

REGISTRATION REPORT

Part A

Risk Management

Product code: SAP2821MCF

Product names: ACTLET C FLOW

Chemical active substances:

Copper compounds (copper hydroxide), 215 g/L (330.1)

Metalaxyl-M, 28.5 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: ASCENZA France

Date: 02/12/2025

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access.....	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims.....	5
2	Details of the authorisation decision	6
2.1	Product identity	6
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling.....	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	7
2.5	Risk management	7
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses.....	8
2.6	Intended uses (only NATIONAL GAP)	9
3	Background of authorisation decision and risk management	11
3.1	Physical and chemical properties (Part B, Section 2)	11
3.2	Efficacy (Part B, Section 3)	11
3.3	Methods of analysis (Part B, Section 5)	11
3.3.1	Analytical method for the formulation.....	11
3.3.2	Analytical methods for residues	12
3.4	Mammalian toxicology (Part B, Section 6)	12
3.4.1	Acute toxicity.....	12
3.4.2	Operator exposure.....	12
3.4.3	Worker exposure.....	15
3.4.4	Bystander exposure	17
3.4.5	Resident exposure.....	17
3.4.6	Combined exposure.....	19
3.5	Residues and consumer exposure (Part B, Section 7)	23
3.6	Environmental fate and behaviour (Part B, Section 8).....	23
3.7	Ecotoxicology (Part B, Section 9)	24
3.8	Relevance of metabolites (Part B, Section 10)	26
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	26

5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	26
5.1.1	Post-authorisation monitoring.....	26
5.1.2	Post-authorisation data requirements	26
Appendix 1	Copy of the product authorisation.....	27
Appendix 2	Copy of the product label	28

PART A

RISK MANAGEMENT

1 Details of the application

The company ASCENZA FRANCE has requested a marketing authorisation in France for the product ACTLET C FLOW (Product code: SAP2821MCF), containing 215 g/L copper¹ (as copper hydroxide, CAS No 20427-59-2) and 28.5 g/L metalaxyl-M² as a fungicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of ASCENZA FRANCE's application submitted on 28/05/2021 to market ACTLET C FLOW in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2021-2215 and 2024-0377) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) No 1107/2009³, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")⁴. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of ACTLET C FLOW has been made using endpoints agreed in the EU peer reviews of copper hydroxide and metalaxyl-M. It also includes assessment of data and information related to ACTLET C FLOW where those data have not been considered in the EU peer review process.

The conclusions of the assessment published by EFSA 2018^{5,6}, as part of the procedure for the renewal of the approval of copper compounds, based on the available information, identify risk for non-target organisms for the representative uses on grapevine, cucurbits and tomatoes, as well as to workers for the grapevine use.

¹ Commission Implementing Regulation (EU) No 2018/1981 of 13 December 2018 renewing the approval of the active substances copper compounds, as candidates for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

² Commission Implementing Regulation (EU) No 2020/617 of 5 May 2020 renewing the approval of the active substance metalaxyl-M, and restricting the use of seeds treated with plant protection products containing it, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

³ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁴ SANCO document "risk envelope approach", European Commission (14 March 2011). [Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5](#)

⁵ Peer review of the pesticide risk assessment of the active substance copper compounds Copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture, EFSA Journal 2018;16(1):515

⁶ Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for copper compounds copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture in light of confirmatory data. EFSA supporting publication 2018:EN-1486.

In the framework of MRL review for copper compounds under Article 12 of Regulation (CE) 396/2005, EFSA published a reasoned opinion (EFSA, 2018⁷). Based on an evaluation of the available data MRL have been proposed and a consumer risk assessment has been conducted. Some information required by the regulation has not been transmitted and a chronic risk for the consumers was identified. Therefore the consumer risk assessment is only tentative and some of the proposed MRL still require a decision by risk managers. Exposure reduction measures could also be investigated. It should be noted that EFSA has published (EFSA, 2025⁸) an updated maximum residue limits (MRLs) for copper compounds in light of EFSA's scientific opinion on the re-evaluation of health-based guide values and exposure assessment from all sources.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁹, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of ACTLET C FLOW.

1.2 Letters of Access

The applicant has provided letters of access for copper hydroxide (and PPP data). These letters of access are available upon request.

No access has been provided to the active substance metalaxyl-M via letter of access. It was concluded that the submitted data matching table (Rapporteur Member State : BE, 26 February 2021) **was not acceptable** for grapes, tomato and eggplant.

1.3 Justification for submission of tests and studies

According to the applicant: *“The study reports submitted within this application are in agreement with the data requirements of the Regulation No 284/2013.”*

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ACTLET C FLOW, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

⁷ REASONED OPINION ADOPTED: 1 March 2018. Review of the existing maximum residue levels for copper compounds according to Article 12 of Regulation (EC) No 396/2005 European Food Safety Authority (EFSA).

⁸ EFSA, 2025. Statement on the update of maximum residue levels (MRLs) for copper compounds in light of the EFSA scientific opinion on the re-evaluation of the health-based guidance values (HBGVs) and exposure assessment from all sources. EFSA Journal. 2025;23:e9271. doi.org/10.2903/j.efsa.2025.9271

⁹ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products.

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

2 Details of the authorisation decision

2.1 Product identity

Product code	SAP2821MCF
Product name in MS	ACTLET C FLOW
Authorisation number	-
Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	ASCENZA FRANCE
Active substance(s) (incl. content)	Copper (as copper hydroxide CAS No 20427-59-2), 215 g/L (330.1 g/L) Metalaxyl-M, 28.5 g/L
Formulation type	Suspension concentrate [SC]
Packaging	N/A : no marketing authorisation granted».
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for ACTLET C FLOW resulted in the decision **to refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

N/A : no marketing authorisation granted

2.4.2 Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017¹⁰ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021¹¹ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Moreover, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation¹² is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021¹³ on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop¹⁴ when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

¹⁰ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation de produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amendé par l'arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

