

REGISTRATION REPORT

Part A

Risk Management

Product code: Fosetyl-aluminium WG 60

Product name: SIGNATURE XTRA STRESSGARD

**Chemical active substance:
fosetyl-aluminium, 600 g/kg**

Southern Zone

Zonal Rapporteur Member State: France

**NATIONAL ASSESSMENT FRANCE
(New application)**

Applicant: Bayer Crop Science Division

Date: 2020/04/28

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PART A

RISK MANAGEMENT

1 Details of the application

The company Bayer Crop Science Division has requested a marketing authorisation in France for the product SIGNATURE XTRA STRESSGARD (formulation code: fosetyl-aluminium WG 60), containing 600 g/kg fosetyl-aluminium¹ as a fungicide 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).

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1.1 Application background

The present registration report concerns the evaluation of Bayer Crop Science Division's application submitted on 23/02/2018 to market SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60) 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 (2018-0456) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², 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")³. 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 SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60) has been made using endpoints agreed in the EU peer review of fosetyl-aluminium. It also includes assessment of data and information related to SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60) 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) 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

² REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

³ 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 546/2011⁴, 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 SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60).

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the approval of the active substance.

1.3 Justification for submission of tests and studies

According to the applicant: “*The studies submitted necessary for 1st authorisation of Fosetyl-aluminium WG 60 are in accordance with Reg. (EU) No. 284/2013.*”

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60), 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	Fosetyl-aluminium WG 60.
Product name in MS	SIGNATURE XTRA STRESSGARD.
Authorisation number	2200150
Kind of use	Professional use.
Low risk product (article 47)	No.
Function	Fungicide.
Applicant	Bayer Crop Science Division.
Active substance (incl. content)	Fosetyl-aluminium, 600 g/kg.
Formulation type	Water-dispersible granule [WG].
Packaging	HDPE bottles 10 L containing 5 kg of product. HDPE/PA bottles 10 L containing 5 kg of product.
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None.
Recommended tank mixtures	None.

⁴ 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 SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60) resulted in the decision to grant 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:

Hazard class(es), categories:	Eye irritation, category 2.
Hazard pictograms:	 GHS07
Signal word:	Warning
Hazard statement(s):	H319: Causes serious eye irritation.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation.</i>
Additional labelling phrases:	To avoid risks to man and the environment, comply with the instructions for use [EUH401].

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

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

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

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

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4 May 2017⁵ 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 2014⁶ 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 extrapolation⁷ 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:

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	
	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	

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 maritime <https://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

⁶ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRGI407093A/jo>

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

SPe 2	To protect groundwater and aquatic organisms, for use on grass lawns, do not apply this product to more than 10 % of the lawnarea.
SPe 2	To protect birds and wild mammals, for use on grass lawns, do not apply this product to more than 10 % of the lawnarea.
SPe 2	To protect aquatic organisms, do not apply this product to artificially drained soils.
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres with an unsprayed planted buffer zone of 5 metres to surface water bodies ⁸ .
Other specific restrictions	
Re-entry period	Not applicable.
Storage	The product must be stored at a temperature below 40 °C.

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 The unsprayed planted buffer zone is applied in order to limit risk from eutrophication.

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2.6 Intended uses (only NATIONAL GAP)

Please note:

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.
 Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2020-04-28

PPP (product name/code): SIGNATURE XTRA STRESSGARD / fosetyl-aluminium WG 60
 Active substance 1: fosetyl-aluminium
 Applicant: Bayer Crop Science Division
 Zone(s): Southern Zone ^(d)
 Verified by MS: Yes
 Field of use: Fungicide

Formulation type: WG ^(a, b)
 Conc. of a.s. 1: 600 g/kg ^(c)
 Professional use: ☒
 Non-professional use: ☐

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 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	France	Golf courses: greens, tees and fairways (NNNZW)	F	<i>Microdochium nivale</i> Microdochium patch MONGNI	Spray (knapsack + lance or boom; vehicle-mounted tank + boom)	All-year-round Established turf (BBCH 29-33)	a) 4* b) 4	14-90 d*	a) 20 kg/ha b) 80 kg/ha	a) 12 000 g a.s./ha b) 48 000 g a.s./ha	200-600 L/ha	-	* two spray blocks separated by a three-month (90 days) interval and maximum two applications per block with a minimum spray interval of 14 days Acceptable

