REGISTRATION REPORT

Part A

Risk Management

Product code: Chlorotoluron 400 g/L + Diflufenican 25 g/L SC

Product name: TRINCO

Active substances: chlorotoluron: 400 g/L

Diflufenican: 25 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: SAPEC Agro France

Date: 2019/02/27

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PART A – Risk Management

The company SAPEC Agro S.A has requested a marketing authorisation in France for the product TRINCO (product code: Chlorotoluron 400 g/L + Diflufenican 25 g/L SC), containing 400 g/L chlorotoluron and 25 g/L diflufenican, for use as a 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 TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) have been made using endpoints agreed in the EU peer reviews of both chlorotoluron and diflufenican.

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

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 SAPEC Agro S.A's application to market TRINCO (Chlorotoluron 400 g/L + Diflufenican 25 g/L 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 first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

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.[1]
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.
There is no EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance.

[1] Approval was subsequently extended until 31/10/2018 by Commission Implementing Regulation (EU) 2017/1511 of 30 August 2017.

A Review Report is available (SANCO/4329/2000 final, 15 February 2005).

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 (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 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.
There is an EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance (EFSA Scientific Report (2007) 122). A Review Report is available (SANCO/3782/08 – rev.1, 14 March 2008)

1.3 Regulatory approach

The present application (2013-1226) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[2] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3] – the highest application rates 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 4 May 2017[4] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

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

[2] French Food Safety Agency, Afssa, before 1 July 2010
[3] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5
[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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

compliance with Regulation (EC) no 1107/2009[5], implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[6], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[7] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

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

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of TRINCO, 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

The applicant has provided a letter of access for diflufenican.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	TRINCO (Chlorotoluron 400 g/L+ Diflufenican 25 g/L SC)
Authorisation number	No autorisation granted in France
Function	Herbicide
Applicant	SAPEC Agro S.A
Composition	400 g/L chlorotoluron 25 g/L diflufenican
Formulation type (code)	Suspension concentrate (SC)
Packaging	HDPE (5 L, 10 L and 20 L)

[5] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC
[6] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products
[7] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo
[8] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards	-	
Health hazards	Skin corrosion/irritation, Category 2 Carcinogenicity, Category 2 Reproductive toxicity, 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	H315	Causes skin irritation
	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 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

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

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

N/A : no authorisation granted in France

2.2.3 Other phrases linked to the preparation

N/A : no authorisation granted in France

2.3 Product uses

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

GAP rev. , date: 2019-02-27

PPP (product name/code):	**TRINCO / Chlorotoluron 400 g/L + Diflufenican 25 g/L SC)**	Formulation type:	**SC** [a, b]
Active substance 1:	Chlorotoluron	Conc. of a.s. 1:	**400 g/L** [c]
Active substance 2:	Diflufenican	Conc. of a.s. 2:	**25 g/L** [c]
Applicant:	**SAPEC Agro S.A**	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	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 in the year of application	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	France	Winter barley	F	Annual grass and broad-leaved weeds	Directed soil spray application	BBCH 00 - 22	a)1 b)1 One application every three years	-	a) 3.75 b) 3.75	a) 1500+93.75 b) 1500+93.75	200-400	F – Applic-ation must be made at growth stage BBCH 22 at the latest	**Not acceptable** (aquatic organisms)
2	France	Soft winter wheat	F	Annual grass and broad-leaved weeds	Directed soil spray application	BBCH 00 - 22	a)1 b)1 One application every three	-	a) 3.75 b) 3.75	a) 1500+93.75 b) 1500+93.75	200-400	F – Applic-ation must be made	**Not acceptable** (aquatic organisms)

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 in the year of application	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
							years					at growth stage BBCH 22 at the latest	

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 RISK MANAGEMENT

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

3.1.1 Physical and chemical properties

TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) is a suspension concentrate (SC). 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 a white liquid, without odour. It is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature of 420 °C. In aqueous solution (1 %), it has a pH value of 9 at 25 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substances' content nor the technical properties were changed (except for a decrease in pH value, because of the sensitivity to light of chlorotoluron). The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a SC formulation.

