REGISTRATION REPORT

Part A

Risk Management

Product code: FSG 01095 H

Product name(s): TORNADO COMBI

Chemical active substance(s):

Metamitron, 350g/L
Ethofumesate, 150g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: ADAMA France S.A.S

Date: 06/12/2019

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PART A
RISK MANAGEMENT

1 Details of the application

The company ADAMA France S.A.S has requested a marketing authorisation in France for the product TORNADO COMBI (product code: FSG 01095 H), containing 350g/L metamitron[1] and 150g/L ethofumesate[2] as an herbicide for professional uses.

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

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

Appendix 3 of this document deals with Letter of Access

1.1 Application background

The present registration report concerns the evaluation of ADAMA France S.A.S's application submitted on 04/04/2017 to market TORNADO COMBI (FSG 01095 H) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the label extension of this product in France and in other MSs of the Southern zone.

The present application (2017-1023) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[3], the implementing regulations, and French regulations. This application was assessed 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")[4]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European Union level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of TORNADO COMBI (FSG 01095 H) have been made using endpoints agreed in the EU peer reviews of metamitron and ethofumesate. It also includes assessment of data and information related to PRODUCT NAME where those data have not been considered in the EU peer review process.

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

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU)

[1] Commission implementing regulation (EU) n° 540/2011 of 25 Mai 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.

[2] Commission implementing regulation (EU) n° 2016/1426 of 25 August 2016 renewing the approval of the active substance ethofumesate in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to commission Implementing Regulation (EU) No 540/2011.

[3] 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.

[4] 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.

No 546/2011[5], and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of TORNADO COMBI (FSG 01095 H).

1.2 Letters of Access

The applicant has provided letters of access for active substance and PPP data. These letters of access are available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « All studies and data provided with this application are requested by current guidelines for amendment of authorization of a plant protection product (here: FSG 01095 H) in EU countries ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of TORNADO COMBI (FSG 01095 H), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	FSG 01095 H
Product name in MS	TORNADO COMBI
Authorisation number	2000046
Kind of use	Professional use
Low risk (article 47)	No
Function	Herbicide
Applicant	ADAMA France S.A.S
Active substance(s) (incl. content)	Metamitron, 350g/L Ethofumesate, 150g/L
Formulation type	Suspension concentrate (SC)
Packaging	Packaging not changed
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

[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.

2.2 Conclusion

The evaluation of the application for TORNADO COMBI (FSG 01095 H) resulted in the decision **to grant** the authorization.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

Classification not changed.

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

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads..
	For other restrictions refer to 2.5

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4th May 2017 [6] provides that:

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

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

Finally, the French Order of 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.

[6] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte.

[7] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo.

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

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:
The applicant is required to comply with the current applicable standard for clothing type PPE (ISO EN 27065)[9].

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details
Bystander and resident protection	
	Respect an unsprayed zone of 5 meters from the extremity of the boom and areas where bystanders or residents could be present. At least 50% drift reduction noozles should be used.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres with a 5-metres permanent planted buffer strip to surface water bodies on the basis of a maximum rate application of 6 L/ha/crop/season.
Other specific restrictions	
-	Beet tops should not be fed after thinning or crop failure.
	Do not grow root vegetables in case of crop failure.
Re-entry period	6 hours.

2.5.2 Specific restrictions linked to the intended uses

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

None.

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

[9] Protective clothing – Performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers. EN ISO 27065:2017.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