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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 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		
2	France	Golf courses: greens, tees and fairways (NNNZW)	F	<i>Colletotrichum</i> Anthracnose COLLGR	Spray (knapsack + lance or boom; vehicle-mounted tank + boom)	All year round Established turf (BBCH 29-33)	a) 4* b) 4	14-90 d*	a) 20 kg/ha b) 80 kg/ha	a) 12 000 g a.s./ha b) 48 000 g a.s./ha	200-600 L/ha	-	* two spray blocks separated by a three-month (90 days) interval and maximum two applications per block with a minimum spray interval of 14 days Acceptable
3	France	Golf courses: greens, tees and fairways (NNNZW)	F	<i>Pythium ulti- mum/P. apha- nidermatum</i> <i>Pythium</i> blight and <i>Pythium</i> root rot PYTHUL	Spray (knapsack + lance or boom; vehicle-mounted tank + boom)	All year round Established turf (BBCH 29-33)	a) 4* b) 4	14-90 d*	a) 20 kg/ha b) 80 kg/ha	a) 12 000 g a.s./ha b) 48 000 g a.s./ha	200-600 L/ha	-	* two spray blocks separated by a three-month (90 days) interval and maximum two applications per block with a minimum spray interval of 14 days Not acceptable (efficacy)
4	France	Golf courses: greens, tees and fairways (NNNZW)	F	<i>Rhizoctonia solani</i> Brown patch RHIZSO	Spray (knapsack + lance or boom; vehicle-mounted tank + boom)	All year round Established turf (BBCH 29-33)	a) 4* b) 4	14-90 d*	a) 20 kg/ha b) 80 kg/ha	a) 12 000 g a.s./ha b) 48 000 g a.s./ha	200-600 L/ha	-	* two spray blocks separated by a three-month (90 days) interval and maximum two applications per block with a minimum spray interval of 14 days Acceptable
5	France	Sports turf (football and rugby pitches, tennis, bowls and cricket pitches) (NNNZW)	F	<i>Microdochium</i> <i>nivale</i> <i>Microdochium</i> patch MONGNI	Spray (knapsack + lance or boom; vehicle-mounted tank + boom)	All year round Established turf (BBCH 29-33)	a) 4* b) 4	14-90 d*	a) 20 kg/ha b) 80 kg/ha	a) 12 000 g a.s./ha b) 48 000 g a.s./ha	200-600 L/ha	-	* two spray blocks separated by a three-month (90 days) interval and maximum two applications per block with a minimum spray interval of 14 days Acceptable

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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 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		
6	France	Sports turf (football and rugby pitches, tennis, bowls and cricket pitches) (NNNZW)	F	<i>Colletotrichum</i> Anthracnose COLLGR	Spray (knapsack + lance or boom; vehicle-mounted tank + boom)	All year round Established turf (BBCH 29-33)	a) 4* b) 4	14-90 d*	a) 20 kg/ha b) 80 kg/ha	a) 12 000 g a.s./ha b) 48 000 g a.s./ha	200-600 L/ha	-	* two spray blocks separated by a three-month (90 days) interval and maximum two applications per block with a minimum spray interval of 14 days Acceptable
7	France	Sports turf (football and rugby pitches, tennis, bowls and cricket pitches) (NNNZW)	F	<i>Pythium ulti- mum/aphaniderma- tum</i> <i>Pythium</i> blight and <i>Pythium</i> root rot PYTHUL	Spray (knapsack + lance or boom; vehicle-mounted tank + boom)	All year round Established turf (BBCH 29-33)	a) 4* b) 4	14-90 d*	a) 20 kg/ha b) 80 kg/ha	a) 12 000 g a.s./ha b) 48 000 g a.s./ha	200-600 L/ha	-	* two spray blocks separated by a three-month (90 days) interval and maximum two applications per block with a minimum spray interval of 14 days Not acceptable (efficacy)
8	France	Sports turf (football and rugby pitches, tennis, bowls and cricket pitches) (NNNZW)	F	<i>Rhizoctonia solani</i> Brown Patch RHIZSO	Spray (knapsack + lance or boom; vehicle-mounted tank + boom)	All year round Established turf (BBCH 29-33)	a) 4* b) 4	14-90 d*	a) 20 kg/ha b) 80 kg/ha	a) 12 000 g a.s./ha b) 48 000 g a.s./ha	200-600 L/ha	-	* two spray blocks separated by a three-month (90 days) interval and maximum two applications per block with a minimum spray interval of 14 days Acceptable