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

The formulation must be stored away from direct sunlight.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of the active substances in the formulation is available and validated. As the active substances diflufenican and chlorotoluron do not contain relevant impurities, no pertinent analytical method is required.

3.1.2.2 Analytical methods for residues

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

Analytical methods are available in the DAR/this dossier and validated for the determination of residues of chlorotoluron in plants, foodstuffs of animal origin, soil, water (surface and drinking) and air.

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

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active substance: chlorotoluron</td></tr>
<tr><td>ADI</td><td colspan="2">0.04 mg/kg bw/d</td><td rowspan="3">EU (2006)</td></tr>
<tr><td>ARfD</td><td colspan="2">Not applicable</td></tr>
<tr><td>AOEL</td><td colspan="2">0.215 mg/kg bw/d</td></tr>
<tr><td rowspan="2">Dermal absorption</td><td colspan="3">Based on default values according to guidance on dermal absorption (Efsa 2012):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
400 g/L</td><td>Spray dilution
(used in formulation)
3.75 g/L</td></tr>
</table>

	Dermal absorption endpoints %	**25**	**75**

Active substance: **diflufenican**			
ADI	0.2 mg/kg bw/d		EU (2009)
ARfD	Not applicable		
AOEL	0.11 mg/kg bw/d		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 25 g/L	Spray dilution (used in formulation) 0.2344 g/L
	Dermal absorption endpoints %	**75**	**75**

3.1.3.1 Acute Toxicity

TRINCO, containing 400 g/L chlorotoluron and 25 g/L diflufenican has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit eye and is not a skin sensitiser. However, classification for skin irritation is applied.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G[9]	Equipment	Application rate L product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Winter barley Soft winter wheat	F	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	3.75 L/ha (chlorotoluron: 1500 g a.s./ha; diflufenican: 93.75 g a.s./ha)	200-400	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL Chlorotoluron	% AOEL Diflufenican
Winter barley Soft winter wheat	Tractor-mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	50.9	9.1

According to the model calculations, it may be concluded that the risk for the operator using TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

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

[9] Open field or glasshouse

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 3.7 % of the AOEL of chlorotoluron and 0.5 % of the AOEL of diflufenican.

It may be concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to TRINCO.

3.1.3.4 Worker Exposure

TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) is used as herbicidal treatment on crops where there is no need to re-enter the treated area after application. Calculation of worker exposure is considered to be not necessary.

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

3.1.3.5 Resident Exposure

Residential exposure was assessed according to the Martin *et al* approach. Exposure is estimated to be 0.18 % of the AOEL of chlorotoluron for adults and 0.28 % of the AOEL of chlorotoluron for children. Exposure is estimated to be 0.02 % of the AOEL of diflufenican for adults and 0.03 % of the AOEL of diflufenican for children. It may be concluded that there is no unacceptable risk to the resident exposed to TRINCO.

Based on the currently available data (2001-2006) in the report of the ORP (French pesticides residues observatory), the respiratory exposure of people living near sprayed areas was estimated as follows:

Chlorotoluron:

		% ADI	% AOEL
Maximum daily measurement (5.15 ng/m³)	Adult	0.005	0.001
	Child	0.007	0.001
Maximum weekly measurement (0.02 ng/m³)	Adult	0.00002	0.000004
	Child	0.00003	0.000005

3.1.4 Residues and Consumer Exposure

Overall conclusion

The data available are considered sufficient for risk assessment. Any exceedence of the current MRLs for wheat and barley for diflufenican and chlorotoluron as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and short-term intakes of diflufenican and chlorotoluron 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, France agrees with the authorisation of the intended uses.

Data gaps: none.

Data required post-authorisation: none.

Summary of the evaluation

TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) is a suspension concentrate (SC) formulation containing 25 g diflufenican and 400 g chlorotoluron per litre. TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) is intended for pre- or post-emergence use in barley and wheat. The intended GAP is defined as spray application at rates up to 93.75 g diflufenican/ha and 1500 g chlorotoluron/ha, and growth stages up to BBCH 22.

