REGISTRATION REPORT

Part A

Risk Management

Product code: Pyridaben 10 SC

Product name(s): NEXTER GOLD

Active Substance(s):

Pyridaben, 100 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(extension of use)

Applicant: Philagro France

Date: 2017/12/15 (Decision)

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PART A – Risk Management

The company Philagro France has requested marketing authorisation in France for the product NEXTER GOLD (formulation code: Pyridaben 10 SC), containing 100 g/L Pyridaben 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 NEXTER GOLD (Pyridaben 10 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of NEXTER GOLD (Pyridaben 10 SC) have been made using endpoints agreed in the EU peer review of Pyridaben.

This document describes the specific conditions of use and labelling required for France for the registration of NEXTER GOLD (Pyridaben 10 SC).

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 Philagro France's application to market NEXTER GOLD (Pyridaben 10 SC) 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 label extension of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Pyridaben

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 pyridaben, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate, — the risk to aquatic organisms and mammals, — the risk to non target arthropods including honeybees. Conditions of authorisation should include risk mitigation measures and monitoring programmes should be initiated to verify the real exposure of honeybees to pyridaben in areas extensively used by such bees for foraging

or by beekeepers, where and as appropriate. The Member States concerned shall request the submission of confirmatory information as regards: — the risks for the water compartment resulting from the exposure to aqueous photolysis metabolites W-1 and B-3, — the potential long term risk for mammals, — the assessment of fat soluble residues. They shall ensure that the applicant provides such confirmatory information to the Commission by 30 April 2013.
An EFSA conclusion is available (EFSA Journal 2016;14(1):4376). A Review Report is available (SANCO/12243/2010 final, 28 October 2010, 19 May 2016).

1.3 Regulatory approach

The present application (2015-0430) 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.

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

The French Order of 4th May 2017[3] [4] 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 1107/2009[5], 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 546/2011[6], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[7] 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 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/AGRG1632554A/jo/texte
[4] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570
[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/AGRG1407093A/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 extrapolation[8] 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 NEXTER GOLD (Pyridaben 10 SC), 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

Not necessary..

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	NEXTER GOLD (Pyridaben 10 SC)
Authorisation number	2150912
Function	Insecticide Acaricide
Applicant	Philagro France
Composition	100 g/L Pyridaben
Formulation type (code)	SC (suspension concentrate)
Packaging	HDPE (1L – 5L)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-
Health hazards	Acute toxicity (oral), Hazard Category 4, Acute toxicity (inhalation), Hazard Category 4
Environmental hazards	Hazardous to the aquatic environment, Acute Hazard, Category 1

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

	Hazardous to the aquatic environment, Chronic Hazard Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H302	Harmful if swallowed
	H332	Harmful if inhaled
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		

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

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

The authorisation of the preparation is linked for professional uses only to the following conditions:

SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 20 metres[9] to surface water bodies, for uses on *Citrus*.
SPe8	Dangerous to bees/To protect bees and other pollinating insects do not apply to crop plants during the honeydew production period/Do not use where bees are actively foraging/Do not apply when flowering weeds are present.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[10]: refer to the Decision in Appendix 1 for the details
Re-entry period[11]: 6 hours
Pre-harvest interval[12]: Citrus : 14 days
Other mitigation measures:
The label may include the following recommendations: - Contains 1,2-benzisothiazol-3(2H) The label must reflect the conditions of authorisation.

[9] The legal basis for this is **Titre III Article 12** 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]

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

[11] 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]

[12] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant,
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2017-12-15

PPP (product name/code) **NEXTER GOLD (Pyridaben 100 SC)** **Formulation type:** **SC**
active substance 1 **Pyridaben** **Conc. of as 1:** **100 g/L**

Applicant: **Philagro France** **professional use** ☒
Zone(s): **southern EU** **non professional use** ☐
Verified by MS: **yes**

Crop and/ or situation (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Citrus	FR	Pyridaben 10 SC	F	Mites *(Panonychus citri, Tetranychus urticae)* Whitefly	SC	Pyridaben 100 g/L	Tractor mounted/ trailed broadcast air assisted sprayer	BBCH 69 – BBCH 83	1	N/A	15 - 20	1500 - 2000	Max 0,3	14	**Acceptable**

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at 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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) 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

NEXTER GOLD (Pyridaben 10 SC), is a suspension concentrate. 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 grey/brown liquid with a slight vanilla odour. It is not explosive and has no oxidizing properties. The product is not flammable. In aqueous solution (1% w/v), it has a pH value 8.0 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE packaging. Its technical characteristics are acceptable for a suspension concentrate formulation.

