

REGISTRATION REPORT
Part A
Risk Management

Product code: AG-DP2-440 SC

Product name(s): CODIX

Chemical active substance(s):

Pendimethalin, 400 g/L

Diflufenican, 40 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(renewal of authorisation according to Art. 43 and label
extension)

Applicant: ADAMA France S.A.S.

Date: 2026-01-27

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PART A

RISK MANAGEMENT

1 Details of the application

The company ADAMA France S.A.S. has requested a marketing authorisation in France for the product CODIX (formulation code: AG-DP2-440 SC), containing 400 g/L pendimethalin¹ and 40 g/L diflufenican² as a herbicide for professional uses.

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 information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to CODIX (AG-DP2-440 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of CODIX (AG-DP2-440 SC) have been made using endpoints agreed in the EU peer review of pendimethalin.

This document describes the specific conditions of use and labelling required for France for the registration of CODIX (AG-DP2-440 SC).

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 ADAMA France S.A.S.'s application to market CODIX (AG-DP2-440 SC) in France as a herbicide (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 renewal of authorisation after approval of the active substance pendimethalin of this product in France and in other MSs of the Southern zone.

The present applications [2017-3328 (renewal), 2019-0804 (extension), 2019-0805 (modifications) and 2019-6163 (modifications)] were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) 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”)³ – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

The current document (RR) based on Anses's assessment of the application submitted for this product is in

¹ Commission Implementing Regulation (EU) 2017/1114 of 22 June 2017 renewing the approval of the active substance pendimethalin, as a candidate for substitution, 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 (Text with EEA relevance.)

² 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 Text with EEA relevance

³ SANCO document “risk envelope approach”, European Commission (14 March 2011). [Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”](http://ec.europa.eu/food/plant/pesticides/registration/submitting_dossiers_en.htm); SANCO/11244/2011 rev. 5

compliance with Regulation (EC) no 1107/2009⁴, 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 on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

1.2 Letters of Access

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

The applicant has provided a letter of access for pendimethaline. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « All studies and data provided with this application are requested by current guidelines for re-authorisation of a plant protection product (here: AG-DP2-440 SC) in EU countries ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CODIX (AG-DP2-440 SC), 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	AG-DP2-440 SC
Product name in MS	CODIX
Authorisation number	2130140
Low risk (article 47)	No
Function	herbicide
Applicant	ADAMA France S.A.S.
Active substance(s) (incl. content)	Pendimethalin, 400 g/L Diflufenican, 40 g/L
Formulation type	Suspension concentrate [SC]
Packaging	- 5 L HDPE/PA - 10 L HDPE

⁴ 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

⁵ 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

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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 CODIX (AG-DP2-440 SC) resulted in the decision to **renew** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

Hazard class(es), categories:	Aquatic Acute 1 Aquatic Chronic 1
Hazard pictograms:	 SGH09
Signal word:	Warning
Hazard statement(s):	H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>
Additional labelling phrases:	EUH208 : Contains pendimethalin and 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

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

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

SP 1	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 2017⁶ 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;
- 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.

Moreover, the French Order of 12 April 2021⁷ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “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 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.

Finally, the French Order of 20 November 2021⁹ 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 crop¹⁰ 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.

⁶ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>

⁷ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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

⁹ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

¹⁰ 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.

2.5.1 Restrictions linked to the PPP

The authorisation renewal 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
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 2	To protect aquatic organisms, do not apply to artificially drained soil at the maximum rate of 2.5 L/ha for the use on winter cereals.
SPe 2	To protect aquatic organisms, do not apply to artificially drained soil with a clay content of 45% or more at the maximum rate of 2 L/ha for the use on winter cereal.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 50 metres with a 20-metre permanent planted buffer strip to surface water bodies for uses on cereals.
Spe 8	To protect bees and other pollinating insects, do not use in the presence of bees and other pollinating insects.
Other specific restrictions	
Re-entry period	48 hours
Storage	Rinse the packaging at least four times before its disposal. The formulation must be stored at a temperature below 35 °C.
Risk mitigation measure	In order to limit contamination of the air compartment by pendimethalin, additional mitigation measures should be implemented, such as increased edge-of-field distances, use of spray reducing equipment, or modified application conditions.
	Do not implant following or replacement crops less than 120 days after treatment with the active substance diflufenican.
	To avoid any risk of phytotoxicity, specify the optimum conditions for planting replacement crops.
Bystander and resident protection	Respect an unsprayed zone of 3 meters from the extremity of the boom and : <ul style="list-style-type: none"> - areas where bystanders are present during treatment - areas where residents could be present

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):

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None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 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.