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008

(c) g/kg or g/l

(d) Select relevant

(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

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

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Remarks columns:	1	Numeration necessary to allow references	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
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	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)	9	Minimum interval (in days) between applications of the same product
	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	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.
	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.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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)

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 green granules, with a medium solvent odour. The product is not explosive and has no oxidising properties. It is not flammable. No self-ignition temperature was observed up to 40 °C. In aqueous solution, it has a pH value around 3.7 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after eight weeks at 40 °C in an HDPE bottle, neither the active substance content nor the technical properties were changed. Due to the type of preparation (WG), compatibility with HDPE/PA is also acceptable.

However persistent foaming and spontaneity of dispersion at the maximum use rate (10 % w/v) should be provided. New studies performed with a use rate of 10 %w/v (dispersion, suspensibility and persistent foaming) are ongoing and will be available at the end of the year 2019. Results must be provided post-authorisation, along with the final report of the shelf-life study (due in November 2019).

The technical characteristics are acceptable for a WG formulation. The product must be stored at a temperature below 40°C.

3.2 Efficacy (Part B, Section 3)

The efficacy level of SIGNATURE XTRA STRESSGARD is considered satisfactory for the control of anthracnose (*Colletotrichum*), *Rhizoctonia solani* and *Microdochium nivale* patch in grass turfs. The efficacy level is considered acceptable for the control of brown patch in grass turfs. **Regarding the lack of dose trials for *Pythium* spp control in grass turfs, the evaluation of SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60)'s efficacy level cannot be finalised for the requested use.**

The use of SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60) according to a programme, with a maximum of four applications per year and a minimum interval of 90 days between second and third treatments shows an agronomic interest restricted to specific cases, depending on local climatic conditions and disease pressure.

The phytotoxicity level of SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60) is considered negligible for the requested uses.

The risk of negative impact on adjacent crops is considered negligible.

The risk of resistance appearing and developing to fosetyl-aluminium does not require any monitoring for the requested uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methodology for the determination of the active substance in the formulation is available and validated. As the active substance fosetyl-aluminium does not contain any relevant impurity, no pertinent analytical method is required.

3.3.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in this dossier and validated for the determination of residues of fosetyl-aluminium in soil, water (surface and drinking) and air. Considering the intended uses, analytical methods for the determination of residues of fosetyl-Al in plants and in foodstuffs of animal origin are not necessary.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active substance: fosetyl-aluminium			
ADI	3 mg/kg bw/d		EU (2007)
ARfD	Not applicable		
AOEL	5 mg/kg bw/d		
AAOEL	None		
Dermal ab- sorption	Default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation)	Spray dilution (used in formulation)
	Dermal absorption endpoints %	25	75
Oral absorption	100 %		

3.4.1 Acute toxicity

SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60), containing 600 g/kg fosetyl-aluminium, has a low acute oral, inhalational and dermal toxicity, and is not irritating to the rabbit eye. It is considered irritating to the rabbit skin but not considered to be a skin sensitiser.