¹¹ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

¹² SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

¹³ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

¹⁴ List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

SAP2821MCF / ACTLET C FLOW

Part A - National Assessment

FRANCE

N/A : no marketing authorisation granted

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2025-12-02

PPP (product name/code): **ACTLET C FLOW / SAP2821MCF**
Active substance 1: Copper* (as copper hydroxide)
Active substance 2: Metalaxyl-M**
Safener: /
Synergist: /
Applicant: ASCENZA FRANCE
Zone(s): Southern Zone ^(d)
Verified by MS: **Yes**
Field of use: Fungicide

Formulation type: SC ^(a, b)
Conc. of a.s. 1: 215 g/L* (330.1 g/L) ^(c)
Conc. of a.s. 2: 28.5 g/L** ^(c)
Conc. of safener: /
Conc. of synergist: /
Professional use: ☒
Non-professional use: ☐

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
1	FR	Grapes	F	<i>Plasmopara viticola</i> (PLASVI)	Spraying	BBCH 71-83	a) 1 b) 2	12 days	a) 3.5 b) 7	a) 752.5* + 94.75** b) 1505* + 189.5**	100 / 1000	28 days	Not acceptable (worker, not access data)

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)
					Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
2	FR	Tomato, eggplant	F	<i>Phytophthora infestans</i> (PHYTIN)	Spraying	BBCH 29-81 Avoid flowering period (BBCH 60-69)	a) 1 b) 3	7 days	a) 3.5 b) 10.5	a) 752.5* + 94.75** b) 2257.5* + 284.25**	100 / 1000	3 – 10 days	Not acceptable (not access data)
3	FR	Potato	F	<i>Phytophthora infestans</i> (PHYTIN)	Spraying	BBCH 36-81 Avoid flowering period (BBCH 60-69)	a) 1 b) 2	7 days	a) 3.5 b) 7	a) 752.5* + 94.75** b) 1505* + 189.5**	100 / 1000	21 days	Not acceptable (MRL)

**Remarks
table
heading:**

- (a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

**Remarks
columns:**

- 1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

- (d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
- 7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

ACTLET C FLOW is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a blue liquid, without characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 389°C. In aqueous solution 1%, it has a pH value of 8.5 at 25°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE bottles or HDHMW-PE containers. Its technical characteristics are acceptable for a SC formulation.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- The efficacy level of the product ACTLET C FLOW is considered to be satisfactory for all the requested uses.
- The phytotoxicity level of ACTLET C FLOW is considered to be acceptable for all the requested uses.
- The risks of negative impact on yield, propagation, succeeding crops and adjacent crops are considered to be negligible. Risks with copper such as spotting of table grape berries or on the wine-making process are known. However, these risks of negative impact are considered to be acceptable.
- The risk of resistance to copper does not require a monitoring for the requested uses. There is a risk of resistance to metalaxyl-M for *Plasmopara viticola* and *Phytophthora infestans* requiring a resistance monitoring and efficacy trials in situation of characterized resistance to metalaxyl-M in grapevine and in potato.
- To avoid the development of resistance of *Plasmopara viticola* and *Phytophthora infestans* to metalaxyl-M, the number of applications is limited to 2 applications per crop cycle on grapevine and potato. To manage the risk of resistance to the active substances with the same mode of action (anilides) it is recommended to follow the limitations of use by chemical group recommended by the French notes on resistance management on grapevine diseases¹⁵ and potato diseases¹⁶.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substances and the relevant impurities in the formulation are available and validated.

¹⁵ Note technique commune résistances - maladies de la vigne : mildiou, oïdium, pourriture grise, black-rot.

¹⁶ Note technique commune - stratégie de lutte contre le mildiou de la pomme de terre (*Phytophthora infestans*).

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of copper in plants (high water, oily, acidic and dry content commodities), soil, water (surface and drinking), air and body fluids.

According to EFSA conclusions, an inter-laboratory validation (ILV) for the analytical methods for the determination of residues of copper in plants is required.

Analytical methods for the determination of residues of copper in food of animal origin are missing and are required. Moreover, the limit of quantification (LOQ) of the available methods for the determination of residues of copper in water is not in accordance with the European Directive 98/83/EC.

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of Metalaxyl-M in plants (high water, oily, acidic and dry content commodities), soil, water (surface and drinking), air and body fluids.

The extraction efficiency of the methods for the determination of residues in plants and in animal matrices is not demonstrated. The solvent used in this method is different of this used in the metabolism studies.

Nevertheless, as the RAR has been performed in 2014, and as the residue trials use the method of the RAR, the guidance SANTE/2017/10632 is not applicable for this product.

Consequently, the analytical methods are considered as validated, nevertheless, with the absence of the demonstration of the extraction efficiency, the applicability of the method for the determination of the incurred residues remain uncertain. As a consequence, the analytical methods for product ACTLET C FLOW cannot be finalised.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Product name and code	SAP2821MCF	
Formulation type	SC	
Category	Fungicide	
Active substance(s) (incl. content)	Metalaxyl-M 28.5 g/L	Copper hydroxide 215 g/L
AOEL systemic	0.08 mg/kg bw/d	0.08 mg/kg bw/d
AAOEL	None	None
Inhalation absorption	100%	100%
Oral absorption	100%	50%
Vapour pressure	3.3 10 ⁻³ Pa at 25°C	Not relevant
Dermal absorption	Concentrate: 3% Dilution: 24% (Based on a dermal absorption study)	Concentrate: 1% Dilution: 9% (Based on dermal absorption studies)

3.4.1 Acute toxicity

SAP2821MCF containing 215 g/L of copper compounds and 28.5 g/L of metalaxyl-M, has a low inhalational and dermal toxicity, is harmful if swallowed (H302), is irritating to the rabbit eye (H318), and is not irritating to the rabbit skin or a skin sensitizer.

