# REGISTRATION REPORT Part A Risk Management

Product code: Picolinafen 750 WG
Product name(s): KRATOS
Chemical active substance(s):
Picolinafen, 750 g/kg

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE (new application)

**Applicant: Certiplant BV** 

Date: 18/08/2025

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### **PART A**

### **RISK MANAGEMENT**

### 1 Details of the application

The company CERTIPLANT BV has requested a marketing authorisation in France for the product KRATOS (product code: Picolinafen 750 WG), containing 750 g/kg picolinafen<sup>1</sup>, as an herbicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

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

### 1.1 Application background

The present registration report concerns the evaluation of CERTIPLANT BV's application submitted on 13/12/2022 to market KRATOS in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation picolinafen of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2023-0903) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009<sup>2</sup>, the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")<sup>3</sup>. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of KRATOS has been made using endpoints agreed in the EU peer review of picolinafen. It also includes assessment of data and information related to KRATOS where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011<sup>4</sup>, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of KRATOS.

Commission Implementing Regulation (EU) 2016/1423 of 25 August 2016 renewing approval of the active substance picolinafen in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

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

SANCO document "risk envelope approach", European Commission (14 March 2011). <u>Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5</u>

COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

### 1.2 Letters of Access

Not necessary: active substance data are not protected any more.

### 1.3 Justification for submission of tests and studies

According to the applicant: « A justification for submission of tests and studies is provided in the relevant section.

No new vertebrate studies have been performed in view of this application ».

### 1.4 Data protection claims

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

### 2 Details of the authorisation decision

### 2.1 Product identity

Product code	Picolinafen 750 WG
Product name in MS	KRATOS
Authorisation number	-
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	CERTIPLANT BV
Active substance(s) (incl. content)	picolinafen, 750 g/kg
Formulation type	Water-dispersible granule [WG]
Packaging	HDPE <sup>5</sup> bottle (0.2 kg, 0.3 kg, 0.5 kg) HDPE container (2, 3, 4.5 kg)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

### 2.2 Conclusion

The evaluation of the application for KRATOS resulted in the decision to **refuse** the authorisation.

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<sup>&</sup>lt;sup>5</sup> HDPE: High density polyethylene

### 2.3 Substances of concern for national monitoring

Refer to 5.1.1.

### 2.4 Classification and labelling

### 2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

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

Hazard class(es), categories:	Skin irritation, category 2 Eye irritation, category 2 Specific target organ toxicity - Repeated exposure, category 2 Hazardous to the aquatic environment - Acute Hazard, category 1 Hazardous to the aquatic environment - Chronic Hazard, category 1
Hazard pictograms:	GHS07 GHS08 GHS09
Signal word:	Warning
Hazard statement(s):	H315: Causes skin irritation. H319: Causes serious eye irritation. H373: May cause damage to organs through prolonged or repeated exposure. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long-lasting effects.
Precautionary statement(s):	For the P phrases, refer to the existing legislation
Additional labelling phrases:	-

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

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

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

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

None.

### 2.5 Risk management

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

The French Order of 4 May 2017<sup>6</sup> provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021<sup>7</sup> provides that:

- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>8</sup> is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

Finally, the French Order of 20 November 2021<sup>9</sup> on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop<sup>10</sup> when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

### 2.5.1 Restrictions linked to the PPP

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

Operator protection:				
- Refer to the Decision in Appendix 1 for the details.				
Worker protection:				
-	Refer to the Decision in Appendix 1 for the details.			

Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <a href="https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte">https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte</a>; <a href="https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id">https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id</a>

https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

Integrated pest management (IPM)/sustainable use:						
	-					
Environmental protection	Environmental protection					
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 50 meters <sup>11</sup> with an unsprayed vegetated buffer zone of 20 meters to surface water bodies for autumn applications on winter cereals.					
	The unsprayed buffer zone to aquatic systems can be reduced from 50 to 20 meters by the use of an application device with a minimal efficacy of drift reduction of 75%.					
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 50 meters <sup>12</sup> with an unsprayed vegetated buffer zone of 5 meters to surface water bodies for spring applications on winter cereals.					
	The unsprayed buffer zone to aquatic systems can be reduced from 50 to 20 meters by the use of an application device with a minimal efficacy of drift reduction of 75%.					
Other specific restriction	ons					
Re-entry period	24 hours.					
Risk mitigation measures	None					

### 2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

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<sup>&</sup>lt;sup>11</sup> in consistency with French Order of 4 May 2017 (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), modified by the French Order of 27 December 2019.

