REGISTRATION REPORT

Part A

Risk Management

Product code: AG-FDC1-400 SC

Product name: CHROME

Chemical active substances:

Chlorotoluron, 280 g/L
Flufenacet, 80 g/L

Diflufenican, 40 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: ADAMA France S.A.S.

Date: 27 November 2024

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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 CHROME (formulation code: AG-FDC1-400 SC), containing 280 g/L chlorotoluron, 80 g/L flufenacet and 40 g/L diflufenican, 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).

1.1 Application background

The present registration report concerns the evaluation of ADAMA France S.A.S.'s application submitted on 19/08/2019 to market CHROME (AG-FDC1-400 SC) 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 first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2019-4926) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[1], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2]. 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 level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of CHROME (AG-FDC1-400 SC) have been made using endpoints agreed in the EU peer reviews of chlorotoluron, flufenacet and diflufenican. It also includes assessment of data and information related to CHROME (AG-FDC1-400 SC) 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) No 546/2011[3], 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 CHROME (AG-FDC1-400 SC).

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1 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

2 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

3 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

1.2 Letters of Access

Not necessary:

The applicant is the owner of data which support the approval of the chlorotoluron.

Active substance data for diflufenican are not protected any more.

Part of flufenacet data are not protected anymore and the applicant has provided a letter of access for data that are still under protection. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « All reports submitted are needed for the first registration of AG-FDC1-400 SC in accordance to the data requirements laid down in Regulation (EC) No. 284/2013. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CHROME (AG-FDC1-400 SC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	AG-FDC1-400 SC
Product name in MS	CHROME
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	ADAMA France S.A.S.
Active substance(s) (incl. content)	Chlorotoluron, 280 g/L Flufenacet, 80 g/L Diflufenican, 40 g/L
Formulation type	Suspension concentrate [SC]
Packaging	Bottle in HDPE[4] (1 L) Can in HDPE (5 L, 10 L) Can in HDPE wich can be equipped with a homogeneisation system (20 L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-

[4] High density polyethylene

Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for CHROME (AG-FDC1-400 SC) resulted in the decision **to refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

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

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

N/A : no marketing authorisation granted.

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

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

N/A : no marketing authorisation granted.

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017 [5] 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.

[5] 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 maritimehttps://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

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 12 April 2021[6] provides that:
- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

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

The Decision, as 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:

N/A : no marketing authorisation granted.

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.

[6] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456
[7] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2024-11

PPP (product name/code):	CHROME / AG-FDC1-400 SC	Formulation type:	SC [a, b]
Active substance 1:	Chlorotoluron	Conc. of a.s. 1:	280 g/L [c]
Active substance 2:	Flufenacet	Conc. of a.s. 2:	80 g/L [c]
Active substance 3:	Diflufenican	Conc. of a.s. 3:	40 g/L [c]
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	ADAMA France S.A.S.	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	**Yes**		

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	FR	Winter wheat (soft) TRZAW Winter wheat (durum) TRZDW Winter barley HORVW Rye SECCW Triticale TTLWI Spelt TRZSP	F	annual dicot (TTTDS) and grass weeds (TTTMS)	soil / foliar, spraying, overall	BBCH 00-09 a**nd BBCH 11-29 Before dormancy**	a) 1 b) 1	-	a) 1.8 b) 1.8	a) 144 flufenacet + 72 diflufenican + 504 chlorotoluron b) 144 flufenacet + 72 diflufenican + 504 chlorotoluron	80-200	F	**Not acceptable** (risk for non-target plants)
2	FR	Winter wheat (soft) TRZAW Winter wheat (durum) TRZDW Winter barley HORVW Rye SECCW Triticale TTLWI Spelt TRZSP	F	annual dicot (TTTDS) and grass weeds (TTTMS)	soil / foliar, spraying, overall	BBCH 00-09 **and BBCH 11-29 Before dormancy**	a) 1 b) 1	-	a) 1.5 b) 1.5	a) 120 flufenacet+ 60 diflufenican + 420 chlorotoluron b) 120 flufenacet+ 60 diflufenican + 420 chlorotoluron	80-200	F	**Not acceptable** (risk for non-target plants)