GAP rev. 1, date: 2019-12-06

PPP (product name/code):	TORNADO COMBI / FSG 01095 H	Formulation type:	SC [a, b]
Active substance 1:	metamitron	Conc. of as 1:	350g/L [c]
Active substance 2:	ethofumesate	Conc. of as 2:	150g/L [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [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	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Sugar beet	F	Weeds (annual grasses and annual dicots)	Field sprayer	BBCH 00-07	a) 1 b) 6 (in total, pre + post emergence)	6	a) 3 L/ha b) 6 L/ha	a) 1050 g/ha metamitron 450 g/ha ethofumesate b) 2100 g/ha metamitron 900 g/ha ethofumesate	100 / 400	F	**Acceptable** scenario 1: application every 3 years, treatment in pre and post emergence programs, max 6 L/ha/season
	FR	Sugar beet	F	Weeds (annual grasses and annual dicots)	Field sprayer	BBCH 10-37	a) 5 b) 6 (in total,	6	a) 1.5 L/ha b) 6 L/ha	a) 525 g/ha metamitron	100 / 400	F	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
							pre + post emergence)			225 g/ha ethofumesate b) 2100 g/ha metamitron 900 g/ha ethofumesate			
2	FR	Sugar beet	F	Weeds (annual grasses and annual dicots)	Field sprayer	BBCH 10-37	a) 5 b) 5	6	a) 2 L/ha b) 6 L/ha	a) 700 g/ha metamitron 300 g/ha ethofumesate b) 2100 g/ha metamitron 900 g/ha ethofumesate	100 / 400	F	**Acceptable** Scenario 2 : application every 3 years, 3 to 5 treatments only in post emergence, max 6 L/ha/season

Remarks table heading:

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

Remarks columns:

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

3 Background of authorisation decision and risk management

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

The physico-chemical properties of the formulation have been evaluated taken into account the concentration of uses (concentration from 0.275% to 1.1% v/v) and considered acceptable during the registration of this formulation.

The concentrations of uses claimed for this extension of uses (concentration from 0.375% to 3% v/v) are not covered by this previously assessment.

The physico-chemical properties provided in the dossier of extension of uses have been evaluated and considered acceptable.

3.2 Efficacy (Part B, Section 3)

The applicant provided preliminary data to support the association, minimum dose justification data, efficacy data and practical value trials, all trials were conducted pre- and post-emergence on a large number of weeds.

Considering the data submitted:

- the efficacy level of TORNADO COMBI (FSG 01095 H) is considered as satisfactory for the claimed use.
- the selectivity level of TORNADO COMBI (FSG 01095 H) is considered as satisfactory for the claimed use.
- the risks of negative impact on yield, quality, transformation processes, propagation and adjacent crops are considered as negligible.
- the risk of negative impact on succeeding crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.
- the risk of resistance development or appearance to ethofumesate and metamitron does not require a monitoring for the claimed use.

3.3 Methods of analysis (Part B, Section 5)

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

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: **Metamitron**					
ADI	0.03 mg/kg body weight/day				EU (2009)
ARfD	0.1 mg/kg body weight				
AOEL	0.036 mg/kg body weight/day				
Dermal absorption	Based on an *in vitro* human study performed on formulation according to guidance on dermal absorption (EFSA 2012):				
		Concentrate (tested) 350 g/L	Diluted formulation (tested) 0.875 g/L		
	In vitro (human) %	0.2%	24%		
		Concentrate (used in formulation) 350g/L	Spray dilution 1 (used in formulation) 2.62g/L	Spray dilution 2 (used in formulation) 1.31g/L	Spray dilution 3 (used in formulation) 1.75g/L
	Dermal absorption endpoints %	**0.2%**	**24%**		

Active Substance: **Ethofumesate**					
ADI	1.0 mg/kg body weight/day				EU (2016)
ARfD	Not applicable				
AOEL	2.5 mg/kg body weight/day				
Dermal absorption	Based on an *in vitro* human study performed on the formulation according to guidance on dermal absorption (Efsa 2012):				
		Concentrate (tested) 150g/L	Diluted formulation (tested) 0.375g/L		
	In vitro (human) %	0.1%	11%		
		Concentrate (used in formulation) 150g/L	Spray dilution 1 (used in formulation) 1.125g/L	Spray dilution 2 (used in formulation) 0.562g/L	Spray dilution3 (used in formulation) 0.75g/L
	Dermal absorption endpoints %	**0.1%**	**11%**		

3.4.1 Acute toxicity

TORNADO COMBI (FSG 01095 H) containing 350g/L metamitron and 150g/L ethofumesate has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitizer.

