REGISTRATION REPORT

Part A

Risk Management

Product code: AG-DPC1-590 SC

Product name: TRINITY

Chemical active substances:

pendimethalin, 300 g/L
chlorotoluron, 250 g/L
diflufenican, 40 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal 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 TRINITY (product code: AG-DPC1-590 SC; authorisation nº 2160208), containing 300 g/L pendimethalin, 250 g/L chlorotoluron and 40 g/L diflufenican, 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 (RR), 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 TRINITY (AG-DPC1-590 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of TRINITY (AG-DPC1-590 SC) have been made using endpoints agreed in the EU peer reviews of pendimethalin, chlorotoluron and diflufenican.

This document describes the specific conditions of use and labelling required for France for the registration of TRINITY (AG-DPC1-590 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 TRINITY (AG-DPC1-590 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 and for the label extension of this product in France and in other MSs of the Southern zone.

The addition of the label extension by the company ADAMA France S.A.S. to the request of renewal led to considere the three active substances pendimethalin, chlorotoluron and diflufenican in the assessment of this product.

The present applications (2017-3309 for renewal, 2019-0763 for extension of use, 2019-0764 for intended uses modification and 2019-4059 for packaging modification) 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")[1] – 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] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

compliance with Regulation (EC) no 1107/2009[2], 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 546/2011[3], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

1.2 Letters of Access

The applicant has provided letters of access for active substances and PPP data. These letters of access are 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-DPC1-590 SC) in EU countries*".

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of TRINITY (AG-DPC1-590 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 renewal decision

2.1 Product identity

Product code	AG-DPC1-590 SC.
Product name in MS	TRINITY.
Authorisation number	2160208.
Low risk (article 47)	No.
Function	Herbicide.
Applicant	ADAMA France S.A.S.
Active substance(s) (incl. content)	Pendimethalin, 300 g/L; Chlorotoluron, 250 g/L; Diflufenican, 40 g/L.
Formulation type	Suspension concentrate [SC].

[2] 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

[3] 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

Packaging	1 L, 5 L, 10 L and 20 L HDPE/PA, 5 L HDPE/EVOH, 5 and 10 L HDPE. Professional user.
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 TRINITY (AG-DPC1-590 SC) resulted in the decision **to grand** the authorisation renewal.

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:	Carcinogenicity, category 2 Reproductive toxicity, category 2 Hazardous to the aquatic environment, Acute Hazard, Category 1. Hazardous to the aquatic environment, Chronic Hazard, Category 1.
Hazard pictograms:	 GHS08 GHS09
Signal word:	Warning.
Hazard statement(s):	H351: Suspected of causing cancer. H361d: Suspected of damaging the unborn child. 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:	To avoid risks to man and the environment, comply with the instructions for use [EUH401].
	Contains pendimethalin and 1,2-benzisothiazolin-3(2H)-one. May produce an allergic reaction [EUH208].

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 2017 [4] 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 26 March 2014[5] 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 extrapolation[6] 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.

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4 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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

5 http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

Finally, the French Order of 20 November 2021[7] 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[8] 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 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 for the uses on winter and spring cereals..
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres with a 20-metre permanent planted buffer strip to surface water bodies for uses on winter and spring cereals.
SPe 8	To protect bees and other pollinating insects, do not use in presence of bees and other pollinating insects
Other specific restrictions	
Re-entry period	48 hours.
Storage	Do not store the product at a temperature > 35 °C. Shake well before use. Rinse the packaging at least twice before disposal
Risk mitigation measure	To limit contamination of the air compartment by pendimethalin, additional mitigation measures should be implemented, such as increased edge-of-field distances, use of drift-reducing equipment, or modified application conditions.

[7] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

[8] 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.

Bystander and resident protection	Respect an unsprayed zone of 3 meters from the extremity of the boom and : - areas where bystanders are present during treatment - areas where residents could be present
	To prevent any risk of phytotoxicity, specify the optimum conditions for planting replacement crops.

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.

