

REGISTRATION REPORT

Part A

Risk Management

Product code/name: CATANE JARDIN

Chemical active substance:

Paraffin oil CAS 64742-46-7, 800g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: TOTAL Fluides

date : 26/05/2020

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	5
2.1	Product identity	5
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)	6
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
3.4	Mammalian toxicology (Part B, Section 6)	11
3.4.1	Acute toxicity	12
3.4.2	Operator exposure	12
3.4.3	Worker exposure	12
3.4.4	Bystander exposure	12
3.4.5	Resident exposure	12
3.4.6	Combined exposure	13
3.5	Residues and consumer exposure (Part B, Section 7)	13
3.6	Environmental fate and behaviour (Part B, Section 8)	13
3.7	Ecotoxicology (Part B, Section 9)	14
3.8	Relevance of metabolites (Part B, Section 10)	14
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	14
5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	14

5.1.1	Post-authorisation monitoring.....	14
5.1.2	Post-authorisation data requirements	14
Appendix 1	Copy of the product authorisation	15
Appendix 2	Copy of the product label.....	20

PART A

RISK MANAGEMENT

1 Details of the application

The company TOTAL FLUIDES has requested a marketing authorisation in France for the product CATANE JARDIN, containing 800g/L paraffin oil (CAS 64742-46-7)¹ as an insecticide/acaricide for non-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 TOTAL FLUIDES's application 18 to market CATANE JARDIN in France for home and garden uses (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 (2018-1842) 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 CATANE JARDIN has been made using endpoints agreed in the EU peer review of paraffin oil CAS 64742-46-7. It also includes assessment of data and information related to CATANE JARDIN 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 CATANE JARDIN.

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.

CATANE JARDIN
Part A - National Assessment
FRANCE version

In addition, an application (2018-1848) has been considered for a special dispensation from the mandatory ban of application of an insecticide during the flowering period or in presence of honeydew according to the French Order of 28 March 2003⁵.

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the approval of the active substance.

1.3 Justification for submission of tests and studies

According to the applicant:

“The test and study reports have been submitted during the application of re-registration of OVISPRAY (Ref 2012-2007 and 2015-1011). The aim of this submission was to make the risk assessment to prove the safe use of OVISPRAY.

However, given that OVISPRAY and CATANE JARDIN are formulations of strictly identical compositions, the test and study are also valid to make the risk assessment and to prove the safe use of CATANE JARDIN.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013”

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CATANE JARDIN, 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	CATANE JARDIN
Product name in MS	CATANE JARDIN
Authorisation number	2200263
Kind of use	Non-professional use
Low risk product (article 47)	No
Function	Insecticide/acaricide
Applicant	TOTAL FLUIDES
Active substance (incl. content)	Paraffin oil, CAS 64742-46-7, 800g/L
Formulation type	Emulsifiable concentrate (EC)

⁵ Arrêté du 28 novembre 2003 relatif aux conditions d'utilisation des insecticides et acaricides à usage agricole en vue de protéger les abeilles et autres insectes pollinisateurs.

CATANE JARDIN
Part A - National Assessment
FRANCE version

Packaging	Self dosing bottles in HDPE ⁶ (200 mL, 250 mL, 400 mL, 500 mL, 800 mL, 1 L)
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 CATANE JARDIN resulted in the decision **to grant** 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

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

Hazard class(es), categories:	Aspiration hazard, category 1
Hazard pictograms:	 GHS08
Signal word:	Danger
Hazard statement(s):	H304: May be fatal if swallowed and enters airways.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	-

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

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

	For other restrictions refer to 2.5

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

⁶ HDPE: High-Density Polyethylene.

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 2017⁷ 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 26 March 2014⁸ 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 extrapolation⁹ 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.

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:	
-	No PPE for amateur users
Worker protection:	
-	No PPE for amateur users

⁷ 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, modifié par l'arrêté du 27 décembre 2019 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>.

⁸ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>.