The formulation is not classified for the physical-chemical part.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical method for the determination of active substance in the formulation is available and validated. As the active substance Pyridaben does not contain relevant impurity, no analytical method is required.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and this dossier and validated for the determination of residues of Pyridaben in plants (high water and high acid content commodities), soil, water (surface and drinking) and air.

The active substance is toxic (T), therefore an analytical method is available in the Draft Assessment Report and validated for the determination of residues of Pyridaben in tissues and body fluids.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active Substance: Pyridaben</td></tr>
<tr><td>ADI</td><td colspan="2">0.01 mg kg bw/d</td><td rowspan="3">EU (2010)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.05 mg/kg bw/d</td></tr>
<tr><td>AOEL</td><td colspan="2">0.005 mg/kg bw/d</td></tr>
<tr><td rowspan="4">Dermal absorption</td><td colspan="3">Based on an in vitro human study performed on formulation:</td></tr>
<tr><td></td><td>Concentrate (tested)
100 g/L</td><td>Diluted formulation (tested)
0.15 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.01 %</td><td>0.08 %</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
100 g/L</td><td>Spray dilution
(used in formulation)
0.15 g/L</td></tr>
<tr><td></td><td>Dermal absorption endpoints %</td><td>0.1 %*</td><td>1 %*</td></tr>
</table>

3.1.3.1 Acute Toxicity

Pyridaben 10 SC (NEXTER GOLD) containing 100 g/L pyridaben is harmful in respect to acute oral and inhalation to rats and has a low toxicity to dermal toxicity. It is not irritating (slightly irritant) to the rabbit skin and eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G [13]	Equipment	Application rate L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Citrus	F	Tractor mounted/trailed broadcast air assisted sprayer	3 L/ha (300 g pyridaben/ha)	1500-2000	German BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL pyridaben
Citrus	Tractor mounted/trailed broadcast air assisted sprayer	Working coverall and gloves during mixing/loading and application	28 %

According to the model calculations, it can be concluded that the risk for the operator using Pyridaben 10 SC (NEXTER GOLD) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.

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 9 % of the AOEL of pyridaben.
It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to Pyridaben 10 SC (NEXTER GOLD).

3.1.3.4 Resident Exposure

Residential exposure was assessed according to Martin et al (2008) model. Exposure is estimated to 0.3 % of the AOEL of pyridaben for adults and 3.7% of the AOEL of pyridaben for children.
It is concluded that there is no unacceptable risk to the resident exposed to Pyridaben 10 SC (NEXTER GOLD).

3.1.3.5 Worker Exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to 24 % of the AOEL of pyridaben.
It is concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with Pyridaben 10 SC (NEXTER GOLD).

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

[13] Open field or glasshouse

3.1.4 Residues and Consumer Exposure

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.5 mg/kg for pyridaben as laid down in Reg. (EU) 396/2005 is not expected.
The chronic and the short-term intakes of pyridaben residues are unlikely to present a public health concern.
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.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).
Noticed data gaps are:none

Summary of the evaluation

The preparation NEXTER GOLD (Pyridaben 10 SC) is composed of pyridaben.

Summary for pyridaben

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. (EC) No 1/2016	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Citrus	Yes	Yes	Yes	Yes	Yes	No	No	Dataset mandarins and oranges pooled

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

A sufficient dataset is available to support the use on mandarins. No residue level in any sample is exceeding the in force MRL and pooled with the orange dataset, the calculated MRL is compliant with the in force MRL on citrus.
The effects of processing on the nature of pyridaben residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

As citrus are perennial crops, there is no need to investigate residues 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 is therefore not necessary.

