

REGISTRATION REPORT

Part A

Risk Management

Product code: TM0057

Product name(s): FLYPACK DACUS ALPHA

Chemical active substance(s):

Deltamethrin (0.015 g/trap)

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: SEDQ Healthy Crops S.L.

Date: 18/08/2025

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PART A

RISK MANAGEMENT

1 Details of the application

The company SEDQ Healthy Crops S.L. has requested a marketing authorisation in France for the product FLYPACK DACUS ALPHA (product code: TM0057), containing 0.015 g/trap deltamethrin¹ and two attractant (Ammonium bicarbonate and Gamma-hexalactone) as an insecticide 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 SEDQ Healthy Crops S.L.'s application submitted on March 2024 to market FLYPACK DACUS ALPHA 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 (2024-1185) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², 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")³. 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 FLYPACK DACUS ALPHA has been made using endpoints agreed in the EU peer review of Deltamethrin. It also includes assessment of data and information related to FLYPACK DACUS ALPHA where those data have not been considered in the EU peer review process.

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 546/2011⁴, 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 FLYPACK DACUS ALPHA.

¹ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

² 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

³ 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](#)

⁴ 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

1.2 Letters of Access

Not necessary: active substance data are not protected any more

All studies conducted for registration purposes on the product FLYPACK DACUS ALPHA are owned by SEDQ Healthy Crops, S.L.

1.3 Justification for submission of tests and studies

According to the applicant: « FLYPACK DACUS ALPHA is a new product never registered in Europe. All studies presented in this dossier are deemed necessary to support the registration in France. ».

1.4 Data protection claims

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

2 Details of the authorisation decision

2.1 Product identity

Product code	TM0057
Product name in MS	FLYPACK DACUS ALPHA
Authorisation number	-
Kind of use	Professional use
Low risk product (article 47)	No
Function	Insecticide (mass-trapping device)
Applicant	SEDQ Healthy Crops, S.L.
Active substance(s) (incl. content)	Deltamethrin (0.015 g/trap)
Formulation type	Trap

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Packaging	<u>1) Unmounted traps:</u> - Lids : LDPE⁵ thermo-sealed bags containing 1, 2, 5, 20, 25, 40, 50, 80, 100, 120, 160 and 240 lids/bag - Bases : LDPE thermo-sealed bags containing 1, 2, 5, 20, 25, 40, 50, 80, 100, 120, 160 and 240 bases/bag - Daculab GH dispensers : LDPE/PA/EVOH⁶ thermo-sealed bags containing 1, 2, 5, 20, 25, 40, 50, 80, 100, 120, 160 and 240 dispensers/bag - Daculab B dispensers : LDPE/PA/EVOH thermo-sealed bags containing 1, 2, 5, 20, 25, 40, 50, 80, 100, 120, 160 and 240 dispensers/bag <u>2) Assembled traps:</u> - Lids + Bases + Daculab GH + Daculab B (device assembled) : Co-extruded LDPE/PA/EVOH thermo-sealed bags, which are placed inside a cardboard box containing 1, 2, 5, 20, 25, 40, 50, 80, 100, 120, 160 and 240 assembled traps/box.
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 PRODUCT NAME 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

⁵ LDPE : Low-Density Polyethylene

⁶ LDPE/PA/EVOH : Low-Density Polyethylene/Polyamide/Ethylene-Vinyl Alcohol

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The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute toxicity (oral), category 4 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	  GHS07 GHS09
Signal word:	Danger/Warning
Hazard statement(s):	H302: Harmful if swallowed. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	The product FLYPACK DACUS ALPHA containing deltamethrin, may cause paresthesia. According to the french “arrêté” of the november 9 th 2004 ⁷ , it should be mentioned on the label to avoid contact with skin. The label must reflect the conditions of authorisation.

See Part C for justifications of the classification and labelling proposals.

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
	For other restrictions refer to 2.5

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 2017⁸ 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;

⁷ Arrêté du 9 novembre 2004 modifiant l'arrêté du 20 avril 1994 relatif à la déclaration, la classification, l'emballage et l'étiquetage des substances.

⁸ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the 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/AGRG1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

- 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.

Moreover, the French Order of 12 April 2021⁹ 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.

Thus, 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 extrapolation¹⁰ 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 2021¹¹ 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 crop¹² 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

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	Remove traps at fruit harvest at the latest, to avoid unnecessary exposure of pollinators and other non target arthropods.
Other specific restrictions	

⁹ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

¹⁰ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

¹¹ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

¹² 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.

