REGISTRATION REPORT

Part A

Risk Management

Product code: AG-DPC1-590 SC

Product name: TRINITY

Active Substances:

diflufenican, 40 g/L

pendimethalin, 300 g/L

chlorotoluron, 250 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: ADAMA FRANCE S.A.S.

Date: 07/04/2016

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PART A – Risk Management

The company ADAMA FRANCE S.A.S. has requested marketing authorisation in France for the product TRINITY (formulation code: AG-DPC1-590 SC), containing 40 g/L diflufenican, 300 g/L pendimethalin and 250 g/L chlorotoluron, for use as an herbicide.

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

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

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of ADAMA FRANCE S.A.S.'s application to market TRINITY 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 first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Diflufenican

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of regulation were as follows : PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diflufenican, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 March 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: — the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, — the protection of non-target plants. Risk mitigation measures such as an in-field no spray buffer zones shall be applied, where appropriate.

An EFSA conclusion is available (EFSA Scientific Report (2007) 122, 1-84).

A Review Report is available (SANCO/3782/08 – rev. 1, 14 March 2008).

Pendimethalin

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.

Commission Regulation (EU) No 823/2012 of 14 September 2012 derogating from Implementing Regulation (EU) No 540/2011 as regards the expiry dates of the approval of the active substances 2,4-DB, benzoic acid, beta-cyfluthrin, carfentrazone ethyl, Coniothyrium minitans Strain CON/M/91-08 (DSM 9660), cyazofamid, cyfluthrin, deltamethrin, dimethenamid-P, ethofumesate, ethoxysulfuron, fenamidone, flazasulfuron, flufenacet, flurtamone, foramsulfuron, fosthiazate, imazamox, iodosulfuron, iprodione, isoxaflutole, linuron, maleic hydrazide, mecoprop, mecoprop-P, mesosulfuron, mesotrione, oxadiargyl, oxasulfuron, pendimethalin, picoxystrobin, propiconazole, propineb, propoxycarbazone, propyzamide, pyraclostrobin, silthiofam, trifloxystrobin, warfarin and zoxamide.

Specific provisions of Regulation (EU) No 540/2011 were as follows :

Only use as herbicide may be authorised.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on pendimethalin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health 3 December 2002 shall be taken into account. In this overall assessment Member States:

— must pay particular attention to the protection of aquatic organisms and non-target terrestrial plants. Conditions of authorisation must include risk mitigation measures, where appropriate,

— must pay particular attention to the possibility of short-range transport of the active substance in air.

The specific provision of Regulation (EU) No 823/2012 was to extend the expiry date of the approval to 31 July 2016.

There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance.

A Review Report is available (7477/VI/98-final 13 January 2003).

Chlorotoluron

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.

Commission Implementing Regulation (EU) No 533/2013 of 10 June 2013 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methyl-cyclopropene, chlorothalonil, chlorotoluron, cypermethrin, daminozide, forchlorfenuron, indoxacarb, thiophanate-methyl and tribenuron.

Specific provisions of Regulation (EU) No 540/2011 were as follows :

Part A

Only uses as herbicide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009,

the conclusions of the review report on chlorotoluron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 February 2005 shall be taken into account. In this overall assessment Member States must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Conditions of authorisation should include risk mitigation measures, where appropriate The specific provision of Regulation (EU) No 533/2013 was to extend the expiry date of the approval to 31 October 2017.
There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance. A Review Report is available (SANCO/4329/2000 final 15 February 2005).

1.3 Regulatory approach

The present application (2012-2662) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.
The French Order of 12 September 2006[3] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], implementing regulations and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] 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 "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order,

[1] French Food Safety Agency, Afssa, before 1 July 2010
[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5
[3] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000425570
[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
[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

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

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

1.4 Data protection claims

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

1.5 Letter(s) of Access

No letters of access are required for this application for the reasons given hereafter:

Diflufenican

Makhteshim-Agan (now ADAMA) have submitted for post Annex I, step 1 own active substances sources and Annex II data to compensate for the protected data according to published "List of Annex II studies which were considered as relied upon for the evaluation with a view to Annex I inclusion and for which the main data submitter has claimed data protection, Version 2 – final 23 April 2008".

On 14 May 2009 the RMS UK have concluded that the submitted A.I. source of Makhteshim Agan is equivalent to the specification that was evaluated during Annex I inclusion. In addition the RMS UK has concluded that Makhteshim-Agan have demonstrated access to an appropriate Annex II dossier. The evaluation of the RMS is available for other MS on CIRCA. – MS France evaluated the dossier too and came to the same conclusion. All members of the Makhteshim-Agan group have unlimited access to these step 1 data.