<sup>&</sup>lt;sup>12</sup> in consistency with French Order of 4 May 2017 (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), modified by the French Order of 27 December 2019.

### 2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

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

When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 18/08/2025

PPP (product name/code): KRATOS / Picolinafen 750 WG Formulation type: WG  $^{(a, b)}$  Active substance 1: picolinafen Conc. of a.s. 1: 750 g/kg  $^{(c)}$ 

Applicant: CERTIPLANT BV Professional use:  $\boxtimes$  Zone(s): Southern Zone (d) Non-professional use:  $\square$ 

Verified by MS: Yes

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-				Application	Application			rr			PHI	Remarks:	
No. (e)	state(s)	or situation (crop destination/purpose of crop)	Fn, Fpn G, Gn, Gpn or I	controlled  (additionally: developmental stages of the pest or pest group)	Method/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	product/ha a) max. rate per appl. b) max. total rate	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x	(days)	e.g. g safener/synergist per ha
Zonal	uses (field	or outdoor uses, co	ertain t	ypes of protected crops)									
1	FR	Winter wheat, TRZAW Winter barley, HORVW Triticale, TTLWI Spelt, TRZSP	F	Annual broad leaved weeds	Field sprayer	BBCH 00-25 Autumn applica- tion pre-emer- gence or early post-emergence BBCH 13-30 Application at the end of win- ter/spring	a) 1 b) 1	-	a) 0.133 b) 0.133	a) 100 b) 100	200/40	F	Not acceptable (product composition, bees)

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### **FRANCE**

Remarks
table
heading:

- a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- 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
- Remarks columns:
- 1 Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. furnigation of a structure)
- 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
- 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.
- 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.

- (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.
- 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
- For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
- 11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
- 12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
- 13 PHI minimum pre-harvest interval
- 14 Remarks may include: Extent of use/economic importance/restrictions

### 3 Background of authorisation decision and risk management

### 3.1 Physical and chemical properties (Part B, Section 2)

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 uniform brown coloured granule, with a musty odour. It is not explosive, has no oxidising properties. The product is not flammable. It has a self ignition temperature of 368 °C. In aqueous solution, it has a pH value around 7.54 at 20 °C. There is no effect of low and high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The 2 year storage stability study at ambient temperature is still ongoing. Its technical characteristics are acceptable for a WG formulation.

The intended concentration of use is 0.033% to 0.13%.

The formulation does not contain hydrocarbons or H304 formulants  $\geq$  10 %.

The preparation is not the representative formulation of the DAR.

There are no toxicologically, ecotoxicologically or environmentally relevant impurities in the formulated product.

For some co-formulants included in the composition of the product, the information provided does not guarantee compliance with Regulation (EU) No 2021/383. Consequently, the assessment of KRATOS cannot be finalised.

Commercial packagings claimed in national data (France):

HDPE bottle 0.2, 0.3, 0.5, 2, 3, 4.5 kg

Commercial packagings claimed in southern zone:

HDPE bottle 0.25, 0.5, 1, 3, 5, 10 L

### 3.2 Efficacy (Part B, Section 3)

The effectiveness level of KRATOS when applied in pre emergence or early post emergence in autumn is considered satisfactory for the control of dicots weeds for all the claimed uses. The efficacy level of KRATOS when applied in post emergence in outing of winter/ spring is considered acceptable for the control of dicots weeds for all the claimed uses.

The selectivity level of KRATOS is considered satisfactory for all the claimed uses.

The risks of negative impact on yield, quality, transformation processes, propagation, are considered acceptable.

The risk of negative impact on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.

The risk of negative impact on adjacent crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops.

The risk of resistance development to picolinafen does not require a survey of resistance.

#### 3.3 Methods of analysis (Part B, Section 5)

### 3.3.1 Analytical method for the formulation

The analytical method for the determination of active substance in formulation is available and validated.

### 3.3.2 Analytical methods for residues

The analytical methods for the determination of active substance residues in matrices (plants and food of animal origin) submitted at European level and in the dossier of the preparation meet the regulatory requirements.