Summary for NEXTER GOLD (Pyridaben 10 SC)

Information on NEXTER GOLD (Pyridaben 10 SC) (KCA 6.8)

Crop	PHI for NEXTER GOLD (Pyridaben 10 SC) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for NEXTER GOLD (Pyridaben 10 SC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pyridaben		
Citrus crops	14 days	Yes	14 days	/

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 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 pyridaben and its metabolites 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.
PEC soil and PECsw derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.
PECgw for pyridaben and its metabolite do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[14].
Therefore, no unacceptable risk of groundwater contamination is expected for the intended use.
Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

Birds
For acute exposure of birds to the active substance pyridaben, the TER for the required use is above the trigger value already at the screening step assessment.
For reproductive exposure of birds, a risk is indicated at the screening step. At Tier 1, the TERs for long-term exposure are above the trigger, except for the scenario "orchards-Spring Summer" and the generic focal species "small insectivorous bird tit" with a TER of 3.5. After refinement, based on measured residues data from canopy dwelling insects, an acceptable reproductive risk for insectivorous birds can be concluded for the application of Pyridaben 10 SC (NEXTER GOLD) according to the proposed use patterns in citrus.
A risk assessment for fish-eating and earthworm-eating birds was conducted for pyridaben and long-term TER values are above the trigger of 5. The risks due to bioaccumulation of pyridaben via the food chain for birds are then acceptable.
The risks for the puddle scenario of the drinking water were considered acceptable.
Therefore, treatment with Pyridaben 10 SC (NEXTER GOLD) in accordance with the proposed use patterns in citrus poses an acceptable risk to birds.

Aquatic organisms
Toxicity studies were conducted with Pyridaben 10 SC (NEXTER GOLD) and indicate that the toxicity of the formulation reflects the toxicity of the active substance. Therefore, the risk assessment was performed based on the active substance endpoints.
Pyridaben is very toxic to aquatic organisms and fish and aquatic invertebrates appear the most sensitive species.
Based on a microcosm study available in EU level containing phytoplankton, zooplankton, periphyton, macro-invertebrates and fish (bluegill) and on a new study considered as a higher tier study with sediment for fish (rainbow trout), refined risk assessments were conducted.
The risk to aquatic non-target organisms is then acceptable when **a non-sprayed buffer zone of 20 m** is applied based on the lowest EAC of 0.68 µg/L (chronic fish).

Terrestrial vertebrates other than birds (mammals)

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

For acute exposure of mammals to the active substance pyridaben, the TER for the required use is above the trigger value already at the screening step assessment.
For reproductive exposure of mammals, a risk is indicated at the screening step. At Tier 1, the TERs for long-term exposure are above the trigger for the small omnivorous mammals, but below the trigger for the other three generic species (small herbivorous mammal, large herbivorous mammal and frugivorous mammal). For the large herbivorous mammal, since the TER is close to the trigger value of 5 (TER_{LT} = 4.7) and given the foraging behaviour of lagomorph, the long-term risk can be considered acceptable based on a weight of evidence approach. For the frugivorous mammal, based on residue data in citrus fruit, the TER_{LT} value is above the trigger value of 5 indicating acceptable long-term risks. Since the vole is managed as pests in southern zone, the risk assessment for the small herbivorous mammal is not considered relevant for the citrus crop and risk assessments for omnivorous and lagomorph are sufficient to conclude for herbivous mammals.
A risk assessment for fish-eating and earthworm-eating mammals was conducted for pyridaben and long-term TER values are above the trigger of 5. The risks due to bioaccumulation of pyridaben via the food chain for mammals are then acceptable.
The risks for the puddle scenario of the drinking water were considered acceptable.
Therefore, treatment with Pyridaben 10 SC (NEXTER GOLD) in accordance with the proposed use patterns in citrus poses an acceptable risk to mammals.

Bees
The calculated HQ values for the the formulation are above 50. Since no new higher tier studies were provided by the applicant, the zRMS concludes that the risk for bees can be considered acceptable only if the following safety phrase SPe 8 is required:
SPe 8: "Dangerous to bees/To protect bees and other pollinating insects do not apply to crop plants during the honeydew production period /Do not use where bees are actively foraging/Do not apply when flowering weeds are present".