3.4.2 Operator exposure

Summary of use patterns:

Crop	F/G	Equipment	Application rate kg/L product/ha (g as/ha) M: Metamitron E: Ethofumesate	Spray dilution (L/ha)	Model
Sugar beet	F	Vehicle mounted *Downward spraying with drift reducing nozzles*	**3 L/ha** M: 0.385 kg/ha E: 0.165 kg/ha	100-400	EFSA[10]
	F	Vehicle mounted *Downward spraying with drift reducing nozzles*	**1.5 L/ha** M: 0.525 kg/ha E: 0.225 kg/ha	100-400	EFSA
	F	Vehicle mounted *Downward spraying with drift reducing nozzles*	**2 L/ha** M: 0.7 kg/ha E: 0.3 kg/ha	100-400	EFSA

Considering proposed uses, operator systemic exposure was estimated using the EFSA model.

The table below corresponds to the use sugar beet, with an application rate of **3 L/ha (worst-case for operator exposure**):

Crop	Equipment	PPE and/or working coverall	% AOEL metamitron	% AOEL ethofumesate
Sugar beet	LCTM (downward spraying)	Without PPE	100.9	0.30
		Working coverall and gloves during mixing/loading and application	8.9	0.04
	LCTM (downward spraying drift **reducing nozzles**)	Without PPE	48	0.15
		Working coverall and gloves during mixing/loading and application	2.2	0.01

According to the model calculations, it can be concluded that the risk for the operator using TORNADO COMBI (FSG 01095 H) is acceptable.

[10] EFSA Journal 2014;12(10):3874.

3.4.3 Worker exposure

EFSA model: Workers may have to enter treated areas after treatment for crop inspection activities. Therefore, estimation of worker exposure was calculated according to EFSA model. Exposure is estimated to 66% of the AOEL of metamitron (with a DFR for metamitron (3 µg/cm²/kg a.s./ha) and a refined foliar DT50=1 day) and 0.5% of the AOEL of ethofumesate. It is concluded that there is no unacceptable risk anticipated for the worker.

3.4.4 Bystander exposure

EFSA model (w/o AAOEL): Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[11].

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

3.4.5 Resident exposure

Use 1: Beetroots, 1 application at 3 L/ha

At the time of application (pre-emergence application), the field is free of any crop or weed. Thus, no contact with treated leaf surface is expected. Applicant's approach consists in using the Appendix F to refine « Re-entry » parameter of the EFSA[11] model calculation. The detailed calculation is provided in the registration report Part B section 6. Considering this refinement, the conclusion is the following:

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) when drift reduction technology and a buffer zone of 3 meters are taken to reduce the resident exposure.

Model (AOEM) - All pathways (mean)	**% AOEL metamitron**
Resident (children)	~~**127**~~ **60**

		Metamitron		**Ethofumesate**	
ZNT : 2-3 meters With drift reduction technology	DT_{50} (days)	1		30	
	DFR (µg/cm²/kg a.s./ha)	3		3	
	Application rate (kg a.s./ha)	1.05		0.45	
	Pathways (percentile)	Total absorbed dose (mg/kg	% AOEL	Total absorbed dose (mg/kg bw/day)	% AOEL

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

		bw/day)			
Resident child Body weight: 10 kg	Drift (75th perc.)	0,0339	94,17%	0,0067	0,27%
	Vapour (75th	0,0011	2,97%	0,0011	0,04%
	Deposits (75th)	0,0023	6,28%	0,0005	0,02%
	Re-entry (75th)	0,00007*	<1%*	0,0084	0,33%
	Sum (mean)		60%		0,47%
Resident adult Body weight: 60 kg	Drift (75th)	0,0081	22,51%	0,0016	0,06%
	Vapour (75th)	0,0002	0,64%	0,0002	0,01%
	Deposits (75th)	0,0009	2,38%	0,0002	0,01%
	Re-entry (75th)	0,0236	65,63%	0,0046	0,19%
	Sum (mean)		65,41%		0,19%

**calculated according to Appendix F*

Note: The risk assessment for resident is also considered acceptable considering a buffer zone of 5 meters and a tractor mounted without drift reduction technology.