### 3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	Picolinafen: 750 g/kg
AOEL systemic (mg/kg bw/d)	0.03 mg /kg bw/d
Inhalation absorption	100%
Oral absorption	60 %
Vapour pressure	n/a
Dermal absorption	Concentrate: 10 % Dilution: 50%

### 3.4.1 Acute toxicity

KRATOS containing 750 g/kg picolinafen shows a low toxicity in respect to acute oral, inhalation and dermal toxicity. KRATOS is irritant (cat.2) to the eye and to the skin and is not a skin sensitiser.

### 3.4.2 Operator exposure

zRMS has amended operator exposure to KRATOS, according EFSA 2022 model.

		Picolinafen				
Model data Level of PPE		Total absorbed dose (mg/kg/day)	% of systemic AOEL			
Vehicle mounted Crop type: Field crops						
Application rate		1*0.100 kg a.s./ha				
Spray application (AOEM; 75 <sup>th</sup> percentile)	Potential exposure	0.03	84.9			
Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.02	54.2			

<u>Conclusion</u>: According to EFSA model 2022, operator exposure is below the AOEL of picolinafen for KRATOS, without PPE.

### 3.4.3 Worker exposure

zRMS has amended worker exposure to KRATOS, according EFSA 2022 model.

		Picolinafen			
Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of systemic AOEL		
Crop inspection, irrig Outdoor	ation				
Work rate: 2 hours/da Body weight: 60 kg	y				
Application rate		0.100 kg a.s./ha			
Body weight: 60 kg	Potential TC: 12500 cm <sup>2</sup> /person/h	0.0625	208.0		
	Work wear (arms, body and legs covered) TC: 1400 cm²/person/h	0.0070	23.3		

<u>Conclusion</u>: According to EFSA model 2022, worker exposure is below the AOEL of picolinafen with PPE (workwear).

### 3.4.4 Bystander exposure

In the absence of the AAOEL determined for picolinafen, it is considered that the risk assessment for the bystander is covered by the resident risk assessment. Indeed, only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2022;20(1):7032): "When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."

### 3.4.5 Resident exposure

zRMS has amended resident exposure to KRATOS, according EFSA 2022 model.

		Picolinafen		
Model data		Total absorbed dose (mg/kg bw/day)	% of systemic AOEL	
Tractor mounted boom spray application outdoors to low crops Buffer zone: 2-3 m Drift reduction technology: no				

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DT <sub>50</sub> : 30 days				
Number of applications and application rate		1 x 0.100 kg a.s./ha		
Resident child Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	0.01	45%	
	Vapour (75 <sup>th</sup> perc.)	0.0008	2.7%	
	Deposits (75 <sup>th</sup> perc.)	0.0008	2.6%	
	Re-entry (75 <sup>th</sup> perc.)	0.008	28.1%	
	Sum (mean)	0.02	51.5%	
Resident adult Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	0.003	10.7%	
	Vapour (75 <sup>th</sup> perc.)	0.0003	0.9%	
	Deposits (75 <sup>th</sup> perc.)	0.0003	1.1%	
	Re-entry (75 <sup>th</sup> perc.)	0.005	15.6%	
	Sum (mean)	0.006	19.2%	

Conclusion: According to EFSA model 2022, resident exposure is below the AOEL of picolinafen .

### 3.4.6 Combined exposure

Not relevant.

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.05\* mg/kg for picolinafen in barley and wheat as laid down in Reg. (EU) 396/2005 is not expected. The chronic and short-term intakes of picolinafen residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France as zRMS agrees with the authorization of the intended uses.

Summary for Picolinafen 750 WG

Summa	y for recommend 750 WG			
Crop	PHI for Picolinafen 750	PHI/ Withholding period* sufficiently supported for	PHI for Pico- linafen 750 WG	zRMS Comments (if different PHI pro-
	WG proposed by applicant	Picolinafen	proposed by zRMS	posed)
Winter wheat	F* or 90 days	Yes	F*-BBCH 00-30	
Barley	F* or 90 days	Yes	F*-BBCH 00-30	

NR: not relevant

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

The PEC of picolinafen and its metabolite in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the

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

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FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

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

PECgw for picolinafen and its metabolite do not occur at levels exceeding those mentioned in regulation EU No 546/2011. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

### 3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5.

For bees, no conclusion can be drawn on risk assessment for chronic test on adult bees and developmental study on larva due to lack of summary on analytical method in section B.5, therefore these studies were considered not reliable for setting endpoints. Therefore, the chronic risk assessment for adult bees and larval development are considered not finalised. No conclusion could be drawn for oral and contact bumblebees studies for Picolinafen 750 WG due to lack of summary on analytical method in section B.5.