In France diflufenican of Makhteshim-Agan origins were recognized as equivalent.

Pendimethalin

All the Annex II data of pendimethalin is out of protection since 1 January 2009. However Makhteshim Agan (now ADAMA) has submitted an own pendimethalin source which was considered equivalent by the RMS Spain (Oct. 2007). The evaluation of the RMS is available via CIRCA to the other MS. Also an Annex II data compensation dossier has been submitted by Makhteshim Agan. – All these Annex II data (A.I. source of pendimethalin and Annex II data compensation) also have been submitted on national level for the registration of pendimethalin straight products. MS France has concluded that the submitted A.I of Makhteshim-Agan origin is equivalent to the specification. In addition the MS France has concluded that Makhteshim Agan have demonstrated access to an appropriate Annex II dossier.

As base for the Risk Assessments however in general the Endpoints from the official published List of Endpoints in Review document SANCO7477/VI/98 (13 January 2003) were used. In cases where there should be any deviation from this procedure this is explained and justified in detail.

Chlorotoluron

Makhteshim-Agan (now ADAMA) as the designated representative of the chlorotoluron Task Force is the main data submitter and notifier of the chlorotoluron Task Force and therefore has access to all the relevant data that was used for Annex I inclusion of the substance. As base for the Risk Assessments however in general the Endpoints from the official published List of Endpoints in Review document SANCO/4329/2000 final, dated 15 Feb. 2005 were used.

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

In cases where there should be any deviation from this procedure this is explained and justified in detail.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	TRINITY (AG-DPC1-590 SC)
Authorisation number	2160208
Function	Herbicide
Applicant	ADAMA FRANCE S.A.S.
Composition	40 g/L diflufenican 300 g/L pendimethalin 250 g/L chlorotoluron
Formulation type (code)	Suspension concentrate (SC)
Packaging	HDPE can (5 L, 10 L)

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-	
Health hazards	Carcinogenicity, Hazard category 2 Reproductive toxicity, Hazard category 2	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	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 statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH208	Contains pendimethalin and 1,2-benzisothiazolin-3(2H)-one. May produce an allergic reaction

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

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

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

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).
SPe 2	To protect aquatic organisms do not apply to artificially drained soils.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres[8] with a permanent vegetative buffer zone of 20 metres to surface water bodies.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural land.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[9]: refer to the Decision in Appendix 1 for the details
Re-entry period[10]: 6 hours
Pre-harvest interval[11]: F- Application must be made at growth stage BBCH 21 the latest
Other mitigation measures: The product must be stored at a temperature below 35 °C. In the event of crop failure, only plant or sow a crop on which use of pendimethalin is authorised.
The label may include the following recommendations: - It is recommended to apply TRINITY only to cereal varieties that are tolerant to chlorotoluron. The label must reflect the conditions of authorisation.

[8] The legal basis for this is **Titre III Article 11** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

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

[10] The legal basis for this is **Titre I Article 3** of the French Order of 12 September 2006 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[11] According to the French Order of 12 September 2006, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

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

GAP rev. 1, date: 2016/04/07

PPP (product name/code):	**TRINITY**/ AG-DPC1-590 SC	Formulation type:	**Suspension concentrate (SC)** [a, b]
active substance 1	diflufenican	Conc. of as 1:	**40 g/L** [c]
active substance 2	pendimethalin	Conc. of as 2:	**300 g/L** [c]
active substance 3	chlorotoluron	Conc. of as 3:	**250 g/L** [c]
Applicant:	**ADAMA FRANCE S.A.S.**	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	France	Winter Wheat Winter spelt	**F**	Grass and broad-leaf weeds	Foliar spray	BBCH 00-07 or BBCH 11-21	1	2	D : 60-80 P : 450-600 C : 375-500	100-400	**F**	**Only on soft winter wheat and spelt (*Triticum spelta*), the latter at the user's own risk**
2	France	Winter Barley	**F**	Grass and broad-leaf weeds	Foliar spray	BBCH 00-07 orBBCH 11-21	1	2	D : 60-80 P : 450-600 C : 375-500	100-400	**F**	**Acceptable**

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 authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

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

3 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

TRINITY (AG-DPC1-590 SC) is a suspension concentrate formulation. All studies have been performed in accordance with the current requirements. The appearance of the formulation is an opaque, viscous, yellow-orange liquid with organic solvent-like odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature > 400 °C and a flash point > 100 °C. In aqueous solution (1%), its pH is 5.93 at ambient temperature.

