

REGISTRATION REPORT

Part A

Risk Management

Product code: GWN-10246

Product name: IMIDAN 40 WG

Active substance:

phosmet 400 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: GOWAN FRANCE S.A.S

Date: 2019/01/18 (Decision)

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PART A – Risk Management

The company GOWAN France S.A.S has requested a marketing authorisation in France for the product IMIDAN 40 WG (product code: GWN-10246), containing 400 g/kg phosmet, for use as an insecticide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to IMIDAN 40 WG (GWN-10246) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of IMIDAN 40 WG (GWN-10246) have been made using endpoints agreed in the EU peer review of phosmet.

This document describes the specific conditions of use and labelling required for France for the registration of IMIDAN 40 WG (GWN-10246).

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

The present registration report concerns the evaluation of GOWAN France S.A.S's application to market IMIDAN 40 WG (GWN-10246) in France as an insecticide (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 MSs of the Southern zone.

1.2 Active substance approval

Phosmet

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 (EU) No 540/2011 were as follows :

PART A

Only uses as insecticide and acaricide 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 phosmet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 24 November 2006 shall be taken into account.

In this overall assessment Member States:

- must pay particular attention to the protection of birds, mammals, aquatic organisms, bees and other non-target arthropods. Conditions of authorisation should include risk mitigation measures, where appropriate, such as buffer zones and reduction of run-off and drainage inputs to surface water,
- must pay particular attention to the operator safety and ensure that conditions of use prescribe the application of adequate personal and respiratory protective equipment.

The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds (acute risk) and herbivorous mammals (long term risk). They shall ensure that the notifier at whose request phosmet has been included in this Annex provides such studies to the Commission within two years from the approval.

An EFSA conclusion is available (EFSA Journal 2011;9(5): 2162).

A review report is available (SANCO/10050/2006 final rev. 1: 15 July 2011; rev. 2: 11 July 2014)

1.3 Regulatory approach

The present application (2014-0978) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)¹ in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)² – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

In addition, an application for a dispensation to 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 2003³ has been considered.

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

The French Order of 4th May 2017⁴ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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 current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) No 1107/2009⁵, implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. 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 conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁶, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁷ 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.

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

² 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

³ 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 polliniseurs.

⁴ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjutants 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>

⁵ 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

⁶ 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

⁷ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

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 extrapolation⁸ 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

Where protection for data is being claimed for information supporting registration of IMIDAN 40 WG (GWN-10246) it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided a letter of access.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	IMIDAN 40 WG (GWN-10246)
Authorisation number	N/A : not registered in France
Function	Insecticide
Applicant	GOWAN France S.A.S
Composition	400 g/kg phosmet
Formulation type (code)	Water-dispersible granule (WG)
Packaging	N/A : no registered in France

2.2 Classification and labelling

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

Physical hazards	-
Health hazards	Acute toxicity (oral),, category 4
Environmental hazards	Hazardous to the aquatic environment, Acute Hazard, Category 1 Hazardous to the aquatic environment, Chronic Hazard, Category 1
Hazard pictograms	
Signal word	Warning

⁸ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

Hazard statements	H302	Harmful if swallowed
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long-lasting effects.
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

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

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

N/A : not registered in France

2.2.3 Other phrases linked to the preparation

N/A : not registered in France

2.3 Product uses

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.