PPP (product name/code):	CODIX/AG-DP2-440 SC	Formulation type:	Suspension concentrate (SC) ^(a, b)
Active substance 1:	Diflufenican	Conc. of a.s. 1:	40 g/L ^(c)
Active substance 2:	Pendimethalin	Conc. of a.s. 2:	400 g/L ^(c)
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	ADAMA France S.A.S.	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Southern Zone ^(d)	Non-professional use:	<input type="checkbox"/>
Verified by MS:	Yes		

Field of use: herbicide

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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													

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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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
39	France	Winter triticale	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-07 or 11-21 before vegetative rest	a) 1 b) 1	n/a	a) 2.5 L/ha b) 2.5 L/ha	a) 100 / 1000 b) 100 / 1000	100-400	F	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)
39b	France	Winter triticale	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-07 or 11-21 before vegetative rest	a) 1 b) 1	n/a	a) 2 L/ha b) 2 L/ha	a) 80 / 800 b) 80 / 800	100-400	F	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)
40	France	Spring barley	F	Weeds	soil / foliar, spraying, overall	Mar-May/ BBCH 00-07 or 11-21	a) 1 b) 1	n/a	a) 2.5 L/ha b) 2.5 L/ha	a) 100 / 1000 b) 100 / 1000	100-400	F	Not acceptable (No efficacy and impact data on following and adjacent crops)
41	France	Soft Winter wheat	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-07 or 11-21 (autumn) before vegetative rest	a) 1 b) 1	n/a	a) 2.5 L/ha b) 2.5 L/ha	a) 100 / 1000 b) 100 / 1000	100-400	The latest time of application must be maximum growth stage	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)
41b	France	Soft Winter wheat	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-21 (autumn) before vegetative rest	a) 1 b) 1	n/a	a) 2 L/ha b) 2 L/ha	a) 80 / 800 b) 80 / 800	100-400	The latest time of application must be maximum growth stage	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)

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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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
42	France	Durum winter wheat	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-07 or 11-21(autumn) before vegetative rest	a) 1 b) 1	n/a	a) 2.5 L/ha b) 2.5 L/ha	a) 100 / 1000 b) 100 / 1000	100-400	The latest time of application must be maximum growth stage	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)
42b	France	Durum winter wheat	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-21(autumn) before vegetative rest	a) 1 b) 1	n/a	a) 2 L/ha b) 2 L/ha	a) 80 / 800 b) 80 / 800	100-400	The latest time of application must be maximum growth stage	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)
43	France	Winter barley	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-07 or 11-21(autumn) before vegetative rest	a) 1 b) 1	n/a	a) 2.5 L/ha b) 2.5 L/ha	a) 100 / 1000 b) 100 / 1000	100-400	The latest time of application must be maximum growth stage	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)
43b	France	Winter barley	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-21(autumn) before vegetative rest	a) 1 b) 1	n/a	a) 2 L/ha b) 2 L/ha	a) 80 / 800 b) 80 / 800	100-400	The latest time of application must be maximum growth stage	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)

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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 or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
44a	France	Winter rye	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-07 or 11-21 (autumn) before vegetative rest	a) 1 b) 1	n/a	a) 2.5 L/ha b) 2.5 L/ha	a) 100 / 1000 b) 100 / 1000	100-400	The latest time of application must be maximum growth stage	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)
44b	France	Winter rye	F	Weeds	soil / foliar, spraying, overall	Sep-Feb/ BBCH 00-21 (autumn) before vegetative rest	a) 1 b) 1	n/a	a) 2 L/ha b) 2 L/ha	a) 80 / 800 b) 80 / 800	100-400	The latest time of application must be maximum growth stage	Acceptable (No efficacy and selectivity data for post-emergence applications in winter)

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.