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Re-entry period	Not applicable for this type of use
Storage	The product must be stored at a temperature below 40 °C.
Risk mitigation measures	None
Risk mitigation measures	None

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.

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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: 18/08/2025

PPP (product name/code): FLYPACK DACUS ALPHA / TM0057

Formulation type: XX ^(a, b)

Active substance 1: Deltamethrin

Conc. of a.s. 1: 0.015 g/trap ^(c)

Applicant: SEDQ Healthy Crops, S.L

Professional use: ☒

Zone(s): Southern ^(d)

Non-professional use: ☐

Verified by MS: Yes

Field of use: Insecticide

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 / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FRANCE	OLVEU Olive	F	DACUOL Olive fly (<i>Bactrocera oleae</i>)	Mass-trapping device with 'Attract-kill and collect' technology	Post-flowering. At fly flight start BBCH 71-80	a) 1 b) 1	n/a	a) 5-100 traps/ha b) 5-100 traps/ha	a) 0.075-1.50 g/ha b) 0.075-1.50 g/ha	n/a	n/a	Not acceptable (Composition of the product)

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.

** The application is possible during the flowering period in line with the application of the French Order of November 20, 2021 (arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques).

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Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(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.
Remarks columns:	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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)

All studies have been conducted in accordance with the current requirements and the results are deemed to be acceptable. The appearance of FLYPACK DACUS ALPHA is that of a plastic fly trap with a clear lid and a yellow base. Inner surface of the lid (named Topprotect) is impregnated with 0.015 g of deltamethrin. Regarding the base, it serves as receptacle for fly cadavers, and also serves to hold two dispensers, each of them containing one of the two chemical compounds used in the formulation for attracting *Bactrocera oleae* flies (one of the dispensers is called Daculab GH → here it is contained the attractant gamma-hexalactone, and the other one is called Daculab B → here it is contained the attractant ammonium bicarbonate). None of the four parts of the trap is explosive, corrosive, or flammable, nor have oxidising properties, and its technical properties will not result in handling problems during application.

Regarding accelerated storage studies, an accelerated study was conducted for Daculab B dispenser at 40°C for 8 weeks, and the result with regards to the ammonium bicarbonate content was acceptable¹³. With regards to Daculab GH, an accelerated storage study at 54 °C for 2 weeks was hired to Cambium, however due to abnormal results we SEDQ as sponsors asked to stop this study¹⁴. For this dispenser no accelerated study is going to be submitted, but only the 2 years “real time” study at 20 °C will be conducted (study plan E23034 by Cambium). Regarding this experiment, as soon as the analytical determinations will be conducted, interim reports after 3, 6, 12, 18 and 24 months of storage will be submitted to the zRMS.

Nevertheless, as it was briefly mentioned before, *the trap is intended to be stored at room temperature*. In this manner, with regards to:

- Daculab B dispenser, the 2-years storage study is concluded, and the results are acceptable.
- Daculab GH, the corresponding study recently started as explained in the paragraph above.
- The lid, which is the part that contains the active substance of this plant protection product, this part of the trap is called ‘Topprotect’, and it is used in other similar devices such as CERATIPACK (AMM 2130114), FLYPACK Walnut Husk (AMM 2170542), FLYPACK Completa (AMM 2180691), FLYPACK Cerasi (AMM 2190253), FLYPACK Dacus (AMM 2200509) and FLYPACK Suzukii (AMM 2210476). Since CERATIPACK was registered, it was shown that deltamethrin is stable when it is impregnated in the lid for 2 years at room temperature (study OA02051, which is submitted again in this FLYPACK DACUS ALPHA dossier). When

¹³ The determination of ammonium bicarbonate in Daculab B dispenser is included in study report E17120 by Cambium. This report also includes the determination of 1,7-dioxaspiro[5,5]undecane in another dispenser called Daculab S, however this dispenser is not present in FLYPACK DACUS ALPHA.

¹⁴ The compounds contained in the attractant dispensers are intended to be released by passive diffusion to the environment, ideally when traps are hung in an orchard. Nevertheless, this is the ideal situation: in practice some emission could occur even during the storage. Moreover, the high-temperature conditions of the accelerated studies significantly push the passive diffusion, and in consequence it is probable that such accelerated conditions do not reflect a room-temperature storage for a longer period of time.

CERATIPACK was under evaluation for its first registration, an accelerated storage study was also conducted for the lid (54 °C, 14 days), and the results found were also considered as acceptable.

In summary, for the definition of a storage term of FLYPACK DACUS ALPHA at room temperature, since the product is composed of a lid + two attractant dispensers, and for one of the dispensers the accelerated storage study failed, depending on the results of the Dacuslab GH real-time study it will be defined the storage of the full trap.