3.4.2 Operator exposure

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹⁷:

		Metalaxyl-M		Copper hydroxide	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Critical use: Grapes					
Tractor mounted outdoor, upward applications					
Application rate		0.1 kg a.s./ha		0.753 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.0553	69.17%	0.1451	181.35%
	Work wear (arms, body and legs covered) M/L and A	0.0188	23.47%	0.0444	55.52%
	Work wear (arms, body and legs covered) and gloves M/L and A	0.0064	8.02%	0.0183	22.91%
Manual hand held outdoor, upward late applications (dense foliage)					
Application rate		0.1 kg a.s./ha		0.753 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	3.3844	4230.47%	1.7602	2200.20%
	Work wear (arms, body and legs covered) M/L and A	0.1947	243.39%	0.0942	117.73%
	Work wear (arms, body and legs covered) and gloves M/L and A	0.1837	229.68%	0.0722	90.22%
	Work wear (arms, body and legs covered) and gloves M/L and A and mask (FP2, P2 and similar) during M/L	0.1827	228.34%	0.0699	87.33%
Manual knapsack, outdoor, upward late applications (dense foliage)					
Application rate		0.1 kg a.s./ha		0.753 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	3.3891	4236.43%	1.7611	2201.37%
	Work wear (arms, body and legs covered) M/L and A	0.1994	249.30%	0.0955	119.34%
	Work wear (arms, body and legs covered) and gloves M/L and A	0.1841	230.19%	0.0725	90.66%

¹⁷ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

	Work wear (arms, body and legs covered) and gloves M/L and A and mask (FP2, P2 and similar) during M/L	0.1827	228.41 %	0.0699	87.36%
--	--	--------	-----------------	--------	--------

Critical use: Tomato

Covering eggplant and potato

Tractor mounted outdoor, downward applications

Application rate		0.1 kg a.s./ha		0.753 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.0189	23.60%	0.0347	43.42%
	Work wear (arms, body and legs covered) M/L and A	0.0118	14.74%	0.0227	28.33%
	Work wear (arms, body and legs covered) and gloves M/L and A	0.0009	1.12%	0.0016	1.97%

Critical use: Tomato

Covering eggplant

Manual hand held outdoor, downward applications

Application rate		0.1 kg a.s./ha		0.753 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.3643	455.40 %	0.2765	345.65 %
	Work wear (arms, body and legs covered) M/L and A	0.0435	54.41%	0.0344	42.98%
	Work wear (arms, body and legs covered) and gloves M/L and A	0.0362	45.23%	0.0279	34.84%

Manual knapsack, outdoor, downward applications

Application rate		0.1 kg a.s./ha		0.753 kg a.s./ha	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential exposure	0.3677	459.62 %	0.1382	172.75 %
	Work wear (arms, body and legs covered) M/L and A	0.0474	59.31%	0.0181	22.66%
	Work wear (arms, body and legs covered) and gloves M/L and A	0.0366	45.69%	0.0142	17.80%

Conclusion for operator exposure:

Based on the exposure assessment using EFSA model, operator exposure to SAP2821MCF is below the AOEL of each active substance for the uses on tomato, eggplant, potato and mechanised application on grapes with personal protective equipment.

Operator exposure to SAP2821MCF is **above the AOEL** of metalaxyl-M for manual application on grapes with personal protective equipment.

3.4.3 Worker exposure

Estimation of operator exposure has been amended by zRMS considering different dermal absorption values. zRMS calculated refined DT50 and DFR initial values for Metalaxyl-M based on field data submitted by applicant on grapevines. The results of calculations estimated using the EFSA model¹⁸ are presented in the table below :

		Metalaxyl-M		Copper hydroxide	
Model data	Level of PPE	Total absorbed dose (mg/kg/day)	% of systemic AOEL	Total absorbed dose (mg/kg/day)	% of systemic AOEL
Critical use: Grapes					
Hand harvesting Outdoor Work rate: 8 hours/day DT ₅₀ : 30 days DFR: 3 µg a.s./cm ² /kg a.s./ha Interval between applications: 14 days					
Application rate and number of applications		0.1 kg a.s./ha x 3 applications		0.753 kg a.s./ha x 3 applications	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential TC: 30000 cm ² /person/h	0.6472	809.02%	1.8275	2284.47%
	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	0.2179	272.37%	0.6152	769.11%
	Work wear (arms, body and legs covered) and gloves TC: No TC available for this assessment	-	-	-	-
Hand harvesting Outdoor Work rate: 8 hours/day DT ₅₀ of metalaxyl-M: 0,51 days / DT ₅₀ of copper hydroxide: 30 days / DFR of metalaxyl-M: 1,61 µg a.s./cm ² /kg a.s./ha / DFR of copper hydroxide: 3 µg/cm ² /kg a.s./ha Interval between applications: 14 days					
Application rate and number of applications		0.1 kg a.s./ha x 3 applications		0.753 kg a.s./ha x 3 applications	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential TC: 30000 cm ² /person/h	0.1545	193.20%	1.8275	2284.47%
	Work wear (arms, body and legs covered) TC: 10100 cm ² /person/h	0.0520	65.04%	0.6152	769.11%

¹⁸ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

	Work wear (arms, body and legs covered) and gloves TC: No TC available for this assessment	-	-	-	-
Critical use: Tomato Covering eggplant					
Reaching, picking Outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg a.s./cm ² /kg a.s./ha Interval between treatments: 7 days					
Application rate and number of applications		0.1 kg a.s./ha x 3 applications		0.753 kg a.s./ha x 3 applications	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential TC: 5800 cm ² /person/h	0.1433	179.17%	0.4047	505.94%
	Work wear (arms, body and legs covered) TC: 3000 cm ² /person/h	0.0618	77.23%	0.1745	218.08%
	Work wear (arms, body and legs covered) and gloves TC: 750 cm ² /person/h	0.0143	17.92%	0.0405	50.59%
Critical use: Potato					
Inspection, irrigation Outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg a.s./cm ² /kg a.s./ha Interval between treatments: 7 days					
Application rate and number of applications		0.1 kg a.s./ha x 3 applications		0.753 kg a.s./ha x 3 applications	
Spray application (AOEM; 75 th percentile) Body weight: 60 kg	Potential TC: 12500 cm ² /person/h	0.0772	96.54%	0.2181	272.59%
	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	0.0086	10.81%	0.0244	30.53%
	Work wear (arms, body and legs covered) and gloves TC: No TC available for this assessment	-	-	-	-

Conclusion for worker exposure:

Based on the exposure assessment using EFSA model, worker exposure to SAP2821MCF is below the

AOEL of each active substance for the uses on tomato, eggplant and potato with personal protective equipment mentioned above.