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Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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)

AG-DP2-440 SC (Pendimethalin 400 g/L / Diflufenican 40 g/L) is a suspension concentrate (SC). 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 an opaque and highly viscous, ochre liquid with a musty and organic solvent-like odour. It is not explosive, has no oxidising properties. The product is not flammable. It has no self-ignition observed up to 400° C. In aqueous solution, it has a pH value around 6.1 at 20.0 °C. There is no effect of low and high temperature on the stability of the formulation, since after 12 weeks at 35 °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 1L PE/PA, COEX bottle. Its technical characteristics are acceptable for a SC formulation.

The intended concentration of use is 0.375% w/v to 2.5% w/v.

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

Renewal of the product on winter soft wheat and winter barley

Considering the original authorisations of the product AG-DPC1 440 SC in France, the product can be re-authorised on winter soft wheat, winter durum wheat and winter barley at 2.5 l/ha in pre emergence between BBCH 00-07 and early post emergence (autumn) between BBCH (11-21) in France.

The risk of resistance development or appearance to pendimethalin or diflufenican does not require a survey for the claimed use

The risk of negative effect on succeeding crops is acceptable. Specific attention should be paid to susceptible replacing crops.

The risk of negative effect on adjacent crops is considered as acceptable.

Use of the product in Winter (From January to March) on winter cereals: France only

Applicant requested this specific use of the product, explaining that this is covered by original authorisation in France. 1st, this is not requested in the intended GAP of the dossier. Secondly, zRMS has checked the original BAD of the product submitted in France and no efficacy nor selectivity data was submitted to support this use originally. **Consequently this specific timing of application for the product on winter cereals is considered not acceptable.**

Extension of use of the product on Winter rye: France only

The level of efficacy of the product applied in pre emergence and in early post emergence in autumn is considered as satisfying.

The selectivity of the product on winter rye considering both applications timing is considered as acceptable.

The risk of negative effect on yield, yield parameter, quality, germination of seeds and adjacent crops is considered as negligible.

The risk of negative effect on succeeding crops is acceptable. Specific attention should be paid to susceptible replacing crops.

The risk of resistance development or appearance to pendimethalin or diflufenican does not require a survey for the claimed use

Extension of use of the product on spring barley: France only

Due to lack of data, the level of efficacy of the product applied in pre emergence and in post emergence, the risk on adjacent crops and on succeeding crops can't be performed. **No extrapolation is possible with other crops on which the product is already authorised.**

The selectivity of the product and the impact on yield, maltry and brewery and quality is considered as satisfying on spring barley when applied in pre emergence or in post emergence.

The risk of resistance development or appearance to pendimethalin or diflufenican does not require a survey for the claimed use

National demand of modification of conditions of use on winter cereals

This demand concerns the use of a reduced dose rate of the product, i.e. 2 L/ha, in pre emergence or in early post emergence.

In this actual submitted biodossier, there is no more efficacy data for spring application on spring barley. So the conclusion for this use is still considered not acceptable.

From the submitted data in this biodossier, the use of a reduced dose rate of AG -DP-440-SC is considered acceptable when applied in pre emergence or early post emergence (autumn application) in winter cereals.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

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

3.4.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of pendimethalin in plants (high water, oily, acidic and dry content commodities), food of animal origin, soil, water (surface and drinking) and air.

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of diflufenican in plants (high water, oily, acidic and dry content commodities), food of animal origin, soil, water (surface and drinking) and air.

