

**REGISTRATION REPORT**  
**Part A**  
**Risk Management**

Product code: CA2157

Product name(s): FUSILADE MAX

Chemical active substances:

Fluazifop-P, 125 g/L

Southern Zone

Zonal Rapporteur Member State: France

**NATIONAL ASSESSMENT FRANCE**  
(label extension)

Applicant: NUFARM S.A.S.

Date: 12/09/2025

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## PART A

### RISK MANAGEMENT

#### 1 Details of the application

The company NUFARM S.A.S. has requested a marketing authorisation in France for the product FUSILADE MAX (product code: CA2157), containing 125 g/L fluzifop-P<sup>1</sup> 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).

#### 1.1 Application background

The present registration report concerns the evaluation of NUFARM S.A.S.' application submitted on 16 June 2023 to market FUSILADE MAX 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 label extension of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2023-1823) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009<sup>2</sup>, 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")<sup>3</sup>. 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 FUSILADE MAX has been made using endpoints agreed in the EU peer review of fluazifop-P. It also includes assessment of data and information related to FUSILADE MAX 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<sup>4</sup>, 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 FUSILADE MAX.

<sup>1</sup> 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.

<sup>2</sup> 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

<sup>3</sup> 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](#)

<sup>4</sup> 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.

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## 1.2 Letters of Access

The applicant has provided a letter of access for active substance (and/or PPP data). This letters of access is available upon request.

## 1.3 Justification for submission of tests and studies

According to the applicant: « *Any new studies submitted with the application are necessary for this label extension on tomatoes to address any data gaps due to new guidance.* ».

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of FUSILADE MAX, 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	CA2157
Product name in MS	FUSILADE MAX
Authorisation number	2000044
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	NUFARM S.A.S.
Active substance(s) (incl. content)	Fluazifop-P, 125 g/L
Formulation type	Emulsifiable concentrate [EC]
Packaging	Packaging not changed
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

## 2.2 Conclusion

The evaluation of the application for FUSILADE MAX resulted in the decision **to grant** the authorisation.

## 2.3 Substances of concern for national monitoring

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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 4 May 2017<sup>5</sup> 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.

Moreover, the French Order of 12 April 2021<sup>6</sup> 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”

<sup>5</sup> Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjutants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

<sup>6</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

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crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>7</sup> 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.

Finally, the French Order of 20 November 2021<sup>8</sup> on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop<sup>9</sup> when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres for the intended uses.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 5 metres to non-agricultural for use at a maximum application rate of 187,5 g a.s./ha.
SPe 3	To protect non-target plants, respect an unsprayed buffer zone of 20 metres to non-agricultural for use at an application rate above 187,5 g a.s./ha until 375 g a.s./ha.
SPe 8	To protect bees and other pollinating insects, for use on tomato do not use in presence of bees and other pollinating insects.
Other specific restrictions	
Re-entry period	48 hours.
Storage	-

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

<sup>8</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

<sup>9</sup> List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

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Risk mitigation measures	-
Agricultural recommendations	Precise the optimal conditions for using the product in order to limit the risk of phytotoxicity on adjacent crops.
bystander and resident protection	<p>For use on tomatoes at a maximum dose of 1.5 L/ha, respect an unsprayed zone of at least 3 meters from the extremity of the boom and:</p> <ul style="list-style-type: none"> <li>- areas frequented by people present during treatment</li> <li>- areas likely to be frequented by residents.</li> </ul> <p>For use on tomatoes at a maximum dose of 2.5 L/ha, respect an unsprayed zone of at least 3 meters from the extremity of the boom and:</p> <ul style="list-style-type: none"> <li>- the area frequented by people present during treatment</li> <li>- the area likely to be frequented by residents;</li> </ul> <p>and use equipment that reduces drift by at least 50%.</p>

The other conditions of use specified in the previous evaluations are not changed.

## 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.

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## 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: **12/09/2025**

PPP (product name/code):	CA2157 / FUSILADE MAX	Formulation type:	EC <sup>(a, b)</sup>
Active substance 1:	Fluazifop-P	Conc. of a.s. 1:	125 g/L <sup>(c)</sup>
Safener:	/	Conc. of safener:	/ <sup>(c)</sup>
Synergist:	/	Conc. of synergist:	/ <sup>(c)</sup>
Applicant:	NUFARM S.A.S.	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	Southern Zone <sup>(d)</sup>	Non-professional use:	<input type="checkbox"/>
Verified by MS:	Yes		
Field of use:	Herbicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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 <sup>(f)</sup>
					Method/Ki nd	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/ma x		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													
1	FR	Tomato (LYPES)	F	Annual grasses	Spraying	Latest BBCH 51	a) 1 b) 1	-	a) 1.5 b) 1.5	a) 187.5 b) 187.5	100-400	70	Acceptable
2	FR	Tomato (LYPES)	F	Perennial grasses	Spraying	Latest BBCH 51	a) 1 b) 1	-	a) 2.5 b) 2.5	a) 312.5 b) 312.5	100-400	70	Acceptable

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<b>Remarks table heading:</b>	(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d) Select relevant
	(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c) g/kg or g/l	(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.
<b>Remarks columns:</b>	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 <sup>3</sup> 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 Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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)

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 clear brown liquid with an oc-tanol like odour. It is not explosive, has no oxidising properties. The product is not flammable/has a flash point of  $85 \pm 4^{\circ}\text{C}$ . It has a self-ignition temperature of  $265 \pm 5^{\circ}\text{C}$ . In aqueous solution, it has a pH value around 5.5 to 6.5 at  $25^{\circ}\text{C}$ . There is no effect of low and high temperature on the stability of the formulation, since after 7 days at  $0^{\circ}\text{C}$  and 14 days at  $54^{\circ}\text{C}$ , neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE<sup>10</sup> and PET<sup>11</sup>. Its technical characteristics are acceptable for an emulsifiable concentrate formulation.

The intended concentration of use is 0.15% to 3%. (Lowest and highest concentration tested 0.09 to 3.75%). Use concentrations already accepted for the renewal: 0.15-3% % w/v.

Use concentrations for this extension: 0.37-2.5 % w/v.

Previous use rates assessed for the renewal cover the one proposed for this extension. Therefore no additional studies are required.