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

CATANE JARDIN
 Part A - National Assessment
 FRANCE version

Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
	Do not discharge into the sink, gutter or any other water hole the non-used container leftovers.
	To protect aquatic organisms do not apply at least 5 meters away from any surface water bodies (well, pond, stream, river...).
	Do not apply when pollinating and/or auxiliary insects such as bees, bumble bees, ladybirds etc. are foraging in the area.
Other specific restrictions	
Re-entry period	Wait until the treated zone or plants have dried.
Storage	Shake product in packaging before using.
Risk mitigation measures	-
Agricultural recommendations	-

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.

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 26 march 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

PPP (product name/code):	CATANE JARDIN	Formulation type:	GAP rev. 1, date: 2020-05-26
Active substance 1:	Paraffin oil CAS 64742-46-7	Conc. of a.s. 1:	Formulation code ^(a, b) 800 g/L ^(c)
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	TOTAL FLUIDES	Professional use:	<input type="checkbox"/>
Zone(s):	Southern Zone ^(d)	Non-professional use:	<input checked="" type="checkbox"/>
Verified by MS:	Yes		
Field of use:	Insecticide/acaricides		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Use- No. ^(e)	Member state(s)	Crop and/ 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) RMS conclusion
					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	g a.s./ha	Water L/ha	min/max		

Zonal uses (field or outdoor uses, certain types of protected crops)

1	France	Pome fruit, Stone fruit (Apple, Cherry, plum, peach, pear , apricot , nectarine , quince , medlar , jujube , azarole , Chinese pear)	F	Winter stages of pests	Pre-pressure sprayer (high crops > 60 cm)	Wintering stages, BBCH 00-11 of crop	a) 1 b) 2	15	a) 37.5 b) 75	a) 30 b) 60	1/1.5	BBCH 11	Acceptable
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CATANE JARDIN

Part A - National Assessment
FRANCE version

2	France	Apple, pear, quince, medlar, jujube, azarole, Chinese pear	F	<i>Mites and phytoptes (summer stages)</i>	Pre-pressure sprayer (high crops > 60 cm)	Spring/summer BBCH 69-85 of the crop	a) 1 b) 2	15	a) 37.5 b) 75	a) 30 b) 60	1/1.5	3 days	Acceptable
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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.
- (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.

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.
- 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)

The product CATANE JARDIN is an EC formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of very pale yellow almost colour-less clear liquid of low viscosity, free from foreign matter, with an aliphatic odour. It is not explosive and has no oxidising properties. The product has a flash point of 150°C. It has a self-ignition temperature of 227°C. In 1% aqueous solution, it has a pH value of 6.3 at 22.5°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C, 14 days at 54°C and 6 weeks at 45°C, neither the active ingredient content was changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. As the stability was performed on HDPE packaging, the HDPE/F packaging can be considered as acceptable.

Only HDPE packagings including a “self dosing” system are considered acceptable for home and garden uses in France

The formulation is classified as H304 Cat1 for the physical-chemical part.

The product must be shaken before use.

3.2 Efficacy (Part B, Section 3)

The efficacy level of the product CATANE JARDIN is considered satisfactory for the claimed uses.

The phytotoxicity level of the product CATANE JARDIN is considered acceptable for all the claimed uses.

The risks of negative impact of CATANE JARDIN on yields, quality, cider-making processes, propagation and adjacent crops are considered acceptable.

The risk of resistance apparition to paraffin oils is considered as very low and does not require any monitoring for the claimed uses.

3.3 Methods of analysis (Part B, Section 5)

An analytical method for the determination of the active substance in the formulation is available and validated. As the active substance Paraffin oil, CAS No 64742-46-7 does not contain relevant impurity, no analytical method is required.

As no MLR and no residue definition are set, no analytical method is necessary for the determination of residues in plants, food of animal origin, soil, water, air and body fluids.

3.4 Mammalian toxicology (Part B, Section 6)

A Endpoints used in risk assessment

Active Substance: paraffin oil (CAS 64742-46-7)		
ADI	Not applicable	EU (2010)

ARfD	Not applicable	
AOEL	Not applicable	
AAOEL	Not applicable	
Dermal absorption	Poorly absorbed <i>via</i> the skin – most remaining in the <i>stratum corneum</i> . Moreover, dermal absorption values are not required (no exposure assessment was deemed necessary).	
Oral absorption	Approx. 2%	EFSA 2008

3.4.1 Acute toxicity

CATANE JARDIN containing 800g/L of paraffin oil CAS 64742-46-7 has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitisier.