Terrestrial non-target arthropods other than bees
The in-field risk assessment based on tier 1 laboratory studies, indicates a potential risk to *T. pyri* and to *A. rhopalosiphi*. However, based on the aged residue studies performed with Pyridaben 75WP, all adverse effects (lethal and sub-lethal) of pyridaben with treatment rate of 300 g/ha had no further toxic effect on *Typhlodromus pyri* and *Aphidius rhopalosiphi* after the ageing period of 49 days. Therefore, it is concluded that populations of non-target arthropods will be able to recolonize leading to population recovery within the one year time-frame stated in ESCORT 2 and the in-field risks are considered acceptable.
The off-field HQ values calculated for *Typhlodromus pyri* and *A. rhopalosiphi* are above the trigger of 2 and a refined off-field risk assessment is required. Based on a field citrus study in Spain, no significant effects were observed at 47 g a.s./ha in field citrus which is slightly below the off-field PER of 47.2 g a.s./ha. Although the off-field PER is slightly above the rate tested in the field study, the zRMS considers that a drift mitigation measure is not necessary to conclude to acceptable off-fields risks.

Earthworm and other soil macro-organisms
The acute TER for the active substance is above the trigger of 10 indicating that the acute risks to earthworms following treatment with Pyridaben 10 SC (NEXTER GOLD) in citrus are acceptable.
In tier 1 risk assessment, the long-term TER value is below the trigger value of 5 for pyridaben. Based on an EU field study performed with Pyridaben 75WP, an acceptable long-term risk is concluded according to the GAP.
For macro-organisms, the TER value is above the trigger of concern, indicating no unacceptable risk for soil non-target macro-organisms, i.e. collembola.

Soil microbial activity
The NOEC of pyridaben exceeds the relevant PEC_{soil} value by a factor of 58, indicating that Pyridaben 10 SC (NEXTER GOLD) does not pose an unacceptable risk to soil micro-organisms.

Effects on non-target plants
Based on screening EU data (effects ≤23% on seedling emergence, survival, plant height and biomass at 0.56 kg a.s./ha), the risk to non-target plants is considered acceptable without mitigation measures.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy of NEXTER GOLD (Pyridaben 10 SC) is considered as satisfactory in the claimed conditions.
- the risk of phytotoxicity of NEXTER GOLD (Pyridaben 10 SC) is considered as negligible in the claimed conditions.
- the risk of negative impact on yield, quality, propagation and adjacent crops is considered as negligible.
- the risk of resistance development or appearance to pyridaben does not require a monitoring for the claimed uses.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

No further information is required.

3.4.2 Post-authorisation data requirements

No further information is required.

3.4.3 Label amendments

The draft label proposed by the applicant in appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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RÉPUBLIQUE FRANÇAISE

anses

Décision relative à une demande d'extension d'usage 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 règlementaire,

Vu la demande d'extension d'usage majeur du produit phytopharmaceutique ***NEXTER GOLD***

de la société *PHILAGRO France*

enregistrée sous le *n°2015-0430*

Vu les conclusions de l'évaluation de l'Anses du 22 août 2017,

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

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.

NEXTER GOLD
AMM n°2150912

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Informations générales sur le produit	
Nom du produit	NEXTER GOLD
Type de produit	Produit de référence
Titulaire	PHILAGRO France 10A rue de la Voie Lactée Parc d'Affaires de Crécy 69370 SAINT DIDIER AU MONT D'OR FRANCE
Formulation	Suspension concentrée (SC)
Contenant	100 g/L - pyridabène
Numéro d'intrant	965-2012.01
Numéro d'AMM	2150912
Fonction	Acaricide, Insecticide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

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

A Maisons-Alfort, le 15 DEC. 2017

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)

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Liste des nouveaux usages autorisés

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)	Mention abeilles
12053103 Agrumes*Trt Part.Aer.*Acariens et phytoptes	3 L/ha	1/an	entre les stades BBCH 69 et BBCH 83	14	20	-	-	-
Efficacité montrée sur *Panonychus citri* et sur *Tetranychus urticae*								
12053107 Agrumes*Trt Part.Aer.*Aleurodes	3 L/ha	1/an	entre les stades BBCH 69 et BBCH 83	14	20	-	-	-

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur pneumatique :

- **Pendant le mélange/chargement**

  - Gants en nitrile certifiés EN 374-3 ;
  - Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
  - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

- **Pendant l'application - Pulvérisation vers le haut**

  Si application avec tracteur avec cabine

  - Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
  - Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

  Si application avec tracteur sans cabine

  - Combinaison de protection de catégorie III type 4 avec capuche ;
  - Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

- **Pendant le nettoyage du matériel de pulvérisation**

  - Gants en nitrile certifiés EN 374-3 ;
  - Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
  - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Pour le travailleur, porter

Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 heures en plein champ.