3.5 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: Pendimethalin		EU(01/09/2017)
ADI	0.125 mg kg bw/d	
ARfD	0.3 mg/kg bw	
AOEL	0.17 mg/kg bw/d	

Dermal absorption	Based on an in vitro human study performed on formulation:		
	Concentrate (tested) 400 g/L	Diluted formulation (tested) 2.5 g/L	
	In vitro (human) %	1.1	15
	Concentrate (used in formulation) 400g/L	Spray dilution (used in formulation) 2.5g/L	
Dermal absorption endpoints %		1.1	15
Oral absorption	57%		

Active Substance: Diflufenican			
ADI	0.2 mg kg bw/d	EU (01/01/2009)	
ARfD	Not applicable		
AOEL	0.11 mg/kg bw/d		
Dermal absorption	Based on an in vitro human study performed on formulation:		
	Concentrate (tested) 40 g/L	Diluted formulation (tested) 0.25 g/L	
In vitro (human) %	2.3	11	
	Concentrate (used in formulation) 40 g/L	Spray dilution (used in formulation) 0.25 g/L	
Dermal absorption endpoints %		2.3	11
Oral absorption	58%		

3.5.1 Acute toxicity

CODIX (AG-DP2-440 SC) containing 400 g/L pendimethalin and 40 g/L diflufenican has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitisier.

3.5.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹¹:

¹¹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

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Model data		Pendmethalin	Diflufenican
	Level of PPE	% AOEL	% AOEL
Application : Tractor / down outdoor Cereals			
Application rate: 2.5 L CODIX /ha	1 kg pendimethalin/ ha	0.1 kg diflufenican/ ha	
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	1.57	0.51

According to the model calculations, it can be concluded that the risk for the operator using CODIX (AG-DP2-440 SC) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.5.3 Worker exposure

EFSA model: Workers may have to enter treated areas after treatment for crop inspection/irrigation or searching, reaching, picking activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is summarized in table below:

		Pendimethalin	Diflufenican
	Level of PPE	%AOEL	%AOEL
Activity: Inspection, irrigation Outdoor Work rate: 2 hours/day Interval between applications: 365 days			
DT50: 30 days			
DFR: 0.3 µg/cm ² /kg a.s./ha			
Nb applications x Application rate (kg as/ha)	1x x 1 kg Pendimethalin/ha	1 x 0.1 kg Diflufenican/ha	
Body weight: 60 kg	Work wear (arms, body and legs covered) + gloves TC: xxx cm ² /person/h	12.35	1.40

It is concluded that there is no unacceptable risk anticipated for the worker.

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

3.5.4 Bystander and resident exposure

EFSA model (w/o AAOEL): Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹².

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 2014;12(10):3874): “*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. 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.*”

3.5.1 Resident exposure

EFSA model: Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child) when mitigation measures such as a buffer zone of 2-3 meters are taken:

Model (AOEM) - All pathways (mean)	% AOEL Pendimethalin	% AOEL Diflufenican
Resident (children)	26.76	3.95
Resident (adults)	9.87	1.31

3.5.1 Combined exposure

Currently no EU-harmonised guidance is available on the risk assessment of combined exposure to multiple active substances. Most assessment approaches employed up to now make use of the Hazard Index (HI) concept. It is therefore suggested to use this as a first tier assessment.

A cumulative assessment for operators, bystanders/residents and workers has been performed. At the first tier, combined exposure is calculated as the sum of the component exposures without regard to the mode of action or mechanism/target of toxicity.

Hazard quotients (HQ) for each active substance and the HI (sum of hazard quotients) are:

Population groups and PPE		Active ingredient	Estimated exposure / AOEL (HQ)
Operators	Working coverall and gloves during mixing/loading and application	Pendimethalin	0.0157
		Diflufenican	0.0051

¹² Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

	Cumulative risk operators (HI)		0.0208
Bystanders /Residents	Children - All pathways (mean)	Pendimethalin	0.2676
		Diflufenican	0.0395
	Cumulative risk bystanders/residents (child) (HI)		0.3071
	Adults - All pathways (mean)	Pendimethalin	0.0987
		Diflufenican	0.0131
Cumulative risk bystanders/residents (adult) (HI)			0.1118
Worker	Working coverall and gloves	Pendimethalin	0.1235
		Diflufenican	0.0140
	Cumulative risk workers (HI)		0.1375

The Hazard Index is < 1. Thus combined exposure to all active substances in CODIX (AG-DP2-440 SC) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current EU-MRLs for pendimethalin and diflufenican as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of pendimethalin and diflufenican residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses on wheat, triticale, rye and barley.