Summary for diflufenican and chlorotoluron

Table 1: Summary for diflufenican

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 603/2015	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Wheat	Yes	Yes	Yes	Yes	Yes	No	No	
Barley	Yes	Yes	Yes	Yes	Yes		No	

Table 2: Summary for chlorotoluron

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 87/2014	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Wheat	Yes	Yes	Yes	Yes	Yes	No	No	
Barley	Yes	Yes	Yes	Yes	Yes		No	

The toxicological profiles of the active substances were evaluated at EU level, which resulted in the proposal of an ADI and that an ARfD was not deemed necessary.

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

As residues of the active substances 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 residues will be present in them.

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

Chronic consumer exposure 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.

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

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

Summary for TRINCO

Table 3: Information on TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC)

Crop	PHI for TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) requested by applicant	PHI/withholding period* sufficiently supported for		PHI for TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		diflufenican	chlorotoluron		
Wheat	F** (until BBCH 22)	Yes	Yes	F – Application must be made at growth stage BBCH 22 at the latest	
Barley	F** (until BBCH 22)	Yes	Yes	F – Application must be made at growth stage BBCH 22 at the latest	

* 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

3.1.5 Environmental fate and behaviour

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

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

PECgw values for diflufenican, chlorotoluron and their metabolites do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater so long as the product is applied every third year. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses when the product is applied every third year.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

3.1.6.1 Birds

For diflufenican, the TER values calculated for recommended scenarios exceed the trigger values of 10 for acute risk and 5 for long-term risk at the screening step, indicating an acceptable risk for this active substance.

For acute exposure of birds to chlorotoluron, a risk is indicated at tier 1; a refined risk assessment was therefore conducted. Based on refined residue data, the TER values are above the trigger of 5, indicating an acceptable acute risk. For chronic exposure, exposure will not occur during the reproductive season for birds (BBCH 00-21) and since endocrine-disrupting properties do not seem to be indicated for the chlorotoluron, the risk can be considered acceptable.

For diflufenican (log Pow > 3), a risk assessment for fish-eating and earthworm-eating birds was conducted and long-term TER values are above the trigger of 5. The risks due to bioaccumulation of diflufenican via the food chain for birds are thus acceptable.

The risks for the puddle scenario of the drinking water are considered acceptable.

Therefore treatment with Chlorotoluron 400 g/L + Diflufenican 25 g/L SC in accordance with the proposed use patterns in winter cereals poses an acceptable risk to birds.

3.1.6.2 Mammals

For the two active substances, the TER values calculated for recommended scenarios exceed the trigger values of 10 for acute risk and 5 for long-term risk at the screening/tier 1 step, indicating acceptable risk following the use of the product.

For diflufenican (log Pow = 4.2), a risk assessment for fish-eating and earthworm-eating mammals was conducted and long-term TER values are above the trigger of 5. The risks due to bioaccumulation of diflufenican via the food chain for mammals are acceptable.

The risks for the puddle scenario of the drinking water are considered acceptable.

Therefore treatment with Chlorotoluron 400 g/L + Diflufenican 25 g/L SC in accordance with the proposed use patterns in cereals poses an acceptable risk to mammals.

3.1.6.3 Aquatic organisms

Toxicity studies were conducted with the formulation and indicate that it is not more toxic than predicted from data available on the active substances.

For diflufenican, the most sensitive organism is algae. Based on the EU refinement approach, the risk to aquatic non-target organisms is acceptable when a non-sprayed planted buffer zone of 20 m is applied. A restriction to not using on artificially drained soil is required (scenarios D2 and D6 are concerned).

For chlorotoluron, the most sensitive organisms are algae and aquatic plants. Based on the standard laboratory endpoints, most TER values are below the trigger of 10 based on Step 4 PEC calculations, and considering a non-sprayed planted buffer zone of 20 m. The margin between the TER values and the trigger is too high to use the recovery studies in a weight-of-evidence approach.

Since no higher-tier studies such as mesocosms are available, an acceptable risk cannot be concluded for chlorotoluron.

3.1.6.4 Honey bees

Overall, the calculated HQ values for the active substances and the product are less than 50. The risk for honeybees is thus considered acceptable when Chlorotoluron 400 g/L + Diflufenican 25 g/L SC is applied as intended.