3.4.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ⁹	Equipment <i>Application method</i>	Maximum applica- tion rate kg product/ha (g a.s./ha)	Minimum vol- ume water (L/ha)
Sports turf (football and rugby pitches, tennis, bowls and cricket pitches)	F	Vehicle mounted <i>Downward spraying</i>	13.5	200
Sports turf (football and rugby pitches, tennis, bowls and cricket pitches)	F	Manual knap- sack <i>Downward spraying</i>	13.5	200
Sports turf (football and rugby pitches, tennis, bowls and cricket pitches)	F	Hand held <i>Downward spraying</i>	13.5	200

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹⁰:

Crop	Equipment	PPE and/or working coverall	% AOEL Fosetyl-Al
Golf courses	Vehicle-mounted <i>Downward spraying</i>	Working coverall during mixing/loading and applica- tion	43.50
		Working coverall and gloves during mixing/loading and application	2.47
Golf courses	Manual knapsack <i>Downward spraying</i>	Working coverall during mixing/loading and applica- tion	93.92
		Working coverall and gloves during mixing/loading and application	80.73
Golf courses	Hand-held <i>Downward spraying</i>	Working coverall during mixing/loading and applica- tion	30.83
		Working coverall and gloves during mixing/loading and application	20.26

According to the model calculations, it may be concluded that the risk for the operator using SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.4.3 Worker exposure

⁹ Open field or glasshouse

¹⁰ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

Workers may have to enter treated areas after treatment for crop maintenance. Therefore, estimation of worker exposure was calculated according to the AOE model. Exposure is estimated to be 71.98 % of the AOEL of fosetyl-aluminium with PPE (workwear and gloves).

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

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

3.4.4 Bystander and resident exposure

Consideration of acute exposure should only be made where an Acute AOEL (AAOEL) has been established during an approval, review or renewal evaluation of an active substance, *i.e.* no acute operator or bystander exposure assessments can be performed with the AOE model where no AAOEL has been set¹¹.

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.”

Residential exposure was assessed according to the EFSA model. An acceptable risk was determined for residents (adult and/or child) without drift reduction and considering default 2-3 m buffer zone.

Model (AOEM) - All pathways (mean)	% AOEL Fosetyl-Al
Resident (children)	30.33
Resident (adults)	10.14

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

The plant protection product SIGNATURE XTRA STRESSGARD (Fosetyl-aluminium WG 60), which contains the eponymous active substance, is exclusively intended for use as a fungicide for turf (professional uses). Therefore, metabolism and residues data are not required in this dossier.

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 predicted environmental concentrations (PEC) in soil values for the active substance and its metabolite 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.

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)

The PEC values of fosetyl-aluminium and its metabolite 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} values derived for the active substance and its metabolite are used for the ecotoxicological risk assessment. The maximum PEC_{sw} values were higher than 35 µg of phosphorous equivalent/L (OECD, 1982¹²). Hence, there is a potential risk of eutrophication for surface water.

PEC_{gw} values for fosetyl-aluminium and its metabolite do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and Directive 98/83/EC¹³ when the formulated product is applied on established turf and assuming spot application ($\leq 10\%$ of the treated area). Therefore, no unacceptable risk of groundwater contamination 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 substance and its metabolite 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.

Risk mitigation measures are needed: see point 2.5.1.

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant.

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

The active substance fosetyl-aluminium is not approved as a candidate for 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

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

¹² O.E.C.D. 1982. Eutrophication of Waters. Monitoring, Assessment and Control. O.E.C.D. Paris. 154 pp.

¹³ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- The persistent foaming and spontaneity of dispersion at maximum use rate (10 % w/v);
- The completed two-year storage stability study at ambient temperature in the commercial packaging.

Appendix 1 Copy of the product authorisation



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anses
agence nationale de sécurité sanitaire
alimentaire, environnementale, 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 réglementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique SIGNATURE XTRA STRESSGARD

<i>de la société</i>	BAYER SAS
<i>enregistrée sous le</i>	n°2018-0456

Vu les conclusions de l'évaluation de l'Anses du 28 octobre 2019,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

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

Avertissement :

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

SIGNATURE XTRA STRESSGARD
AMM n°2200150

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Fosetyl-aluminium WG 60 / SIGNATURE XTRA STRESSGARD
 Part A - National Assessment
 FRANCE DEPR version



