)

Assessment of Plant Products v. 1.7 2019

The dossier must be prepared in accordance with the Northern zone guidance document and the Danish Framework for the Assessment of Plant Protection Products. In addition, a list of new studies and a justification for the new data submitted must be included in the application submission.

- A complete Annex II dossier for every active substance in the product (unless this information has already been submitted). The applicant is encouraged to submit the dossier in an easy to read format, as for example Caddy XML format
- A list of the intended uses (GAP table) in the zone and in the Member States where an application has been submitted. For zonal applications, the GAP table and the dRR should only cover the Northern Zone (not countries in the other zones)
- SDS for the product and co-formulants
- Complete detailed composition of the formulation and co-formulants including details on impurities. Table of the detailed composition of co-formulants preferable to be submitted by supplier.
- A draft label (instructions for use of the product. The requirements for a master label are described in the Guidance for evaluation of efficacy in the Northern Zone
- Letters of Access if the applicant does not own data used in the evaluation

https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/types-of-applications/new-products/

Guiding applicants to submit sufficient information

- **Guidance on DEPA website**
- **Detailed request for additional information on co-formulants**
  - **Substances and mixtures**
  - **Polymers**
  - **UVCBs**
- **Specifying that the suppliers can send confidential information directly to DEPA**
- **Currently building a database based on the information on complete composition of all authorised PPPs to make best use of the information we have available already**

2. Collecting, sharing and reporting data on Human health

Search for information on components

Hierachy

- **Additional information on acute toxicity**
- **Long-term toxicity**
- **Product identifiers**

Component	RAC opinion	Harmonised classification	ECHAs regstration database	MSDS
Cyclohexanone	no	H226, H332 (CLP00)	1 - Harmonised (2756 joint) 2 - self-classification H335, H226, H302, H312, H332, H315, H318 (106 joint)	H312, H332, H302, H318, H315, H226
Alcohols, C11-14-iso-,C13-rich, ethoxylated	no	no	No factsheet C&L: 463: H318 205: H302+H318 176: H315 + H400 85: H318 + H412	H302, H318
Leuno-alkansulfonat containing ”Paraffin oils, sulfochlorinated, saponified”	No	No	**H361d** H302, H315, H319 H412	H302, H315, H319 H412
Copper sulphate pentahydrate	2014 – ATP09	H302, H318, H400, H410 (ATP09/17)	H302, H319, H315, H410	H302, H315, H319

Reporting

Part C

- Grey boxes with details on identity and toxicity
- If HH hazard assessment based on information on single components
  - Sources of data
  - Calculations

Double confidential parts C (confidential to applicant)

- Currently not shared at CIRCABC

Summary

Increased complexity

- Product composition
- Collecting data from relevant sources
- Use of alternative approaches

Harmonisation and detailed guidance

Thank you very much for your attention!