Use 2: Beetroots, 5 application at 1.5 L/ha

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) when drift reduction technology and a buffer zone of 3 meters are taken to reduce the resident exposure.

Model (AOEM) - All pathways (mean)	**% AOEL metamitron**	**% AOEL ethofumesate**
Resident (children)	79	0.7
Resident (adults)	33	0.3

Use 3: Beetroot, 5 applications at 2 L/ha – Max 6 L/ha (per season) – Split application

Split application can be modeled as following:
Case 1: 5 applications at 2 L/ha as 10 L/ha/season
Case 2: 3 applications at 2 L/ha as 6 L/ha/season
Case 3: 5 applications at 1.2 L/ha as 6 L/ha/season

Case 1:

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) when drift reduction technology and mitigation measures such as a buffer zone of 5 meters are taken to reduce the resident exposure.

Model (AOEM) - All pathways (mean)	**% AOEL metamitron**	**% AOEL ethofumesate**
Resident (children)	91	0.8
Resident (adults)	41	0.4

Case 2:

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and child) when drift reduction technology and mitigation measures such as a buffer zone of 5 meters are taken to reduce the resident exposure.

Model (AOEM) - All pathways (mean)	**% AOEL metamitron**	**% AOEL ethofumesate**
Resident (children)	91	0.6
Resident (adults)	41	0.3

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

Model (AOEM) - All pathways (mean)	**% AOEL metamitron**	**% AOEL ethofumesate**
Resident (children)	87	0.6
Resident (adults)	32	0.3

3.4.6 Combined exposure

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

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

Application scenario	**PPE**	**Active ingredient**	**Estimated exposure / AOEL (HQ)**
Operator	Working coverall and gloves during mixing/loading and application	**metamitron**	0.02
		ethofumesate	0.0004
	Cumulative risk operator (HI)		**0.02**
Bystanders/ Residents (**child**)	No PPE	**metamitron***	0.6*
		ethofumesate	0.005
	Cumulative risk bystanders (child) (HI)		**0.6***
Bystanders/ Residents (**adult**)	No PPE	**metamitron**	0.65
		ethofumesate	0.002
	Cumulative risk bystanders (adult) (HI)		**0.7**
Worker	Working coverall	**metamitron**	0.98
		ethofumesate	0.003
	Cumulative risk worker (HI)		**0.98**

**considering a refinement according to Appendix F for the parameter 'entry into treated crops'.*

The Hazard Index is < 1. Thus combined exposure to all active substances in TORNADO COMBI (FSG 01095 H) is not expected to present a risk for operator, worker or bystanders/ residents.

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

Overall conclusion

An exceedance of the current MRL for metamitron as laid down in Commission Regulation (EC) No 149/2008 of 29. January 2008 amending Reg. (EU) 396/2005 is not expected.

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

An exceedance of the current MRLs for ethofumesate as laid down in Commission Regulation (EU) 2016/1016 of 17 June 2016 amending Reg. (EC) No 396/2005 is not expected.

The chronic intake of ethofumesate residues is unlikely to present a public health concern. For ethofumesate no acute intake calculation is required because no ARfD was allocated.

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

Moreover, according to available data, specific mitigation measures should apply:

- Tops should not be fed after thinning or crop failure or after application at BBCH 37.
- Do not grow root vegetables in case of crop failure.

