

REGISTRATION REPORT

Part A

Risk Management

Product code: DPX-MP062 30WG

Product name: STEWARD

Active substance:

Indoxacarb 300g/kg

COUNTRY:

FRANCE

NATIONAL ASSESSMENT

Application for a label extension according to Art. 51

-

Minor uses

Applicant: CHEMINOVA Agro France S.A.S

Date: 31/12/2019

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PART A – Risk Management

The company CHEMINOVA Agro France S.A.S has requested a label extension in France for the product STEWARD (DPX-MP062 30WG) according to article 51 Regulation (EC) no 1107/2009¹.

This document describes the specific conditions of use and labelling required for extension of the registration of STEWARD (DPX-MP062 30WG) containing indoxacarb in France.

The conclusions of the risk assessment are based on the already existing registration of the preparation in France. Therefore, the evaluation of the current application is limited to the points not covered by the existing registration.

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of access.

1 DETAILS OF THE APPLICATION

1.1 Application background

STEWARD (DPX-MP062 30WG) is water dispersible granules containing 300g/kg of indoxacarb, for use as an insecticide for the control of various pests. The aim of this registration application is to gain a label extension for crops of chickpeas.

The complete GAP for the national application in France is provided below, under point 2.3.

1.2 Active substance approval

Indoxacarb

Regulations 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.

Specific provisions of regulation were as follows :

PART A

Only uses as insecticide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on indoxacarb, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 September 2005 shall be taken into account.

In this overall assessment Member States must pay particular attention to the protection of aquatic organisms.

Conditions of use should include risk mitigation measures, where appropriate.

An EFSA conclusion is available (EFSA Journal 2018;16(1):5140).

A Review Report is available (SANCO/1408/2001 – rev.3, 23 September 2005).

¹ 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

1.3 Regulatory approach

The present application (n° 2017-2569) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)².

The current document based on Anses' assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009, implementing regulations and French regulations.

Since the application is intended for use in France only, the draft Part A was not circulated for comments.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French order.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) N°546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁵ provides that:

- an authorisation granted for a « reference » crop applies also for “linked” crops unless formally stated in the decision
- the “reference” and “linked 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 “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁶ 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.

1.4 Data protection claims

There is no new data submitted with this application.

² French Food Safety Agency, Afssa, before 1 July 2010

³ 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 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>

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

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

⁶ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

1.5 Letter(s) of access

Not relevant for this application.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	STEWARD (DPX-MP062 30WG)
Authorisation number	9800144
Function	Insecticide
Applicant	CHEMINOVA Agro France S.A.S
Composition	300g/kg indoxacarb
Formulation type (code)	Water dispersible granules (WG)
Packaging	Not relevant for extension of authorization according article 51.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not relevant for extension of authorization according article 51.

2.2.2 Classification and labelling in accordance with Regulation (EC) No1272/2008

Not relevant for extension of authorization according article 51.

2.2.3 Other phrases in compliance with Regulation (EU) No 547/2011

Refer to the decision of product authorization.

Other mitigation measures as defined in previous risk assessment apply.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁷ : refer to the Decision in Appendix 1.
Re-entry period ⁸ : 6 hours.
Other mitigation measures: -
The label must reflect the conditions of authorisation.

⁷ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

⁸ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, evaluated and concluded as safe uses by France as RMS. 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.

PPP (product name/code): STEWARD (DPX-MP062 30WG) **Formulation type:** Water dispersible granules (WG)
active substance: indoxacarb **Conc. of as:** 300g/kg
Applicant: CHEMINOVA Agro France S.A.S **professional use** ☒
Zone(s): France **non-professional use** ☐
Verified by MS: yes

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)	g product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Minor uses according to Article 51 (zonal uses)													
1	France	Chickpea (RAPSR)	F	<i>Helicoverpa armigera</i> (CIEAR)	Ramp sprayer	1 pre-flowering application (from BBCH30-59) + 1 post-flowering application (after stage BBCH69) or 2 post-flowering applications (after stage BBCH69)	a) 2 b) 2	10 days	a) 125 g/ha	a) 37,5 g/ha	80 - 200	10	Not acceptable (MLR exceedance)

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.	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 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

Not relevant for extension of authorisation according article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

3.1.2.2 Analytical methods for residues

Further data for this application are not necessary.

3.1.3 Mammalian Toxicology

The preparation is already registered in France. If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

For details of personal protective equipment for operators and workers, refer to the Decision in Appendix 1.

3.1.4 Residues and Consumer Exposure

The data available are not considered sufficient for risk assessment purposes. Any exceedance of the current MRL for indoxacarb as laid down in Regulation (EU) No 396/2005 cannot be verified on chickpeas since northern trials were not provided.