3.1.6.5 Terrestrial non-target arthropods

The in-field HQ values calculated for *Typhlodromus pyri* and *Aphidius rhopalosiphi* are below the trigger value of 1, indicating that Chlorotoluron 400 g/L + Diflufenican 25 g/L SC poses no unacceptable risk to in-field non-target arthropods following application as intended.

On this basis, no off-field assessment is required and no risk mitigation measures are necessary to protect off-field areas.

3.1.6.6 Earthworms and other soil non-target macro-organisms

The acute TER for the active substances, their metabolites and the formulation are above the trigger value of 10, indicating that the acute risks to earthworms following treatment with Chlorotoluron 400 g/L + Diflufenican 25 g/L SC are acceptable.

The long-term TER values are above the trigger value of 5 for diflufenican but below the trigger for the formulation. However, the NOEC of 40 mg/kg soil (corrected: 20 mg/kg soil) is the highest tested concentration in the study and no significant sub-lethal effects were observed at any tested concentrations (no dose-dependent effects). In addition, diflufenican has a low chronic toxicity to earthworms. Therefore, the long-term risk can be considered acceptable for the formulation.

3.1.6.7 Non-target soil micro-organisms

The studies showed no effects on soil nitrification and respiration due to the two active substances and their metabolites applied at application rates higher than the maximum PEC soil value. Therefore it may be concluded that the risks to micro-organism populations are acceptable for the intended uses.

3.1.6.8 Terrestrial non-target plants

Based on a probabilistic risk assessment taking into account the most sensitive endpoints from 10 species tested in the vegetative vigour study, the risk for non-target terrestrial plants is considered acceptable if a 20 m buffer zone is applied.

3.1.7 Efficacy

This conclusion concerns the preparation TRINCO, containing 400 g/L chlorotoluron and 25 g/L diflufenican. These active substances are already approved in Europe and used in France as herbicides in early crop growth stages of cereals crops. France is zRMS for this dossier. No CMSs have been designated.

Considering the data submitted:

The efficacy of TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) is considered satisfactory.
The level of phytotoxicity of TRINCO (CHLOROTOLURON 400 G/L + DIFLUFENICAN 25 G/L SC) is considered acceptable.
The risk of negative impact (on yield, quality, transformation processes, propagation, succeeding and adjacent crops) is considered acceptable.
The risk of resistance developing or appearing exists. Recommendations from the applicant limiting the risk are considered satisfactory. No monitoring is necessary for these uses.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation cannot be granted (due to risk to aquatic organisms – plants and algae)**. A copy of the Decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

3.4 N/A no authorisation granted in France 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

N/A no authorisation granted in France

3.4.2 Label amendments

N/A no authorisation granted in France

Appendix 1 – Copy of the French Decision

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agence nationale de sécurité sanitaire alimentation, environnement, travail

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 la demande associée du produit phytopharmaceutique ***TRINCO***

de la société *SAPEC AGRO France*

enregistrées sous les *n°2013-1226 et 2016-1311*

Vu les conclusions de l'évaluation de l'Anses du 19 décembre 2018,

Considérant que les niveaux d'exposition estimés pour les espèces non cibles aquatiques dû à la l'utilisation du produit sont supérieurs aux valeurs toxicologiques de référence pour les algues et les plantes aquatiques pour le chlorotoluron,

Considérant les risques d'effets inacceptables pour les algues et les plantes aquatiques,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

TRINCO
AMM n°-

Page 1 sur 3

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Informations générales sur le produit	
Nom du produit	TRINCO
Type de produit	Produit de référence
Titulaire	SAPEC AGRO France 2/12 Chemin des Femmes Immeuble l'Odyssée -Bâtiment A-3ème étage 91300 MASSY France
Formulation	Suspension concentrée (SC)
Contenant	400 g/L - chlorotoluron 25 g/L - diflufénicanil
Numéro d'intrant	9879-2013.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 27 FEV. 2019

Françoise WEBER
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés			
Usages	**Dose d'emploi**	**Nombre maximum d'applications**	**Délai avant récolte (jours)**
15105912 Blé*Désherbage	3,75 L/ha	1/an	-
	Motivation du refus : L'usage sur blé tendre d'hiver est refusé en raison d'un risque d'effet inacceptable pour les algues et les plantes aquatiques.		
15105913 Orge*Désherbage	3,75 L/ha	1/an	-
	Motivation du refus : L'usage sur orge d'hiver est refusé en raison d'un risque d'effet inacceptable pour les algues et les plantes aquatiques.		