Data gaps

Noticed data gaps are:

- none

Summary of the evaluation

Toxicological reference values for the dietary risk assessment of metamitron and ethofumesate

Reference value	Source	Year	Value	Study relied upon	Safety factor
Metamitron					
ADI	EFSA (2008) 185, 1-95	2008	0.03 mg/kg bw/d	Two-year dog study	100
ARfD			0.1 mg/kg bw	Rat developmental study	100
Ethofumesate					
ADI	SANTE/10119/2016 Rev. 2[1] EFSA, 2016	2016	1.0 mg/kg bw/d	2 year rat	100
ARfD			Not necessary	-	-

1 FINAL Renewal report for the active substance ethofumesate finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 12 July 2016 in view of the renewal of the approval of ethofumesate as active substance in accordance with Regulation (EC) No 1107/2009

Summary for metamitron

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?
1	Sugar beet, fodder beeet	Yes	Yes	Yes	Yes	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
intended cGAP, a last application at BBCH31 is proposed from availa-ble data

As residues of metamitron do not exceed the trigger values defined in Reg (EU) No 544/2011, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

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 is therefore not necessary.

Summary for ethofumesate

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?
1	Sugar beet	Yes	Yes	Yes	Yes	Yes	No	n.a.[2]

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
n.a. not applicable

According to the requirements of Reg. (EU) No 283/2013 and based on the intended uses of TORNADO COMBI (FSG 01095 H) processing studies with ethofumesate are not mandatory, as the trigger for requiring such studies is not met by the GAP uses assessed and the TMDI represents less than the trigger value of 10 % ADI.

Nevertheless, the effects of processing on the nature of ethofumesate residues have been investigated in the framework of Annex I renewal. Data on effects of processing on the amount of residue were reported in the framework of Annex I peer review. The available processing factors were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP use and following mitigation measure has been proposed:

Do not grow root vegetables in case of crop failure.

Considering the livestock dietary burden based on the intended uses, there was no significant difference

of the livestock intake to the intake calculated by EFSA, 2016. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary.

Summary for TORNADO COMBI (FSG 01095 H)

Crop	PHI for TORNADO COMBI (FSG 01095 H) proposed by applicant	PHI/ Withholding period* sufficiently supported for		PHI for TORNADO COMBI (FSG 01095 H) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Metamitron	Ethofumesate		
Sugar beets	F**	Yes	Yes	F	-

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

Waiting periods before planting succeeding crops

Overall waiting period proposed by zRMS for TORNADO COMBI (FSG 01095 H)			
Crop group	**Led by metamitron**	**Led by ethofumesate**	
Root vegetables	/	120 days	Do not grow root vegetables in case of crop failure

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

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

3.6.1 Predicted environmental concentrations in soil (PEC_{soil}), in groundwater (PEC_{gw}) and in surface water (PEC_{sw})

The PEC of metamitron, ethofumesate 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.
PEC_{soil} and PEC_{sw} derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.
PEC_{gw} for metamitron, ethofumesate and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

3.6.2 Predicted environmental concentrations in air (PEC_{air})

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.

3.7 Ecotoxicology (Part B, Section 9)

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

Mitigation measures are required to protect aquatic organisms (see 2.5.1 below).

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to 3.6 for conclusion on the risk of groundwater contamination.

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

The active substances ethofumesate and metamitron are not approved as a candidate of substitution, therefore a comparative assessment is not foreseen.

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

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'extension d'usages 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'extension d'usage majeur du produit phytopharmaceutique ***TORNADO COMBI***

de la société *ADAMA FRANCE SAS*

enregistrée sous le *n°2017-1023*

Vu les conclusions de l'évaluation de l'Anses du 18 novembre 2019,

La modification de l'autorisation de mise sur le marché du produit désigné ci-après **est autorisée** dans les conditions précisées dans la présente décision.

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.

TORNADO COMBI
AMM n°2000046

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Informations générales sur le produit	
Noms du produit	TORNADO COMBI GOLTIX DUO
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES France
Formulation	Suspension concentrée (SC)
Contenant	150 g/L - éthofumesate 350 g/L - métamitrone
Numéro d'intrant	2000046
Numéro d'AMM	2000046
Fonction	Herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

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

A Maisons-Alfort le, 06 DEC. 2019

Caroline SEMAILLE
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 : Modalités d'autorisation du produit

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 (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15055911 Betterave industrielle et fourragère* Désherbage	**3 L/ha**	**1/an**	entre les stades BBCH 00 et BBCH 07	F (BBCH 07)	5 (dont DVP 5)	-	-	-
	Ne pas dépasser la dose totale de 6 L/ha par cycle cultural, tous stades d'applications confondus.							
	6 L/ha	**1/an**	entre les stades BBCH 10 et BBCH 37	F (BBCH 37)	5 (dont DVP 5)	-	-	-
	Fractionnement obligatoire en 3 à 5 applications au maximum, à la dose maximale d'emploi de 2 L/ha par application, sans dépasser la dose totale de 6 L/ha par cycle cultural, tous stades d'applications confondus, et en respectant un intervalle minimum de 6 jours entre les applications.							