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 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
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: 2026-01-27

PPP (product name/code):	TRINITY/AG-DPC1 590 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:	300 g/L [c]
Active substance 3:	Chlorotoluron	Conc. of a.s. 3:	250 g/L [c]
Applicant:	ADAMA FRANCE S.A.S.	Professional use:	☒
Zone(s):	Southern Zone[d]	Non-professional use:	☐
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:**
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		e.g. g safener/synergist per ha [f]
Zonal uses (field or outdoor uses, certain types of protected crops)													
52	France	Winter triticale	F	Weeds	soil/foliar spraying, overall	00-07 and 11 – 21 **Before vegetative rest**	a) 1 b) 1	n.a.	a) 2 L/ha b) 2 L/ha	a) 80/600/500 b) 80/600/500	100-400	n.a.	**Acceptable** (No efficacy and no selectivity data for application in winter).

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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
53	France	Durum winter wheat	F	Weeds	soil/foliar spraying, overall	00-07 and 11 – 21 **Before vegetative rest**	a) 1 b) 1	n.a.	a) 2 L/ha b) 2 L/ha	a) 80/600/500 b) 80/600/500	100-400	n.a.	**Acceptable** (No efficacy and no selectivity data for application in winter).
54	France	Spelt	F	Weeds	soil/foliar spraying, overall	00-07 and 11 – 21 **Before vegetative rest**	a) 1 b) 1	n.a.	a) 2 b) 2	a) 80/600/500 b) 80/600/500	100-400	F – the latest time of application is growth stage BBCH 21 (autumn) at the latest	**Acceptable** (No efficacy and no selectivity data for application in winter).
55	France	Winter rye [extension of use]	F	Weeds	soil/foliar spraying, overall	00-07 and 11 - 21 **Before vegetative rest**	a) 1 b) 1	n.a.	a) 2 b) 2	a) 80/600/500 b) 80/600/500	100-400	F – the latest time of application is growth stage BBCH 21 (autumn) at the latest	**Acceptable** (No efficacy and no selectivity data for application in winter).

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)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
56	France	Soft Winter wheat	F	Weeds	soil/foliar spraying, overall	00-07 and 11 – 21 **Before vegetative rest**	a) 1 b) 1	n.a.	a) 2 b) 2	a) 80/600/500 b) 80/600/500	100-400	F – the latest time of application is growth stage BBCH 21 (autumn) at the latest	**Acceptable** (No efficacy and no selectivity data for application in winter).
57	France	Winter barley	F	Weeds	soil/foliar spraying, overall	00-07 and 11 – 21 **Before vegetative rest**	a) 1 b) 1	n.a.	a) 2 b) 2	a) 80/600/500 b) 80/600/500	100-400	F – the latest time of application is growth stage BBCH 21 (autumn) at the latest	**Acceptable** (No efficacy and no selectivity data for application in winter).
58	France	Spring barley	F	Weeds	soil/foliar spraying, overall	00-07 and 11 - 21	a) 1 b) 1	n.a.	a) 2 b) 2	a) 80/600/500 b) 80/600/500	100-400	F – the latest time of application is growth stage BBCH 21 at the latest	**Not acceptable** (no efficacy and selectivity data)

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

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

TRINITY (AG-DPC1-590 SC) is an SC formulation. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of an opaque and viscous, yellow-orange liquid with an organic solvent-like odour. It is not explosive and has no oxidising properties. The product is not flammable (water-based suspension concentrate with determined flash point of > 100 °C). The auto-ignition temperature is 425 °C. The pH of an aqueous solution and of the neat formulation is respectively 5.93 and 7.04 at 20 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 12 weeks at 35 °C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in PE/EV containers. The technical characteristics are acceptable for a suspension concentration formulation.

Implications for labelling:
Do not store the product at a temperature > 35 °C.
Shake after storage (i.e., shake well before use).
Rinse the packaging at least twice before disposal.

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 590 SC (TRINITY) in France and Spain, the product can be re-authorised on winter soft wheat and winter barley at 2 L/ha between BBCH 00-07 and between BBCH 11-21 in France.

The risk of resistance developing or appearing to the three a.s.s does not require monitoring for the requested uses.

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

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

Use of the product in winter (from January to March) on winter cereals: France only
The applicant requested this specific use of the product, explaining that this is covered by original authorisation in France.

However, this is not requested in the intended GAP of the dossier. Second, France as zRMS has checked the original BAD of the product submitted in France and no efficacy or selectivity data were submitted to support this use originally. **Consequently this specific timing of application for the product on winter cereals is considered to be not acceptable.**

Extension of use of the product on winter rye: France only
The level of efficacy of the product applied pre-emergence and early post-emergence in the autumn is

considered satisfactory.

