

# **Confidentiality and filtering**

**Simone Gabbi** 

Legal and Assurance Services Unit

Trusted science for safe food



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

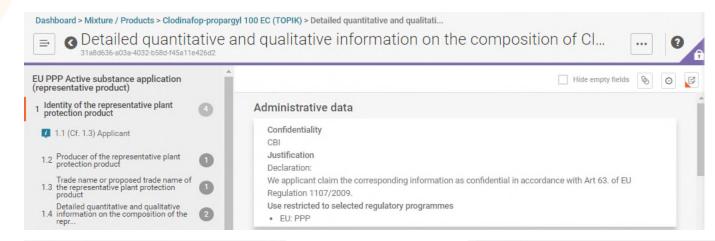
authors of any unpublished studies



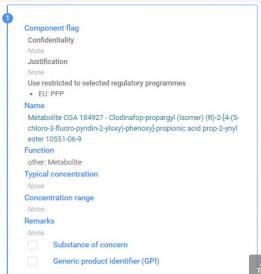
	European Food Sarety Authority	
g. When submitting an application, supporting scientific data and other supplementary information under Regulation (EC) No 1107/2009		
Legal basis under which the request may be submitted	Items that may be claimed confidential	
Article 63(2)(a) of Regulation (EC) No 1107/2009 (making reference to Article 39 of Regulation EC No	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;	
178/2002)	commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;	
	commercial information revealing sourcing, market shares or business strategy of the applicant	
	quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety	
Article 63(2)(b) of Regulation (EC) No 1107/2009	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	
Article 63(2)(c) of Regulation (EC) No 1107/2009	results of production batches of the active substance including impurities	
Article 63(2)(d) of Regulation (EC) No 1107/2009	information on the complete composition of a plant protection product	
Article 39(e)(2) of Regulation (EC) No 178/2002	names and addresses of natural persons authoring unpublished studies any other personal data except for	
	<ul> <li>a. the name and address of the applicant;</li> <li>b. the names of authors of published or publicly available studies supporting such requests; and</li> <li>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.</li> </ul>	
Article 39(e)(2) of Regulation (EC) No 178/2002	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	

# Mapping to IUCLID format - quantitative composition





Confidentiality can be claimed at the IUCLID document level



Decision dependant on relevance of impurity/met abolite

Substance of concern = True or False

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Nor Jus Use Refe DUI Typi <=( Con:	Infidentiality Infide	IUCLID elements filtering could be applied
	MMY example relevant impurity: The corresponding impurity is a relevant impurity. It or mufacturing process of technical material (Dummy data).  This impurity is considered relevant for the classification and labelling of the	

## 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 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 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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