DVP : Dispositif Végétalisé Permanent.

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Conditions d'emploi du produit

Les phrases :

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Et

- Respecter une distance d'au moins 3 m entre la rampe de pulvérisation et l'espace susceptible d'être fréquenté par des personnes présentes ou des résidents.

Sont remplacées par les phrases :

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.

Et

- Respecter une distance d'au moins 5 mètres entre la rampe de pulvérisation et l'espace susceptible d'être fréquenté par des personnes présentes ou des résidents, et utiliser un matériel permettant une atténuation de la dérive d'au moins 50 %.

TORNADO COMBI
AMM n°2000046

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Appendix 2 Copy of the product label

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

MODE D'ACTION - PROPRIÉTÉS

Tornado® Combi est un herbicide (traitement des parties aériennes) qui agit par absorption racinaire et foliaire. C'est une association de deux substances actives complémentaires, l'éthofumésate et la métamitrone.
Tornado® Combi est efficace sur un large spectre de dicotylédones et de graminées annuelles.

MODE D'EMPLOI

Usages et doses homologués :

Libellé de l'usage	Cultures associées pour le produit	Dose	Stade d'application
Betterave industrielle et fourragère*Désherbage	Betterave industrielle et fourragère	6 L/ha	BBCH 37 max

ADAMA France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures et cibles telles que prévues par le catalogue des usages fixé par l'arrêté du 26 mars 2014.
Ainsi, l'attention de l'utilisateur est attirée sur les risques éventuels de non-conformité de cet élargissement permis par ce catalogue.
Ne pas dépasser 1000 g/ha d'éthofumesate par période de 3 ans sur la même parcelle.
Pleine dose : 6 L/ha par cycle cultural, fractionnement possible jusqu'à 5 applications, sans dépasser la dose de 2 L/ha par application soit 3 applications à 2 L/ha ou 4 applications à 1,5 L/ha ou 5 applications à 1,2 L/ha.
Application possible en prélevée sans dépasser la dose de 3 L/ha.
Les Limites Maximales de Résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm
Délai de rentrée des travailleurs sur la parcelle : 6h après traitement conformément à l'arrêté du 12 juin 2015 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L.253-1 du code rural.
Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur selon l'arrêté du 7 avril 2010 modifié par l'arrêté du 12 juin 2015.

Conditions d'emploi :

Tornado® Combi s'applique à partir de BBCH 00 et au plus tard au stade BBCH 37, sur des adventices non levées ou déjà présentes lors du traitement.
Le **Tornado® Combi** s'applique en programme avec 3 ou 4 ou 5 applications de post. La dose totale appliquée à l'hectare ne doit pas dépassé 6 L/ha.
Tornado® Combi est préférentiellement utilisé en mélange avec des herbicides complémentaires dans des programmes fractionnés.
Traiter sur une culture saine, en absence de vent, de préférence le matin en période sèche pour profiter d'une bonne hygrométrie. Eviter les interventions si le risque de gel est présent.

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Les applications de post-levée doivent être réalisées sur des betteraves saines, en bon état végétatif. Les variations climatiques, les attaques parasitaires, les herbicides peuvent provoquer un ralentissement de végétation : dans ce cas, appliquer **Tornado® Combi** seul et après récupération des plantes.
Ne pas nourrir les animaux avec les feuilles de betteraves après un échec cultural ou un éclaircissage ou après des applications effectuées au stade BBCH 37.