For some coformulants in the product's composition, the information provided does not ensure compliance with Regulation (EU) No 2021/383¹⁵. Hence, the evaluation of product FLYPACK DACUS ALPHA cannot be finalized.

It should be noticed in the label :

- “The product FLYPACK DACUS ALPHA must not be stored at temperatures above 40°C”

3.2 Efficacy (Part B, Section 3)

The level of efficacy of FLYPACK DACUS ALPHA is considered acceptable for the claimed use, but only in situations of low infestation of *Bactrocera oleae* (based on the efficacy tests provided and comparison with the reference product FLYPACK DACUS, authorised under similar conditions).

Regarding the nature of the active substance contained in the traps (insecticide) and the type of device used (“attract-and-kill” traps with no exposure), no phytotoxicity is expected on the intended crop following the use of FLYPACK DACUS ALPHA.

For the same reason, no risk of negative impact is expected on yield, quality and propagation.

It can be considered that the assessment of the risk of adverse effects on succeeding and adjacent crops is not relevant in this case.

As FLYPACK DACUS ALPHA is a closed system, the selection pressure following contact of *Bactrocera oleae* with the active substance is considered low compared to insecticide treatment by foliar spraying. The risk of resistance to deltamethrin under the conditions of use in the traps is therefore considered to be low and does not require monitoring for the intended use.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Sufficiently sensitive and selective analytical methods are available for the active substance in the plant protection product.

¹⁵ Règlement (UE) 2021/383 de la Commission du 3 mars 2021 modifiant l'annexe III du règlement (CE) no 1107/2009 du Parlement européen et du Conseil fixant la liste de coformulants ne pouvant pas entrer dans la composition des produits phytopharmaceutiques.

3.3.2 Analytical methods for residues

As FLYPACK DACUS ALPHA is a closed attract-kill and collect device, there is no contact of deltamethrin with olives when the trap is hung in olive trees. Therefore, there is no need of an analytical method for measuring residues of deltamethrin in olives.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

FLYPACK DACUS ALPHA has a low toxicity in respect to inhalation and dermal toxicity, is not irritating to the skin or the eye and is not a skin sensitiser. However, FLYPACK DACUS ALPHA is classified for the acute oral toxicity (H302 Harmful if swallowed).

3.4.2 Operator exposure

FLYPACK DACUS ALPHA is a closed device. Considering the proposed use, the formulation type (ready-to use) and the application mode of the product, no unacceptable risk for operator exposure to FLYPACK DACUS ALPHA is expected. However, zRMS recommends to wear protective gloves when handling the traps, in order to prevent any dermal exposure.

3.4.3 Worker exposure

FLYPACK DACUS ALPHA is a closed device. No contact with the active substance deltamethrin is expected. However, in case of contact with the ready to use traps protective clothing is recommended.

3.4.4 Bystander and Resident exposure

FLYPACK DACUS ALPHA is a closed device. Considering the proposed use, the formulation type (ready-to use) and the application mode of the product, no risk is expected for residents and bystanders.

3.4.5 Combined exposure

Not relevant. The product contains only one active substance.

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 of 1 mg/kg for deltamethrin in table olives and 0.6 mg/kg in olives for oil production, as laid down in Reg. (EU) 396/2005, is not expected.

Considering the application mode (attract and kill traps), no contact between the active substance and the crop is expected to occur. Due to the no residue situation in olives, the use of FLYPACK DACUS ALPHA in olive crop is unlikely to present a public health concern.

As far as consumer health protection is concerned, France agrees with the authorization of the intended use.

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Information on FLYPACK DACUS ALPHA (KCA 6.8)

Crop	PHI for product code proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		deltamethrin		
Olive	NR	NR	NR	

NR: not relevant

Waiting periods before planting succeeding crops.

Not relevant for FLYPACK DACUS ALPHA

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

Considering the intended use for the product FLYPACK DACUS ALPHA, exposure of environmental compartments to the active substance is considered negligible. Consequently, no exposure calculations for environmental compartments are deemed necessary.

3.7 Ecotoxicology (Part B, Section 9)

Considering the intended use for the preparation FLYPACK DACUS ALPHA, exposure of environmental compartments to the active substance is considered negligible. Consequently, no risk assessment for birds, aquatic organisms, mammals, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants is deemed necessary.

The risk for bees and other non-target arthropods is considered acceptable when the following mitigation is respected:

Remove traps at harvest at the latest to avoid unnecessary exposure of pollinators.