The selectivity of the product on winter rye, considering both application timings, is considered acceptable.

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

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

The risk of resistance developing or appearing to the three a.s.s does not require monitoring for the requested 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 pre- and post-emergence, the selectivity of the product applied pre-emergence, the risk evaluation for adjacent and succeeding crops cannot 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 and quality is considered satisfactory on spring barley when applied post-emergence.
The selectivity of the product on spring barley when applied pre-emergence could not be assessed due to lack of data.

The risk of resistance developing or appearing to the three a.s.s does not require monitoring for the requested use.

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 or Renewal Assessment Reports (DARs/RARs)/this dossier and validated for the determination of residues of active substances in plants, foodstuffs of animal origin, soil, water (surface and drinking) and air.

3.5 Mammalian toxicology (Part B, Section 6)

Information on active substances:

Active substance(s) (incl. content)	**Pendimethalin** 300 g/L	**Chlorotoluron** 250 g/L	**Diflufenican** 40 g/L
AOEL systemic	0.17 mg/kg bw/d	0.215 mg/kg bw/d	0.11 mg/kg bw/d

Active substance(s) (incl. content)	**Pendimethalin** 300 g/L	**Chlorotoluron** 250 g/L	**Diflufenican** 40 g/L
AAOEL	None	None	None
Inhalation absorption (%)	100	100	100
Oral absorption (%)	57	> 80	58
Vapour pressure	3.34 x 10^{-3} Pa at 25 °C	5 x 10^{-6} Pa at 25.0 °C	4.25 × 10^{-6} Pa at 25 °C
Dermal absorption	Concentrate: 0.63 % Dilution: 31 % (Dilution rate: 1:200) (Based on product (AG-DPC1-590 SC))	Concentrate: 0.72 % Dilution: 16 % (Dilution rate: 1:200) (Based on product (AG-DPC1-590 SC))	Concentrate: 1.4 % Dilution: 22 % (Dilution rate: 1:200) (Based on product (AG-DPC1-590 SC))

3.5.1 Acute toxicity

AG-DPC1-590 SC (TRINITY), containing 300 g/L pendimethalin, 250 g/L chlorotoluron and 40 g/L diflufenican, has no acute oral, inhalational or dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.5.2 Operator exposure

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model[9]:

Model data		**Pendimethalin**	**Chlorotoluron**	**Diflufenican**
	Level of PPE	**% AOEL**	**% AOEL**	**% AOEL**
Application : Vehicle mounted/*downward spraying* **Outdoor** **Cereals**				
Application rate: 2 L/AG-DPC1-590 SC/ha		600 g pendimethalin/ha	500 g chlorotoluron/ha	80 g diflufenican/ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	1.7%	0.72%	0.58%

According to the model calculations, it may be concluded that the risk for the operator using AG-DPC1-590 SC is acceptable with a working coverall and gloves during mixing/loading and application.

[9] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

3.5.3 Worker exposure

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

		Pendimethalin	**Chlorotoluron**	**Diflufenican**
	Level of PPE	**% AOEL**	**% AOEL**	**% AOEL**
Activity: Inspection/irrigation Outdoor Work rate: 2 hours/day Interval between applications: n/a				
DT_{50}: 30 days				
DFR: 3 µg/cm²/kg a.s./ha				
Nº applications x Application rate (g a.s./ha)		1 x 600	1 x 500	1 x 80
Body weight: 60 kg	Work-wear (arms, body and legs covered) TC: 1400 cm²/person/h	15 %	5.2 %	2.2 %

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

3.5.4 Bystander and resident exposure

Bystander: 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 AOE model where no AAOEL has been set[10].

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*."