Préparation de la bouillie :
Verser la bouillie dans la cuve à demi remplie d'eau en maintenant le système d'agitation, puis compléter avec la quantité d'eau nécessaire. Maintenir l'agitation pendant toute la duré de l'épandage.
Veiller à la régularité de la pulvérisation au sol en utilisant un volume de bouillie de 100 à 300 L/ha.

Sensibilité des végétaux traités :
Des symptômes d'enroulements de feuilles et de légères décolorations peuvent apparaître en cas de fortes amplitudes thermiques. Ces symptômes sont passagers et sans conséquence sur le rendement.

Incidences sur les cultures limitrophes :
L'application du produit est sans incidence pour les cultures limitrophes dans le cadre d'une utilisation respectant les bonnes pratiques agricoles.

Cultures suivantes et de remplacement :
Après la récolte des betteraves ou 3 mois après la dernière application, toute culture peut être semée, sauf légumes raçines. Ne pas implanter de légumes racines sur la parcelle dans les 9 mois suivant l'application d'une préparation à base d'éthofumesate.
Lorsque les conditions climatiques sont mauvaises (sécheresse prolongée suivie de précipitations importantes), des dommages peuvent apparaître sur les cultures suivantes, spécialement les céréales d'hiver. Un travail du sol profond et minutieux est nécessaire avant le semis ou la plantation des cultures suivantes. Labourer à une profondeur de 15 à 20 cm.
En cas d'échec de la culture en place, ne replanter que des betteraves sucrières ou fourragères. Si l'échec apparaît tardivement, les cultures suivantes peuvent être plantées ou semées : betteraves sucrières et fourragères, maïs et pommes de terre.
Ne planter du maïs en culture de remplacement qu'après un labour.

PRÉCAUTIONS GÉNÉRALES

Equipements de Protection Individuelle (EPI) :
Pour protéger l'opérateur, porter :
Mélange/ Chargement :
• EPI vestimentaire dédié aux traitements phytopharmaceutiques, complété par une blouse ou un tablier à manches longues de type 3 ou PB3 conformes avec la directive EPI 89/686/CEE et évalué notamment selon la norme EN 14605+A1 : 2009 ou
• Combinaison de type 3 ou 4 conforme avec la directive EPI 89/686/CEE, évaluée notamment selon la norme EN 14605+A1:2009
• Gants en nitrile réutilisables évalués selon les normes EN 374-1 et EN 374-3, et conformes avec la directive EPI 89/686/CEE.

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Application :

- EPI vestimentaire dédié aux traitements phytopharmaceutiques
- Gants en nitrile à usage unique évalués selon les normes EN 374-1 et EN 374-2, et conformes avec la directive EPI 89/686/CEE (nécessaire lors d'interventions sur le matériel de pulvérisation et les gants doivent être stockés en dehors de la cabine).

Nettoyage :

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

Gestion du risque d'apparition de résistance :

L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants.

Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.

Dans le cadre des Bonnes Pratiques Agricoles :

Emballages vides : Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre service de collecte spécifique. Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Nettoyage de l'équipement : Ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. 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 : Eloigner la victime de la zone dangereuse. Transporter la victime à l'air frais et selon les symptômes, consulter le médecin.

Contact avec la peau : Laver abondamment à l'eau et ôter immédiatement les vêtements contaminés et éclaboussés. En cas d'irritation de la peau (rougeur, etc.), consulter le médecin.

Contact avec les yeux : Ôter les verres de contact. Rincer abondamment à l'eau pendant plusieurs minutes. Si nécessaire, consulter le médecin.

Ingestion : Rincer soigneusement la bouche à l'eau. faire boire abondamment de l'eau, consulter le médecin.