### 3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

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

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

When the conclusions of the assessment is "Not acceptable", please refer to relevant summary under point 3, "Background of authorisation decision and risk management".

### **5.1.1** Post-authorisation monitoring

None.

### **5.1.2** Post-authorisation data requirements

The following data would have been required to update the dossier:

- Stability study at room temperature of the product in its commercial packaging.

## Appendix 1 Copy of the product authorisation



### **Appendix 2** Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

### KRATOS

Granulé dispersable (WG) contenant 750 g/kg (75% p/p) picolinafène.

Kratos est un herbicide anti-dicotylédones des céréales.

Réservé à un usage exclusivement professionnel.

GROUP 12 HERBICIDE

### MENTIONS DE DANGER

H315 : Provoque une irritation cutanée.

H319 : Provoque une sévère irritation des yeux.

H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

### Conseils de prudence

P264 : Se laver les mains soigneusement après manipulation.

P273 : Éviter le rejet dans l'environnement.

P280 : Porter des gants de protection et des vêtements de protection.

P302+P352 : EN CAS DE CONTACT AVEC LA PEAU: Laver abondamment à l'eau.

P332+P313 : En cas d'irritation cutanée: consulter un médecin. P337+P313 : Si l'irritation oculaire persiste: consulter un médecin.

P501 : Éliminer le contenu/récipient conformément à la réglementions locale.

### ATTENTION





### Informations supplémentaires environnement :

SP1 Ne pas polluer l'eau avec le produit au 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.

SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau pour les applications avant repos végétatif sur céréales d'hiver.

SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 50 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 10 mètres en bordure des points d'eau pour les applications après la reprise de végétation sur céréales d'hiver.

### Informations supplémentaires santé humaine :

Délai de rentrée sur la parcelle traitée : 24 heures.

Respecter une distance d'au moins 3 m entre la rampe de pulvérisation et :

- l'espace fréquenté par des personnes présentes lors du traitement,
- l'espace susceptible d'être fréquenté par des résidents.



Ce pictogramme indique que l'emballage de ce produit peut être collecté par les distributeurs partenaires de la filière A.D.I.VALOR

### Distribué en France par :

Belcrop BV

Tiensestraat 300, 3400 Landen, Belgique Tél: +32 11 59 83 60, fax: +32 11 59 83 61 N° d'appels d'urgence 24h/24h: +32 11 68 79 80 Fiche de sécurité: www.belcrop.be ou +32 11 59 83 61

### <u>EN CAS D'URGENCE,</u> 5 ou le 112 ou contacter le (

appelez 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).

### Réemploi de l'emballage interdit.

d'emploi et dose : consulter se livret avant tout utilisation.

Date de production : voir emballage. Numéro du lot : voir emballage.

### Détenteur de l'A.M.M. :

Certiplant B.V., Lichtenberglaan 2045, 3800 Sint-Truiden (Belgique). Tél: +32 11 88 03 92, Fax: +32 11 70 74 84

### KRATOS

### PREMIER SOINS

<u>En cas de contact cutané</u>: enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.

En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre anti-poison.

<u>En cas d'ingestion</u>: rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours: le 15, le 112 ou un centre anti-poison. 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 : contacter votre vétérinaire. »

### DESCRIPTIF DU PRODUIT

### Tableau des usages autorisés

Cultures	Dose	Nombre maximum	Stade	DAR	ZNT aquatique
		d'application	d'application (BBCH)		
Blé tendre	133	1/an	Entre BBCH 00 et	DAR F	Application avant le repos
d'hiver	g/ha	1 application par	BBCH 30	(BBCH	végétatif : 50 m avec un DVP de 20
Blé dur		culture et par parcelle		30)	m
d'hiver					
Triticale					
Epeautre					
Orge d'hiver	1				Application après la reprise de
					végétation : 50 avec un DVP de 10 m

Les conditions d'utilisation de la préparation, compte tenu des bonne pratiques agricoles critiques proposées pour chaque usage figurant dans la liste des usages autorisés, permettent de respecter les limites maximales de résidus.

### Mode d'action

Le picolinafen est absorbé principalement au niveau des feuilles, plus partiellement par les racines. Il est également absorbé pendant la phase de germination et de levée des adventices. Il agit localement par contact puis est véhiculé par systémie ascendante vers les zones de croissance des plantes sensibles.