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

Data gaps

Noticed data gaps are: None.

3.6.1.1 Summary for AG-DP2-440 SC

Table 3.6-1: Information on AG-DP2-440 SC (KCA 6.8)

Crop	PHI for AG-DP2-440 SC proposed by applicant	PHI sufficiently supported for		PHI for AG-DP2-440 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pendimethalin	Diflufenican		
Wheat, triticale, rye, and barley	n.a.	Yes	Yes	F (BBCH 21)	

n.a. = not applicable (PHI is covered by the time remaining between application and harvest)

Waiting periods before planting succeeding crops

Not relevant

3.7 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substances and their 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 active substances pendimethalin, diflufenican and their 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.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

PEC soil derived for pendimethalin, diflufenican and their metabolites are used for the ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

PEC_{gw} for pendimethalin, diflufenican and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

PEC_{sw}/sed derived for pendimethalin, diflufenican and their metabolites are used for the ecotoxicological risk assessment and mitigation measures are proposed.

3.8 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 and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses. Risk mitigations are required for aquatic organisms.

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

3.9 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to 3.7 for conclusion on the risk of groundwater contamination.

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

CODIX (AG-DP2-440 SC) contains pendimethalin, which is approved as a candidate for substitution because it fulfills two of PBT criteria (Persistant and Toxic).

As a conclusion of the comparative assessment, uses on wheat and barley are not suitable for substitution because:

Step 1 (French guidance document 27 July 2015):

- Taking into account the management of resistance:
 - In accordance with Article 50(1)(c) of Regulation (EC) N 1107/2009, in the framework of taking the prevention of the appearance of resistance into account, the candidate a.s. for substitution is an important part of the resistance management strategy and there are too few modes of action¹³ available, substitution will not be considered for the uses to control: weed control on wheat, rye and barley.

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

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

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Appendix 1 Copy of the product authorisation



CODIX_PREX_2017-3
328_D3.pdf

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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.



ADAMA

CODIX®



AMM N°2130140
 SC - Suspension concentrée
 Diflufenicanil 40 g/L (3.6%)
 + pendiméthaline 400 g/L (35.6%)

Attention

H410 : Très毒ique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
 EUH208 : Contient de la pendiméthaline et du 1,2-Benzisothiazolin-3-one. Peut produire une réaction allergique.
 EUH401 : Respecter les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement ou port de protections appropriées.

P102 : Tenir hors de portée des enfants.

P501 : Éliminer le contenu / récipient dans un centre de collecte des déchets dangereux ou spéciaux.

SP1 : Ne pas polluer l'eau avec le produit ou son emballage.

SPe2 : Pour protéger les organismes aquatiques, ne pas appliquer le produit sur sol artificiellement drainé.

SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau.

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL.
 Consulter le livret avant toute utilisation.

Titulaire de l'AMM : ADAMA France s.a.s
 33 rue de Verdun - 92156 Suresnes Cedex
 Tél. : 01 41 47 33 33

S4725B/06

Produit fabriqué en Israël

N° de lot	VOIR SUR L'EMBALLAGE
Date de fabrication	



3 700249 107559

5 Litres

MODE D'ACTION - PROPRIÉTÉS

Codix® est un herbicide à large spectre graminées et dicotylédones, utilisé en pré-levée et en post-levée précoce. Il est composé de deux matières actives complémentaires, le diflufénicanil (groupe HRAC F1) et la pendiméthaline (groupe HRAC K1). Codix® agit en bloquant la germination des graines et la croissance des jeunes plantules et maîtrise ainsi les levées échelonnées.