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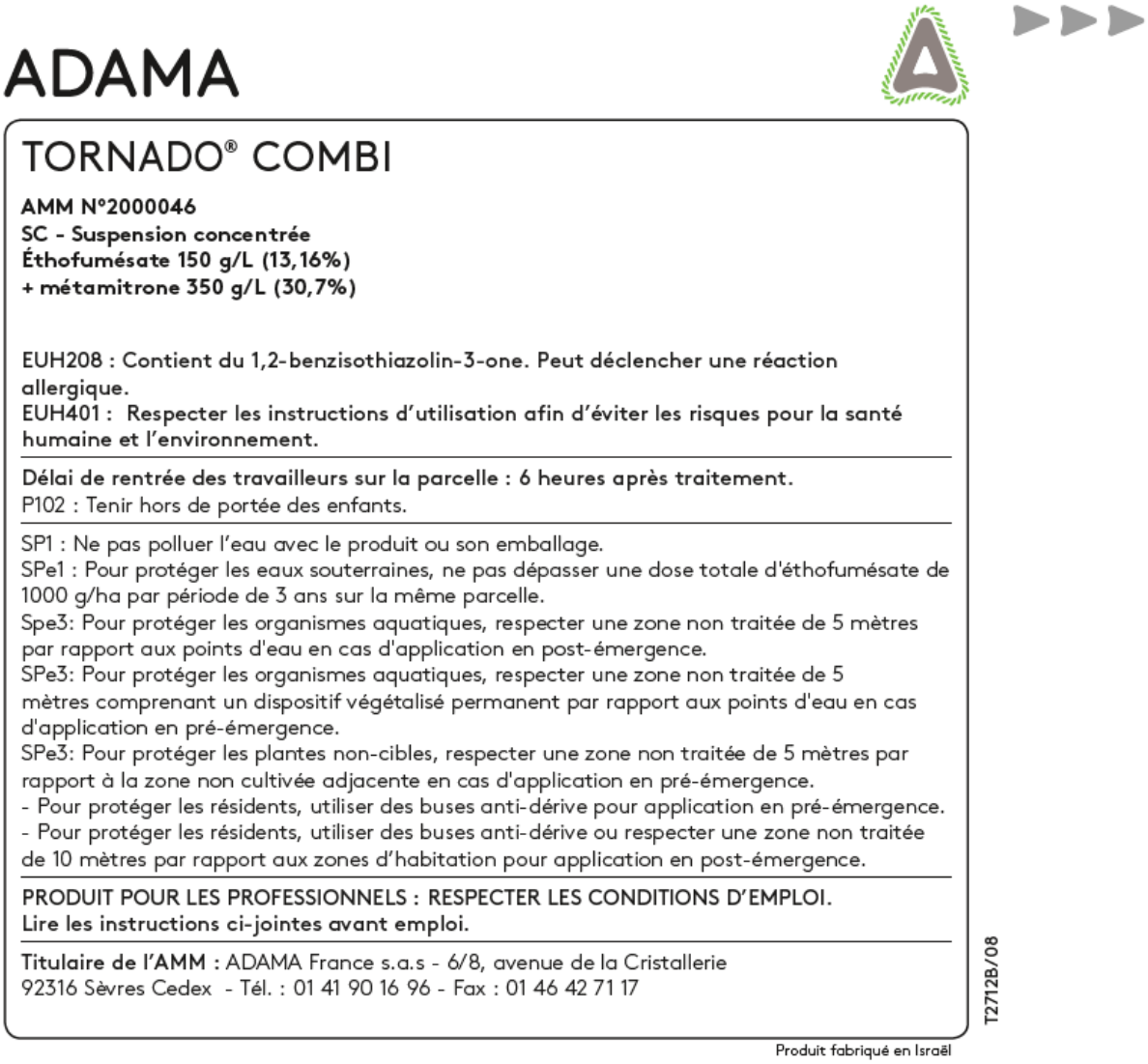
Mesures d'urgence :

En cas d'urgence, appeler le 15 ou le centre antipoison le plus proche de votre domicile. Présenter aux secours l'étiquette et la Fiche de Données de Sécurité.

N° vert de PHYT'ATTITUDE (réseau de toxicovigilance agricole de la MSA) : Tél. 0 800 887 887.

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



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Étiquette Marketing

Appendix 3 Letter of Access

Available upon requested