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

GAP rev. 1, date: 2018-11-16

PPP (product name/code):	IMIDAN 40 WG (GWN-10246)	Formulation type:	WG ^(a, b)
Active substance 1:	phosmet	Conc. of a.s. 1:	400 g/kg ^(c)
Applicant:	GOWAN France S.A.S	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	southern	Non-professional use:	<input type="checkbox"/>
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 product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Citrus: Lemon Orange Pummelo Mandarin Clementine Sweet lemon	F	Mediterranean fruit fly <i>Ceratitis capitata</i>	Overall foliar spray	90 % of final fruit size to fruit ripe for consumption (BBCH 79-89). Nov. - June	1	-	a) 1.25 kg/ha b) 1.25 kg/ha	a) 500 g/ha b) 500 g/ha	1000 / 2000	14	Not acceptable (risk for the operator)
2	FR	Nut trees: Hazelnut	F	Nut weevil <i>Curculio nucum</i> Sap sucker <i>Gonocerus acuteangulatus</i>	Overall foliar spray	BBCH 15-89 March – Sept.	2	14 days	a) 1.875 kg/ha b) 3.75 kg/ha	a) 750 g/ha b) 1500 g/ha	1000	7	Not acceptable (risk for the operator and worker, efficacy)
3	FR	Nut tree: Walnut	F	Codling moth <i>Cydia pomonella</i>	Overall foliar spray	Fruits have reached from 20 % of final size to harvest (BBCH 72-89) June – Sept.	2	14 days	a) 1.25 kg/ha b) 2.5 kg/ha	a) 500 g/ha b) 1000 g/ha	1000	7	Not acceptable (risk for the operator and worker, efficacy)

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 product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
4	FR	Nut trees: Walnut	F	Walnut husk fly <i>Rhagoletis completa</i>	Overall foliar spray	Fruits have reached from 20 % of final size to harvest (BBCH 72-89) June – Sept.	2	14 days	a) 1.875 kg/ha b) 3.75 kg/ha	a) 750 g/ha b) 1500 g/ha	1000	7	(Not acceptable (risk for the operator)
5	FR	Olive	F	Olive moth <i>Prays oleae</i>	Overall foliar spray	From flowering (BBCH 51) May – June	2	10 days	a) 1.875 kg/ha b) 3.75 kg/ha	a) 750 g/ha b) 1500 g/ha	1000	14	Not acceptable (risk for the operator and worker)
6	FR	Olive	F	Olive fruit fly <i>Dacus oleae</i>	Overall foliar spray	Fruits have reached from 20 % of final size to beginning of fruit coloration (BBCH 72-85) Sept. – Oct.	2	10 days	a) 1.875 kg/ha b) 3.75 kg/ha	a) 750 g/ha b) 1500 g/ha	1000	14	Not acceptable (risk for the operator (including by mechanical application) and worker)
7	FR	Persimmon	F	Mealy bug <i>Pseudococcus viburni</i> , Tree scale <i>Ceroplastes japonicus</i> , Bohemian mealy bug <i>Helicoccus bohemicus</i>	Overall spraying	BBCH 75-87 May - July	1	-	a) 1.875 kg/ha b) 1.875 kg/ha	a) 750 g/ha b) 750 g/ha	1000	42	Not acceptable (risk for the operator and worker, efficacy)
8	FR	Pome fruits : Apple, Pear , Quince, Nashi	F	Codling moth <i>Cydia pomonella</i>	Overall foliar spray	Flowers fading to advanced fruit ripening (BBCH 67-85) May – Sept.	2	10 days	a) 1.875 kg/ha b) 3.75 kg/ha	a) 750 g/ha b) 1500 g/ha	1000	28	Not acceptable (risk for the operator and worker)

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 product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
9	FR	Stone fruits: Peach (Nectarine)	F	Mediterranean fruit fly <i>Ceratitis capitata</i> Peach twig borer <i>Anarsia lineatella</i> Oriental peach moth <i>Cydia molesta</i> Spotted wing drosophila <i>Drosophila suzukii</i>	Overall foliar spray	Fruit development to advanced fruit colouring (BBCH 71-87) June – Sept.	2	10 days	c) 1.875 kg/ha d) 1.875 kg/ha	c) 750 g/ha d) 750 g/ha	1000	14	Not acceptable (risk for the operator and worker)
10	FR	Stone fruits: Cherry	F	European cherry fruit fly <i>Rhagoletis cerasi</i> Spotted wing drosophila <i>Drosophila suzukii</i>	Overall foliar spray	During maturation (BBCH 79-87) May – July	1	-	a) 1.875 kg/ha b) 1.875 kg/ha	a) 750 g/ha b) 750 g/ha	1000	14	Not acceptable (risk for the operator and worker)

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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

IMIDAN 40WG is a water-dispersible granule formulation (WG). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a homogeneous, beige-brown solid, with characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature > 400 °C. In aqueous solution (1 % w/v), it has a pH value of 7.7 at 18 °C. There is no effect of high temperature on the stability of the formulation, since after eight weeks at 40 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in PE/Al/PE. Nevertheless, the complete shelf life study must be provided post-authorisation.