3.8 Relevance of metabolites (Part B, Section 10)

Not applicable, see Environmental fate and behaviour above.

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

The active substance deltamethrin is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

None.

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- A two-year stability study at room temperature for Dacuslab GH attractant in commercial packaging.

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Appendix 1 Copy of the product authorisation

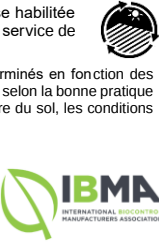


FLYPACKDAC_PAMM
_2024-1185_D.pdf

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.

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		FLYPACK[®] DACUS ALPHA	
Piège pour la lutte par piégeage massif de la mouche de l'olive Contient 15 mg/unité de deltaméthrine		Classe IRAC: 3A	
AMM N° XXXXXXX. Détendeur d'AMM: SEDQ Healthy Crops, S.L. C./ Lluïl, 41, 08005 Barcelone, Espagne (www.sedq.es)		20 PIÈGES	
Produit réservé à un usage exclusivement professionnel			
CULTURES, USAGES & DOSES D'EMPLOI			
Olivier	Bactrocera oleae (Mouche de l'olive)	Max. 100 pièges par hectare. 1 application/an. Pose des pièges entre les stades BBCH 71 et BBCH 80.	
■ Les pièges doivent être suspendus à une branche de l'arbre à une hauteur de 1,50 à 2,00 m du sol du côté sud-est de l'arbre. ■ Les pièges doivent être distribués de façon homogène et alternée. ■ Les pièges doivent être placés avant que les olives soient attractives et laissés en place jusqu'à la récolte, et même plus longtemps si vous le souhaitez afin de réduire la population de mouches pour la campagne suivante. La durée de diffusion des attractifs contenus dans le piège est de 270 jours. Il est recommandé d'évaluer périodiquement le nombre de captures de certains pièges afin de déterminer le niveau de mouches dans la parcelle et décider le moment optimal pour appliquer un traitement. En cas de forte infestation, il est recommandé de compléter le piégeage massif avec un programme phytosanitaire (adulticide et/ou barrière minérale). Limites maximales de résidus (LMR): se reporter aux LMR en vigueur au niveau de l'Union Européenne et consultables à l'adresse: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls. Compte tenu de la méthode d'application du produit, il n'est pas nécessaire de fixer de délai avant récolte pour les usages autorisés. Stockage : Conserver les pièges dans leur emballage d'origine, à une température comprise entre 10 et 25 °C, à l'abri du soleil. Dans ces conditions, le produit peut être conservé jusqu'à 2 ans à compter de la date de fabrication.			
■ Produit utilisable en production biologique selon le Règlement Européen UE 2018/848.			
Le produit contient de la deltaméthrine (0.015 g/couvercle), susceptible de provoquer des paresthésies. Eviter le contact avec la peau.  ATTENTION H302 Nocif en cas d'ingestion. H410 Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme. P273 Éviter tout contact avec les yeux, la peau ou les vêtements. P280 Porter des gants de protection et des vêtements de protection. P391 Recueillir le produit répandu. P501 Éliminer le contenu / le conteneur dans un centre de collecte des déchets dangereux ou spéciaux. Délai de rentrée : non nécessaire. Protection de l'opérateur : EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et gants en nitrile certifiés NF EN ISO 74-1/A1 et NF EN 16523-1+A (type A). Protection pour le travailleur : EPI vestimentaire conforme à la norme NF EN ISO 27065/A1. L'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles. Le port de la combinaison de travail ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, 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. Protection de l'eau : SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.			
EN CAS D'URGENCE Composer le 15 ou le 112 ou contacter le centre anti-poison le plus proche N° vert Phyt-attitude: 08 00 88 78 87		UFI : XXXX-XXXX-XXXX-XXXX	
Elimination du produit et de l'emballage: Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique.			
Remarques: Respectez les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage, qui ont été déterminés en fonction des caractéristiques et des applications pour lesquelles le produit est préconisé. Conduisez, sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, 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 de ces produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché du Ministère de l'Agriculture. La société ne sera pas responsable des pertes ou des dégâts occasionnés par une utilisation non conforme à ses recommandations. L'utilisateur assume tous les risques associés à un tel usage, non conforme à ces recommandations. Nouveau catalogue des usages (arrêté du 12 avril 2021): L'utilisation de ce produit est préconisée uniquement sur les cultures et cibles précisées dans les préconisations et usages homologués. La société décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou contre des cibles non préconisées.			
LOT DE FABRICATION: voir emballage		DATE DE FABRICATION: voir emballage	