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# Confidentiality and filtering

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Legal and Assurance Services Unit

Trusted science for safe food

# Items that may be claimed confidential (under Regulation (EC) No 1107/2009)

## g. When submitting an application, supporting scientific data and other supplementary information under Regulation (EC) No 1107/2009

| Legal basis under which the request may be submitted  | Items that may be claimed confidential   |
|---|--|
| <b>Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of Regulation EC No 178/2002)</b> | <p>the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;</p> <p>commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;</p> <p>commercial information revealing sourcing, market shares or business strategy of the applicant</p> <p>quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety</p> |
| <b>Article 63(2)(b) of Regulation (EC) No 1107/2009</b>   | the specification of impurity of the active substance and the related methods of analysis for impurities in the active substance as manufactured, except for the impurities that are considered to be toxicologically, ecotoxicologically or environmentally relevant and the related methods of analysis for such impurities  |
| <b>Article 63(2)(c) of Regulation (EC) No 1107/2009</b>   | results of production batches of the active substance including impurities   |
| <b>Article 63(2)(d) of Regulation (EC) No 1107/2009</b>   | information on the complete composition of a plant protection product  |
| <b>Article 39(e)(2) of Regulation (EC) No 178/2002</b>  | <p>names and addresses of natural persons authoring unpublished studies</p> <p>any other personal data except for</p> <ol style="list-style-type: none"> <li>the name and address of the applicant;</li> <li>the names of authors of published or publicly available studies supporting such requests; and</li> </ol> <p>the names of all participants and observers in meetings of the Scientific Committee and the Scientific Panels, their working groups and any other ad hoc group meeting on the subject matter.</p>   |
| <b>Article 39(e)(2) of Regulation (EC) No 178/2002</b>  | personal data (names and addresses) of individuals involved or contained in testing on vertebrate studies and in toxicological information and personal data of individuals involved or contained in human studies, as well as the name of authors of any unpublished studies  |

# Mapping to IUCLID format - quantitative composition

Dashboard > Mixture / Products > Clodinafop-propargyl 100 EC (TOPIK) > Detailed quantitative and qualitati...

31a8d636-a03a-4032-b58d-f45a11e426d2

Detailed quantitative and qualitative information on the composition of Cl...

EU PPP Active substance application (representative product)

- 1 Identity of the representative plant protection product
  - 1.1 (Cf. 1.3) Applicant
  - 1.2 Producer of the representative plant protection product
  - 1.3 Trade name or proposed trade name of the representative plant protection product
  - 1.4 Detailed quantitative and qualitative information on the composition of the repr...

Administrative data

Confidentiality

CBI

Justification

Declaration:

We applicant claim the corresponding information as confidential in accordance with Art 63. of EU Regulation 1107/2009.

Use restricted to selected regulatory programmes

- EU: PPP

Confidentiality can be claimed at the IUCLID document level

1

Component flag

Confidentiality

None

Justification

None

Use restricted to selected regulatory programmes

- EU: PPP

Name

Metabolite CGA 184927 - Clodinafop-propargyl (isomer) (R)-2-[4-(5-chloro-3-fluoro-pyridin-2-yloxy)-phenoxy]-propionic acid prop-2-ynyl ester 10551-06-9

Function

other: Metabolite

Typical concentration

None

Concentration range

None

Remarks

None

☐ Substance of concern

☐ Generic product identifier (GPI)

Decision dependant on relevance of impurity/metabolite

Substance of concern = True or False

Impurities

1

Confidentiality

None

Justification

Use restricted to selected regulatory programmes

- EU: PPP

Reference substance

DUMMY example relevant impurity: Toluene Methylbenzene 108-88-3 203-625-9

Typical concentration

<= 0.10 % (w/w)

Concentration range

>= 0.08 <= 0.12 % (w/w)

Remarks

DUMMY example relevant impurity: The corresponding impurity is a relevant impurity. It originates from manufacturing process of technical material (Dummy data).

☐ This impurity is considered relevant for the classification and labelling of the substance

IUCLID elements filtering could be applied

# Mapping to IUCLID format - GDPR

## Manufacturing plant 1

Legal entity

Other legal entity owners

None

Remarks

None

Other IT system identifiers

## Contact address

Confidentiality

CBI

Justification

Declaration:

We, applicant claim the corresponding information as confidential in accordance with Art. 63 of Regulation 1107/2009.

Use restricted to selected regulatory programmes

- EU: PPP

Address 1

XY

Address 2

None

Postal code

None

City

None

Region / State

None

Country

None

Phone

None

Fax

None

E-mail

None

Web site

None

## Acute Oral Toxicity (LD50) of clodinafop-propargyl to Mallard ducks.

### General information

Reference Type

study report

Title

Acute Oral Toxicity (LD50) of clodinafop-propargyl to Mallard ducks.

Author

Hakin, B., Rodgers, M., Norman, A.J., Anderson, A., Dawe, I.S.

Year

1990

Bibliographic source

None

Testing facility

Huntington Research Centre Ltd., Huntington, Cambridgeshire, UK

Report no.

CBG 468/89444

Study sponsor

Ciba-Geigy AG, Basel, Switzerland

Study no.

CGA184927/0008

Report Date

Feb 26, 1990

Remarks

None

# Mapping to IUCLID format - Attachments

## Overall remarks, attachments

### Overall remarks

None

### Attached background material

### Attached full study report

IDD0000138433.pdf

### Illustration (picture/graph)

None

Need to discriminate  
between GLP study reports  
and 'Sanitised' versions

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