[10] 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)

Resident: Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) without mitigations measures (no drift reduction technology; buffer zone of 2-3 metres):

		Pendimethalin	**Chlorotoluron**	**Diflufenican**
	Level of PPE	**%AOEL**	**%AOEL**	**%AOEL**
Tractor-mounted spray application outdoors to cereals, Buffer strip: 2-3 m Vapour pressure: low-volatility substances, having a vapour pressure of < 5 x 10^{-3} at 25 °C Body weight adult: 60 kg Body weight child: 10 kg				
Nº applications x Application rate (g a.s./ha)		1 x 600	1 x 500	1 x 80
Resident – Child: All pathways (mean)		33 %	11.5 %	5.7 %
Resident – Adult: All pathways (mean)		12 %	4.2 %	2.0 %

3.5.5 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 was 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:

Application scenario	Active Ingredient	Estimated exposure/AOEL (HQ)
Operators – tractor-mounted downward spraying, working coverall and gloves during mix/loading and application	pendimethalin	0.012
	chlorotoluron	0.007
	diflufenican	0.006
	Cumulative risk Operators (HI)	**0.03**
Workers - inspection and irrigation,wearing work-wear.	pendimethalin	0.15
	chlorotoluron	0.05
	diflufenican	0.02
	Cumulative risk Workers (HI)	**0.23**
Resident - Child (all pathways)	pendimethalin	0.33
	chlorotoluron	0.12
	diflufenican	0.06
	Cumulative risk Resident – Child (HI)	**0.50**
Resident - Adult (all pathways)	pendimethalin	0.12
	chlorotoluron	0.04
	diflufenican	0.02
	Cumulative risk Resident – Adult (HI)	**0.18**

The Hazard Index is < 1. Thus combined exposure to all active substances in AG-DPC1-590 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. No exceedance of the current EU-MRLs (Reg. (EU) 2019/1791 for pendimethalin, Reg. (EU) 2017/623 for diflufenican and Reg. (EU) 87/2014 for chlorotoluron), as laid down in Reg. (EU) 396/2005, is expected.

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

As far as consumer health protection is concerned, France as zRMS agrees with the authorisation renewal of the intended uses.

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

Data gaps**:** none.

Data required in post-authori**s**ation**:** none.

Summary for AG-DPC1-590 SC

Table 1 : Information on AG-DPC1-590 SC (KCA 6.8)

Crop	PHI for AG-DPC1-590 SC requested by applicant	PHI sufficiently supported for			PHI for AG-DPC1-590 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pendimethalin	Diflufenican	Chlorotoluron		
Cereals	n.a.	Yes	Yes	Yes	F (last application at BBCH 21 (spring))	-

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

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 predicted environmental concentration (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 values of the three active substances and their respective 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})

PECsoil values derived for pendimethalin, diflufenican, chlorotoluron and their respective metabolites are used for the ecotoxicological risk assessment.

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

PECgw values for pendimethalin, diflufenican, chlorotoluron and their respective metabolites do not occur at levels exceeding those mentioned in Regulation (EC) no 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})

PECsw and PECsed values derived for pendimethalin, diflufenican, chlorotoluron and their respective metabolites are used for the ecotoxicological risk assessment and mitigation measures are proposed.

3.8 Ecotoxicology (Part B, Section 9)

3.8.1 Effects on terrestrial vertebrates

The risk assessment for terrestrial vertebrates was carried out according to the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).

No unacceptable risk for birds is expected for acute or long-term exposure to contaminated food, as indicated by TER_A and TER_{LT} values above the corresponding trigger values for pendimethalin and diflufenican. However, for chlorotoluron, the long-term/reproductive risk for birds due to the use of AG-DPC1-590 SC in cereals cannot be finalised due to the lack to justify the refinement of certain parameters.

No unacceptable risk for mammals is expected for acute or long-term exposure to contaminated food, as indicated by TER_A and TER_{LT} values above the corresponding trigger values under consideration of appropriate refinements.

Furthermore, no unacceptable risks are expected to arise from other routes of direct exposure or secondary poisoning (residue uptake from drinking water or bio-accumulation in food chains). In conclusion, an acceptable overall risk for mammals (not finalised to birds) is indicated for the uses of AG-DPC1-590 SC in cereals according to the intended GAP.

3.8.2 Effects on aquatic species

The risk assessment for aquatic organisms was carried out according to the *Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters* (EFSA Journal 2013;11(7):3290). Based on the PEC/RAC[11] calculations for the active substances, no unacceptable risk for aquatic organism is indicated, if appropriate risk mitigation measures are applied (see 2.5.1 for the details of the required mitigation measures). Further, the risk arising from bio-accumulation of the active substances as well as their metabolites potentially of concern in aquatic systems is considered to be low.