MODE D'EMPLOI

Usages et doses homologués :

Libellé de l'usage	Cultures associées pour le produit	Dose homologuée	Nombre maxi d'application	Stade d'application	Zone non traitée par rapport aux points d'eau
Blé*Désherbage ¹	Blé tendre d'hiver	2,5 L/ha	1 application max/an	Prélevée (BBCH 00-07) ou post levée précoce (BBCH 11-21 max)	20 mètres comportant un dispositif végétalisé
	Blé dur d'hiver				
	Triticale				
Orge*Désherbage ¹	Orge d'hiver	2,5 L/ha	1 application max/an	Prélevée (BBCH 00-07) ou post levée précoce (BBCH 11-21 max)	20 mètres comportant un dispositif végétalisé

¹Ne pas traiter au moment de la levée de la céréale.

ADAMA France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures et cibles telles que prévues par le catalogue des usages fixé par l'arrêté du 26 mars 2014.

Ainsi, l'attention de l'utilisateur est attirée sur les risques éventuels de non-conformité de cet élargissement permis par ce catalogue.

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse :

<http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement conformément à l'arrêté du 4 mai 2017.

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur selon l'arrêté du 7 avril 2010 modifié par l'arrêté du 12 juin 2015.

Recommandations :

- Traiter sur des semis réguliers, effectués à une profondeur d'au moins 2 cm, sur un sol non motteux, finement préparé et exempt de résidus de cultures. Ne pas traiter sur un semis mal enterré.
- Ne pas rouler ou herser la culture dans les jours qui précèdent ou suivent l'application. Appliquer Codix® sur une céréale en bon état végétatif.
- Éviter de traiter sur des sols filtrants ou humifères (taux de MO > 6%).
- Ne pas traiter si des pluies importantes sont annoncées dans les jours suivant le traitement.

En présence de fortes infestations de graminées, l'efficacité de Codix® peut être insuffisante ; dans ces situations, il est nécessaire de compléter son activité par une utilisation en programme ou en mélange avec un autre produit anti-graminées. Le cas échéant, il est nécessaire de valider avec votre conseiller-culture la faisabilité de cette association et la compatibilité des produits mélangés.

Doses d'applications :

Adventices	Faible infestation	Forte infestation ou stade avancé
Vulpin	Codix® 2,5 L/ha	Codix® 2,5 L/ha + prosulfocarbe* 2000 g/ha
Ray grass	Codix® 2,5 L/ha	Codix® 2,5 L/ha + chlortoluron 1800 g/ha Codix® 2,5 L/ha + prosulfocarbe* 2000 g/ha
Pâturins	Codix® 2 L/ha	Codix® 2,5 L/ha

*Avant toute utilisation, lire attentivement l'étiquette des spécialités concernées.

Les doses d'application sont modulables en fonction des situations, il est nécessaire de les valider avec votre conseiller-culture.

Pour de meilleurs résultats d'efficacité en post-levée, il est préconisé d'utiliser Codix® du stade 1 feuille de la céréale (BBCH11) au stade 3 feuilles de la céréale (BBCH13).

Codix® doit être appliqué sur un sol frais, légèrement humide afin d'obtenir un bon positionnement du produit et une activité maximale.

Il est possible de traiter sur un sol gelé (en cas d'hiver précoce ou de semis tardif). Éviter cependant d'utiliser Codix® pendant les périodes de fortes amplitudes thermiques.

Sur blé dur, appliquer avant BBCH 14.

Cultures suivantes :

Respecter un délai de 300 jours entre l'application et le semis de toute culture sur laquelle la pendiméthaline n'est pas autorisée, et autre que des céréales.

Cultures de remplacement :

En cas de destruction accidentelle de la culture après une application de Codix® à l'automne, les cultures de remplacement possibles au printemps, après un labour profond, sont orge de printemps, tournesol, maïs, pois fourrager.

Préparation de la bouillie :

Remplir le pulvérisateur à moitié d'eau et mettre l'agitation en marche. Introduire Codix®, compléter le remplissage de la cuve avec de l'eau sous agitation jusqu'à la fin de l'application.
Traiter avec un volume d'eau de 100 à 200 L/ha.

PRÉCAUTIONS GÉNÉRALES

Gestion du risque d'apparition de 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, 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 culturelle que dans la rotation.

Dans le cadre des Bonnes Pratiques Agricoles :

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 boisson, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées. Stocker la préparation à une température inférieure à 35°C.