3.1.2 Analytical method for the formulation

Its technical characteristics are acceptable for a WG formulation.

The formulation is not classified for the physico-chemical aspect.

The formulation must be stored at a temperature below 40 °C.

3.1.2.2 Analytical methods for residues

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

Analytical methods are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of phosmet in plants, foodstuffs of animal origin, soil, water (surface and drinking) and air.

The active substance is neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.2 Mammalian Toxicology

Endpoints used in risk assessment

Active substance: phosmet			
ADI	0.01 mg/kg bw/d		
ARfD	0.045 mg/kg bw		EU (2007)
AOEL	0.02 mg/kg bw/d		
Dermal absorption	Based on an <i>in vitro</i> human study performed on the formulation:		
	Concentrate (tested) 400 g/kg	Diluted formulation II (tested) 0.26 g/L	
<i>In vitro</i> (human) %	1	17	
	Concentrate (used in formulation) 400 g/kg	Spray dilution (used in formulation) 0.375 g/L	
Dermal absorption endpoints %	1	17	

3.1.3.1 Acute Toxicity

IMIDAN 40 WG (GWN-10246), containing 400 g/kg phosmet, has an acute toxicity in respect to acute oral toxicity, has no acute inhalation and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitisier.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G ⁹	Equipment	Application rate kg/L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Orchards (excluding <i>Citrus</i> fruit crops)	F	Tractor-mounted/trailed air-assisted sprayer	1.875 kg IMIDAN 40 WG (GWN-10246)/ha (750 g phosmet/ha)	1000	German model
<i>Citrus</i> fruits and tree nut crops			1.25 kg IMIDAN 40 WG (GWN-10246)/ha (500 g phosmet/ha)	1000	

Considering proposed uses, operator systemic exposure was estimated using the German BBA model:

Crop	Equipment	PPE and/or working coverall	% AOEL Phosmet
Orchards (excluding <i>Citrus</i> fruit crops)	Tractor-mounted/trailed air-assisted sprayer	Working coverall and gloves during mixing/loading and application	174
<i>Citrus</i> fruits, tree nuts , including olives			116

According to the model calculations, it may be concluded that the risk for the operator using IMIDAN 40 WG (GWN-10246) is unacceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application for orchard crops, including *Citrus* fruits and olive crops, when a tractor-mounted/trailed air-assisted sprayer is used.

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

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 90 % of the AOEL of phosmet for orchard crops, considering those as worst-case scenario.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to IMIDAN 40 WG (GWN-10246).

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. **Exposure is estimated to be 255 % of the AOEL of phosmet for orchard crops (excluding *Citrus* fruits and tree nut crops at 1.25 kg GWN-10246/ha) and 85 % of the AOEL of phosmet for *Citrus* fruits and tree nuts at 1.25 kg IMIDAN 40 WG (GWN-10246)/ha.**

⁹ Open field or glasshouse

It may be concluded that without taking into account a re-entry period, for workers wearing a working coverall and gloves, when re-entering treated crops, there is:

- **An unacceptable risk anticipated with IMIDAN 40 WG (GWN-10246) for orchard crops (excluding *Citrus* fruits and tree nut crops).**
- An acceptable risk anticipated with IMIDAN 40 WG (GWN-10246) for *Citrus* fruit and tree nut crops at 1.25 kg IMIDAN 40 WG (GWN-10246)/ha.