3.8.3 Effects on bees

The evaluation of the risk for bees was performed in accordance with the recommendations of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev.2 (final), October 17, 2002). Based on the Tier-1 risk assessment for honeybees, it may be reasonably concluded that the intended use of AG-DPC1-590 SC in cereals is of acceptable risk under field conditions.

However, while the chronic risk to adult honeybees is considered acceptable, the risk to the development of larvae cannot be finalised. Indeed, the study of effects on larvae is not considered sufficient to address the requirement on development of honeybees since the study was completed at day 8 and did not cover the potential effects on emergence. Thus, Member States may consider the risk for bees to be not finalised, or requiring mitigation measures to avoid exposure of bees, and/or requesting a toxicity study covering

[11] RAC: regulatory acceptable concentration

their emergence, at post-authorisation. At national level, France as zRMS will conclude that the risk for bees is not finalised.

3.8.4 Effects on other arthropod species other than bees

The risk assessment was conducted according to the ESCORT 2 Guidance Document (2000) and the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 (final), October 17, 2002). Based on the results of extended laboratory tests on overall four arthropod species, it may be concluded that there is an acceptable risk for non-target arthropods in both in-field and off-field habitats, considering the intended GAP uses of AG-DPC1-590 SC. Risk mitigation measures are not required.

3.8.5 Effects on soil organisms

The evaluation of the risk for soil organisms was performed in accordance with the recommendations of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2 (final), October 17, 2002). Assessments were performed in consideration of the worst-case application scenario leading to maximum soil load, i.e., 1 × 2.0 L product/ha applied to cereals at pre-emergence (0 % crop interception, covering also the post-emergence application scenario of AG-DPC1-590 SC).

Soil macro- and meso-fauna

Tier-1 TER values calculated for the active substances, the metabolites potentially of concern in soil and the formulated product are above the trigger values of 10 and 5 established for acute (*only provided as supportive information*) and long-term exposure, indicating no unacceptable risk for the meso- and macro-fauna in soil.

Soil microorganisms

Effects within a range of ±25 % compared with the control were observed at exposure levels which clearly exceed the maximum PEC values in soil calculated based on the worst-case exposure scenario. Thus, an acceptable overall risk for soil micro-organisms is indicated for all uses of AG-DPC1-590 SC.

3.8.6 Effects on non-target terrestrial plants

The evaluation of the risk for non-target terrestrial plants was performed in accordance with the recommendations of the *Guidance Document on Terrestrial Ecotoxicology*, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002). Based on a deterministic approach recommended by the SANCO guideline for herbicides, it may be concluded that there is a safe use (with respect to an acceptable risk for terrestrial non-target plants) for the intended uses for AG-DPC1-590 SC in cereals. No mitigation measures (buffer zones and/or drift-reducing techniques) need to be applied.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Adequate risk assessments were performed for all indicator species relevant in the natural environment. In summary, acceptable acute, short-term and long-term risks were indicated for each of the indicator species including birds, mammals, aquatic organisms, bees and other terrestrial non-target arthropods, soil macro- and meso-organisms, micro-organisms, and terrestrial non-target plants, in consideration of the uses intended for AG-DPC1-590 SC. Therefore, further data/studies/calculations on non-target species other than those species mentioned above are not required (and thus were not provided).

3.9 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 for conclusion on the risk of groundwater contamination.

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

TRINITY (AG-DPC1-590 SC) contains pendimethalin, which is approved as a candidate for substitution (CFS) because it fulfils two PBT[12] criteria (persistent and toxic).

As a conclusion of the comparative assessment, uses on wheat, rye 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 (pendimethalin) is an important part of the resistance management strategy and there are too few modes of action available; substitution will not be considered for the uses: 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.