For grapes:

- Based on default values for DFR and DT50, worker exposure to SAP2821MCF is **above the AOEL** of metalaxyl-M and copper hydroxide for grapes with personal protective equipment mentioned in Table 6.1-3.
- When DFR initial and DT50 are refined (see Section A.2.11) worker exposure to SAP2821MCF is **below the AOEL** of metalaxyl-M with workwear.
- However worker exposure in grape vine is still **above the AOEL** of copper hydroxide. combined exposure is not necessary for this scenario.
- No realistic re-entry interval can be derived for copper, since at least 89 days* would be necessary to obtain a worker exposure below the AOEL.

*Calculation of re-entry interval after last application:

$t_{\text{re-entry}} = (1/k) \times \ln(\% \text{AOEL after last application}/100)$

$= (DT50/\ln 2) \times \ln(\% \text{AOEL after last application}/100)$

$= (30/\ln 2) \times \ln(769.11/100)$

3.4.4 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹⁹.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): *“No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.”*

3.4.5 Resident exposure

Estimation of resident exposure has been amended by zRMS considering different dermal absorption values. Based on data submitted by Applicant for grapevines, Refined DT50 and DFR initial for metalaxyl-M have been calculated by zRMS, see details in Part B6, section A.2.11.

Residential exposure was assessed according to the EFSA model²⁰ incorporating a distance of 3 metres from the spray boom/ incorporating a distance of 10 metres from the spray boom and a drift reduction technology

The estimated resident exposure is presented in the table below :

The estimated residue exposure is presented in the table below :					
		Metalaxyl-M		Copper Hydroxide	
Model data	Pathways	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL
Critical use: Grapes					

¹⁹ Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

²⁰ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

AOEM calculator (EFSA Model) Tractor mounted, upward application Buffer zone: 10 m Drift reduction technology: no DT ₅₀ : 30 days for copper DFR: 3 µg/cm ² /kg a.s./ha for copper Interval between treatments: 14 days Volume min: 100 L/ha					
Number of applications and application rate		0.1 kg a.s./ha x 3 applications		0.753 kg a.s./ha x 3 applications	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0334	41.75%	0.0951	118.87%
	Vapour (75 th perc.)	0.0011	1.34%	0.0011	1.34%
	Deposits (75 th perc.)	0.000078	0.10%	0.00053	0.66%
	Re-entry (75 th perc.)	0.0022	2.72%	0.0257	32.13%
	Sum (mean)	0.0248	31.05%	0.0846	105.8%
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0018	23.13%	0.0524	65.51%
	Vapour (75 th perc.)	0.0002	0.29%	0.00023	0.29%
	Deposits (75 th perc.)	0.0000298	0.04%	0.000189	0.24%
	Re-entry (75 th perc.)	0.0012	1.51%	0.01428	17.85%
	Sum (mean)	0,0054	16.64%	0,04605	57.57%
Critical use: Grapes (refinement)					
AOEM calculator (EFSA Model) Tractor mounted, upward application Buffer zone: 10 m Drift reduction technology: yes DT ₅₀ : 30 days for copper / 0.51 day for metalaxyl-M DFR: 3 µg/cm ² /kg a.s./ha for copper / 1.61 for metalaxyl-M Interval between treatments: 14 days Volume min: 100 L/ha					
Number of applications and application rate		0.1 kg a.s./ha x 3 applications		0.753 kg a.s./ha x 3 applications	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0167	20.88%	0.0475	59.44%
	Vapour (75 th perc.)	0.0011	1.34%	0.0011	1.34%
	Deposits (75 th perc.)	0.000039	0.05%	0.0002645	0.33%
	Re-entry (75 th perc.)	0,0022	2.72%	0.0257	32.13%
	Sum (mean)	0.0138	17.28%	0.0531	66.38%
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0092	11.56%	0.0262	32.76%
	Vapour (75 th perc.)	0.0002	0.29%	0.0002	0.29%
	Deposits (75 th perc.)	0.0000149	0,02%	0.000094	0.12%
	Re-entry (75 th perc.)	0.0012	1.51%	0.014278	17.85%

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

	Sum (mean)	0.0072	9.07%	0.0288	36.04%
--	-------------------	---------------	--------------	---------------	---------------

Critical use: Tomato Covering eggplant and potato.					
AOEM calculator (EFSA Model) Tractor mounted, downward application Buffer zone: 2-3 m Drift reduction technology: no DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days Volume min: 500 L/ha					
Number of applications and application rate		0.1 kg a.s./ha x 3 applications		0.753 kg a.s./ha x 3 applications	
Resident child Body weight: 10 kg	Drift (75 th perc.)	0.0013	1.61%	0.0037	4.58%
	Vapour (75 th perc.)	0.0011	1.34%	0.0011	1.34%
	Deposits (75 th perc.)	0.0015	1.39%	0.0033	4.16%
	Re-entry (75 th perc.)	0.0091	13.03%	0.0091	36.8%
	Sum (mean)	0.0135	13.63%	0.0135	36.26%
Resident adult Body weight: 60 kg	Drift (75 th perc.)	0.0017	0.39%	0.0008	1.09%
	Vapour (75 th perc.)	0.0002	0.29%	0.0002	0.29%
	Deposits (75 th perc.)	0.0004	0.53%	0.0012	1.49%
	Re-entry (75 th perc.)	0.0051	7.24%	0.0163	20.44%
	Sum (mean)	0.0054	6.63%	0.0145	18.2%

Conclusion for resident exposure:

Based on the exposure assessment using EFSA model, resident exposure to ACTLET C FLOW is below the AOEL of each active substance for the uses on tomato, eggplant and potato with personal protective equipment mentioned in Table 6.1-3.

Resident exposure to ACTLET C FLOW is below the AOEL of each active substance for grapes with personal protective equipment mentioned in Table 6.1-3 and drift reduction technology.