3.1.3.5 Resident Exposure

Residential exposure was assessed according to Martin *et al.* Exposure is estimated to be 40 % and 78 % of the AOEL of phosmet for an adult and child respectively (for orchard crops, considering those as worst-case scenario). It may be concluded that there is no unacceptable risk to the resident exposed to IMIDAN 40 WG (GWN-10246).

Based on the currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory), the respiratory exposure of people living near sprayed areas was estimated for phosmet:

		% ADI	% AOEL
Maximum daily measurement (0.11 ng/m ³)	Adult	< 0.1	< 0.1
	Child	< 0.1	< 0.1
Maximum weekly measurement (0.57 ng/m ³)	Adult	< 0.1	< 0.1
	Child	< 0.1	< 0.1

3.1.4 Residues and Consumer Exposure

Critical GAP(s) and overall conclusion

The data available are considered sufficient for risk assessment. Any exceedence of the current MRL of as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and short-term intakes of phosmet residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France agrees with the authorisation of the intended use(s).

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

Data gaps: none.

Data required post-authorisation: none.

Summary of the evaluation

The preparation IMIDAN 40 WG (GWN-10246) contains phosmet.

Summary for phosmet

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 737/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Citrus	Yes	Yes	Yes	Yes	Yes	No	No	
2 + 3+4	Walnut and hazelnut	Yes	Yes	Yes	Yes	Yes		No	
5+6	Olive: table and oil production	Yes	Yes	Yes	Yes	Yes		No	

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 737/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
7	Persimmon	Yes	No (2SEU)	Yes	Yes	Yes		No	only PHI of 42 d is sufficiently supported
8	Pome fruits	Yes	Yes	Yes	Yes	Yes		No	
9	Peach and nectarine	Yes	Yes	Yes	Yes	Yes		No	
10	Cherry	Yes	Yes	Yes	Yes	Yes		No	
12+13	Oilseed rape and mustard	Yes	Yes	Yes	Yes	Yes		No	
14	Potato	Yes	Yes	Yes	Yes	Yes		No	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of phosmet residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated, taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

Summary for IMIDAN 40 WG (GWN-10246)

Information on IMIDAN 40 WG (GWN-10246)

Crop	PHI for IMIDAN 40 Wg (GWN- 10246) requested by applicant (days before harvest)	PHI/withholding period* sufficiently supported for		PHI for IMIDAN 40 WG (GWN- 10246) proposed by zRMS (days before harvest)	zRMS Comments (if different PHI proposed)
		phosmet			
Citrus	14	Yes			
Walnut and Hazelnut	7	Yes			
Olive: table and oil production	14	Yes			
Persimmon	30	No		FR: 42	only PHI of 42 d is sufficiently supported by residue trials
Pome fruits	28	Yes			
Peach and nectarine	14	Yes			
Cherry	14	Yes			
Oilseed rape and mustard	e.g. F** BBCH 31-59	Yes			

Crop	PHI for IMIDAN 40 Wg (GWN- 10246) requested by applicant (days before harvest)	PHI/withholding period* sufficiently supported for	PHI for IMIDAN 40 WG (GWN- 10246) proposed by zRMS (days before harvest)	zRMS Comments (if different PHI proposed)
		phosmet		
Potato	7	Yes		

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).

3.1.5 Environmental fate and behaviour

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 predicted environmental concentration (PEC) values for the active substance for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC values of phosmet 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.

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

PECgw values for phosmet do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater. 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.

3.1.6 Ecotoxicology

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 and its 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, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

The applicant requested a derogation from the restrictions in French legislation¹⁰, to allow application during the period of flowering or production of exudates. No specific evaluation was supplied in support of either request. Accordingly, the request for such a derogation could not be granted.

3.1.7 Efficacy

¹⁰ Articles 2 and 3 of the Order of 28 November 2003

This is a request for authorisation of the preparation IMIDAN 40 WG (GWN-10246), based on phosmet (400 g/kg), an insecticide. The request was submitted by GOWAN. France is zRMS and Greece, Italy and Spain are cMS.