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/m^3 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)

CHROME (AG-FDC1-400 SC) is an aqueous suspension concentrate (SC) containing 280 g/L of chlorotoluron (CTU), 40 g/L of diflufenican (DFF) and 80 g/L of flufenacet (FFA). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a yellow liquid suspension. It is not explosive and has no oxidising properties. The product is has a flash point up to 100 °C. It has a self- ignition temperature of 435 °C. The pH value of the neat formulation is 5.2 at ambient temperature. There is no effect of low temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither actives ingredients contents nor the technical properties were changed. The 2 years shelf life study is on-going and should be provided at post-authorization. Based on the accelerated storage stability study, the shelf life is expected to be at least 2 years at ambient temperature when stored in 1L HDPE bottle. Final report of the long term stability study in the commercial packaging is required in post-authorization. Its technical characteristics are acceptable for an aqueous suspension concentrate (SC) formulation.

3.2 Efficacy (Part B, Section 3)

From the submitted data, representative only of French conditions of use, it can be conluded that:

o the efficacy level of CHROME (AG-FDC1-400 SC) when applied in autumn in pre emergence or in post emergence of winter cereals at the dose rate of 1.8 L/ha is considered satisfactory for all the requested uses.

o the efficacy level of CHROME (AG-FDC1-400 SC) when applied in autumn in pre emergence or in post emergence of winter cereals at the dose rate of 1.5 L/ha is considered acceptable for all the requested uses. It has to be noted that the level of effectiveness of the product applied post emergence has only been demonstrated on newly emerged weeds (growth stage BBCH 08-13). It is therefore not recommended to use the product on highly developed flora.

o the phytotoxicity level of CHROME (AG-FDC1-400 SC) is considered satisfactory for all the requested uses. For reasons of selectivity, the product should not be applied at the “first pointing leaf (BBCH 10)” stage on all crops claimed. For the same reasons, it is recommended not to reapply flufenacet-based products on crop.

o the risks of negative impact on yield, quality, transformation processes, propagation are considered as acceptable .

o the risk of negative impact on succeeding crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops in case of crop failure.

o the risk of negative impact on adjacent crops is considered acceptable. Nevertheless, specific attention should be paid to susceptible adjacent crops.

o There is a risk of resistance development or appearance for flufenacet requiring a survey of resistance for the claimed uses, especially on *Lolium sp*. and *Alopecurus myosuroides.*

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of chlorotoluron, diflufenican and flufenacet in the formulation are available and validated.

3.3.2 Analytical methods for residues

Pre-registration analytical methods are available for the determination of chlorotoluron, diflufenican and flufenacet residues in plant/animal products, water and bee (ecotoxicological studies). Some residue trials cannot be taken into account for the risk assessment of this dossier (See dRR Part B5).

Post-authorisation control and monitoring analytical methods are available in the Draft Assessment Report/Renewal Assessment Report/this dossier and validated for the determination of residues of chlorotoluron, diflufenican and flufenacet in plants (dry and high water content), food of animal origin, soil, water (surface and drinking), air and body fluids.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

CHROME (AG-FDC1-400 SC) containing 80 g/L flufenacet, 40 g/L diflufenican and 280 g/L chlorotoluron 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

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[8]:

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

		Flufenacet		Diflufenican		Chlorotoluron	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% AOEL**	**Total absorbed dose (mg/kg/day)**	**% AOEL**	**Total absorbed dose (mg/kg/day)**	**% AOEL**
Cereals Outdoor – Downward spraying – vehicle mounted Application rate: 0.144 kg flufenacet/ha, 0.072 kg diflufenican/ha and 0.504 kg chlorotoluron/ha							
EFSA Operator Model (75^{th} quantile regression) Body weight: 60 kg	Potential exposure	0.0092	54.14	0.0047	4.3	0.1966	91.43
	Work wear - arms, body and legs covered	0.006	35.34	0.003	2.75	0.1256	58.43
	Work wear - arms, body and legs covered and gloves during M/L and A	0.0009	5.12	0.0004	0.4	0.0048	2.24