3.4.2 Operator exposure

No exposure assessment was deemed necessary, as the substance does not present a toxicological concern.

The proposed packaging has been described in sufficient details, and its compliance can therefore be finalised.

In summary, compliance with the provisions of French Decree No. 2010-1755 of 30 December 2010 and Orders of 30 December 2010 relating to the use of certain plant protection products by non-professional users is considered to be finalised.

The following packaging is considered as guaranteeing a minimal exposure of non-professional users: 200, 250, 400, 500 and 800 mL and 1L bottles of the self-dosing.

Other packaging (bottles without self dosing system) of 250 mL, 500 mL and 1 L are not acceptable for non professional users.

3.4.3 Worker exposure

No exposure assessment was deemed necessary, as the substance does not present a toxicological concern.

3.4.4 Bystander exposure

No exposure assessment was deemed necessary, as the substance does not present a toxicological concern.

3.4.5 Resident exposure

No exposure assessment was deemed necessary, as the substance does not present a toxicological concern.

3.4.6 Combined exposure

Not required.

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

The active substance Paraffin oil (CAS 64742-46-7) is included in Annex IV of Reg. EU 396/2005.

These consideration is also applicable in the context of the current application for the product CATANE JARDIN, i.e. no metabolism and residue data are considered required in the frame of this use extension.

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

According to available data, no specific mitigation measures should apply.

Information on CATANE JARDIN (KCA 6.8)

Crop	PHI for CATANE JARDIN proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CATANE JARDIN proposed by zRMS	zRMS Comments (if different PHI pro- posed)
		Paraffin oils (CAS 64742-46-7)		
3-Cherry	BBCH11	Yes (incl. annex IV Reg EU 396/2005)	BBCH11	-
3-Peach	BBCH11	Yes (incl. annex IV Reg EU 396/2005)	BBCH11	-
4-Apple	1 day	Yes (incl. annex IV Reg EU 396/2005)	1 day	-
3-Apple	BBCH11	Yes (incl. annex IV Reg EU 396/2005)	BBCH11	-
3-Plum	BBCH11	Yes (incl. annex IV Reg EU 396/2005)	BBCH11	-

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops : Not relevant on orchards

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 substance and its 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 of paraffin oil (CAS 64742-46-7) in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

Considering the home and garden intended uses for the formulated product no PECsoil calculation is required.

PECsw derived for the active substance are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for paraffin oil (CAS 64742-46-7) do not occur at levels exceeding those mentioned in regulation EC 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses. 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.

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(s) and its/their metabolites 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.

Based on the guidance documents, the risks for birds and aquatic organisms are acceptable for the intended uses. **Risk mitigations are required for aquatic organisms.**

Risk assessment for mammals, other non-target arthropods than bees, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are not considered relevant for home and garden uses.

According to new requirements of Reg. No. 284/2013, information on chronic effects on adult bees and on development of bees should have been submitted as exposure of bees to the formulation cannot be excluded. In absence of these data, the risk for bees can not be finalized.

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)

The active substance paraffin oil CAS 64742-46-7 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

None.

Appendix 1 Copy of the product authorisation



Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

*Vu la demande d'autorisation de mise sur le marché et d'attribution de la mention « abeilles » du produit phytopharmaceutique **CATANE JARDIN***

de la société **TOTAL FLUIDES**
enregistrées sous les n°2018-1842 et 2018-1848

Vu les conclusions de l'évaluation de l'Anses du 9 avril 2020,

Considérant que la demande d'attribution de la mention « abeilles » n'est pas pertinente pour un produit phytopharmaceutique destiné à un emploi par des utilisateurs non professionnels,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

CATANE JARDIN
Part A - National Assessment
FRANCE version



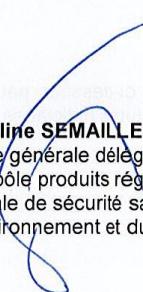
Informations générales sur le produit		
Nom du produit	CATANE JARDIN	
Type de produit	Deuxième gamme	
Titulaire	TOTAL FLUIDES 24 cours Michelet 92800 PUTEAUX France	
Formulation	Concentré émulsionnable (EC)	
Contenant	800 g/L - huile de paraffine (CAS n°64742-46-7)	
Produit de référence	Nom commercial	OVISPRAY
	N° AMM	9400496
Numéro d'intrant	489-2018.01	
Numéro d'AMM	2200263	
Fonction	Acaricide, insecticide	
Gamme d'usage	Amateur / emploi autorisé dans les jardins	