Considering the data submitted:

- ✓ the efficacy of IMIDAN 40 WG (GWN-10246) is considered satisfactory for the requested uses, **except for nut weevil (CURCNU), sap sucker (GONRAC) on hazelnut and mealybugs on persimmon, because no efficacy trials were provided and no extrapolation is possible.**
- ✓ the selectivity of IMIDAN 40 WG (GWN-10246) is considered satisfactory.
- ✓ The risk of negative impact (on yield, quality, transformation processes, propagation, succeeding and adjacent crops) is considered acceptable.
- ✓ There is a risk of resistance developing or appearing to phosmet for *Cydia pomonella* on pome fruit and tree nuts, which requires monitoring.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

N/A : not registered in France

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

3.4.1 Post-authorisation monitoring

3.4.2 Post-authorisation data requirements

N/A : not registered in France

3.4.3 Label amendments

N/A : not registered in France

Appendix 1 – Copy of the French Decision



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 du produit phytopharmaceutique **IMIDAN 40 WG***

de la société **GOWAN FRANCE**
enregistrée sous le **n°2014-0978**

Vu les conclusions de l'évaluation de l'Anses du 10 décembre 2018,

Considérant que l'estimation de l'exposition liée à l'utilisation du produit est supérieure au niveau acceptable pour l'opérateur,

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

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.



Informations générales sur le produit

Nom du produit	IMIDAN 40 WG
Type de produit	Produit de référence
Titulaire	GOWAN FRANCE 5 Rue du Gué 77139 PUISIEUX France
Formulation	Granulé dispersable (WG)
Contenant	400 g/kg - phosmet
Numéro d'intrant	9628-2014.01
Numéro d'AMM	-
Fonction	Insecticide
Gamme d'usage	Professionnel

A Maisons-Alfort le,

18 JAN. 2019

Françoise WEBER

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 : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12053102 Agrumes*Trt Part.Aer.* Mouches	1,25 kg/ha	1/an	14
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs.		
12203101 Cerisier*Trt Part.Aer.* Mouches	1,875 kg/ha	1/an	14
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs.		
12253101 Fruits à coque*Trt Part.Aer.* Balanin	1,875 kg/ha	2/an	7
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs. L'usage est également refusé en raison de l'absence de données d'efficacité.		
12753101 Kaki*Trt Part.Aer.* cochenilles	1,875 kg/ha	1/an	42
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs. L'usage est également refusé en raison de l'absence de données d'efficacité.		
12403111 Noisetier*Trt Part.Aer.* Punaisses et tigres	1,875 kg/ha	2/an	7
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs. L'usage est également refusé en raison de l'absence de données d'efficacité.		

IMIDAN 40 WG
AMM n°.

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12453101 Noyer*Ttr Part.Aer.* Chenilles foreuses des fruits	1,25 kg/ha	2/an	7
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs.			
002412019 Noyer*Ttr Part.Aer.* Mouches	1,875 kg/ha	2/an	7
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs.			
12503102 Olivier*Ttr Part.Aer.* Chenilles phytophages	1,875 kg/ha	2/an	14
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs.			
12503101 Olivier*Ttr Part.Aer.* Mouche de l'olive	1,875 kg/ha	2/an	14
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs.			
12553103 Pêcher*Ttr Part.Aer.* Chenilles foreuses des fruits	1,875 kg/ha	2/an	14
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs.			
12553101 Pêcher*Ttr Part.Aer.* Mouches des fruits	1,875 kg/ha	2/an	14
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs.			
12603103 Pommier*Ttr Part.Aer.* Chenilles foreuses des fruits	1,875 kg/ha	2/an	28
Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les opérateurs et les travailleurs.			

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

IMIDAN® 40 WG

Insecticide

400 g/kg de phosmet (40% m/m) - Granulés dispersables dans l'eau (WG)

Contre le carpocapse des pommes, poires, coings, nashis et noix,
la mouche méditerranéenne des pêches, nectarines et agrumes,
la mouche des brous du noyer,
le balanin et la punaise des noisettes,
la petite mineuse, la tordeuse orientale et la drosophile des pêches et nectarines,
la teigne de l'olivier et la mouche de l'olive,
la mouche et la drosophile du cerisier,
les cochenilles farineuses et le céropaste du kaki.