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

TRINCO®

Suspension Concentrée (SC)

contenant 400 g/l de chlortoluron + 25 g/l de diflufénicanil

Fongicide Liquide Vigne et Tomate

Autorisation de Mise sur le Marché n° XXXXXX

« RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL »

Homologué par:

SAPEC AGRO S.A.

Avenida do Rio Tejo - Herdade das Praias

2910-440 SETÚBAL - PORTUGAL

Tel: +351 265710100

Lot N°.....

Date de fabrication :

TRINCO®
Suspension Concentrée contenant 400 g/l de chlortoluron + 25 g/l de diflufénicanil
AMM n° XXXXXX

H315	**Provoque une irritation cutanée.**
H351	**Susceptible de provoquer le cancer.**
H361d	**Susceptible de nuire au fœtus.**
H400	**Très toxique pour les organismes aquatiques.**

P102	Tenir hors de portée des enfants.
P270	Ne pas manger, boire ou fumer en manipulant le produit.
P273 + 391	Éviter le rejet dans l'environnement.
P280	Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.
P301 + 315	EN CAS d'ingestion : appeler immédiatement un CENTRE ANTIPOISON ou un médecin.
P308 + P313	EN CAS d'exposition prouvée ou suspectée : consulter un médecin.
P405	Garder sous clef.
P501	Éliminer le contenu/récipient conformément à la réglementation nationale.

Conditions d'emploi
Respectez les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.
- Délai de rentrée des travailleurs sur la parcelle: 24 heures après traitement.
- SP1- 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.
- SPe2 : Pour protéger les organismes aquatiques, ne pas appliquer sur sols drainés.
- SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 10 mètres selon les usages par rapport aux points d'eau (voir tableau des usages).

Distributeur :

La fiche de données de sécurité est disponible sur demande chez votre fournisseur de produits phytopharmaceutiques et elle est également téléchargeable et imprimable à partir des sites www.sapecagro.fr et www.quickfds.com.

En cas d'urgence **appelez le n° 15 ou le Centre Anti-poison** (Paris : 01 40 05 48 48) puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Fabriqué au PORTUGAL **Contenu : XX L e**

TRINCO® -Marque déposée par SAPEC AGRO
SAPEC AGRO, S.A. Avenida do Rio Tejo - Herdade das Praias, 2910-440 Setúbal – Portugal

TRINCO
Chlortoluron 400 g/l + Diflufénicanil 25 g/l

PRESENTATION ET MODE D'ACTION

TRINCO est un herbicide développé pour le contrôle des adventices annuelles ; il possède :

- une forte action sur un large spectre de dicotylédones et graminées annuelles,
- une longue persistance d'action pour un désherbage efficace,
- une flexibilité d'utilisation, avec un traitement en pré-émergence ou post-émergence précoce,
- une sélectivité :
  - Sur l'orge d'hiver,
  - Sur les blés tendres d'hiver tolérants au chlortoluron (voir liste ci-après).