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Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

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

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau.

- SPe 8 : Dangereux pour les abeilles. Pour protéger les abeilles et autres insectes pollinisateurs, ne pas appliquer pendant la période de production d'exsudats. Ne pas utiliser en présence d'abeilles. Ne pas appliquer lorsque des adventices en fleurs sont présentes.

Les autres conditions d'emploi du produit restent inchangées.

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

Project of LABEL: NEXTER GOLD

Insecticide/Acaricide

1 Litre

100 g/l de pyridabène
Suspension concentrée (SC)
AMM n°

NEXTER GOLD®

Insecticide/Acaricide contre les acariens et les aleurodes pour la culture des agrumes.

Logo Philagro

PHILAGRO France
69771 Saint-Didier-au-Mont-d'Or cedex
Tél : 04 78 64 32 64
Fax : 04 72 53 04 58

Bien lire l'étiquette avant l'utilisation du produit, respecter les précautions d'emploi

NEXTER GOLD® est un insecticide de contact, non systémique efficace contre les différents stades de développement des acariens et des aleurodes (larves et adultes).
NEXTER GOLD® est un inhibiteur du complexe mitochondrial I. Il empêche la respiration cellulaire.

Usages autorisés par la Ministère de l'Agriculture

Cultures	Efficacité sur les ravageurs suivants	Dose	Délai avant récolte
Agrumes	Panonychus citri Tetranychus urticae	3 l/ha	14

Les limites maximales de résidus applicables dans les pays de l'Espace Economique Européen sont consultables à l'adresse suivante : http://ec.europa.eu/sanco_pesticides/public/index.cfm
Pour les autres pays susceptibles d'importer les denrées traitées, il est de la responsabilité de l'exportateur d'assurer la conformité en matière de quantité de résidus.

Mode d'action

NEXTER GOLD agit en inhibant le complexe I mitochondrial de transport des électrons. Selon l'IRAC, il est classé dans le groupe 21A, connu sous le nom METI (Inhibiteurs Mitochondriales de Transport d'Electrons. Les composés METI, comme le pyridabène, sont très efficaces contre tous les stades de tétranyques et sont actuellement utilisés dans de nombreuses cultures à travers le monde.

Recommandations d'emploi

NEXTER GOLD® s'utilise à l'infestation et entre les stades BBCH 69 à 83 pour les agrumes.

Observer régulièrement la culture pour détecter rapidement les premiers individus ou foyers d'insectes ou d'acariens.

Intervenir rapidement pour éviter tout développement des populations.

Délai de rentrée : 6 heures

NEXTER GOLD® s'applique avec des volumes d'eau compris entre 1500 et 2000 l/ha pour les agrumes.

Cultures	Dose	Nombre maximum d'application par an	Zone Non Traitée (ZNT)
Agrumes	3 l/ha	1	20

Préparation de la bouillie et mise en œuvre

- Vérifier le bon état du matériel de pulvérisation. Utiliser de préférence des buses à jet pinceau et une basse pression.
- S'assurer que la cuve ne contient aucun résidu de traitement précédent.
- Remplir la cuve au tiers d'eau et verser NEXTER GOLD® directement dans la cuve.
- Ne préparer que la quantité de bouillie nécessaire à la superficie à traiter. Adapter la quantité d'eau utilisée au volume de végétation afin d'assurer une bonne couverture du feuillage.
- En cas de mélange, respecter les recommandations ci-dessous :
  - introduire NEXTER GOLD® en premier, attendre sa mise en suspension puis ajouter le produit partenaire ;
- Mettre l'agitation en marche et compléter le remplissage de la cuve.
- Surveiller le remplissage afin d'éviter tout débordement.
- Eviter toute contamination des eaux lors de la préparation du traitement et du rinçage des emballages.
- Répartir la bouillie uniformément sur l'ensemble du feuillage, régler correctement la pression de traitement ainsi que la vitesse d'avancement.

Ne pas utiliser NEXTER GOLD® à une dose supérieure à sa dose homologuée de 3 l/ha.

Appliquer NEXTER GOLD® aux stades de croissances de la culture et de développement du parasite indiqués ci-dessus.

Immédiatement après utilisation de NEXTE GOLD®, le nettoyage du pulvérisateur selon la procédure est obligatoire.