En bloquant le fonctionnement de la phytogène désaturase, une enzyme qui intervient dans la chaîne des caroténoïdes, le picolinafen provoque l'arrêt de la synthèse de ces pigments qui servent de protecteur à la chlorophylle. Celle-ci se dégrade, empêchant le déroulement normal de la photosynthèse, entraînant ainsi la mort des plantes avec des symptômes de blanchiments typiques de l'action de cette matière active.

Le picolinafen est classé dans le groupe HRAC 12.

### INFORMATIONS RELATIVES À L'EMPLOI

### Conditions d'application

Blé tendre d'hiver, blé dur d'hiver, orge d'hiver, triticale :

Dose: 133 g/ha

Pour répondre à un objectif de désherbage sur une flore plus diversifiée, Kratos s'utilise en mélange avec d'autres spécialités à dose réduite :

Dose: 70 à 100 g/ha en fonction du partenaire. Se reporter à la réglementation en vigueur sur les mélanges.

### Périodes et stades d'application

Sur céréales d'hiver Kratos peut s'employer avant le repos végétatif ou à la reprise de végétation (ne pas appliquer pendant la phase de repos végétatif). Il s'emploie en post-semis prélevée ou du stade 1 feuille (BBCH 11) à épi 1 cm (BBCH 30) des céréales.

L'efficacité de Kratos est optimale sur des adventices peu développées, du stade cotylédons au stade 4 à 6 feuilles.

### Précautions d'emploi

- S'applique sur une céréale en bon état végétatif.
- S'utilise sur tous les types de sol.
- Conditions climatiques favorables à la pousse : température minimum de l'ordre de 5 à 7°C, hygrométrie supérieure à 60%, absence de gelée dans les 10 jours qui suivent le traitement, en évitant les périodes de fortes amplitudes thermiques (>15°).
- Si les conditions mentionnées ci-dessus ne sont pas respectées, des marquages peuvent apparaître sur les feuilles. Ils sont sans incidence sur le rendement.
- Traiter par temps calme, en absence de vent afin d'éviter toute dérive de bouillie sur les cultures voisines
- Ne pas traiter des céréales couvrant des légumineuses.

### Cultures de remplacement

Kratos est sans restriction pour les cultures suivantes : toutes les cultures suivantes d'automne et de printemps sont possibles, avec ou sans labour.

En cas de remplacement d'une culture de céréales, traitée à l'automne avec Kratos, il est possible de semer :

- Quel que soit le travail du sol : betterave, céréales de printemps, colza, maïs, navette, raygrass, soja, sorgho, tournesol, trèfle.
- Avec labour obligatoire : pois protéagineux, vesce

### Préparation de la bouillie

Remplir la cuve au 3/4 du volume d'eau nécessaire. Mettre l'agitation en marche et agiter le bidon de Kratos avant de verser la quantité nécessaire, puis compléter avec de l'eau jusqu'au volume final. Rincer le bidon manuellement 3 fois à l'eau claire en l'agitant et en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur, ou rincer pendant au moins 30 secondes avec le rince-bidon du bac incorporateur (ou rincebidon indépendant). Laisser égoutter les bidons.

Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation.

### PRÉVENTION ET GESTION DE LA RÉSISTANCE

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, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit. 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 cette préparation liée à ces phénomènes de résistance. De ce fait, Certiplant BV décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

### MISE EN ŒUVRE RÉGLEMENTAIRE ET BONNES PRATIQUES

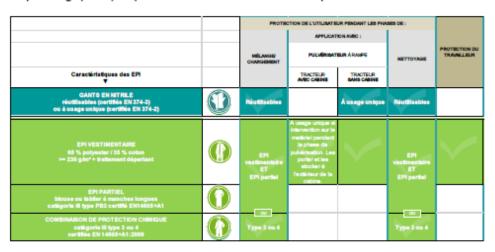
### Stockage du produit

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées.

### Protection de l'opérateur et du travailleur

Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée.

Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit.



Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination de produits dangereux.

### Nettoyage du pulvérisateur et gestion des fonds de cuve

À la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses...) doit être rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

### Élimination du produit, de l'emballage

### Réemploi de l'emballage interdit.

Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

### En cas de déversement accidentel

Se protéger (EPI) et sécuriser la zone. Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens. Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.



### AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite ». « Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous les 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 et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les autorités compétentes françaises. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.