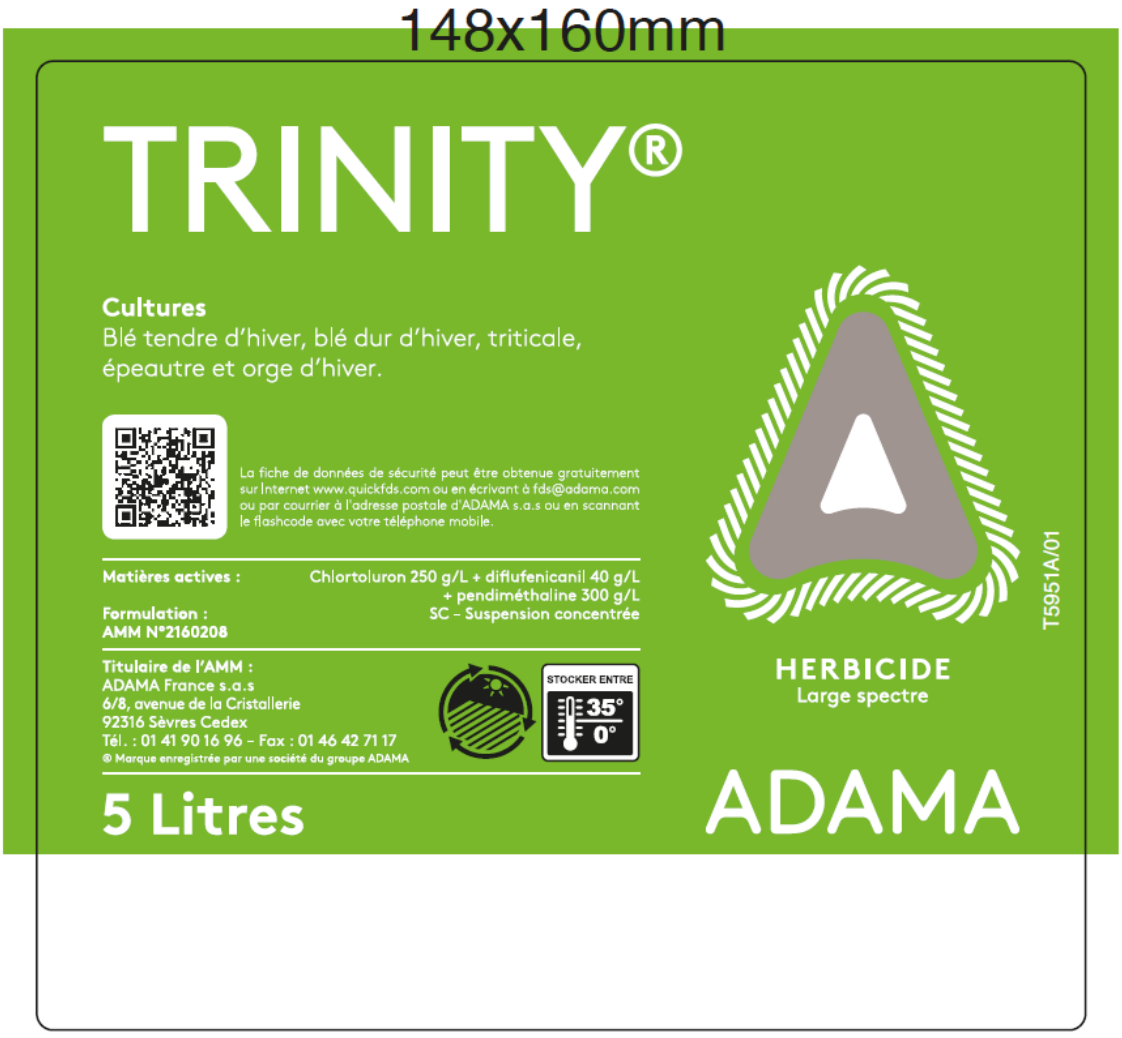
[12] PBT: persistent, bio-accumulative and toxic substances.