Stability data indicate a shelf life of at least 2 years at ambient temperature (HDPE-EVOH). Its technical characteristics are acceptable for a suspension concentrate formulation.

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

The product must be stored at a temperature below 35 °C.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

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

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Reports and in this dossier and validated for the determination of residues of diflufenican, chlorotoluron and pendimethalin in plants (dry commodities), foodstuffs of animal origin, soil, water (surface and drinking) and air.

To update the dossier and to be in accordance with SANCO 825/00/rev8.1, the following analytical methods would be required at the renewal of active substance aproval:

A confirmatory method for the determination of pendimethalin in eggs and milk

A confirmatory method for the determination of pendimethalin in surface water

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

3.1.3 Mammalian Toxicology

3.1.3.1 Acute Toxicity

TRINITY was of low acute toxicity by the oral and dermal routes. It was neither irritating to rabbit skin nor to the eyes. In a maximisation test (Magnusson & Kligman) test on guinea pigs, TRINITY was not a skin sensitiser.

According to the CLP criteria, TRINITY is labelled as shown in Section 2.2.

3.1.3.2 Operator Exposure

Dermal absorption

Dermal absorption values of pendimethalin in TRINITY are 0.4 % for undiluted and 33 % for diluted formulation based on a comparative in vitro study through human skin with a product of similar composition.

The dermal absorption value of chlorotoluron in TRINITY is 7 % for both undiluted and diluted formulation based on a comparative in vitro study through rat/human skin with a product of similar composition.

The dermal absorption value of diflufenican in TRINITY is 5 % for both undiluted and diluted formulation based on a comparative in vitro study through human skin with a product of similar composition.

Operator exposure

Operator exposure for use on cereals has been performed according to the German (BBA) and UK models. The results of operator exposure calculations using the BBA model show that operator exposure is acceptable for the proposed uses even without personal protective equipment.

An additional evaluation has been performed with the German model with similar entry parameters as those presented in the dRR, though taking into account a protection factor of 90 % for working coveralls and gloves.

Tractor-mounted/trailed boom sprayer: hydraulic nozzles: With this consideration the estimated operator exposure represented 0.6 % of the Acceptable Operator Exposure Level (AOEL) of diflufenican, 6.4 % of the AOEL of pendimethalin, and 2.4 % of the AOEL of chlorotoluron with working coveralls and PPE.

3.1.3.3 Bystander Exposure

Bystander exposure has been calculated according to the EUROPOEM II model and is acceptable (0.7 % of the AOEL of pendimethalin, < 0.1 % of the AOEL of diflufenican and 0.2 % of the AOEL of chlorotoluron).

3.1.3.4 Worker Exposure

TRINITY is applied as a pre- or post-emergence product to winter cereals; accordingly no cultivation work is performed. Estimation of worker exposure is considered unnecessary.

Re-entry period: 6 hours

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedence of the current MRL for wheat and barley of 0.05* mg/kg for diflufenican, 0.1 mg/kg for chlorotoluron and 0.05* mg/kg for pendimethalin as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and short-term intakes of diflufenican, chlorotoluron and pendimethalin residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern. As far as consumer health protection is concerned, FR agrees with the authorisation of the intended use(s).

According to available data, the following specific mitigation measures are recommended:

- in the event of crop failure, only plant or sow a crop on which use of pendimethalin is authorised.

Summary of the evaluation

The formulation AG-DPC1-590 SC (TRINITY) is a suspension concentrate (SC) containing 40 g diflufenican, 250 g chlorotoluron and 300 g pendimethalin per litre. Authorisation is sought for pre- or post-emergence use in barley and wheat. The intended GAP is defined as spray application at rates of up to 80 g diflufenican/ha, 600 g pendimethalin/ha, 500 g chlorotoluron/ha, and growth stages up to BBCH 21.

Use No.	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Diflufenican									
1	wheat	Yes	Yes	Yes	Yes	Yes (Reg. 603/2015)	No	No	
2	barley	Yes	Yes	Yes	Yes	Yes (Reg. 603/2015)		No	
Chlorotoluron									
1	wheat	Yes	Yes	Yes	Yes	Yes (Reg. 87/2014)	No	No	
2	barley	Yes	Yes	Yes	Yes	Yes (Reg. 87/2014)		No	
Pendimethalin									
1	wheat	Yes	Yes	Yes	Yes	Yes (SANTE 00042/2015)	No	No	
2	barley	Yes	Yes	Yes	Yes	Yes (SANTE 00042/2015)		No	

The toxicological profiles of diflufenican, chlorotoluron and pendimethalin were evaluated at EU level, which resulted in the proposal of ADIs; ARfDs were not deemed necessary.