3.4.6 Combined exposure

A cumulative assessment for operators, residents (adult and child) and workers was performed. At the first tier, combined exposure was calculated as the sum of the component exposures, without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each substance and the hazard index (HI: sum of hazard quotients) are detailed in the table below. In this table, the scenarios for which the exposure is already unacceptable for one of the two substances have been excluded:

Risk assessment from combined exposure (longer term exposure)

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

Application scenario	Active ingredient	Estimated exposure / AOEL (HQ)
Operators _Grapes: Vehicle-mounted Upward spray application outdoor Application rate: 3 x 1 L product/ha Spray application (AOEM; 75th percentile) Body weight: 60 kg With PPE : Work wear (arms, body and legs covered) M/L and A	Metalaxyl-M (HQ)	0.2347
	Copper hydroxide (HQ)	0.5552
	Cumulative risk operators (HI)	0.7899
Operators _Grapes: Manual handheld Upward spray application outdoor Application rate: 3 x 1 L product/ha Spray application (AOEM; 75th percentile) Body weight: 60 kg With PPE : Work wear (arms, body and legs covered) M/L and A	Metalaxyl-M (HQ)	2.2834
	Copper hydroxide (HQ)	0.8733
	Cumulative risk operators (HI)	
Operators _Fruiting vegetables: Vehicle-mounted Downward spray application outdoor Application rate: 3 x 1 L product/ha Spray application (AOEM; 75th percentile) Body weight: 60 kg Without PPE : Potential exposure	Metalaxyl-M (HQ)	0.2360
	Copper hydroxide (HQ)	0.4342
	Cumulative risk operators (HI)	0.6702
Operators _Fruiting vegetables: Manual handheld Downward spray application outdoor Application rate: 3 x 1 L product/ha Spray application (AOEM; 75th percentile) Body weight: 60 kg With PPE : Work wear (arms, body and legs covered) M/L and A	Metalaxyl-M (HQ)	0.5441
	Copper hydroxide (HQ)	0.4298
	Cumulative risk operators (HI)	0.9739
Operators _Fruiting vegetables: Manual Knapsack Downward spray application outdoor Application rate: 3 x 1 L product/ha Spray application (AOEM; 75th percentile) Body weight: 60 kg With PPE : Work wear (arms, body and legs covered) M/L and A	Metalaxyl-M (HQ)	0.5931
	Copper hydroxide (HQ)	0.2266
	Cumulative risk operators (HI)	0.8197
Worker—Grapes: Upward spraying Work rate: 8 hours/day DT50: 0.58 day for metalaxyl-M / 30 days for copper DFR initial: 1.61 µg a.s./cm ² /kg a.s./ha for metalaxyl-M / 3 µg a.s./cm ² /kg a.s./ha for copper TC: 10100 cm ² /h	Metalaxyl-M (HQ)	0.6504
	Copper Hydroxide (HQ)	7.6911
	Cumulative risk workers (HI)	8.3415
Workers – Tomato: Downward spray application outdoor Work rate: 8 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days With PPE : Work wear (arms, body and legs covered) and gloves Application rate: 3 x 1 L product/ha TC: 750 cm ² /h	Metalaxyl-M (HQ)	0.1792
	Copper hydroxide (HQ)	0.5059
	Cumulative risk workers (HI)	0.6851
Workers – Potato: Downward spray application outdoor Work rate: 2 hours/day, DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days	Metalaxyl-M (HQ)	0.1081
	Copper hydroxide (HQ)	0.3053
	Cumulative risk workers (HI)	0.4134

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

With PPE : Work wear (arms, body and legs covered) Application rate: 3 x 1 L product/ha TC: 1400 cm ² /h		
Resident- child - <i>Grapes: Vehicle-mounted Upward spray application outdoor</i> Buffer zone: 10 (m) Drift reduction technology: Yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days Dilution min : 100L Application rate: 3 x 1 L product/ha Body weight: 10 kg	Metalaxyl-M (HQ)	
	Drift	0.2088
	Vapour	0.0134
	Deposits	0.0005
	Re-entry	0.0272
	Sum (mean)	0.1728
	Copper hydroxide (HQ)	
	Drift	0.5944
	Vapour	0.0134
	Deposits	0.0033
	Re-entry	0.3213
	Sum (mean)	0.6736
	Cumulative risk resident – child (HI)	
	Drift	0.8032
	Vapour	0.0268
	Deposits	0.0038
	Re-entry	0.3485
	Sum (mean)	0.8464
Resident- adult - <i>Grapes: Vehicle-mounted Upward spray application outdoor</i> Buffer zone: 10 (m) Drift reduction technology: Yes DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 14 days Dilution min : 100L Application rate: 3 x 1 L product/ha Body weight: 60 kg	Metalaxyl-M (HQ)	
	Drift	0.1156
	Vapour	0.0029
	Deposits	0.0002
	Re-entry	0.0151
	Sum (mean)	0.0907
	Copper hydroxide (HQ)	
	Drift	0.3276
	Vapour	0.0029
	Deposits	0.0012
	Re-entry	0.1785
	Sum (mean)	0.3658
	Cumulative risk resident – adult (HI)	
	Drift	0.4432
	Vapour	0.0058
	Deposits	0.0014
	Re-entry	0.1933
	Sum (mean)	0.4565
Resident- child - <i>Tomato: Vehicle-mounted Downward spray application outdoor</i>	Metalaxyl-M (HQ)	
	Drift	0.1077