Appendix 1 Copy of the product authorisation

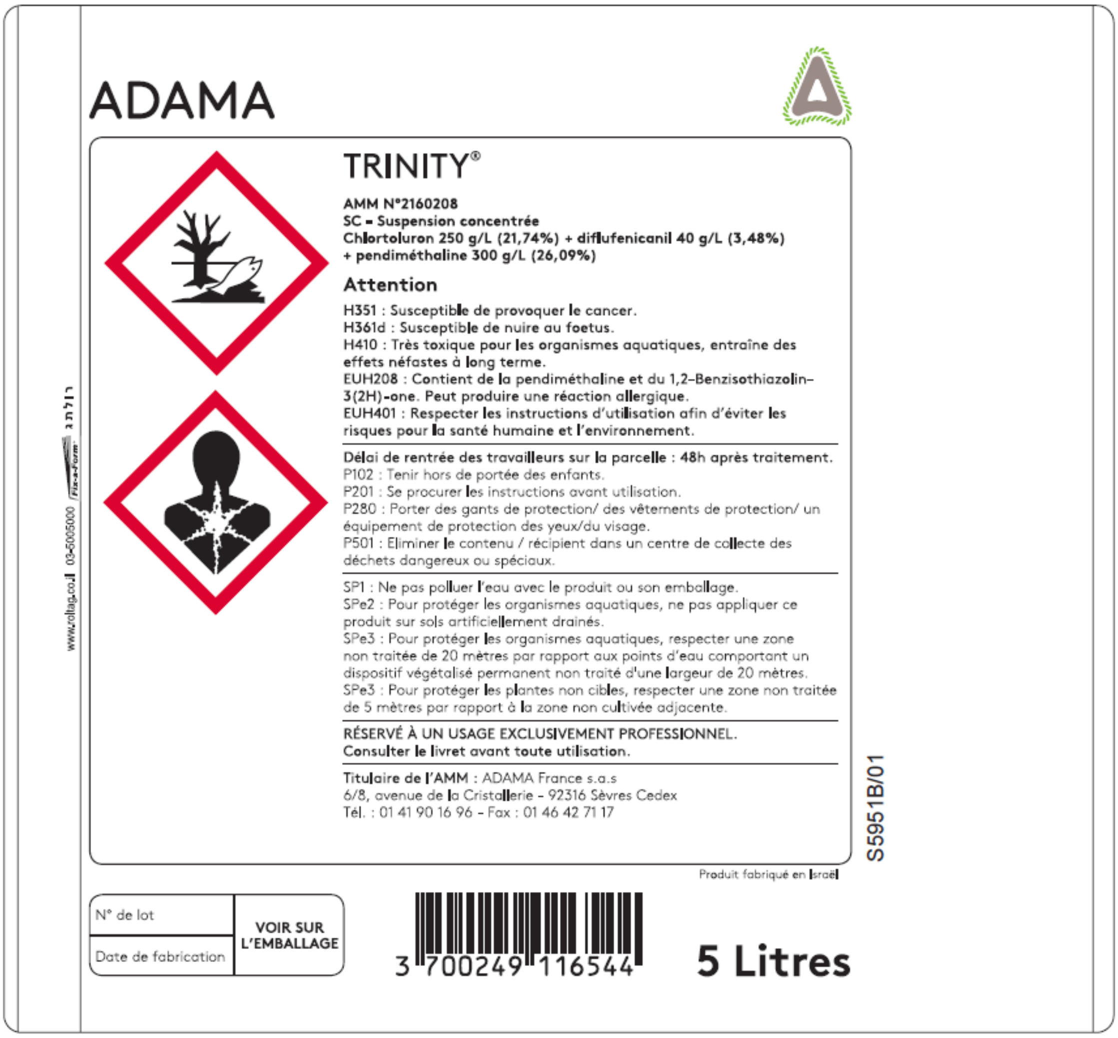
TRINITY_PREX_2017-3309_D3.pdf

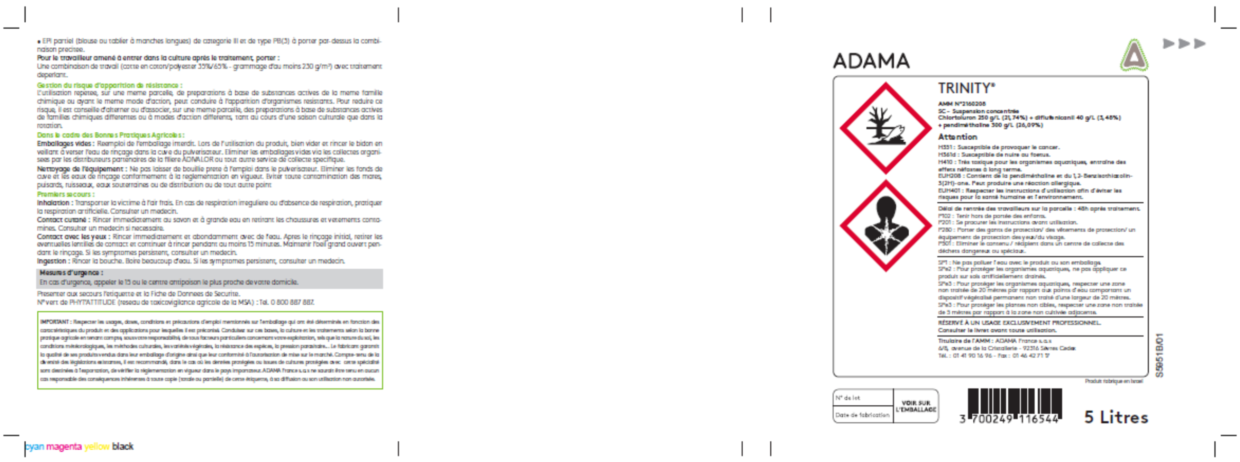
Appendix 2 Copy of the product label

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.



148x160mm


ADAMA
TRINITY®
AMM N°2160208
SC – Suspension concentrée
Chlortoluron 250 g/L (21,74%) + diflufenicanil 40 g/L (3,48%)
+ pendiméthaline 300 g/L (26,09%)
Attention
H351 : Susceptible de provoquer le cancer.
H361d : Susceptible de nuire au foetus.
H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
EUH208 : Contient de la pendiméthaline et du 1,2-Benzisothiazolin-3(2H)-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 : 48h après traitement.
P102 : Tenir hors de portée des enfants.
P201 : Se procurer les instructions avant utilisation.