For diflufenican, despite the fact that AG-DPC1-590 SC (TRINITY) may be applied at later growth stages than the representative use in the EU (up to BBCH 21 vs. BBCH 13), the cereal metabolism studies evaluated during the MRLs review adequately support the use of AG-DPC1-590 SC (TRINITY) up to growth stage BBCH 21. Based on these data the relevant residue of diflufenican in plants was defined as parent diflufenican (for both monitoring and risk assessment).

Primary crop metabolism of chlorotoluron and pendimethalin was sufficiently investigated to define residue for enforcement and risk assessment in the crops under consideration.

Regarding the magnitude of residues in cereals, a sufficient number of diflufenican, chlorotoluron and pendimethalin residue trials is available to support all the intended GAPs in France. These data allowed the expected residue concentrations to be estimated in the relevant plant commodities, and to confirm that no MRL exceedence will result from the intended uses.

As residues of diflufenican, chlorotoluron and pendimethalin do not exceed the trigger value of 0.1 mg/kg in treated crops, and the overall chronic exposure did not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that diflufenican and chlorotoluron residues will be present in succeeding crops. In the event of crop failure, only a crop on which pendimethalin is authorised may be sown or planted in a treated plot.

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

Confirmatory data have to be submitted and assessed by the RMS in the framework of the MRLs review of chlorotoluron to confirm these conclusions:

- Final report of the storage stability study in dry-content matrices,
- Final report of the ongoing metabolism study in lactating goat.

Information on AG-DPC1-590 SC

Crop	PHI for AG-DPC1-590 SC proposed by applicant	PHI/Withholding period* sufficiently supported for			PHI for AG-DPC1-590 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
		diflufenican	chlorotoluron	pendimethalin		
wheat	F** (BBCH 21 at the latest)	Yes	Yes	Yes	F	
barley	F** (BBCH 21 at the latest)	Yes	Yes	Yes	F	

* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

3.1.4.2 Consumer exposure

Chronic consumer exposure for the three active substances resulting from the uses proposed in the framework of this application was calculated. Based on EFSA PRIMo (rev2), chronic exposure was considered acceptable for all groups of consumers.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substances pendimethalin, diflufenican and chlorotoluron 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 pendimethalin, diflufenican and chlorotoluron 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 review or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for pendimethalin, diflufenican and chlorotoluron and their metabolites do not exceed the trigger of 0.1 µg/L. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT50 calculation, no significant contamination of the air compartment is expected for the intended uses.

Implications for labelling resulting from environmental fate assessment: None.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU reviews for the active substances and 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, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms are acceptable for the uses in winter cereals.

For aquatic organisms, the risks are acceptable when a non-sprayed vegetative buffer zone of 20 metres is applied.

A restriction for not using on artificially drained soils is required.

An acceptable risk to non-target higher plants from exposure to AG-DPC1-590 SC can be concluded when a 5-metre buffer zone is applied.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

- The efficacy of TRINITY is considered satisfactory.
- The selectivity of TRINITY is considered satisfactory. The selectivity on spelt is unknown.
- The risk of negative impact (yield, quality, processing procedure, succeeding and adjacent crops) is considered acceptable.
- The risk of resistance developing or appearing is considered low, except for *Alopecurus myosuroides*, for which it is considered moderate.

Crops	Target	Country	Application				Conclusion
			Method	Growth stage	No.	Rate per treatment	
Soft winter wheat (including spelt)	Annual weeds (dicots and grasses	FR	Sprayer	BBCH 00-07 BBCH 11-21	1	2.0 L/ha	Acceptable
Winter Barley							Acceptable

3.2 Conclusions arising from French assessment

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

No further information is required.

3.4.2 Post-authorisation data requirements

No further information is required.

3.4.3 Label amendments (see label in Appendix 2):

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

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

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché et les demandes de modification des informations déclarées du produit phytopharmaceutique ***TRINITY***

de la société	*ADAMA FRANCE SAS*
enregistrées sous le	*n°2012-2662, 2015-0344 et 2015-0497*

Vu les conclusions de l'évaluation du 23 février 2016,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Nom du produit	TRINITY
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 6/8 avenue de la Cristallerie, 92316 Sèvres CEDEX FRANCE
Formulation	Suspension concentrée (SC)
Contenant	300 g/L - pendiméthaline 250 g/L - chlortoluron 40 g/L - diflufénicanil
Numéro d'intrant	963-2012.01
Numéro d'AMM	2160208
Fonction	Herbicide
Gamme d'usages	Professionnel

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active qui arrivera à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 juillet 2017.

Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

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

A Maisons-Alfort, le - 7 AVR. 2016

Françoise WEBER
Directrice générale adjointe des produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation ne peut mettre sur le marché le produit que dans les emballages suivants:	
Emballage	**Contenance**
Bidon en polyéthylène haute densité	5 L ; 10 L

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	**Mention de danger**
Cancérogénicité, catégorie 2	H351 : Susceptible de provoquer le cancer
Toxicité pour la reproduction, catégorie 2	H361d : Susceptible de nuire au fœtus
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraine des effets néfastes à long terme
EUH208 : Contient de la pendiméthaline et de la 1.2-Benzisothiazol-3(2H)-one. Peut produire une réaction allergique. Pour les phrases P se référer à la règlementation en vigueur. Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	

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Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jour(s))	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15105913 Orge*Désherbage	**2 L/ha**	**1/an**	Pré-levée (BBCH 00 - BBCH 07) ou Post-levée précoce (BBCH 11-BBCH 21)	F (jusqu'au stade BBCH 21)	20 dont DVP 20	-	5	-
	Uniquement autorisé sur orge d'hiver.							
15105912 Blé*Désherbage	**2 L/ha**	**1/an**	Pré-levée (BBCH 00 - BBCH 07) ou Post-levée précoce (BBCH 11-BBCH 21)	F (jusqu'au stade BBCH 21)	20 dont DVP 20	-	5	-
	Uniquement autorisé sur blé tendre d'hiver et épeautre.							

DVP : Dispositif Végétalisé Permanent.

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Conditions d'emploi du produit

Stockage et utilisation du produit
Ne pas stocker à plus de 35°C.

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'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 :

• Pendant le mélange/chargement

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

• Pendant l'application - Pulvérisation vers le bas

Si application avec tracteur avec cabine

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

Si application avec tracteur sans cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• Pendant le nettoyage du matériel de pulvérisation

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

Pour le travailleur amené à entrer dans la culture après traitement porter

Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m^2) avec traitement déperlant.

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Délai de rentrée
6 heures en application de l'arrêté du 12 septembre 2006.

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

En cas d'échec de la culture, implanter uniquement une culture sur laquelle une préparation à base de pendiméthaline est autorisée.

Protection de l'environnement (milieux, faune et flore)
Protection de l'eau
- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. / Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes].

Protection de la faune
- SPe 2 : Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sols artificiellement drainés.

- SPe 3 : 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

Protection de la flore
- SPe 3 : Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

Recommandations relatives à l'étiquette du produit

Faire figurer l'information suivante sur l'étiquette :

« La préparation contenant du chlortoluron, il est recommandé d'appliquer la préparation TRINITY seulement sur des variétés tolérantes à cette substance active (sélectivité non garantie sur épeautre). »