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of worker exposure was calculated according to AOEM model:

		Flufenacet		Diflufenican		Chlorotoluron	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Cereals Inspection, irrigation Outdoor Work rate: 2 hours/day DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha							

Number of applications and application rate:		1 x 0.144 kg a.s./ha		1 x 0.072 kg a.s./ha		1 x 0.504 kg a.s./ha	
Body weight: 60 kg	Potential TC: 12500 cm^2/person/h	0.0432	254.12	0.0144	13.09	0.0756	35.16
	Work wear (arms, body and legs covered) TC: 1400 cm^2/person/h	0.0048	28.46	0.0016	1.47	0.0085	3.94
	Work wear (arms, body and legs covered) and gloves TC: Not available	-	-	-	-	-	-

3.4.4 Bystander and resident exposure

Bysander

In the absence of AAOEL determined for the 3 a.s., it is considered that the risk assessment for the bystander is covered by the resident risk assessment.

Indeed, 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*."

Resident

Resident exposure was assessed according to EFSA model without mitigation measures, a distance of 2-3 metres from the spray boom and no drift reduction technology was considered:

Model data		**Flufenacet**		**Diflufenican**		**Chlorotoluron**	
		Total absorbed dose (mg/kg/day)	**% AOEL**	Total absorbed dose (mg/kg/day)	**% AOEL**	Total absorbed dose (mg/kg/day)	**% AOEL**
Cereals Downward – Vehicle mounted Buffer zone: 2-3m Drift reduction technology: no Number of applications : 1 Interval between treatments: 365 days							
DT_{50}		30 days		30 days		30 days	
DFR		3 µg/cm^2/kg a.s./ha		3 µg/cm^2/kg a.s./ha		3 µg/cm^2/kg a.s./ha	
Resident (children)	Spray drift (75th percentile)	0.0116	68.37	0.0039	3.53	0.0143	6.66

Body weight: 10 kg	Vapour (75th percentile)	0.0011	6.29	0.0011	0.97	0.0011	0.5
	Surface deposits (75th percentile)	0.0006	3.65	0.0002	0.18	0.0013	0.6
	Entry into treated crops (75th percentile)	0.0058	34.31	0.0019	1.77	0.0102	4.75
	All pathways (mean)	**0.0126**	**74.01**	**0.0049**	**4.46**	**0.0181**	**8.4**
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	0.0028	16.34	0.0009	0.84	0.0034	1.59
	Vapour (75th percentile)	0.0002	1.35	0.0002	0.21	0.0002	0.11
	Surface deposits (75th percentile)	0.0002	1.39	0.0001	0.07	0.0004	0.19
	Entry into treated crops (75th percentile)	0.0032	19.06	0.0011	0.98	0.0057	2.64
	All pathways (mean)	**0.0043**	**25.33**	**0.0016**	**1.44**	**0.0067**	**3.11**

3.4.5 Combined exposure

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

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

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

Population groups and PPE		**Active ingredient**	**Estimated exposure / AOEL (HQ)**
Operators	Working coverall and gloves during mixing/loading and application	Flufenacet	0.0512
		Diflufenican	0.004
		Chlorotoluron	0.0224
	Cumulative risk operators (HI)		**0.0776**
Worker	Working coverall and gloves	Flufenacet	0.2846
		Diflufenican	0.0147
		Chlorotoluron	0.0394
	Cumulative risk workers (HI)		0.3387

Bystanders /Residents	Children - All pathways (mean)	Flufenacet	0.7401
		Diflufenican	0.0446
		Chlorotoluron	0.084
	Cumulative risk bystanders/residents (child) (HI)		**0.8687**
	Adults - All pathways (mean)	Flufenacet	0.2533
		Diflufenican	0.0144
		Chlorotoluron	0.0311
	Cumulative risk bystanders/residents (adult) (HI)		**0.2988**

The Hazard Index is < 1. Thus combined exposure to all active substances in CHROME (AG-FDC1-400 SC) is not expected to present a risk for operators, workers, residents and bystanders. No further refinement of the assessment is required.

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of cereals for flufenacet, diflufenican and chlorotoluron as laid down in Regulation (EU) 396/2005 is not expected.