Autorisation de vente n°XXXXXXX, délivrée le JJ/MM/AAAA

Détenteur de l'A.M.M. : Gowan France

Contenance : XX kg

® = Marque déposée GOWAN - N° de lot et date de fabrication : voir sur l'emballage

Lire attentivement les recommandations d'emploi avant toute utilisation

	IMIDAN® 40 WG			
	Contient du phosmet (CAS N°732-11-6)			
	H302	Nocif en cas d'ingestion.		
	H410	Très毒ique pour les organismes aquatiques, entraîne des effets néfastes à long terme.		
	P260	Ne pas respirer les poussières / brouillards.		
	P273	Éviter le rejet dans l'environnement.		
	P301+P310	EN CAS D'INGESTION : appeler immédiatement un centre anti-poison ou un médecin.		
	P501	Éliminer le contenu/récipient dans un centre de collecte des déchets dangereux agréé, conformément à la réglementation locale, régionale, nationale et/ou internationale.		
	EUH401	Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.		
ATTENTION				
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.			
SPe3-1	Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres par rapport aux points d'eau et prévoir un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau.			
SPe3-2	Pour protéger les arthropodes non ciblés/les insectes, respecter une zone non traitée de 15 mètres par rapport aux zones non cultivées adjacentes.			
SPe8	Dangereux pour les abeilles. Pour protéger les abeilles et autres insectes pollinisateurs ne pas appliquer en période de production d'essudats. Ne pas utiliser en présence d'abeilles (appliquer le soir).			
Délai de rentrée : 6 heures après traitement Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.				
Distribué par : Gowan France S.A.S. - 5, rue du Gué - 77139 Puisieux - France				

En cas d'urgence,appelez le 15 ou le centre anti-poison, puis signalez vos symptômes au réseau "Phyt'attitude", n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

En cas d'incident ou d'accident,appelez le 01 49 64 57 33.

Fiche de données de sécurité disponible sur demande pour les professionnels.

IMIDAN® 40 WG - Insecticide

Réservé à un usage exclusivement professionnel.

IMIDAN® 40 WG est un insecticide organophosphoré contenant 400 g/kg de phosmet sous forme de granulés dispersables dans l'eau (WG). Il agit par contact et par ingestion. Il a une action rapide sur les insectes cibles.

TABLEAU DES USAGES AUTORISÉS

Culture	Ravageur	Concentration d'emploi	Volume de bouillie	Nombre maximal de traitements par an	Délai avant récolte (DAR)
Pommier, poirier, cognassier, nashi	Carpocapse	0.187 kg/hL	1000 L/ha	2 (20 j min. entre applications)	28 jours
Noyer	Carpocapse	0.125 kg/hL	1000 L/ha	2 (14 j min. entre applications)	7 jours
	Mouche des brous du noyer	0.187 kg/hL	1000 L/ha	2 (14 j min. entre applications)	7 jours
Noisetier	Balanin des noisettes Punaise des noisettes	0.187 kg/hL	1000 L/ha	2 (14 j min. entre applications)	7 jours
Pêche, nectarine	Mouche méditerranéenne Petite mineuse Tordeuse orientale Drosophile du cerisier	0.187 kg/hL	1000 L/ha	2 (10 j min. entre applications)	14 jours
Agrumes	Mouche méditerranéenne	0.125 kg/hL	1000 L/ha	1	14 jours
		0.062 kg/hL	2000 L/ha	1	14 jours
Olive	Teigne de l'olivier Mouche de l'olive	0.187 kg/hL	1000 L/ha	2 (10 j min. entre applications)	14 jours
Cerise	Mouche de la cerise Drosophile du cerisier	0.187 kg/hL	1000 L/ha	1	14 jours
Kaki	Cochenilles farineuses Céropaste	0.187 kg/hL	1000 L/ha	1	30 jours