Informations générales sur le produit	
Nom du produit	SIGNATURE XTRA STRESSGARD
Type de produit	Produit de référence
Titulaire	BAYER SAS 16, rue Jean-Marie Leclair, CS 90106 69266 LYON CEDEX 09 France
Formulation	Granulé dispersable (WG)
Contenant	600 g/kg - fosétyl d'aluminium
Numéro d'intrant	130-2018.01
Numéro d'AMM	2200150
Fonction	Fongicide
Gamme d'usage	Professionnel

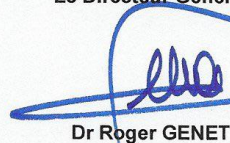
L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 30 avril 2021.

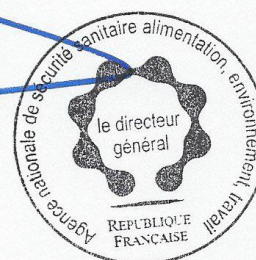
Le dépôt d'une demande de renouvellement conformément à l'article 43 du règlement (CE) 1107/2009, dans les trois mois suivant le renouvellement de l'approbation de la substance active, prolonge de plein droit l'autorisation de mise sur le marché après son arrivée à échéance de la durée nécessaire pour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

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

A Maisons-Alfort, le 28 avril 2020

Le Directeur Général


 Dr Roger GENET



SIGNATURE XTRA STRESSGARD
 AMM n°2200150

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ANNEXE I : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Bouteilles en polyéthylène haute densité	10 L contenant 5 kg de produit.
Bouteilles en polyéthylène haute densité / polyamide	10 L contenant 5 kg de produit.

Classification du produit	
La classification retenue est la suivante :	
Catégorie de danger	Mention de danger
Lésions oculaires graves et irritation oculaire - Catégorie 2	H319 : Provoque une sévère irritation des yeux
Pour les phrases P se référer à la réglementation en vigueur. Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.	

Fosetyl-aluminium WG 60 / SIGNATURE XTRA STRESSGARD
Part A - National Assessment
FRANCE DEPR version



Liste des usages autorisés

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
01006001 Gazons de graminées*Trt Part.Aer.* Anthracnose(s)	20 kg/ha	4/an	-	Non applicable	5 (dont DVP 5)	-	-	-
Uniquement sur gazon établi. Efficacité montrée sur <i>Colletotrichum</i> . Intervalle minimum entre les applications : 14 jours entre la première et la deuxième, ainsi qu'entre la troisième et la quatrième application et 90 jours entre la deuxième et la troisième application.								
18503201 Gazons de graminées*Trt Part.Aer.* Fusarioses, complexe à helminthosporioses	20 kg/ha	4/an	-	Non applicable	5 (dont DVP 5)	-	-	-
Uniquement sur gazon établi. Efficacité montrée sur <i>Microdochium nivale</i> . Intervalle minimum entre les applications : 14 jours entre la première et la deuxième, ainsi qu'entre la troisième et la quatrième application et 90 jours entre la deuxième et la troisième application.								
18503205 Gazons de graminées*Trt Part.Aer.* Rhizoctoniose	20 kg/ha	4/an	-	Non applicable	5 (dont DVP 5)	-	-	-
Uniquement sur gazon établi. Efficacité montrée sur <i>Rhizoctonia solani</i> . Intervalle minimum entre les applications : 14 jours entre la première et la deuxième, ainsi qu'entre la troisième et la quatrième application et 90 jours entre la deuxième et la troisième application.								

DVP : Dispositif Végétalisé Permanent.

SIGNATURE XTRA STRESSGARD
AMM n°2200150

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
18503212 Gazons de graminées*Trt Part.Aer.* Champignons (pythiacées)	20 kg/ha	4/an	-
Motivation du refus : L'usage est refusé car l'efficacité à la dose revendiquée n'est pas démontrée.			

SIGNATURE XTRA STRESSGARD
AMM n°2200150

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Ne pas stocker le produit dans un local où la température peut dépasser 40°C.