VARIETES TOLERANTES

Accor	Bastide	Enesco	Hyxo	Paledor	Seyrac
Accroc	Bermude	Ephoros	Innov	Palladio	Sirtaki
Acoustic	Boisseau	Equilibre	Instinct	Paroli	SO 207
Adagio	Boregar	Espéria	Intérêt	Pepidor	Sobbel
Adéquat	Boston	Euclide	Invicta	Pericles	Sogood
Adhoc	Brevent	Eureka	Iridium	Plainedor	Soissons
Aérobic	Buenno	Exelcior	Isengrain	Player	Sokal
Aligator	Camp Rémy	Exotic	Isidor	Prévert	Solehio
Allez y	Campero	Expert	Istabraq	PR22R20	Sophytra
Altamira	Caphorn	Farandole	kalystar	PR22R58	Sorrial
Altigo	Capvern	Farinelli	Koreli	Quality	Sublim
Ambition	Caribou	Figaro	Lear	Quatuor	Sumo
Andalou	CCB Ingénio	Flair	Levis	Québon	Sweet
Antonius	Cézanne	Flamenko	Limes	Renan	Swinggy
Apache	Charger	Fluor	Manager	Ressor	Sy Mattis
Aprilio	Chevalier	Folklor	Marcelin	Richepain	Tapidor
Aramis	Chevron	Forblanc	Messager	Rimbaud	Tiago
Arche	Claire	Galactic	Minotor	Rize	Titlis
Arezzo	Compil	Galibier	Musik	Rodrigo	Toisondor
Aristote	Copernico	Galopain	Nirvana	Runal	Trocadéro
Arlequin	Courtot	Galvano	Nuage	Rustic	Tulip
As de coeur	Craklin	Garantus	Nucleo	Saint Ex	Uski
Athlon	Croisade	Goncourt	Oakley	Samurai	Valodor
Attitude	Contrefor	Graindor	Oratorio	Sankara	Velours
Aurele	Crousty	Hybery	Orvantis	Santana	Vergain
Azzerti	Dialog	Hymack	Oxebo	Scenario	Volontaire
Bagou	Dinosor	Hystar	Paindor	Sebasto	
Barok	Einstein	Hysun	Pakito	Selekt	

TRINCO est un herbicide qui agit par systémie, résiduel, il permet de lutter contre de nombreuses dicotylédones adventices de l'orge et du blé.

Le chlortoluron est un herbicide de pré-levée utilisé sur les céréales d'hiver qui appartient à la famille chimique des urées substituées. Il s'agit d'une molécule mobile dans la plante qui est absorbée et véhiculée dans toute l'adventice. Le chlortoluron agit contre la plupart des adventices dicotylédones en inhibant la photosynthèse et perturbant le phénomène de respiration, causant un épuisement des réserves en glucides et entrainant une nécrose de la plante.

Le diflufénicanil est un herbicide foliaire de contact et résiduel qui appartient à la famille des carboxamides. Son action biochimique lui confère un pouvoir de sélection, permettant ainsi le contrôle des graminées annuelles et dicotylédones et pré ou post-levée. Le diflufénicanil agit par inhibition de l'enzyme phytoène désaturase, nécessaire à la synthèse des caroténoïdes (pigments protecteurs de la chlorophylle), responsables de la coloration des plantes, et cause ainsi la nécrose des graminées annuelles et des dicotylédones.

USAGES, DOSES, SPECIFICATIONS D'USAGE, DELAI AVANT RECOLTE (DAR), ZONE NON TRAITEE (ZNT).

Culture	Cibles & Usages	Dose (L/ha)	Nombre d'applications	DAR (jours)	ZNT (en m)	Délai réentrée (heures)
Blé tendre d'hiver	Désherbage graminées et dicotylédones	4,5 L/HA	1	-	10	24
Orge d'hiver	Désherbage graminées et dicotylédones	4,5 L/HA	1	-	10	

Les limites maximales de résidus sont disponibles sur le site : http://ec.europa.eu/sanco_pesticides/public/index.cfm

RECOMMANDATION D'UTILISATION

BLE D'HIVER et ORGE D'HIVER

TRINCO s'utilise sur des cultures en bon état végétatif et en pleine croissance ; La lutte sera d'autant plus efficace que les adventices seront jeunes.

TRINCO doit être appliqué avec des conditions météorologiques adéquates, à savoir un vent inférieur à 19 km/h et une absence de gel.

Le traitement avec TRINCO ne doit être réalisé qu'une seule fois par campagne agricole, en incluant tous les herbicides assimilés et en respectant les conditions suivantes:

- Traiter du stade BBCH00 au stade BBCH22,
- Ne pas dépasser 4,5 L/HA,
- Ne pas utiliser TRINCO à plus de 1800 g ma/ha,
- Ne pas traiter en période d'écoulement des drains,
- Ne pas traiter en fin d'automne ou avec des températures basses, pour éviter la gelée,
- Ne pas appliquer au stade pointant de la céréale,
- Diminuer la dose à 3,5 voire 4 L/HA dans le cas de sols sableux ou argileux-sablonneux,
- Dans les sols très lourds ou sur mauvaises herbes développées, raisonner la destruction des adventices dans le cadre de programmes et augmenter la dose sans dépasser 4,5 L/HA.