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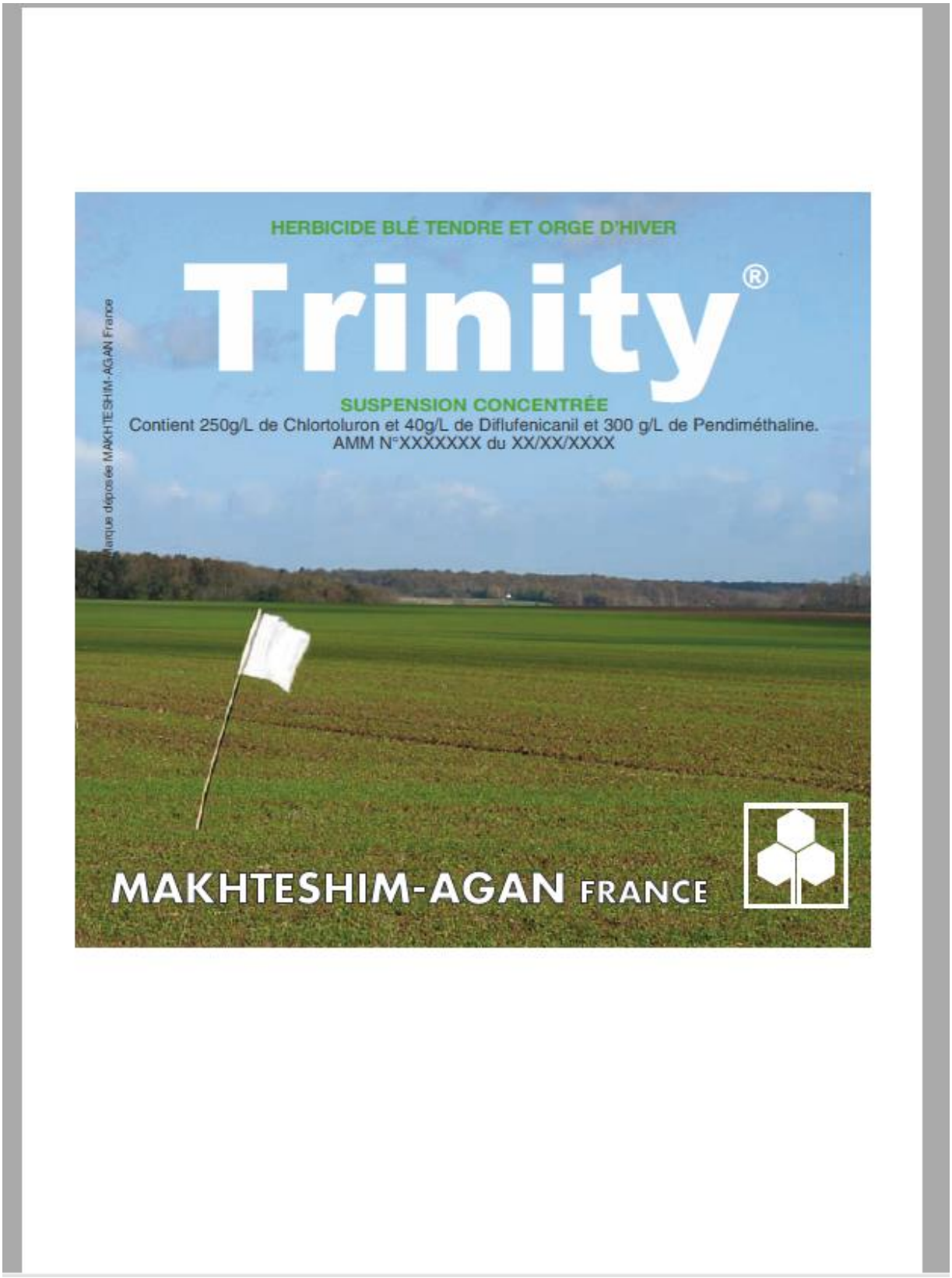
Appendix 2 – Copy of the draft product label as proposed by the applicant



MODE D'ACTION – PROPRIÉTÉS :

TRINITY® est un herbicide à large spectre utilisé en pré-levée et en post-levée précoce. Il est composé de trois matières actives complémentaires, le chlortoluron (groupe HRAC C2), le diflufénicanil (groupe HRAC F1) et la pendiméthaline (groupe HRAC K1), efficaces sur dicotylédones et graminées. Ces matières actives agissent en bloquant la germination des graines et la croissance des jeunes plantules. **TRINITY®** maîtrise ainsi les levées échelonnées.

CHAMPS D'ACTIVITÉ :

Dicotylédones	Coquelicot, lamier, fumeterre, repousses de colza, matricaire, seneçon, pensée, véroniques, capselle, anthémis, renouée, géranium, moutarde, gaillet, ravenelle
Graminées	Vulpin, pâturin, ray grass, agrostide

USAGES ET DOSES HOMOLOGUES :

Culture	Dose homologuée	Nombre d'applications	Stade d'application
Blé tendre d'hiver	2,0 L/ha	1	Pré-levée (BBCH 00-07) ou post-levée précoce (BBCH 11-21)
Orge d'hiver	2,0 L/ha	1	

Délai de rentrée des travailleurs sur la parcelle : 6 heures après traitement conformément à l'arrêté du 12 septembre 2006 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L.253-1 du code rural.

Les Limites Maximales de Résidus sont consultables à l'adresse suivante :
http://ec-europa.eu/food/plant/protection/pesticides/database_pesticide_en.htm

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels. Consulter le site : http://e-phy.agriculture.gouv.fr

PRÉCAUTIONS D'EMPLOI :

Orge d'hiver : traiter les cultures en bon état végétatif. Ne pas traiter en période de gel.