Emballages vides : Réemploi de l'emballage interdit. Bien vider et l'éliminer via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre service de collecte spécifique. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Nettoyage de l'équipement : Ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. Éliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Éviter toute contamination des mares, puisards, ruisseaux, eaux souterraines ou de distribution ou de tout autre point d'eau, par le produit, la bouillie de pulvérisation et les eaux de rinçage des emballages et équipements de traitement.

Protection de l'opérateur et du travailleur :

Il convient de rappeler que 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 complémentaires comme les protections individuelles.

En tout état de cause, le port de combinaison de travail dédiée ou d'équipement de protection individuelle (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 avec pulvérisateur à rampe :

Pendant le mélange/chargement :

- Gants en nitrile réutilisables conformes aux exigences de la directive EPI (89/686/CEE) notamment évalués selon la norme EN 374-1:2004 et EN 374-3:2004
- EPI vestimentaire dédié aux traitements phytopharmaceutiques complété par une blouse ou un tablier à manches longues de type 3 ou PB3 conformes aux exigences de la directive EPI (89/686/CEE) évalué notamment selon la norme EN 14605+A1:2009 ou combinaison de type 3 ou 4 conforme aux exigences de la directive EPI (89/686/CEE), évaluée notamment selon la norme EN 14605+A1:2009.

Pendant l'application – pulvérisation vers le bas :

Si application avec tracteur avec cabine :

- Gants en nitrile à usage unique conformes aux exigences de la directive EPI (89/686/CEE) notamment évalués selon la norme EN 374-1 et EN 374-2 ou EN 374-1:2004 et EN 374-3:2004) en cas d'intervention à l'extérieur ; dans ce cas, les gants doivent être stockés et portés à l'extérieur de la cabine
- EPI vestimentaire dédié aux traitements phytopharmaceutiques.

Si application avec un tracteur sans cabine :

- Gants en nitrile à usage unique conformes aux exigences de la directive EPI (89/686/CEE) notamment évalués selon la norme EN 374-1 et EN 374-2 ou EN 374-1:2004 et EN 374-3:2004.
- EPI vestimentaire dédié aux traitements phytopharmaceutiques

Pendant le nettoyage du matériel de pulvérisation :

- Gants en nitrile réutilisables conformes aux exigences de la directive EPI (89/686/CEE) notamment évalués selon la norme EN 374-1:2004 et EN 374-3:2004
- EPI vestimentaire dédié aux traitements phytopharmaceutiques complété par une blouse ou un tablier à manches longues de type 3 ou PB3 conformes aux exigences de la directive EPI (89/686/CEE) évalué notamment selon la norme EN 14605+A1:2009 ou combinaison de type 3 ou 4 conforme aux exigences de la directive EPI (89/686/CEE), évaluée notamment selon la norme EN 14605+A1:2009.

Premiers secours :

- **Inhalation** : Transporter la victime à l'air frais. Si les symptômes persistent, consulter un médecin.
- **Contact cutané** : Rincer immédiatement et abondamment à l'eau pendant au moins 15 minutes. Si l'irritation cutanée persiste, consulter un médecin. Rincer immédiatement au savon et à grande eau.
- **Contact avec les yeux** : Rincer immédiatement et abondamment avec de l'eau. Après le rinçage initial, retirer les éventuelles lentilles de contact et continuer à rincer pendant au moins 15 minutes. Si les symptômes persistent, consulter un médecin.
- **Ingestion** : Rincer la bouche. Boire beaucoup d'eau. Si les symptômes persistent, consulter un médecin.

EN CAS D'URGENCE

Composer le 15 ou le 112 ou contacter le centre antipoison le plus proche.

Présenter aux secours l'étiquette et la Fiche de Données de Sécurité. N° vert de PHYT'ATTITUDE (réseau de toxicovigilance agricole de la MSA) : Tél. 0 800 887 887.

AVERTISSEMENT Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases 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, la pression parasitaire... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché. Compte-tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées protégées ou issues de cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. ADAMA France s.a.s ne saurait être tenu en aucun cas responsable des conséquences inhérentes à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée.