Thus, the chronic and short-term intakes of indoxacarb residues resulting from the use proposed in the framework of this application cannot be finalized.

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

Information on STEWARD:

Crop	PHI for STEWARD proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for STEWARD proposed by zRMS	zRMS Comments (if different PHI proposed)
		indoxacarb		
chickpea	10 days	No	/	Not acceptable

NR: not relevant

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops: Not relevant.

3.1.5 Environmental fate and behaviour

According to previous risk assessments performed by Anses, no unacceptable risk for groundwater is expected. Similar mitigation measures as defined in previous risk assessment apply.

3.1.6 Ecotoxicology

According to previous risk assessments performed by Anses, no unacceptable risk for terrestrial and aquatic non-target organisms is expected. Similar mitigation measures as defined in previous risk assessment apply.

3.1.7 Efficacy

According to Article 51 of Regulation (EC) No 1107/2009, the efficacy assessment and the absence of any phytotoxicity risk on the crop is not necessary.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorization **cannot be granted** as proposed in Appendix 1 – Copy of the product Decision.

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

No further information is required.

Appendix 1 – Copy of the French Decision



Décision relative à une demande d'extension d'usages 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'extension d'usage mineur du produit phytopharmaceutique **STEWARD***

de la société CHEMINOVA Agro France SAS

enregistrée sous le n°2017-2569

Vu les conclusions de l'évaluation de l'Anses du 15 novembre 2019,

Considérant que le manque de données fournies ne permet pas d'exclure un risque de dépassement des limites maximales de résidus sur l'usage concerné par cette décision,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

L'autorisation de mise sur le marché du produit référencé ci-après **n'est pas étendue** aux usages décrits dans la présente décision.

STEWARD

AMM n°9800144

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Informations générales sur le produit	
Noms du produit	STEWARD AVAUNT WG EXPLICIT WG
Type de produit	Produit de référence
Titulaire	CHEMINOVA Agro France SAS 11 Bis Quai Perrache 69002 LYON France
Formulation	Granulé dispersable (WG)
Contenant	300 g/kg - indoxacarbe
Numéro d'intrant	9800144
Numéro d'AMM	9800144
Fonction	Insecticide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 31 DEC. 2019

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)

STEWARD

AMM n°9800144

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ANNEXE I : Conditions de mise sur le marché demandées

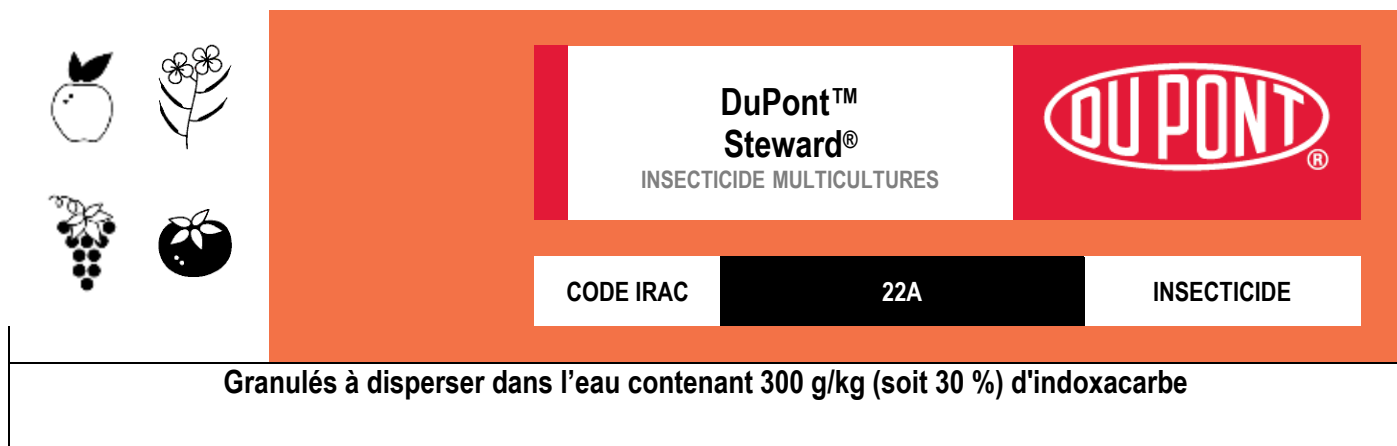
Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00517070 Légumineuses potagères (sèches)* Trt Part.Aer.* Chenilles phytophages	125 g/ha Motivation du refus : L'usage est refusé en raison d'un manque de données permettant d'exclure un risque de dépassement des limites maximales de résidus.	2/an	10

STEWARD
AMM n°9800144

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Appendix 2 – Copy of the draft product label as proposed by the applicant