Les Limites Maximales de Résidus (LMR) sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

Les ravageurs cités ci-dessus correspondent aux noms scientifiques suivants :

- Carpocapse : *Cydia pomonella*
- Mouche des brous du noyer : *Rhagoletis completa*
- Balanin des noisettes : *Curculio nucum*
- Punaise des noisettes : *Gonocerus acuteangulatus*
- Mouche méditerranéenne : *Ceratitis capitata*
- Petite mineuse : *Anarsia lineatella*
- Tordeuse orientale : *Cydia molesta*
- Drosophile du cerisier : *Drosophila suzukii*
- Teigne de l'olivier : *Prays oleae*
- Mouche de l'olive : *Dacus oleae*
- Mouche de la cerise : *Rhagoletis cerasi*
- Cochenilles farineuses : *Planococcus (=Pseudococcus) viburni* et *Helicococcus boemicus*
- Céropaste : *Ceroplastes japonicus*

CONDITIONS D'UTILISATION

Bien mouiller l'ensemble de la végétation. Effectuer des applications préventives suivant les recommandations des instituts techniques.

Les concentrations d'emploi sont calculées par rapport à un volume de bouillie de 1000 L/ha. Lorsque le volume de végétation est important et que le volume de bouillie doit être supérieur à 1000 L/ha, la concentration de la bouillie doit être diminuée afin de ne pas dépasser les doses de IMIDAN® 40 WG de 1.25 kg/ha (noyer - carpocapse, agrumes) ou 1.875 kg/ha (pommier, poirier, cognassier, nashi, noyer – mouche des brous, noisetier, pêcher, olivier, cerisier, kaki).

IMIDAN® 40 WG n'est pas rugogène sur pommes.

PRÉPARATION DE LA BOUILLIE

Remplir à moitié la cuve avec de l'eau et mettre en marche l'agitation. Verser petit à petit la quantité nécessaire de IMIDAN® 40 WG dans la cuve. Remplir la cuve avec de l'eau au volume requis. Maintenir l'agitation durant toute la durée de l'application.

MÉLANGES

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels.

PRÉCAUTIONS D'EMPLOI

Pendant le stockage :

- Conserver le produit uniquement dans le contenant d'origine, à l'abri de l'humidité, du gel, dans un endroit frais, à l'écart des aliments et boissons y compris ceux pour les animaux.

Pendant la préparation de la bouillie et en cours d'application :

Pour protéger l'opérateur, porter :

> pendant le mélange/chargement et le nettoyage du matériel de pulvérisation :

- Combinaison de travail 65% polyester/35% coton d'un grammage au minimum de 230 g/m² avec un traitement déperlant,
- Gants en nitrile conformes à la norme EN 374-3,
- EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison de travail.

> pendant l'application :

- Combinaison de travail 65% polyester/35% coton d'un grammage au minimum de 230 g/m² avec un traitement déperlant,
- Gants en nitrile conformes à la norme EN 374-3 (dans le cas d'utilisation d'un tracteur à cabine, le port de gants pendant l'application n'est nécessaire que lors d'interventions sur le matériel de pulvérisation et les gants doivent être stockés à l'extérieur de la cabine),

- Ne pas respirer le brouillard de pulvérisation.

Éviter les rejets dans l'environnement :

- Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
- Ne pas traiter en présence de vent.
- Éliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur.

Après application :

- Nettoyer très soigneusement et rincer le pulvérisateur aussitôt après le traitement.
- Immédiatement après l'application, changer de vêtements et se rincer le visage et les mains à l'eau savonneuse.

- Pour protéger le travailleur, porter une combinaison de travail 65% polyester/35% coton d'un grammage au minimum de 230 g/m² avec un traitement déperlant et des gants en nitrile conformes à la norme EN 374-3.

Élimination 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.

Appendix 3 – Letter(s) of Access

Provided upon request