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

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

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à dos ou d'une lance

- **pendant le mélange/chargement**
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de protection de catégorie III type 5/6 ;
- **pendant l'application**
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de protection non tissée de catégorie III type 5/6 ;
 - Bottes de protection certifiées EN 13 832-3 ;
- **pendant le nettoyage du matériel de pulvérisation**
 - Gants en nitrile certifiés EN 374-3 ;
 - Combinaison de protection non tissée de catégorie III type 5/6 ;

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe

- **pendant le mélange/chargement**
 - Gants en nitrile certifiés EN 374-3 ;
 - EPI vestimentaire certifié EN ISO 27065 ;
 - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;
- **pendant l'application**

Si application avec tracteur avec cabine

 - EPI vestimentaire certifié EN ISO 27065 ;
 - Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

 - EPI vestimentaire certifié EN ISO 27065 ;
 - Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;
- **pendant le nettoyage du matériel de pulvérisation**
 - Gants en nitrile certifiés EN 374-3 ;
 - EPI vestimentaire certifié EN ISO 27065 ;
 - EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;



Pour le travailleur, porter :

- un vêtement de protection certifié EN ISO 27065 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 24 heures.

Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013) :

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :

- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

- SPe 2: Pour protéger les eaux souterraines, ne pas appliquer ce produit sur plus de 10 % de la parcelle.

Protection de la faune

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

- SPe 2 : Pour protéger les oiseaux et les mammifères sauvages, ne pas appliquer ce produit sur plus de 10 % de la parcelle.

- 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.

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Réurrence (mois)
Fournir la détermination de la persistance de la mousse à la concentration maximale d'utilisation.	24	-
Fournir la détermination de la spontanéité de la dispersion à la concentration maximale d'utilisation.	24	-
Fournir les résultats de l'étude en cours de réalisation, concernant la stabilité au stockage pendant 2 ans à température ambiante.	24	-

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.

Projet étiquette SIGNATURE XTRA STRESSGARD

○ Facing 1 :

SIGNATURE XTRA STRESSGARD : Fongicide gazon large spectre

AMM : XXXX

Contient : 600 g/kg de fosetyl-aluminium sous forme de Granulé à disperser dans l'eau (WG).

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

Conditionnement : 5kg

Fongicide systémique à utiliser en pulvérisation foliaire pour la gestion des fusarioses hivernales, du rhizoctone, de l'anthracnose et des pythiums.

○ Facing 2 :

Pavé réglementaire :

SIGNATURE XTRA STRESSGARD

AMM XXXXXXXX

Contient : 600 g/kg de fosetyl-aluminium (60.0% m/m)

Granulé à disperser dans l'eau (WG)

Détenteur de l'AMM : BAYER S.A.S. (69)

Classement :

ATTENTION

H319 Provoque une sévère irritation des yeux.

EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.

P280 Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux.

P337 + P313 Si l'irritation oculaire persiste: consulter un médecin.

Délai de réentrée : 24h

Mesures de protection des individus : se reporter impérativement au paragraphe de l'étiquette intitulé « Précautions à prendre

PREMIERS SOINS

Conseils généraux S'éloigner de la zone dangereuse. Enlever immédiatement tout vêtement souillé et le mettre à l'écart. Si des symptômes apparaissent et persistent, consulter un médecin.

Inhalation Amener la victime à l'air libre. Appeler immédiatement un médecin ou un centre AntiPoison.

Contact avec la peau Laver immédiatement et abondamment avec de l'eau et du savon.

Contact avec les yeux Laver immédiatement et abondamment à l'eau pendant au moins 15 minutes. Si une irritation se développe et persiste, consulter un médecin.

Ingestion Ne PAS faire vomir. Appeler immédiatement un médecin ou un centre AntiPoison. Garder la victime au repos et la maintenir au chaud.

Lire les instructions avant emploi.

Fiche de données de sécurité disponible sur Internet : www.quickfds.fr

Numéro d'appel d'urgence 24h/24h : 04 72 85 25 25

○ Facing 3 :

Caractéristiques :

Présentation

SIGNATURE XTRA STRESSGARD® est un fongicide large spectre systémique à usage professionnel, à base de fosetyl-aluminium.