#### 3.2 Efficacy (Part B, Section 3)

- The efficacy level of FUSILADE MAX applied post-emergence at 1.5 or 2.5 L/ha in tomato is considered to be satisfactory for the control of annual and perennial grass weeds, respectively ;
- The selectivity level of FUSILADE MAX is considered to be satisfactory for the claimed use;
- The risks of negative impact on yield, quality and propagation are considered to be negligible ;
- The risk of negative impact on succeeding crops is considered to be acceptable ;
- The risk of negative impact on adjacent crops is considered to be acceptable. Nevertheless, specific attention shall be paid to the application of the product next to adjacent crops.
- There is a risk of resistance to fluazifop-P for *Digitaria sanguinalis* requiring a survey.

##### Monitoring data:

Survey of resistance to fluazifop-P should be put in place based on the analysis of field efficacy failures as indicated in Part 5.1.1.

#### 3.3 Methods of analysis (Part B, Section 5)

##### 3.3.1 Analytical method for the formulation

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<sup>10</sup> HDPE: High density polyethylene

<sup>11</sup> PET: Polyethylene terephthalate

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Analytical methods for the determination of Fluazifop-p butyl and the relevant impurity 2-chloro-5-(trifluoromethyl) pyridine in the product FUSILADE MAX (product code: CA2157) are available and validated.

### 3.3.2 Analytical methods for residues

- Analytical methods for monitoring are available in MRLs dossier (Art.6)/Draft Assessment report and validated for the determination of residues of Fluazifop-P in plants, animals, air and body tissues.
- Analytical methods for monitoring for soil, water and body fluids are provided for ongoing renewal of approval and will be evaluated when the renewal is available.
- Two new validation studies of the method for risk assessment for ecotoxicology (Lakaschus, S., Kühn, C., Kiraly Turnsek, S (2020) and (567, R2140050, Staffel, J. (2022) have been submitted and are considered to be validated.

## 3.4 Mammalian toxicology (Part B, Section 6)

### Endpoints used in risk assessment

Active substance	<b>Fluazifop-P-butyl</b>
AOEL systemic	0.02 mg/kg bw/d
AAOEL	-
Oral absorption	100%
Vapour pressure	1.2 10 <sup>-4</sup> Pa at 20°C
Reference	EFSA Conclusion (EFSA Journal 2012;10(11):2945); SANCO/11238/2011 rev 5
Dermal absorption	Concentrate: 1.3% Dilution: 22% (0.469 g/L)

### 3.4.1 Acute toxicity

FUSILADE MAX has a low acute oral, inhalational and dermal toxicity and is not irritating to the skin or eye and is not a skin sensitisier.

### 3.4.2 Operator exposure

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model<sup>12</sup>:

### Long term exposure

Model data		<b>Fluazifop-P-butyl</b>
	<b>Level of PPE</b>	<b>% AOEL</b>
<b>Application : Low vegetables - Vehicle mounted downwards spray outdoors</b>		
Application rate	0.3125 kg a.s./ha	

<sup>12</sup> EFSA Journal 2022;20(1):7032

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<b>Spray application</b> (EFSA; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) during M/L and A	97.7%
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According to the exposure assessment using the EFSA model, the operator exposure to FUSILADE MAX is below the AOEL value of Fluazifop-P-butyl, with a working coverall during mixing/loading and application.

### 3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop inspection and irrigation activities. Therefore, the estimation of the worker exposure was calculated according to the EFSA model<sup>8</sup>.

Model data		Fluazifop-P-butyl
	Level of PPE	% AOEL
Activity: Inspection, irrigation Outdoor Work rate: 2 hours/day Number of applications : 1 Interval between treatments: NA DT50: 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha		
Application rate (kg as/ha)		0.3125 kg a.s./ha
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1250 cm <sup>2</sup> /person/h	48.1%

According to the exposure assessment using the EFSA model, the worker exposure to FUSILADE MAX is below the AOEL value of Fluazifop-P-butyl, with a working coverall .

### 3.4.4 Bystander exposure

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<sup>13</sup>.

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 2022;20(1):7032): “*When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. 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

The resident exposure was assessed according to the EFSA model.

<sup>13</sup> 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)

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Model data	Fluazifop-P-butyl	
	% AOEL	
Scenario: Vehicle mounted spray application outdoors Buffer zone: <b>2-3 (m)</b> Drift reduction technology: <b>no</b> Number of applications : 1 Interval between treatments: NA days DT50: 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha		
Application rate		<b>0.1875 kg a.s./ha</b>
Resident (children) Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	56%
	Vapour (75 <sup>th</sup> perc.)	4%
	Deposits (75 <sup>th</sup> perc.)	3.8%
	Re-entry (75 <sup>th</sup> perc.)	34.8%
	<b>Sum (mean)</b>	<b>65.1%</b>
Resident (adults) Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	13.3%
	Vapour (75 <sup>th</sup> perc.)	1.4%
	Deposits (75 <sup>th</sup> perc.)	1.4%
	Re-entry (75 <sup>th</sup> perc.)	19.3%
	<b>Sum (mean)</b>	<b>24%</b>
Scenario: Vehicle mounted spray application outdoors Buffer zone: <b>2-3 (m)</b> <b>Drift reduction technology: yes</b> Number of applications : 1 Interval between treatments: NA days DT50: 30 days DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha		
Application rate		<b>0.3125 kg a.s./ha</b>
Resident (children) Body weight: 10 kg	Drift (75 <sup>th</sup> perc.)	46.6%
	Vapour (75 <sup>th</sup> perc.)	4%
	Deposits (75 <sup>th</sup> perc.)	3.1%
	Re-entry (75 <sup>th</sup> perc.)	58%
	<b>Sum (mean)</b>	<b>78%</b>
Resident (adults) Body weight: 60 kg	Drift (75 <sup>th</sup> perc.)	11.1%
	Vapour (75 <sup>th</sup> perc.)	1.4%
	Deposits (75 <sup>th</sup> perc.)	1.2%
	Re-entry (75 <sup>th</sup> perc.)	32.2%
	<b>Sum (mean)</b>	<b>33.1%</b>

According to the exposure assessment performed by the EFSA model, the resident exposure to FUSILADE MAX is below the AOEL value of Fluazifop-P-butyl, with a buffer zone of 3 meters without drift reduction technology for the low dose (1.5 L/ha) and with a buffer zone of 3 meters and drift reduction technology for the high dose (2.5 L/ha).