The acute and chronic intakes of the active substances flufenacet, diflufenican and chlorotoluron residues are unlikely to present a public health concern.

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

Table : Information on CHROME (KCA 6.8)

Crop	PHI for CHROME proposed by applicant	PHI/ Withholding period* sufficiently supported for			PHI for CHROME proposed by zRMS	zRMS Comments (if different PHI proposed)
		Flufenacet	Diflufenican	Chlorotoluron		
Cereals (wheat, barley, rye, triticale, spelt)	F**	Yes	Yes	Yes	F** last application at BBCH 29	

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

3.6 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.

The PEC of flufenacet, 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.

It is highlighted that available PECgw and PECsw calculations cover only applications done pre-emergence or post-emergence before dormancy.

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

PECgw for flufenacet, diflufenican, chlorotoluron and their metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011 and guidance document SANCO 221/2000[9]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses before dormancy.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the require-ments of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms are acceptable for the intended uses.

For aquatic organisms, the risks are acceptable when the mitigation measures reported in point 2.5.1 are applied.

In addition, as the method of analysis cannot be validated for toxicity tests on non-target plants (seedling emergence and vegetative vigour), no reliable endpoint could be determined from these studies and thus, it is not possible to finalize the risk assessment for non-target plants.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

CHROME (AG-FDC1-400 SC) contains active substances approved as a candidates for substitution,

- because two of the criteria for PBT are met (persistent, bio accumulative, toxic) for chlorotoluron,

[9] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

flufénacet and diflufénican;

- because of its suspected endocrine disruption properties for chlorotoluron.

Step 1:

- Taking into account the management of resistance in accordance with Articles 50(1)(c) of Regulation (EC) No 1107/2009:

- As the active substances candidates for substitution are an important part of the resistance management strategy and the diversity of available modes of action is not sufficient against grassweeds (especially *Lolium sp.* and *Alopecurus myosuroides*), the substitution is not considered for the uses on cereal crops (winter wheat, winter barley, rye, triticale, spelt).

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

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

5.1.1 Post-authorisation monitoring

N/A : no marketing authorisation granted.

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted.

Appendix 1 Copy of the product authorisation

Docusign Envelope ID: 23D254B8-05FD-4C82-A63A-3318D2D78BE1

RÉPUBLIQUE FRANÇAISE
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anses

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

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

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

Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique CHROME

de la société	*ADAMA FRANCE SAS*
enregistrées sous les	*n° 2019-4926, 2020-3275, 2021-2850 et 2023-2447*

Vu les conclusions de l'évaluation de l'Anses du 26 juillet 2024,

Considérant que les méthodes d'analyses utilisées dans les tests de toxicité observant les effets sur l'émergence des graines et la vigueur végétative n'ont pas été validées,

Considérant en conséquence qu'un risque d'effet inacceptable pour les plantes terrestres non-cibles, lié à l'utilisation du produit ne peut être exclu,

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.

CHROME
AMM n° -

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Informations générales sur le produit	
Nom du produit	CHROME
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES France
Formulation	Suspension concentrée (SC)
Contenant	80 g/L - flufénacet 40 g/L - diflufénicanil 280 g/L - chlorotoluron
Numéro d'intrant	654-2019.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 27/11/2024

DocuSigned by:
Charlotte Grastilleur
AE2B1A955A42464...

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 : 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	1,5 L/ha	1/an	F (BBCH 29)
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non-cibles, ni d'exclure un risque d'effet inacceptable pour les organismes aquatiques et un risque inacceptable de contamination pour les eaux souterraines pour une application après la reprise de végétation.		
15105913 Orge*Désherbage	1,5 L/ha	1/an	F (BBCH 29)
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non-cibles, ni d'exclure un risque d'effet inacceptable pour les organismes aquatiques et un risque inacceptable de contamination pour les eaux souterraines pour une application après la reprise de végétation.		
15105915 Seigle*Désherbage	1,5 L/ha	1/an	F (BBCH 29)
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les plantes terrestres non-cibles, ni d'exclure un risque d'effet inacceptable pour les organismes aquatiques et un risque inacceptable de contamination pour les eaux souterraines pour une application après la reprise de végétation.		