P280 : Porter des gants de protection/ des vêtements de protection/ un équipement de protection des yeux/du visage.
P501 : Eliminer 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 ce produit sur sols artificiellement drainés.
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres.
SPe3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.
RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL.
Consulter le livret avant toute utilisation.
Titulaire de l'AMM : ADAMA France s.a.s
6/8, avenue de la Cristallerie - 92316 Sèvres Cedex
Tél. : 01 41 90 16 96 - Fax : 01 46 42 71 17
S5951B/01
Produit fabriqué en Israël
N° de lot
Date de fabrication
VOIR SUR L'EMBALLAGE
3 700249 116544
5 Litres
www.roltag.co.il 03-5005000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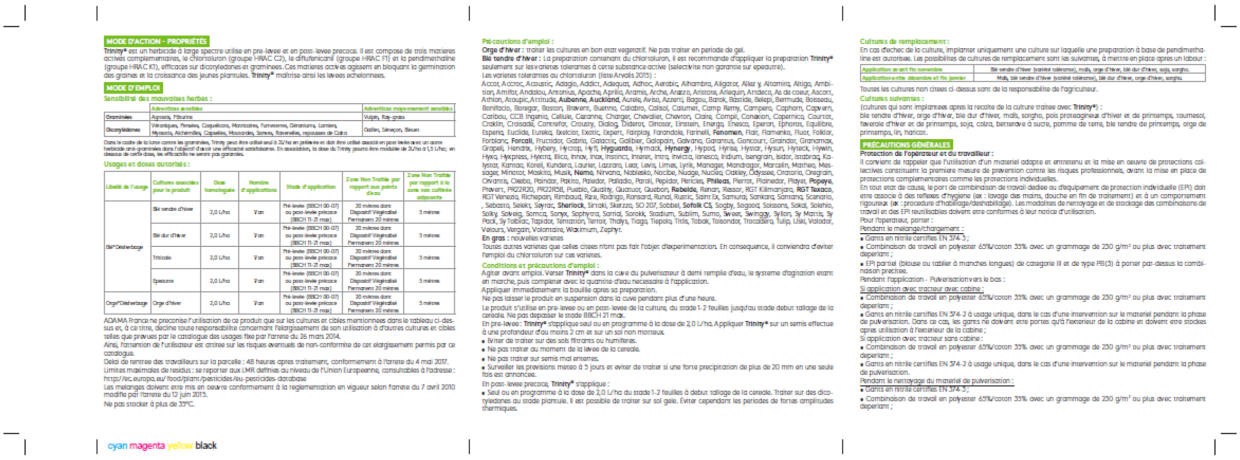
5 Litres



165x300mm CMYK