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### 3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

### Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.06 mg/kg on tomato for fluazifop-P as laid down in Regulation (EU) No 396/2005 is not expected.

The short-term intakes of fluazifop-P residues are unlikely to present a public health concern. However, the chronic intake of fluazifop-P residues are above the ADI (154% ADI) using PRIMO Rev 3.1<sup>14</sup>.

However, it should be noted that:

- The estimated levels of chronic intakes, linked to the intended uses of FUSILADE MAX for which an MRL exceedance is not expected, contribute to a maximum of 0.36% of the ADI (with the intended use on tomato).

As a consequence, the available data could not ensure the finalisation of the estimated levels of chronic intakes of fluazifop-P for the consumer.

zRMS considers no firm conclusion can be reached for the intended use of the product FUSILADE MAX. According to available data, no specific mitigation measures should apply.

### Data gaps

-

### Summary for CA2157

Crop	PHI for CA2157 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for CA2157 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Fluazifop-p		
Tomato	70 days	Yes	70 days	-

\* Purpose of withholding period to be specified

### Waiting periods before planting succeeding crops

Not relevant.

## 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 values of Fluazifop-P-butyl and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from

<sup>14</sup> Pesticide Residue Intake Model version 3.1

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the FOCUS models and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PECsw values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.

PECgw values for Fluazifop-P-butyl and its metabolites do not occur at levels exceeding those mentioned in regulation (EU) No 546/2011 and guidance document SANCO 221/2000<sup>15</sup>. 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(s) and its/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, non-target arthropods (except for bees), earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5.

The information provided in the “Registrations Reports” on the analytical methods of tested concentrations in toxicity studies for bees (chronic adult and larval) are insufficient and do not allow the validation of these methods according to the methodology in force at European level. Therefore, there is uncertainty about the toxicity values from these studies. Thus, in the absence of reliable reference toxicity values, the risk assessment could not be finalised for bees.

### **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)**

The active substance fuazifop-P 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”.

### **5.1.1 Post-authorisation monitoring**

<sup>15</sup> 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.

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A survey of resistance to fluazifop-P should be put in place, in particular on *Digitaria sanguinalis*, based on the analysis of field efficacy failures. A report on the results of the monitoring should be provided at the time of the authorisation renewal of the product.

### **5.1.2 Post-authorisation data requirements**

None.

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## Appendix 1 Copy of the product authorisation



FUSILADEMA\_PMAJ\_  
2023-1823\_D.pdf

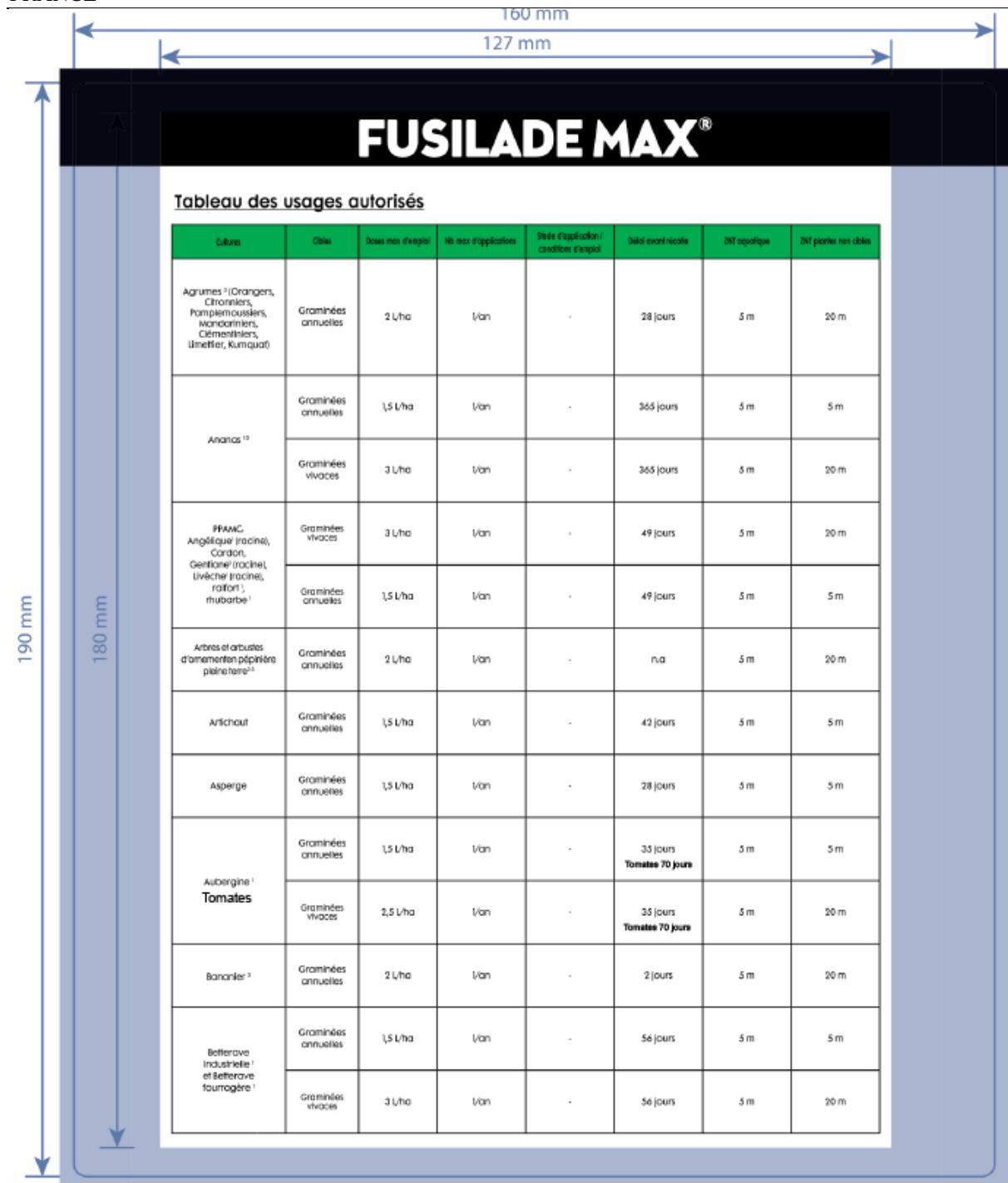
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## Appendix 2 Copy of the product label