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.

Protection de l'opérateur et du travailleur

Il convient de rappeler que l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections complémentaires comme les protections individuelles.

En tout état de cause, le port de combinaison de travail dédiée ou d'équipement de protection individuelle (EPI) doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage). Les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Caractéristiques des EPI	PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE : MÉLANGE/ CHARGEMENT	APPLICATION AVEC : PULVÉRISATEUR PORTÉ OU TRAÎNÉ À RAMPE, PNEUMATIQUE OU ATOMISEUR ; PULVÉRISATION VERS LE BAS — TRACTEUR AVEC CABINE	APPLICATION AVEC : PULVÉRISATEUR PORTÉ OU TRAÎNÉ À RAMPE, PNEUMATIQUE OU ATOMISEUR ; PULVÉRISATION VERS LE BAS — TRACTEUR SANS CABINE	NETTOYAGE	PROTECTION DU TRAVAILLEUR
GANTS EN NITRILE réutilisables (certifiés EN 374-3) ou à usage unique (certifiés EN 374-2)	Réutilisables	À usage unique*	À usage unique	Réutilisables	
EPI VESTIMENTAIRE conforme à la norme NF EN ISO 27065	EPI vestimentaire ET EPI partiel			EPI vestimentaire ET EPI partiel	
EPI PARTIEL blouse ou tablier à manches longues catégorie III type PB3 certifié EN 14605+A1					
COMBINAISON DE PROTECTION CHIMIQUE catégorie III type 3 ou 4 certifiée EN 14605+A1:2009					
LUNETTES ou ÉCRAN FACIAL certifiés EN 166:2002 (CE, sigle 3)					
PROTECTION RESPIRATOIRE demi-masque ou masque (EN 140:1998) équipé d'un filtre P3 (EN 143:2007) ou A2P3 (EN 14387:2020)					
BOTTES certifiées EN 13 832-3:2006					

*EN CAS D'INTERVENTION À L'EXTÉRIEUR ; DANS CE CAS, LES GANTS DOIVENT ÊTRE STOCKÉS ET PORTÉS À L'EXTÉRIEUR DE LA CABINE

Nettoyage du pulvérisateur et gestion des fonds de cuve

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

Élimination du produit, de l'emballage

Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et l'éliminer via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR ou tout autre service de collecte spécifique.

En cas de déversement accidentel

Se protéger (EPI) et sécuriser la zone.

Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens.

Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.

LES BONS GESTES POUR TRAITER EN TOUTE SÉCURITÉ

AVERTISSEMENT

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

ADAMA

CHROME®

AMM N°XXXX.XX
SC - Suspension concentrée
Flutenacet 80 g/L (7.5%) + diflufenicanil 40 g/L (3.7%)
+ chlortoluron 280 g/L (25.6%)

Attention

H351 : Susceptible de provoquer le cancer.
H361d : Susceptible de nuire au fœtus.
H410 : Très toxique pour les organismes aquatiques, entraîne des effets à long terme.
EUH208 : Contient du flufenacet, de la 1,2-benzisothiazolin-3-one et du mélange de 5-chloro-2-méthyl-4-isothiazolin-3-one et de 2-méthyl-4-isothiazolin-3-one. Peut produire une réaction allergique.
EUH401 : Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

Délai de rentrée des travailleurs : 48 heures après traitement.
P102 : Tenir hors de portée des enfants.
P201 : Se procurer les instructions spéciales avant utilisation.
P280 : Porter des gants de protection/ des vêtements de protection/un équipement de protection des yeux/du visage.
P501 : Éliminer le contenu / récipient dans un centre de collecte des déchets dangereux ou spéciaux.

SPI : Ne pas polluer l'eau avec le produit ou son emballage.
SPe2 : Pour protéger les organismes aquatiques, ne pas appliquer la préparation sur les sols artificiellement drainés.
SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres.

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL.
Consulter la livret avant toute utilisation.
RÉEMPLOI DE L'EMBALLAGE INTERDIT.

Produit fabriqué en Israël

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

5 L