Face visible - Face visible - Face visible - Face visible - Face visible



RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Consulter cette étiquette et ce livret avant toute utilisation

USAGES AUTORISES * – en traitement des parties aériennes

Vigne	Tordeuses de la grappe, Cicadelles, Chenilles phytophages
Pêcher	Chenilles foreuses des fruits
Tomate	Chenilles phytophages
Poivron	Chenilles phytophages
Choux**	Chenilles phytophages
Concombre	Chenilles phytophages
Melon	Chenilles phytophages
Maïs doux	Chenilles phytophages
Maïs	Chenilles phytophages, Pyrales
Crucifères oléagineuses***	Coléoptères phytophages
Houblon	Coléoptères phytophages
Légumineuses potagères (sèches)****	Chenilles phytophages

* Conformément à l'arrêté du 26 mars 2014, référence NOR : AGRG1407093A. Se reporter au tableau des pratiques pour consulter les cultures et cibles soutenues pour chacun des usages autorisés. Consulter les recommandations d'emploi avant toute utilisation.

** Ne pas appliquer sur chou de Bruxelles et chou feuillu.

*** Utiliser uniquement sur Colza et Moutarde brune.

**** Utiliser uniquement sur Pois-chiche

Fiche de données de sécurité disponible sur www.quickfds.fr ou en flashant ce code.	Variable	 Ce pictogramme indique que l'emballage de ces produits peut être collecté par les distributeurs partenaires de la filière AIVALOR
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Le site du département « Protection des Cultures » de DuPont est consultable à l'adresse suivante : www.agfrance.dupont.com

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Département Protection des Cultures
22 rue Brunel - 75017 Paris
Tél. 01 56 60 47 00
RCS Paris 492 951 306

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Steward®

Autorisation de Mise sur le Marché N°9800144

EUH208 - Contient de l'indoxacarbe. Peut produire une réaction allergique

Danger :

H302 – Nocif en cas d'ingestion.

H372 – Risque avéré d'effets graves pour les organes à la suite d'expositions répétées ou d'une exposition prolongée.

H411 – Toxique pour les organismes aquatiques, entraîne des effets à long terme.

Délai de rentrée des travailleurs sur la parcelle : 6 heures (en cas d'application en milieu fermé : 8 heures) après traitement en cohérence avec l'arrêté du 4 mai 2017 (NOR : AGRG1632554A)

Conseils de prudence :

P260 – Ne pas respirer les poussières/brouillards/aérosols.

P264 – Se laver les mains et le visage soigneusement après manipulation.

P270 – Ne pas manger, boire ou fumer en manipulant le produit.

P314 – Consulter un médecin en cas de malaise.

P391 – Recueillir le produit répandu.

P501 – Eliminer le produit non utilisable (P.P.N.U.) / l'emballage vide conformément aux recommandations reprises ci-après dans le paragraphe « Environnement / Emballages vides ».

Risques particuliers et mesures de sécurité :

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

SPe3 – Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau pour les usages vigne, tomate, poivron, choux, concombre, melon, maïs doux, maïs, crucifères oléagineuses, houblon et pois-chiche et 20 mètres pour les usages sur pêcher.

SPe3 – Pour protéger les arthropodes non-cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

SPe8 – Dangereux pour les abeilles. Pour protéger les abeilles et autres insectes pollinisateurs ne pas appliquer durant la floraison ou en période de production d'exsudat. Ne pas utiliser en présence d'abeilles. Ne pas appliquer lorsque des adventices en fleurs sont présentes. Couper ou éliminer les fleurs des plantes adventices avant l'application du produit.

EUH401 – Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

EN CAS D'URGENCE

Composer le 15 ou le 112 ou contacter le centre anti poison le plus proche

Puis signaler vos symptômes au réseau Phyt'Attitude, N° Vert : 0 800 887 887 (Appel gratuit depuis un poste fixe)
Contactez également Chemtrec au 09 75 18 14 07 (24h/24h)

PREMIERS SOINS

S'éloigner de la zone dangereuse.

En cas de contact cutané : enlever tout vêtement souillé ; laver immédiatement et abondamment la peau avec de l'eau et du savon. En cas d'irritation ou éruption cutanée, consulter un médecin.

En cas de projection dans les yeux : rincer immédiatement et doucement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Si on peut enlever facilement les verres de contact portés, le faire. Consulter 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 : Contacter sans délai le 15, le 112 ou un centre antipoison. Ne pas faire vomir sans avis médical. Rincer la bouche avec de l'eau si la personne est consciente. Ne jamais rien faire avaler à une personne inconsciente. 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 puis le réseau national de toxicovigilance animale approprié (Lyon : 04 78 87 10 40, Nantes : 02 40 68 77 40, Maisons-Alfort : 01 43 96 71 00).