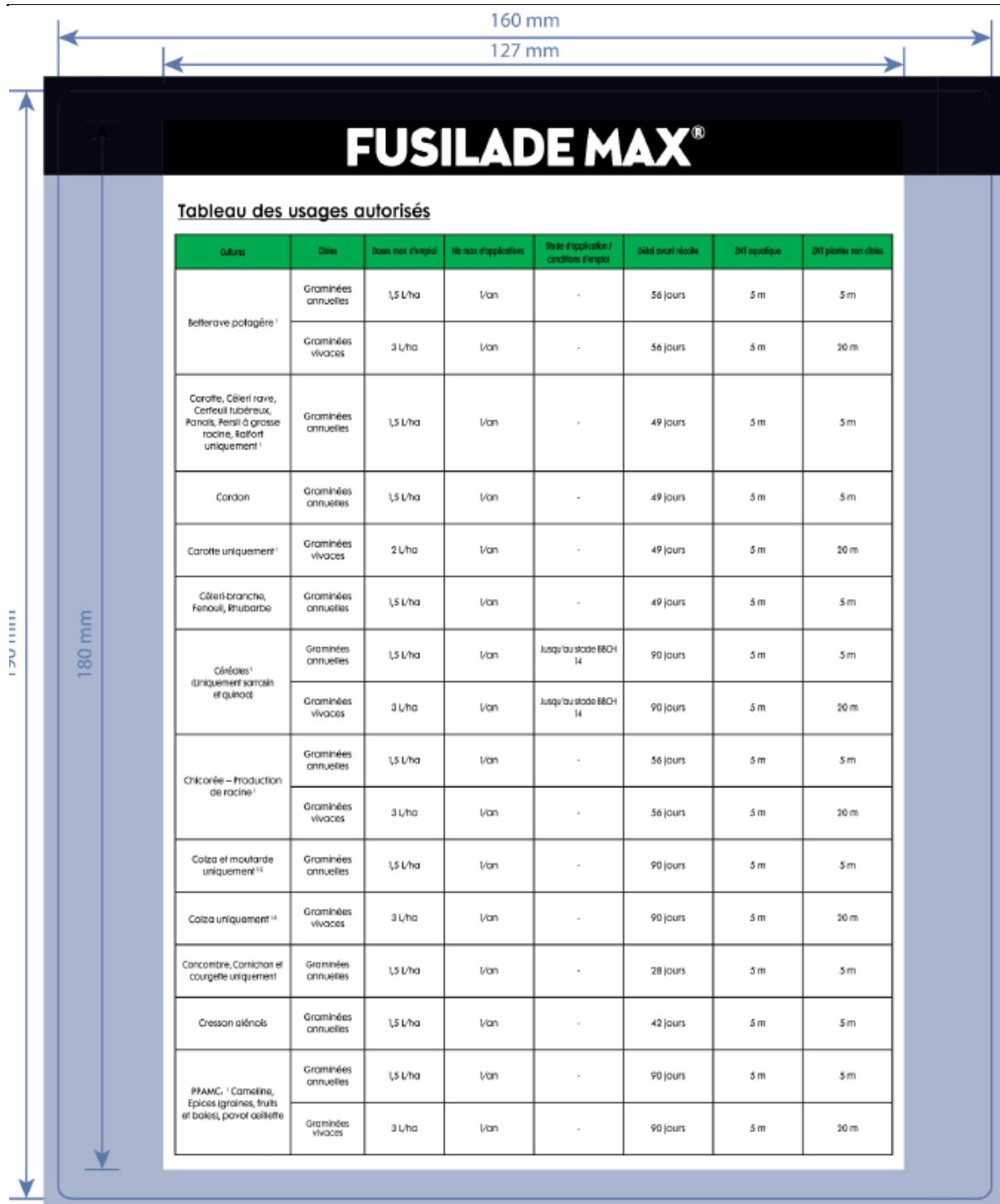
The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.