Volume de bouille préconisé par hectare :
- pulvérisateur : 150 – 300 L/HA

TRINCO étant actif par contact, il est indispensable de soigner la pulvérisation par une application homogène.

D'une manière générale, pour déclencher tout traitement, il est conseillé de consulter son technicien habituel, de se conformer aux avis issus des organismes de prescription officiels et de baser sa décision sur les observations localisées de la pression parasitaire sur les cultures.

PREPARATION DE LA BOUILLE

TRINCO® s'utilise en pulvérisation après dilution dans l'eau. Remplir la cuve au 3/4 du volume d'eau nécessaire. Mettre l'agitation en marche et bien agiter le bidon de TRINCO avant de verser progressivement la quantité nécessaire, puis compléter avec de l'eau jusqu'au volume final.
Dans le cadre des bonnes pratiques agricoles, rincer trois fois les emballages à l'eau claire et verser l'eau de rinçage dans la cuve du pulvérisateur.
Laisser l'agitateur en fonctionnement pendant le trajet et jusqu'à la fin de la pulvérisation.
Utiliser un volume d'eau de 100 à 300 l/ha selon la culture, son stade et le matériel de traitement utilisé.

Protection de l'utilisateur lors de la préparation de la bouillie : Gants en nitrile ou néoprène (EN 374), lunettes de sécurité (en résine polymérisée ou en acétate EN 166, sigle3), masque avec filtre A2P3 (EN 166, EN 141 et EN 143), bottes de protection marquage S5 ou P5, combinaisons de protection contre les risques chimiques de catégorie III type 4 et tablier catégorie III type 3.

APPLICATION
Pour une bonne réussite de l'emploi de TRINCO® veiller à réduire de façon optimale ou Bien enfouir les résidus de la culture précédente. L'efficacité du produit sera favorisée par un lit de semis assez fin et humide, et des précipitations suivant l'application.

CONDITIONS D'EMPLOI

COMPATIBILITÉ
Egalement pour tout mélange autorisé, il est préférable de tester la compatibilité physique des produits.

PHYTOTOXICITE
TRINCO peut seulement être appliqué sur des variétés tolérantes du chlorotoluron pour éviter des impacts possibles sur la qualité des cultures et leur rendement.

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

PRECAUTIONS D'EMPLOI

- Stockage :
  - Conserver le produit sous clé, dans son emballage d'origine, dans un endroit frais, à l'abri de l'humidité et à l'écart des aliments et boissons, y compris ceux des animaux.
  - Vérifier sur l'emballage les températures de stockage adaptées au produit.
  - Conserver hors de la portée des enfants.

- Application :
  - Porter un vêtement de protection et des gants appropriés.
  - Ne pas traiter les cours d'eau et fossés en eau. Appliquer la bouillie dans les cultures par temps calme, sans vent fort, pour éviter toute dérive de pulvérisation vers les fossés, cours d'eau, chemins, abords de ferme ou bâtiments.

- Nettoyer très soigneusement et rincer les pulvérisateurs aussitôt après le traitement.
- Appliquer, après dilution, les fonds de cuve conformément à la législation en vigueur.
- Changer de vêtements et se rincer les mains et le visage à l'eau savonneuse immédiatement après l'utilisation.

- Emballage :
  - Réemploi de l'emballage interdit ; rincer soigneusement trois fois le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur, ou dans la cuve de rinçage pour l'injection directe.
  - Éliminer les emballages vides *via* une collecte organisée par un service de collecte spécifique (ADIVALOR).
  - Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Important
Respecter les usages, doses, conditions et précautions d'emploi mentionnées sur l'emballage. Elles ont été déterminées en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé.

Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces…

Le fabricant garantit la qualité 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 de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

Appendix 3 – Letter(s) of Access

Available on request