Blé tendre d'hiver : Les variétés tolérantes au chlortoluron (liste Arvalis 2011):
Accor, Accroc, **Acoustic**, Adagio, Adéquat, **Adhoc**, Aérobic, Aligator, **Allez y**, Altamira, Altigo, Ambition, Andalou, Antonius, Apache, Aprilio ,Aramis, Arche, Arezzo, Aristote, Arlequin, As de cœur, Athlon, Attitude, Aurele, Azzerti, Bagou, Barok, Bastide, Bermude ,Boisseau, Boregar, Boston, Brevent ,Buenno, Camp Rémy, Campero, Caphorn, Capvern, Caribou, CCB Ingénio ,Cézanne, Charger, Chevalier, Chevron, Claire, Compil, Copernico, Courtot, Craklin, **Croisade**, **Contrefor**, Crousty, Dialog, Dinosor, Einstein, Enesco, Ephoros, Equilibre, Espéria, Euclide, Eureka, Exelcior, Exotic, Expert, Farandole, **Farinelli**, **Figaro**, Flair, **Flamenko**, **Fluor**, ***Folklor***, Fortblanc, Galactic, Gallbier, Galopain ,Galvano, Garantus, Goncourt, Graindor, **Hybery**, Hymack, Hystar, Hysun, Hyxo, Illico, Innov, Instinct, Intérêt, **Invicta**, Iridium, Isengrain, Isidor, Istabraq, Kalystar, Korali, Lear, Levis, Limes, Manager, Marcelin, Messager, Minotor, **Musik**, Nirvana, Nuage, Nucleo, Oakley, Oratorio, Orvantis, Oxabo, Paindor, **Pakito**, Paledor, Palladio, Paroli, Pepidor, Pericles, Plainedor, Player, Prévert, PR22R20, PR22R58, Quality, Quatuor, Québon, Renan, Ressor, Richepain, Rimbaud, Rize, Rodrigo, Runal, Rustic, **Saint Ex**, Samurai Sankara, Santana, **Scenario**, Sebasto, Selekt, Seyrac, Sirtaki, SO 207, Sobbel, Sogood, Soissons, **Sokal** ,Solehio, Sophytra, Sorrial, Sublim ,Sumo , **Sweet**, Swinggy, **Sy Mattis**, Tapido, Tiago, Titlis, Toisondor, Trocadéro, **Tulip**, Uski, Valodor, Velours, Vergain, Volontaire
En gras : nouvelles variétés
Toutes autres variétés que celles citées dans ces tableaux n'ont pas fait l'objet d'expérimentation. En conséquence, il conviendra d'éviter l'emploi du chlortoluron sur ces variétés.

CONDITIONS D'EMPLOI :

Porter des gants et un vêtement de protection pendant toutes les phases d'utilisation du produit.
Le produit s'utilise en pré-levée ou en post-levée de la culture, du stade 1-2 feuilles de la céréale à début tallage.
En pré-levée : **TRINITY®** s'applique seul ou en programme à la dose de 2,0 L/ha. Appliquer **TRINITY®** sur un semis effectué à une profondeur d'au moins 2 cm et sur un sol non motteux.
- Eviter de traiter sur des sols filtrants ou humifères.
- Ne pas traiter au moment de la levée de la céréale.
- Ne pas traiter sur semis mal enterrés.

En post-levée précoce, **TRINITY®** s'applique
- Seul ou en programme à la dose de 2,0 L/ha du stade 1-2 feuilles à début tallage de la céréale. Traiter sur des dicotylédones au stade plantule. Il est possible de traiter sur sol gelé. Eviter cependant les périodes de fortes amplitudes thermiques.

CULTURES DE REMPLACEMENT ET CULTURES SUIVANTES :

En cas d'accident climatique ou de destruction parasitaire de la céréale d'hiver, les possibilités de cultures de remplacement sont les suivantes, à mettre en place après un labour :

Application avant fin novembre	Blé tendre d'hiver (variété tolérante), maïs, orge d'hiver, blé dur d'hiver, soja, sorgho, luzerne
Application entre décembre et fin janvier	Maïs, blé tendre d'hiver (variété tolérante), blé dur d'hiver, orge d'hiver, sorgho

Toutes les cultures non citées ci-dessus sont de la responsabilité de l'agriculteur.
Délai avant implantation des cultures suivantes (cultures qui sont implantées après la récolte de la culture traitée avec **TRINITY®**) :

	Sans délai	Avec un délai
CULTURE	- blé tendre d'hiver, - orge d'hiver, - blé dur d'hiver, - maïs - sorgho - pois protéagineux d'hiver et de printemps - tournesol - féverole d'hiver et de printemps - soja	- Colza : délai de 250 jours. - Betterave à sucre: délai de 300 jours. - Pomme de terre : délai de 190 jours. - blé tendre de printemps, orge de printemps : 200 jours. - lin : 200 jours - haricot : 200 jours

GESTION DU RISQUE 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 culturale que dans la rotation.