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180 mm

160 mm

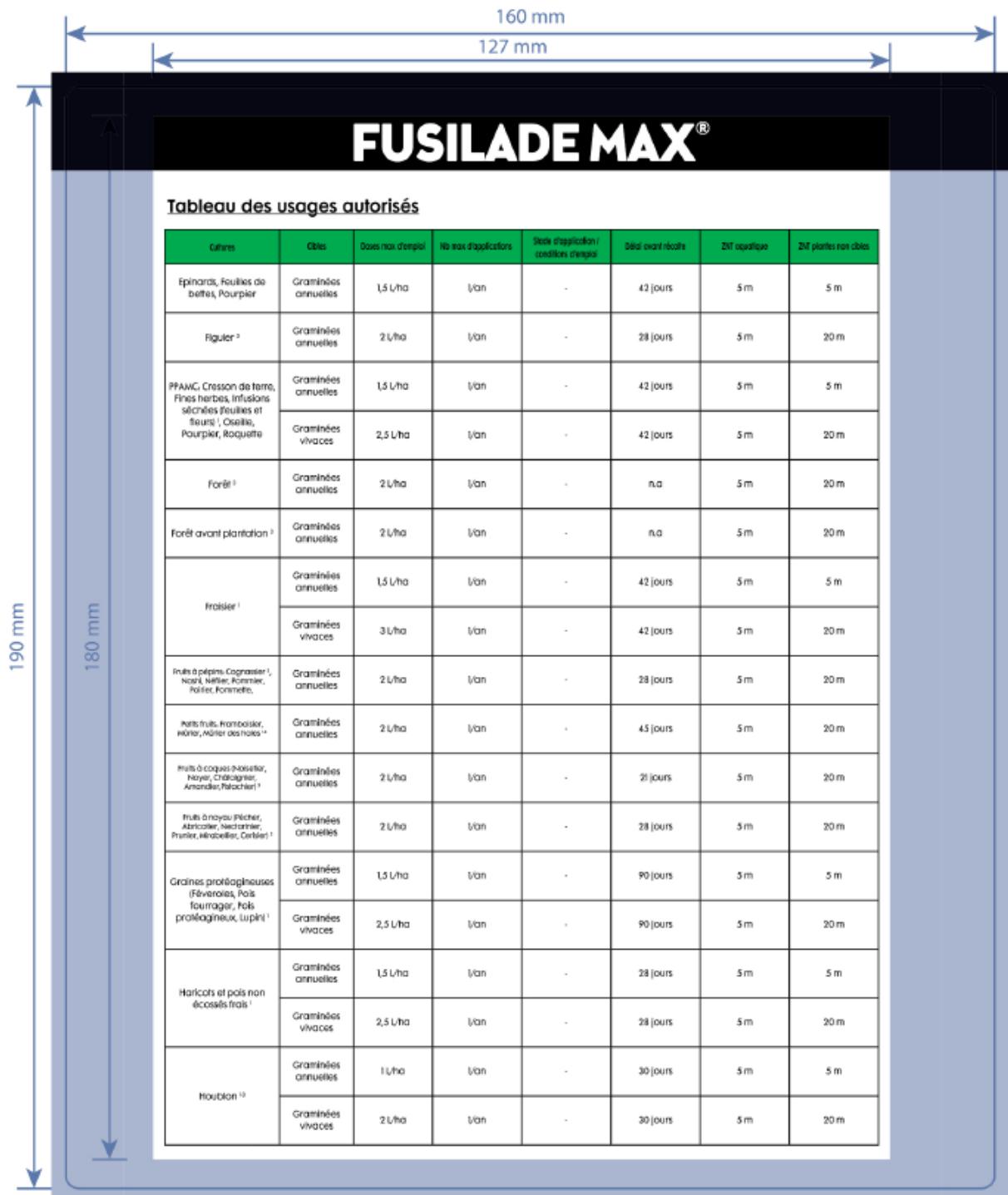
127 mm

**FUSILADE MAX®**

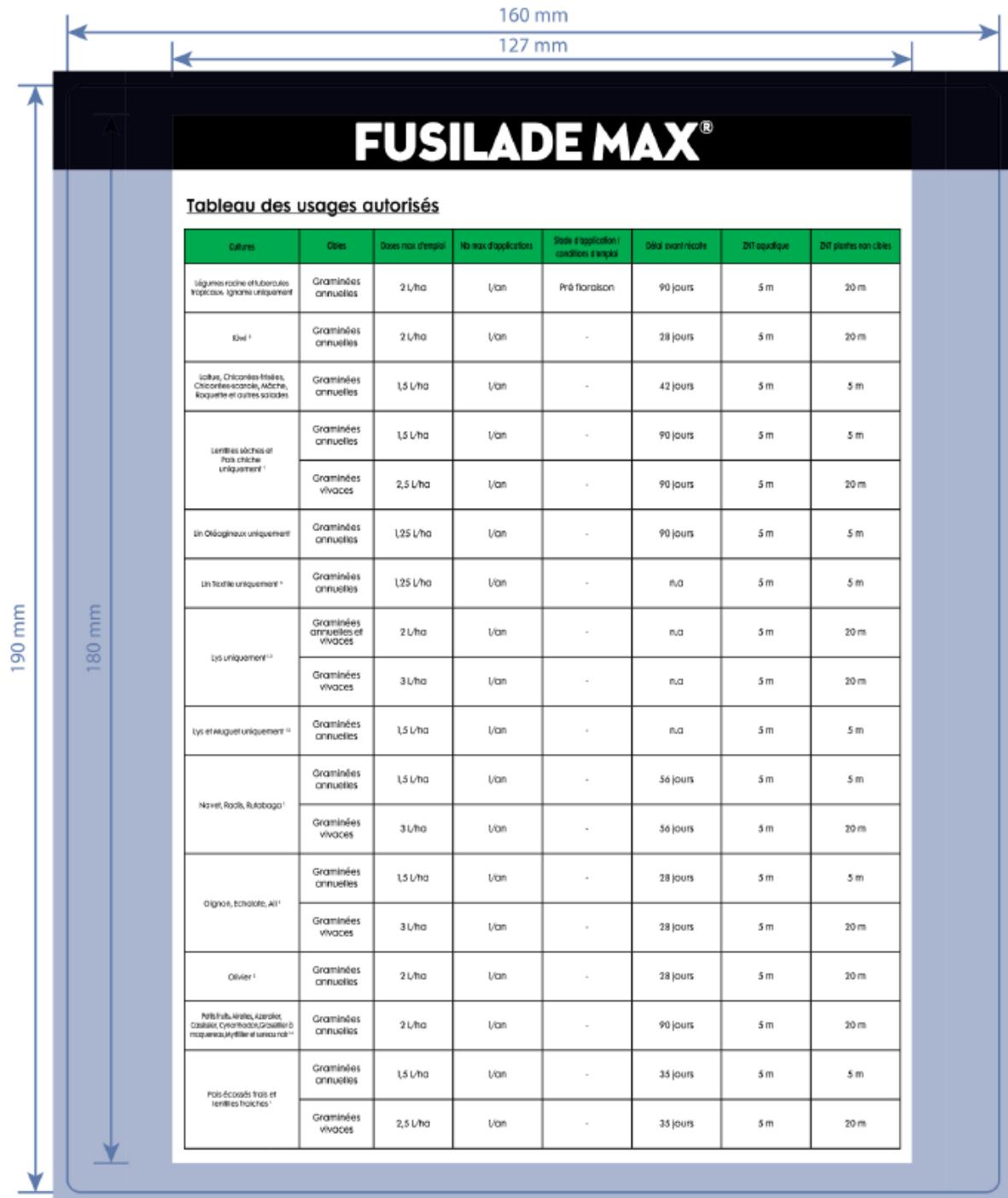
**Tableau des usages autorisés**

Cultures	Classe	Doses max d'emploi <sup>1</sup>	Nombre max d'application	Statut d'application / conditions d'emploi	Delay avant récolte	DNT aquatique	DNT pluies sur chêne
Betterave potagère <sup>1</sup>	Graminées annuelles	1,5 l/ha	1/an	-	56 jours	5 m	5 m
	Graminées vivaces	3 l/ha	1/an	-	56 jours	5 m	20 m
Carotte, Céleri rare, Céreuil tubéreux, Panais, Persil à grosse racine, Radis <sup>1</sup> uniquement <sup>1</sup>	Graminées annuelles	1,5 l/ha	1/an	-	49 jours	5 m	5 m
Cordon	Graminées annuelles	1,5 l/ha	1/an	-	49 jours	5 m	5 m
Carotte uniquement <sup>1</sup>	Graminées vivaces	2 l/ha	1/an	-	49 jours	5 m	20 m
Céleri-branche, Fenouil, Rhubarbe	Graminées annuelles	1,5 l/ha	1/an	-	49 jours	5 m	5 m
Céreales <sup>1</sup> (Uniquement sarments et quenots)	Graminées annuelles	1,5 l/ha	1/an	Jusqu'au stade BBCH 14	90 jours	5 m	5 m
	Graminées vivaces	3 l/ha	1/an	Jusqu'au stade BBCH 14	90 jours	5 m	20 m
Chicorée – Production de racine <sup>1</sup>	Graminées annuelles	1,5 l/ha	1/an	-	56 jours	5 m	5 m
	Graminées vivaces	3 l/ha	1/an	-	56 jours	5 m	20 m
Colza et moutarde uniquement <sup>1,2</sup>	Graminées annuelles	1,5 l/ha	1/an	-	90 jours	5 m	5 m
Colza uniquement <sup>1,2</sup>	Graminées vivaces	3 l/ha	1/an	-	90 jours	5 m	20 m
Concombre, Cornichon et courgette uniquement	Graminées annuelles	1,5 l/ha	1/an	-	28 jours	5 m	5 m
Cresson dénoisé	Graminées annuelles	1,5 l/ha	1/an	-	42 jours	5 m	5 m
PfAMC, l'Cameline, Epices (graines, fruits et baies), pavot oïllette	Graminées annuelles	1,5 l/ha	1/an	-	90 jours	5 m	5 m
	Graminées vivaces	3 l/ha	1/an	-	90 jours	5 m	20 m