Compatibilités

Seuls les mélanges autorisés peuvent être utilisés. La liste des incompatibilités mentionnées n'est pas exhaustive. Tout mélange doit être préalablement testé.

Nos recommandations tiennent compte des informations disponibles à la date de fabrication.

Précautions d'emploi

- Pendant toutes les étapes de manipulation du produit, porter un vêtement de protection, des gants appropriés et un appareil de protection des yeux et du visage. Utiliser des gants en nitrile ou PVC pour la manipulation du produit. Ces gants doivent être renouvelés après chaque demi-journée de travail lorsqu'ils ont été souillés par des projections de produit.
- Éviter le contact du produit avec la peau.
- Ne pas respirer les brouillards de pulvérisation.
- Traiter une culture en bon état végétatif. Ne pas appliquer NEXTER GOLD® sur une culture souffrant d'un stress consécutif à la sècheresse, à des températures trop basses, à une attaque parasitaire, à une carence minérale ou à tout autre facteur ayant réduit sa croissance.

- Pour éviter tout contact ou dérive sur les cultures voisines, utiliser un matériel de pulvérisation adapté et permettant de cibler la zone à traiter.
- S'assurer que la bouillie insecticide/acaricide ne débordera pas de la surface à traiter.
- Immédiatement après l'application et avant toute prise de nourriture, changer de vêtement et rincer le visage et les mains à l'eau savonneuse.
- En cas de contamination, enlever les vêtements souillés, rincer la peau à l'eau immédiatement et abondamment.
- Stocker et conserver le produit uniquement dans le récipient d'origine, à l'abri de l'humidité et du gel (T > 0°C), dans un endroit frais et hors de portée des enfants.

Nettoyage du matériel de pulvérisation

Respecter les bonnes pratiques agricoles.

– Vider complètement le pulvérisateur (en appliquant sur la parcelle.)

– Diluer 5 fois minimum le volume de la bouillie restant dans la cuve et le réservoir de l'appareil et l'épandre sur la parcelle traitée.

– Rincer IMMEDIATEMENT soigneusement l'intérieur de la cuve et du réservoir (sans oublier la paroi du haut) à l'eau claire et faire passer à travers les tuyaux et les rampes une quantité d'eau au-moins égale à 10% de la capacité de la cuve (ex. 60 litres pour 600 litres). Ensuite, vider complètement le pulvérisateur.

– Démonter les jets et filtres puis nettoyés les séparément à l'eau claire.

– Répéter le rinçage si nécessaire jusqu'à disparition complète du traceur.

L'élimination des eaux de vidange ou de rinçage doit se faire en respectant la législation en vigueur.

Important

PRODUIT POUR LES PROFESSIONNELS

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage et qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces. Le fabricant garantit la qualité du produit vendu dans son emballage d'origine ainsi que sa conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues de cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.

En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité de l'insecticide/acaricide liée à ces phénomènes de résistance. De ce fait, nous déclinons toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

Nissan Chemical industries Ltd ou Philagro France ne sauraient être en aucun cas tenues pour responsables des conséquences inhérentes à toute copie, totale ou partielle, de cette étiquette et la diffusion ou l'utilisation non autorisée de cette dernière.

NEXTER GOLD® (SC) – Pyridabène 100 g/l
AMM n°

ATTENTION
H302 : Nocif en cas d'ingestion
H332 : Nocif par inhalation
H400 : Très toxique pour les organismes aquatiques
H410 : Très toxique pour les organismes aquatiques, entraine des effets à long terme.

P261 : Éviter de respirer les brouillards.
P273 : Éviter le rejet dans l'environnement.
P281 : Utiliser les équipements de protection individuels requis.
P312 : Appeler un CENTRE ANTIPOISON ou un médecin en cas de malaise.
P391 : Recueillir le produit répandu.
SP1 : Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. /Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes].
EUH401 : Respecter les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Délai de rentrée : 6 heures.

Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

Fiche de Données de Sécurité disponible sur simple appel au 04 78 64 32 18 ou sur Internet : www.quickfds.com
Numéro d'urgence: 0 800 21 01 55

Emballages : réemploi interdit. Bien vider lors de l'utilisation du produit, rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.
Logo ADIVALOR
N° lot / date de fabrication : voir sur l'emballage

Appendix 3 – Letter(s) of Access

Not applicable.