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2021.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort le, 26 MAI 2020


Caroline SEMAILLE
 Directrice générale déléguée
 en charge du pôle produits réglementés
 Agence nationale de sécurité sanitaire de
 l'alimentation, de l'environnement et du travail (ANSES)



ANNEXE I : Modalités d'autorisation du produit

Vente et distribution

Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :

Emballage	Contenance
Bouteilles en polyéthylène haute densité équipées d'un système auto doseur	200 mL ; 250 mL ; 400 mL ; 500 mL ; 800 mL ; 1 L

Les emballages autres que ceux disposant d'un système auto doseur sont refusés car ces emballages ne permettent pas de garantir une exposition minimale de l'utilisateur.

Classification du produit

La classification retenue est la suivante :

Catégorie de danger	Mention de danger
Danger par aspiration - Catégorie 1	H304 : Peut être mortel en cas d'ingestion et de pénétration dans les voies respiratoires.

Pour les phrases P se référer à la réglementation en vigueur.

Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.



Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
 En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)
12203118 Cerisier*Trt Part.Aer.* Stad. Hivern. Ravageurs	37,5 mL/10 m²	2/an	entre les stades BBCH 00 et BBCH 11	^F (BBCH 11)	5	-	-
Intervalle minimum entre les applications : 15 jours.							
12553145 Pêcher*Trt Part.Aer.* Stad. Hivern. Ravageurs	37,5 mL/10 m²	2/an	entre les stades BBCH 00 et BBCH 11	^F (BBCH 11)	5	-	-
Intervalle minimum entre les applications : 15 jours.							
12603134 Pommier*Trt Part.Aer.* Acanthos et phytopotes	37,5 mL/10 m²	2/an	entre les stades BBCH 69 et BBCH 85	3	5	-	-
Intervalle minimum entre les applications : 15 jours.							
12603123 Pommier*Trt Part.Aer.* Stad. Hivern. Ravageurs	37,5 mL/10 m²	2/an	entre les stades BBCH 00 et BBCH 11	^F (BBCH 11)	5	-	-
Intervalle minimum entre les applications : 15 jours.							
12553123 Prunier*Trt Part.Aer.* Stad. Hivern. Ravageurs	37,5 mL/10 m²	2/an	entre les stades BBCH 00 et BBCH 11	^F (BBCH 11)	5	-	-
Intervalle minimum entre les applications : 15 jours.							



Conditions d'emploi du produit

Stockage et manipulation du produit

- Agiter le produit dans son emballage avant utilisation.

Délai de rentrée

- Attendre le séchage complet de la zone traitée.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés.

Protection de la faune

- Pour protéger les organismes aquatiques, ne pas appliquer à moins de 5 mètres d'un point d'eau (puits, bassin, mare, ruisseau, rivière, fossé...).
- Ne pas appliquer en présence d'insectes pollinisateurs et/ou auxiliaires (abeilles, bourdons, coccinelles...).

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.



DANGER

Mentions de danger

H304 - Peut être mortel en cas d'ingestion et de pénétration dans les voies respiratoires
EUH401 - Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement

Conseils de prudence

P102 - Tenir hors de portée des enfants
P261 - Éviter de respirer les poussières / fumées / gaz / brouillards / vapeurs/aérosols
P280 - Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage
P301 + P310 : EN CAS D'INGESTION: appeler immédiatement un CENTRE ANTIFOISON ou un médecin
P331 - NE PAS faire vomir

Premiers secours

Conseils généraux : EN CAS DE TROUBLES GRAVES OU PERSISTANTS, APPELER UN MEDECIN OU DEMANDER UNE AIDE MEDICALE D'URGENCE.

Contact avec les yeux : Rincer immédiatement et abondamment à l'eau, y compris sous les paupières, pendant au moins 15 minutes.