SIGNATURE XTRA STRESSGARD® est destiné à être utilisé sur gazons de graminées (terrains sportifs, golfs) pour lutter contre :

- l'antracnose (*Colletotrichum graminicola*),
- les pythiums (*Pythium ultimum/aphanidermatum*),
- le rhizoctone brun (*Rhizoctonia solani*),
- les fusarioses hivernales (*Microdochium nivale*)

SIGNATURE XTRA STRESSGARD® s'utilise en application foliaire à la dose de 20kg par hectare. Il peut être appliqué toute l'année sur gazon en repos végétatif ou en croissance active et affiche une activité préventive et curative.

6 applications par an sont autorisées.

Enfin, Signature Xtra Stressgard offre un mode d'action unique et s'adapte parfaitement à la gestion de la résistance via des programmes rotatifs avec tous les autres modes d'action sur le marché (par exemple DMI, SDHI, Qoi et autres)

Mode d'action

La substance active fosetyl-aluminium fait partie du groupe chimique des phosphanates, et possède des propriétés d'activité entièrement systémique. Le fosetyl est absorbé rapidement par les parties humides de la plante et transporté par voie acropétale et basipétale dans le flux de sève de la plante. Après l'absorption, le lessivage par les précipitations n'est plus possible. Ces propriétés entièrement systémiques assurent la protection à la fois des parties de plantes traitées et de la nouvelle croissance formée entre deux traitements. De plus, les racines sont protégées. **SIGNATURE XTRA STRESSGARD®** a une activité directe sur les champignons et stimule en outre les défenses naturelles des plantes.

SIGNATURE XTRA STRESSGARD® a principalement une efficacité protectrice (préventive), à utiliser avant l'apparition des maladies, mais peut aussi efficacement réduire et/ou retarder le développement de la maladie lorsqu'il est appliqué aux premiers symptômes de maladies. **SIGNATURE XTRA STRESSGARD®** a montré un haut niveau d'efficacité sur les maladies ciblées du gazon telles que les fusarioses, l'antracnose, le rhizoctone et les pythium sur gazon de graminées.

Usages autorisés :

- Gazons de graminées*Trt Part.Aer.*Fusarioses, complexe à helminthosporioses
- Gazons de graminées*Trt Part.Aer.*Anthracnose(s)
- Gazons de graminées*Trt Part.Aer.*Champignons (pythiacées)
- Gazons de graminées*Trt Part.Aer.*Rhizoctoniose

Nombre et intervalles d'applications: jusqu'à 6 applications possible par an. Selon les conditions de pression des maladies, il est possible de réaliser jusqu'à 4 applications consécutives à intervalle de 14 jours minimum. Si 4 applications consécutives sont réalisées, attendre au minimum 8 semaines avant de faire une 5ème application. Respecter un délai de 2 semaines après la 5ème application avec SIGNATURE XTRA STRESSGARD®.

SIGNATURE XTRA STRESSGARD® s'utilise sur gazons établis (BBCH 29-33). Il est sélectif de la plupart des espèces et variétés de gazons de golf, de terrains de sport. Liste des espèces testées dans le cadre des essais effectués pour l'homologation :

- Fétuque (*Festuca sp.*)
- Pâleurin (*Poa sp.*)
- Ray-Grass (*Lolium sp.*)
- Agrostide stolonifère (*Agrostis stolonifera*)
- Chiendent (*Cynodon sp.*)
- Paspalum (*Paspalum sp.*)

Lors de la pulvérisation, éviter tout entraînement et toute projection sur des surfaces autres que le gazon (comme par exemple massif ornemental, allée égravillonnée, bordures).

Conditions d'emploi : Dose	Volume d'eau	Nombre maximum d'application		Restriction
Terrains de golf	20 kg/ha	200 et 600 L/ha	6*	Sur la totalité des greens et départs. Sur fairway : en localisé sans dépasser 5% de la surface du fairway.
Terrains de sport	20 kg/ha	200 et 600 L/ha	6*	Ne pas appliquer sur plus de 10% de la surface.