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

Buffer zone: 2-3 (m) Drift reduction technology: No DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days Dilution min : 500L Application rate: 3 x 1 L product/ha Body weight: 10 kg Covers eggplant and potato	Vapour	0.0064
	Deposits	0.0070
	Re-entry	0.0754
	Sum (mean)	0.1311
	Copper hydroxide (HQ)	
	Drift	0.0267
	Vapour	0.0024
	Deposits	0.0017
	Re-entry	0.0187
	Sum (mean)	0.0333
	Cumulative risk resident – child (HI)	
	Drift	0.1344
	Vapour	0.0088
	Deposits	0.0087
	Re-entry	0.0941
	Sum (mean)	0.1644
Resident- adult - <i>Tomato: Vehicle-mounted Downward spray application outdoor</i> Buffer zone: 2-3 (m) Drift reduction technology: No DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha Interval between treatments: 7 days Dilution min : 500L Application rate: 3 x 1 L product/ha Body weight: 60 kg Covers eggplant and potato	Metalaxyl-M (HQ)	
	Drift	0.0258
	Vapour	0.0014
	Deposits	0.0030
	Re-entry	0.0419
	Sum (mean)	0.0493
	Copper hydroxide (HQ)	
	Drift	0.0064
	Vapour	0.0005
	Deposits	0.0008
	Re-entry	0.0104
	Sum (mean)	0.0124
	Cumulative risk resident – adult (HI)	
	Drift	0.0322
	Vapour	0.0019
	Deposits	0.0038
	Re-entry	0.0523
	Sum (mean)	0.0617

Conclusion:

Based on the above scenarios and PPE:

- For grapes: Hazard Index is > 1 for workers and operators using manual hand-held applications, and is < 1 for operators using vehicle-mounted & drift reducing nozzles, and residents vehicle-mounted and drift reducing nozzles or manual handheld.
- For uses other than grapes, hazard index is < 1 for operators, workers and residents.

3.5 Residues and consumer exposure (Part B, Section 7)

The data available are considered sufficient for risk assessment.

An exceedance of the current MRL for copper as laid down in Regulation (EC) No 396/2005 of 50 mg/kg in grapes (max. 2 applications per crop cycle) and 5.0 mg/kg in tomato is not expected.

An exceedance of the current MRL for metalaxyl-m as laid down in Regulation (EC) No 396/2005 of 2 mg/kg in grapes (max. 2 applications per crop cycle), 0.3 mg/kg in tomato and 0.02 mg/kg in potato is not expected.

Due to an MRL exceedances on potato for copper the uses on potatoes cannot be recommended.

The chronic and the short-term intakes of metalaxyl-M residues are unlikely to present a public health concern.

The acute exposure calculations were not carried out for copper because an acute reference dose (ARfD) was not deemed necessary. For chronic intake of copper residues, the calculation includes a lot of uncertainties linked to the methodology. Therefore, zRMS considers that the risk assessment for consumers **can not be finalized**.

zRMS considers no firm conclusion can be reached for any of the intended uses of the product ACT-LET C FLOW.

Information on SAP 2821MCF/ACTLET C FLOW (KCA 6.8)

Crop	PHI for SAP 2821MCF proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for SAP 2821MCF proposed by zRMS	zRMS Comments (if different PHI proposed)
		M-metalaxyl	Copper hydroxide		
Table Grapes	28 days	Yes	Yes		
Wine Grapes	28 days	Yes	Yes		
Potato	21 days	Yes	No	/	MRL exceedance
Tomato	3/10 days	Yes	Yes		

NR: not relevant

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

Not relevant.

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of copper, metalaxyl-M and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

For metalaxyl-M:

PEC soil and PEC_{sw} values derived for the active substance are used for the ecotoxicological risk assessment.

For all intended uses, PEC_{gw} values for metalaxyl-M and its metabolites CGA108906, CGA67868 and CGA62826 do not occur at levels exceeding those mentioned in Regulation (EU) No 546/2011 and guidance document SANCO 221/2000²¹. However, the PEC_{gw} values of metabolite CGA108906 exceed 10 µg/L for one scenario for 3 applications on vines (max. value of 10.32 µg/L), but are below the trigger value for 2 applications on vines (values ranged from 3.751 to 9.717 µg/L). Thus, no unacceptable risk of groundwater contamination is expected for these intended uses on potato, tomato and aubergine and for two applications on vines.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

For copper:

No reliable PEC_{soil} were available for the active substance mainly due to a shorter period considered for estimating the accumulation in soil. Therefore, the risk assessment for the non-target terrestrial organisms cannot be finalised for all intended uses.

Given the uncertainties identified by zRMS in the notifier's exposure calculation (FOCUS STEP 1-2 for all entries to water bodies and FOCUS STEP 1-2 PEC_{sw} including mitigation measures) and the absence of results for all FOCUS scenarios, PEC_{sw} values derived for the active substance cannot be used for the ecotoxicological risk assessment. As a consequence, the risk assessment **cannot be finalised** for the non-target aquatic organisms.

PEC_{gw} values for copper do not occur at levels exceeding those mentioned in Directive 98/83/CE²² for uses on vines, tomatoes and aubergines. Therefore, no unacceptable risk of groundwater contamination is expected for these intended uses. However, no reliable PEC_{gw} are available for use on potatoes. Therefore the risk assessment of groundwater contamination of copper **cannot be finalised** for this latter use.

Based on vapour pressure, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

²¹ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

²² Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

Based on the guidance documents, the risks for **soil micro-organisms and non-target terrestrial plants** are acceptable for the intended uses.

For aquatic organisms, as the toxicity reference value for copper proposed by the applicant was based on an approach rejected at European level, it could not be used. In addition, no reliable PEC_{sw} and PEC_{sed} values were provided by the applicant for all uses. Therefore, the risk assessment for non-target aquatic species **could not be finalised** for all intended uses.

For birds and mammals, the risk is not acceptable for copper at Tier 1 for all intended uses. The arguments provided by the applicant to refine the risk assessment are identical to those that were considered insufficient at the European level. Therefore, without further data, the risk assessment for birds and mammals **cannot be finalised** for all intended uses.

For bees, the acute risk assessment provided by the applicant shows that the hazard quotient for oral exposure is above the trigger value of 50 indicating a theoretical acute oral risk to bees from exposure to the product and copper. No further data is provided by the applicant to address the acute oral risk for bees from the exposure to the product. Thus, the acute risk due to exposure to the product for bees could not be finalised.

In addition, since chronic studies are available with the product ACTLET C FLOW, a chronic risk assessment should have been provided by applicant according to the EFSA bee guidance document (EFSA 2013). In the absence of a chronic risk assessment, the chronic risk assessment for bees could not be finalised.