PRÉCAUTIONS GÉNÉRALES :

DANS LE CADRE DES BONNES PRATIQUES AGRICOLES :

Conditions de stockage : Conserver le produit dans son emballage d'origine, dans un local réservé à cet usage, à l'abri de la chaleur et à une température supérieure à 0°C.

Emballages vides : Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et l'éliminer via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre service de collecte spécifique.
Makhteshim Agan France est membre de la filière ADIVALOR.
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. Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Eviter 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.

PREMIERS SECOURS

Inhalation : Amener la victime à l'air libre. En cas de respiration difficile respiration artificielle. Faire appel à un médecin.
Contact avec la peau : Enlever vêtements et chaussures contaminés. Nettoyer la quantité restante avec beaucoup d'eau.
Contact avec les yeux : Rincer à l'eau abondamment, au moins 15 minutes, en maintenant la paupière bien ouverte. Consulter un médecin.
Ingestion : Rincer la bouche avec beaucoup d'eau. Ne jamais rien faire avaler par la bouche à une personne inconsciente. Faire appel à un médecin.
Mesures d'urgence : En cas d'urgence, contacter le centre antipoison le plus proche de votre domicile ou appeler le 15. Présentez aux secours la fiche de données de sécurité. Puis signalez vos symptômes au réseau Phyt'attitude : tél. 0 800 887 887 (numéro vert).

RECOMMANDATIONS : Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage et qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant votre exploitation, telles 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 vente du Ministère de l'Agriculture. Compte tenu des applications antérieures, il appartient à l'utilisateur, dans le cas où les données issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur. Makhteshim Agan ne saurait être tenu en aucun cas pour responsable des conséquences inhérentes à toute copie (totale ou partielle) de cette étiquette, à sa diffusion ou son utilisation non autorisée.

Xn Nocif

Trinity®

SC – Suspension Concentrée
Contient 250 g/L de chlortoluron (21,74%)
et 40 g/L de diflufenicanil (3,48%)
et 300 g/L de pendiméthaline (26,09%)

N-Dangereux pour l'environnement

Contient de la pendiméthaline, peut déclencher une réaction allergique.

R40 Effets cancérogènes suspectés : preuves insuffisantes.
R63 Risque possible pendant la grossesse d'effets néfastes pour l'enfant.
R50/53 Très nocif pour les organismes aquatiques, peut entraîner des effets à long terme sur l'environnement.

Délai de rentrée des travailleurs sur la parcelle : 6h après traitement.

S2 Conserver hors de portée des enfants.
S13 Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
S24 Eviter le contact avec la peau.
S35 Ne se débarrasser de ce produit et de son récipient qu'en prenant toute précaution d'usage.
S36/37 Porter un vêtement de protection et des gants appropriés.
S46 En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
S57 Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant.
S61 Eviter le rejet dans l'environnement. Consulter les instructions spéciales/ la fiche de sécurité

Respecter les instructions d'utilisations pour éviter les risques pour l'homme et l'environnement :

SP1 Ne pas polluer l'eau avec le produit ou son emballage.
SPe2 Pour protéger les organismes aquatiques, ne pas appliquer sur sols artificiellement drainés pendant la période de drainage.
SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau et prévoir un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau.
Spe3 Pour protéger la flore non cible, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

PRODUIT POUR LES PROFESSIONNELS : RESPECTER LES CONDITIONS D'EMPLOI.
Lire les instructions ci-jointes avant emploi.

La fiche de données de sécurité peut être obtenue gratuitement sur Internet www.quickfds.com ou à partir de www.ma-france.com ou en écrivant à fds@ma-france.com ou par courrier à l'adresse postale de Makhteshim Agan France.

Produit fabriqué en Israël
Responsable de l'emballage :
Agan Chemical Manufacturers Ltd.
P.O.B. 262, Northern Industrial Zone Ashdod
77102 - Israël

Homologué par :
MAKHTESHIM AGAN France
2, rue Troyon
92316 Sèvres Cedex
Tél. : 01 41 90 16 95
Fax : 01 46 42 71 17

Volume net :
10 L

Voir emballage
N° de lot et date de fabrication

Appendix 3 – Letter(s) of Access

Not applicable