Contact avec la peau : Enlever les vêtements et les chaussures contaminés. Laver avec de l'eau et du savon. Laver les vêtements contaminés avant réutilisation.

Inhalation : En cas d'exposition à des concentrations importantes de vapeurs, de fumées ou d'aérosols, transporter la personne à l'air, hors de la zone contaminée, la maintenir au chaud et au repos.

Ingestion : NE PAS faire vomir. Appeler immédiatement un médecin. En cas d'ingestion suivie de vomissement, le produit peut pénétrer dans les poumons. Dans ce cas, la victime doit être immédiatement transportée en milieu hospitalier.

Protection pour les secouristes : Utiliser un équipement de protection individuelle.

Protection des utilisateurs

Respecter les bonnes pratiques agricoles, usage, dose, conditions d'emploi.
Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.

Délai de rentrée : 6 heures



CATANE JARDIN
Concentrée Emulsionnable (EC)
INSECTICIDE / ACARACIDE

Composition
Substance active huile de paraffine
CAS n° 64742-46-7 800 g/L (96.9%)

USAGE NON PROFESSIONNEL avec MENTION ABÉILLES
Jardins et usages domestiques

N°AMM :

Titulaire de l'autorisation de mise sur le marché
TOTAL Fluides S.A.S
24 Cours Michelet - 92800 Puteaux France
Tel. +33 1 41 35 40 00

Contenance : 200 ml, 250 ml, 400 ml, 500 ml, 800 ml et 1 L
Lot de fabrication :

Date de fabrication :

Protection de l'environnement
Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.
Eliminer les déchets de résidus/produits non utilisés conformément aux Directives Européennes sur les déchets et les déchets dangereux.
Eliminer le contenu / le récipient conformément à la réglementation nationale.

De par la nature de CATANE JARDIN, il n'est pas attendu d'impact négatif sur les cultures adjacentes.

DIRECTION D'EMPLOI

Mode d'action
CATANE JARDIN a une action insecticide et acaricide. Il est utilisé contre les stades d'hivernage et d'été des acariens, des cochenilles, des psylles et des pucerons. Il agit naturellement en créant un film qui provoque l'asphyxie des insectes cibles (adultes, larves et œufs).

Conditions d'emploi
CATANE JARDIN est destiné à être appliqué sur les feuilles. Un intervalle de 15 jours doit être respecté entre deux applications.

Culture	Ravageurs	Dose (ml/10 m ²)	Volume de bouteille (L/10 m ²)	Stade et nombre d'application
Agrumes	Pucerons, acariens et cochenilles	10 – 22.5 (max 4 applications)	1/1.5	BBCH 00-89 (stades hivernants)
Agrumes	Cochenilles	10 – 40 (max 4 applications)	1/2	BBCH 69-85 (stades d'été)
Arbres fruitiers	Pucerons, acariens et cochenilles	25 – 37.5 (max 2 applications)	1/1.5	BBCH 00-11 (stades hivernants)
Arbres fruitiers	Pucerons, acariens, psylles et cochenilles	20 – 30 (max 2 applications)	1/1.5	BBCH 69-85 (stades d'été)
Vigne	Cochenilles	15 (max 2 applications)	0.6	BBCH 00-11 (stades hivernants)

Préparation de pulvérisation
Remplir le réservoir du pulvérisateur au quart avec de l'eau propre, démarer l'agitation et ajouter la quantité requise de CATANE JARDIN directement dans le réservoir sans nettoyage préalable. Continuer l'agitation pendant le remplissage du réservoir et pendant la pulvérisation.

Précautions d'emploi
Ne pas appliquer CATANE JARDIN si la température ambiante est inférieure à 5 °C ou supérieure à 30 °C ou si l'humidité relative est inférieure à 30%.
Ne pas appliquer sur les arbres atténués en raison de la maladie, de la sécheresse, du vent sec ou de la forte fertilisation azotée.
Ne pas appliquer dans les 30 jours suivant l'application du soufre. L'application du captane, du folpet ou du dithion sur les pommeiers ne doit pas être précédée ou suivie d'au moins une semaine.
Emploi autorisé pendant la période de floraison et au cours des périodes de production d'exsudats, en dehors de la présence d'abeilles.

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