For bees, the acute risk from exposure to copper for adults is not acceptable at Tier 1 for all intended uses. Higher-tier studies (cage and tunnel tests) are available and demonstrate that no adverse effects on adult honey bees are expected for all intended uses. For honey bee larvae, the risk assessment from exposure to copper to bees cannot be completely fulfilled and the risk assessment for bees cannot be finalised for all intended uses.

Overall, the risk for bees **cannot be finalised** for all requested uses.

In addition, it is zRMS opinion that a specific acute contact risk assessment for bumble bees should have been submitted, especially since standard OECD acute toxicity tests are now available for bumble bees (acute contact toxicity test No 246 and acute oral toxicity test No 247, published on October 09, 2017). Therefore, without risk assessment performed for bumble bees, the risk for bees cannot be finalised for all requested uses.

For non-target arthropods, 2 toxicity studies for the product are available (1 extended toxicity study and 1 aged-residue toxicity study). However, additional toxicity studies should have been provided in accordance with the ESCORT 2 guidance document. The data package available for the product is thus incomplete and does not allow to conclude to an acceptable risk for non-target arthropods.

Overall, the risk assessment for non-target arthropods is incomplete and therefore **not finalised** for all requested uses.

For soil organisms, since PEC_{soil} accumulation are not reliable for copper, a Tier 1 risk assessment cannot be conducted. **For earthworms**, the higher tier earthworm field trial data from a study conducted over 10 years with copper application every year demonstrates that there is an acceptable risk to earthworms for applications up to 4kg cu/ha/yr. Therefore, an acceptable risk for earthworms is demonstrated for all intended uses of ACTLET C FLOW.

For other soil meso- and macro-organisms, no higher-tier studies are available and extrapolating the results of the multiyear field study with earthworms to other soil macro-organisms was not supported by the experts at the Peer Review experts' meeting 169.

Therefore, the risk for soil meso- and macro-organisms other than earthworms **could not be finalised** for all intended uses of ACTLET C FLOW.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

ACTLET C FLOW (SAP2821MCF) contains copper compounds, which is approved as a candidate for substitution because it fulfils two PBT criteria (Persistent and Toxic).

Step 1 (French guidance document 27 July 2015):

- Taking into account the management of resistance:

In accordance with Article 50(1)(c) of Regulation (EC) No 1107/2009, in the frame of resistance emergence or development prevention, copper is considered as an important tool in strategies to prevent resistance toward the partner organic substance, **substitution will not be considered for all intended uses.**

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

A monitoring of resistance to metalaxyl-M should be put in place for *Plasmopara viticola* on grapevine and for *Phytophthora infestans* on potato (one monitoring for all products based on metalaxyl-M). Efficacy trials in situation of characterized resistance to metalaxyl-M should also be put in place for *Plasmopara viticola* on grapevine and for *Phytophthora infestans* on potato.

A report on the results of the survey put in place (monitoring and efficacy trials) should be provided at the time of the demand of renewal for the products based on this active substance.

5.1.2 Post-authorisation data requirements

None.

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

Appendix 1 Copy of the product authorisation



ACTLET FLO_PAMM
_2021-2215_D.pdf

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.



Description du produit*

(* CF. tableau des usages dans le livret)

Hydroxyde de cuivre 330,1 g/L (17,06% p/p) et Métalaxyl-M 28,5 g/L (2,26% p/p) – Suspension concentrée (SC)

Quantité nette g



B-H

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL

« Consulter les informations mentionnées sur l’emballage avant toute utilisation »

AMM N°

Distribué et homologué par (EMB) :
ASCENZA France SAS
Immeuble Odyssée – A3
2-12 rue du chemin des Femmes
91300 MASSY
www.ascenza.fr
Tél. : 01 69 53 98 89

RÉEMPLOI DE L'EMBALLAGE INTERDIT

N° LOT : voir sur le bidon / sac

Date de fabrication : voir sur le bidon / sac

ACTLET C FLOW® : marque déposée par ASCENZA

IMPORTANT : LIRE LES INSTRUCTIONS CI-JOINTES AVANT L'EMPLOI

ACTLET C FLOW®

Hydroxyde de cuivre 330,1 g/L (17,06% p/p) et Métalaxyl-M 28,5 g/L (2,26% p/p) – Suspension concentrée (SC)

DESCRIPTIF DU PRODUIT ET MODE D'ACTION

• **Tableau des usages autorisés**

Cultures	Cibles	Doses maximum d'emploi	Nombre maximum d'applications	Intervalle minimum entre les applications	Stades d'application BBCH	Délai avant récolte (DAR) en jours
Tomate	Mildiou(s)	3,5 L/ha	3/an	7 jours	Entre les stades BBCH 29 et BBCH 81 (éviter la période de floraison BBCH 60 à 69)	3-10
Aubergine	Mildiou(s)					
Vigne (raisin de cuve et raisin de table)	Mildiou(s)	3,5 L/ha	3/an	12 jours	Entre les stades BBCH 71 et BBCH 83	28
Pomme de terre	Mildiou(s)	3,5 L/ha	3/an	7 jours	Entre les stades BBCH 36 et BBCH 81 (éviter la période de floraison BBCH 60 à 69)	21

¹ Zone Non Traitée (Voir phrase SPe3)

Les limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultable à l'adresse : <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>

ASCENZA ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, décline toute responsabilité concernant son utilisation aux autres usages prévus par le catalogue des usages en vigueur.

RECOMMANDATIONS D'EMPLOI

Tomate – Aubergine

ACTLET C FLOW® s'utilise en préventif dès le début du risque mildiou dès « 2 feuilles étalées » et jusqu'à « début maturation du fruit », à la dose de 3,5 L/ha, dans la limite de 3 traitements par saison. Sa persistance d'action est de 10 jours, à adapter en fonction des conditions climatiques et de la pression mildiou. En cas de forte pression parasitaire (se référer aux Bulletins de Santé du Végétal), l'intervalle entre deux traitements pourra être réduit à 7 jours.

ACTLET C FLOW® est autorisé sur cultures de plein champ et sous serre.

Vigne

Pomme de terre

D'une manière générale, pour déclencher tout traitement, il est conseillé de consulter son technicien habituel, de se conformer aux avis issus des organismes de prescription officiels et de baser sa décision sur les observations localisées de la pression parasitaire sur les cultures.

- **Mélanges extemporanés**

Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur. Consulter le site : <https://ephy.anses.fr/>

- **Préparation de la bouillie**

D'une manière générale, pour déclencher tout traitement, il est conseillé de consulter son technicien habituel, de se conformer aux avis issus des organismes de prescription officiels et de baser sa décision sur les observations localisées de la pression parasitaire sur les cultures.

PREVENTION ET GESTION DE LA RÉSISTANCE

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques, respecter les conditions d'emploi du produit et vérifier que la parcelle à traiter ne présente pas de souches de parasites résistantes.

Pour réduire les risques de baisse d'efficacité, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de cette préparation liée à ces phénomènes de résistances. De ce fait, ASCENZA décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

MISE EN OEUVRE REGLEMENTAIRE ET BONNES PRATIQUES

- **Stockage du produit :**

- Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux
- Conserver hors de la portée des enfants et des personnes non autorisées.
- Températures de stockage : Stocker à l'abri du gel et de la lumière directe du soleil dans un endroit sec, frais et bien ventilé.

- **Protection de l'opérateur et du travailleur**

Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée.
Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.

Dans le cadre des bonnes pratiques, il convient de privilégier les mesures de protection collective, mais aussi d'envisager l'adaptation du poste de travail. Par ailleurs, l'utilisation d'un matériel adapté et entretenu est cruciale, avant la mise en place de protections complémentaires comme les protections individuelles.

Le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène, (comme par exemple se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

TABLEAU DES EPI

1.1 Pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A)
- Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;
- OU
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

1.2 Pendant l'application

1.2.1 Sans contact intense avec la végétation

➤ Culture basse (<50 cm)

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1;
- Bottes de protection certifiées EN 13 832-3 ;

➤ Culture haute (>50 cm)

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

1.2.2 Avec contact intense avec la végétation

➤ Cultures hautes et basses

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);;
- Combinaison de protection de catégorie III type 3 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

1.3 Pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
 - Combinaison de protection de catégorie III type 4 ou 3 (selon le niveau de protection recommandé pendant la phase d'application) ;
 - Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;
- OU
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
 - EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
 - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
 - Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

1- Protection du travailleur

Il est recommandé le port des protections suivantes :

EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.

• Nettoyage du pulvérisateur et gestion des fonds de cuve:

- Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouillie dans les cultures par temps calme, sans vent fort, pour éviter toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments.
- A la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses...) doit être rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.
- S'assurer d'un rinçage complet et soigné du pulvérisateur.

- **Elimination du produit, de l'emballage :**
 - Réemploi de l'emballage interdit.
 - Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.
 - Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.
- **En cas de déversement accidentel**
 - Se protéger (EPI) et sécuriser la zone.
 - Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens.
 - Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse.
 - Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.

LES BONS GESTES POUR TRAITER EN TOUTE SÉCURITÉ



► N'utilisez les produits phytopharmaceutiques que si nécessaire.



► Protégez votre santé et celle de votre entourage.



► Surveillez les conditions météorologiques.



► Protégez les points d'eau.



► Protégez les pollinisateurs.



► Préservez la faune sauvage.





D'INFOS SUR WWW.MON-PHYTO-PRATIQUE.FR : FLASHEZ-MOI

LES BONS GESTES POUR TRAITER EN TOUTE SÉCURITÉ



► N'utilisez les produits phytopharmaceutiques que si nécessaire.



► Protégez votre santé et celle de votre entourage.



► Surveillez les conditions météorologiques.



► Protégez les points d'eau.



► Protégez les pollinisateurs.



► Préservez la faune sauvage.





D'INFOS SUR WWW.MON-PHYTO-PRATIQUE.FR : FLASHEZ-MOI

AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises.

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.

ACTLET C FLOW ®

Hydroxyde de cuivre 330,1 g/L (17,06% p/p) et Métalaxyl-M 28,5 g/L (2,26% p/p) – Suspension concentrée (SC)
AMM n° xxxxx



DANGER

H302 Nocif en cas d'ingestion.

H318 Provoque de graves lésions des yeux.

H410 Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

P280 Porter des gants de protection/ des vêtements de protection/ un équipement de protection des yeux/du visage

P301 + P312 En cas d'INGESTION : appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise

P304 + P340 En cas d'INHALATION : transporter la victime à l'extérieur et la maintenir dans une position où elle peut confortablement respirer

P305+ P351+ P338 EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.

P310 Appeler immédiatement un CENTRE ANTIPOISON ou un médecin

P501 Eliminer le contenu/réceptacle conformément à la réglementation nationale

Conditions d'emploi

Tenir hors de la portée des enfants

Peut porter atteinte aux insectes pollinisateurs. Eviter toute exposition inutile.

EUH208 Contient de la 1,26benzisothiazol-3(2H)-one. Peut produire une réaction allergique.

EUH401 : Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement

SP1 : Ne pas polluer l'eau avec le produit ou son emballage.[Ne pas nettoyer le matériel d'application près des eaux de surface / Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes]

SPe 2 Pour protéger les organismes aquatiques, ne pas rejeter les eaux usées des serres hors sol directement dans les eaux de surface

Délai de rentrée : 24 heures

PREMIERS SECOURS :

Premiers soins :

S'éloigner de la zone dangereuse.

- **En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.**

- **En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter immédiatement un spécialiste.**

- **En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.**

- **En cas d'ingestion : rincer immédiatement la bouche avec de l'eau si la personne est consciente. Ne pas faire vomir sans avis médical. Ne rien faire avaler à une personne inconsciente. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.**

SAP2821MCF / ACTLET C FLOW
Part A - National Assessment
FRANCE

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

En cas d'intoxication animale, contactez votre vétérinaire.

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre
anti poison le plus proche

Puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fiche de Données de Sécurité disponible sur : www.quickfds.com et www.ascenza.fr

RÉSERVÉ A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Quantité nette : xxx g

ACTLET C FLOW® - Marque déposée par ASCENZA