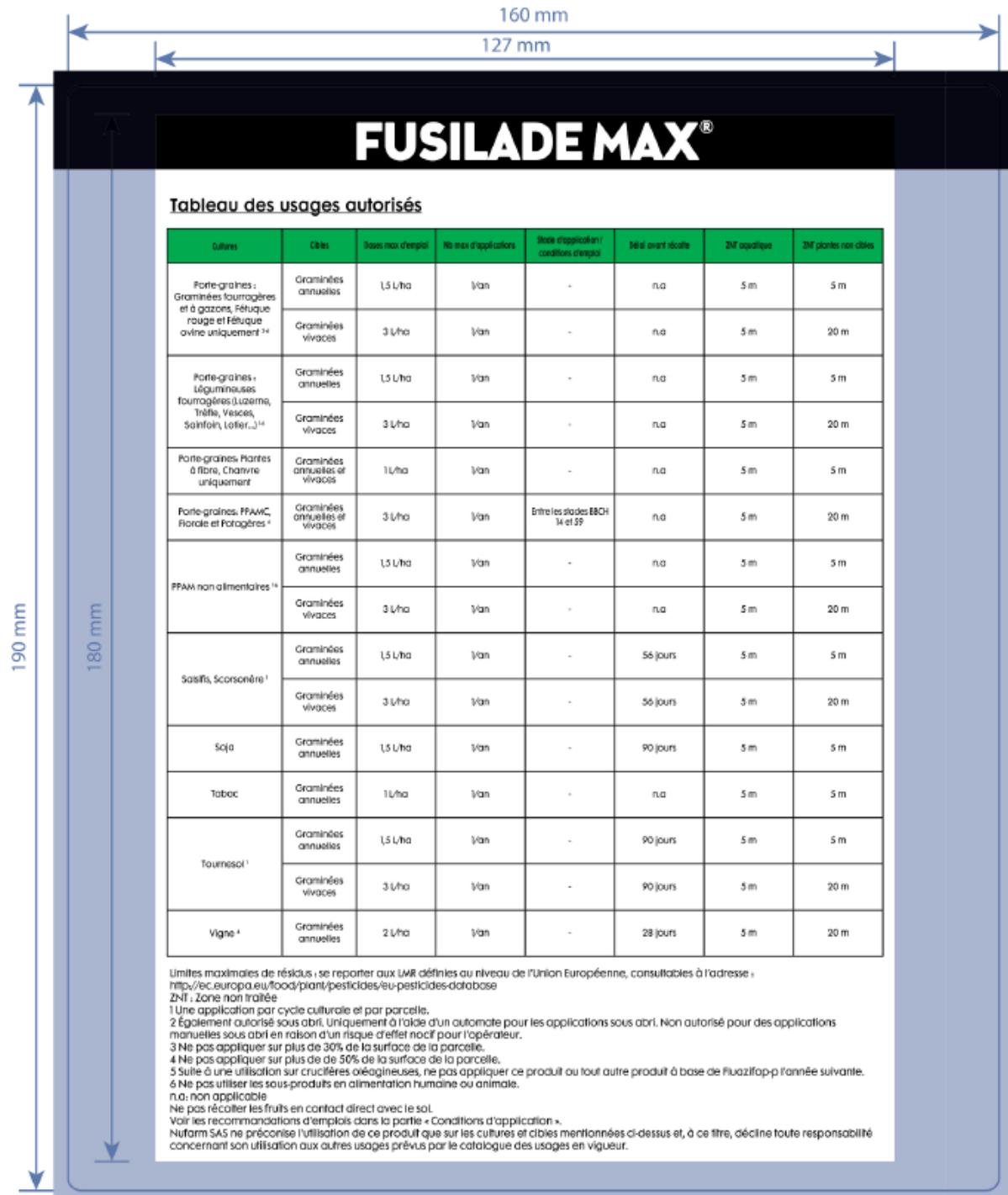
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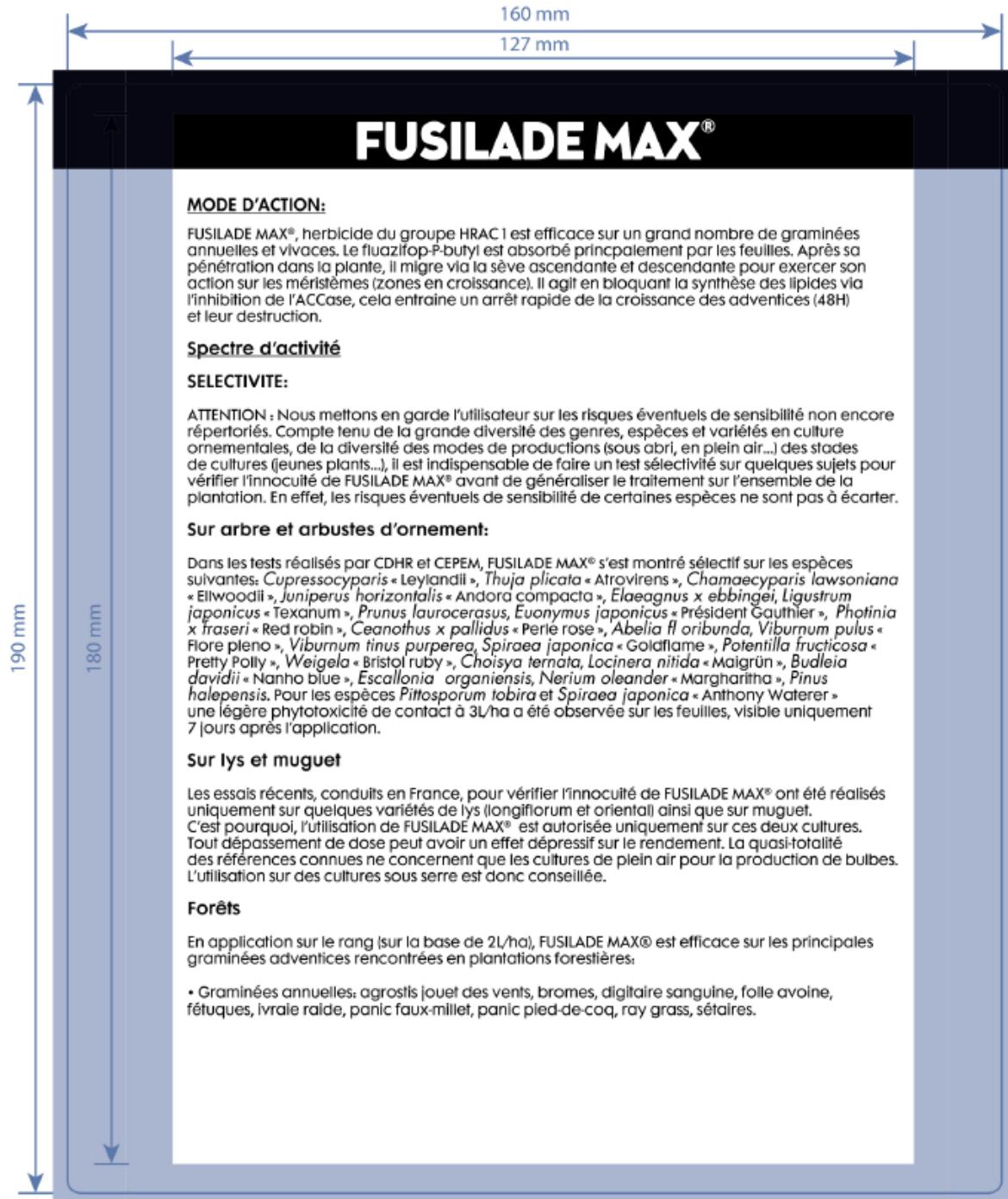
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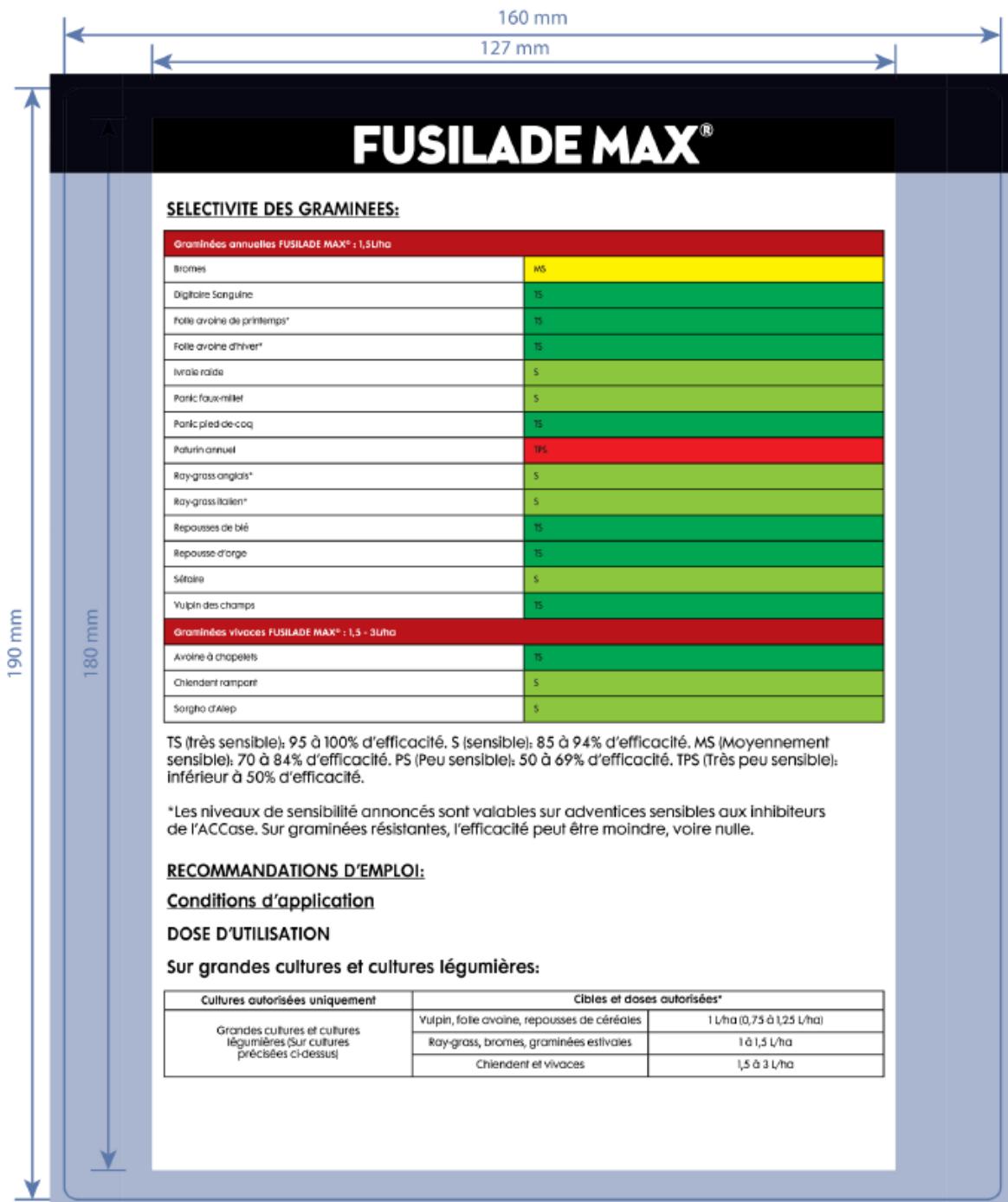
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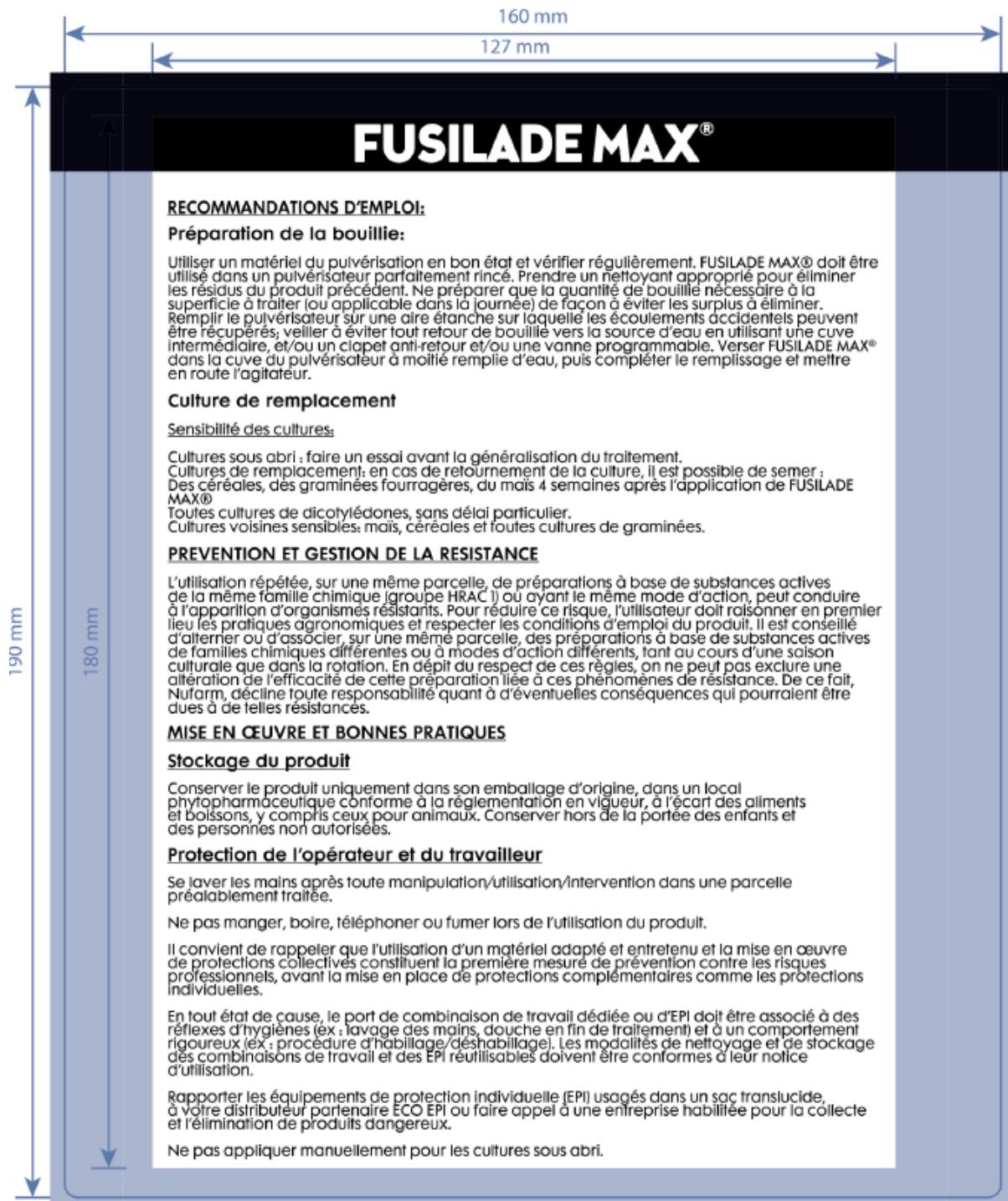
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160 mm  
127 mm

190 mm  
180 mm

**FUSILADE MAX®**

**PROTECTION DE L'OPERATEUR PENDANT LES PHASES DE:**

**MÉLANGE / CHARGEMENT**

Caractéristiques des EPI	LANCE Uniquement autorisé en plein champ	PULVÉRISATEUR À DOS - uniquement autorisé en plein champ	AUTOMATE Usage sous abris	PULVÉRISATEUR À RAMPE
	Réutilisables	Réutilisables	Réutilisables	Réutilisables
GANTS EN NITRILE NF EN ISO 374-1/A1 réutilisables NF EN 16523-1 + A1 (type A) ou à usage unique NFEN 374-2 (types A, B ou C)				
EPI VESTIMENTAIRE conforme à la norme NF EN ISO 27065/A1	EPI vestimentaire		EPI vestimentaire	EPI vestimentaire
EPI PARTIEL blouse ou tablier à manches longues catégorie III type PB3	EPI partiel		EPI partiel	EPI partiel
COMBINAISON DE PROTECTION CHIMIQUE catégorie III type 3 ou 4	OU	Type 4		
PROTECTION RESPIRATOIRE demi-masque ou masque (NF EN 143:1991) équipée d'un filtre P (NF EN 143:2006) ou A2P3 (NF EN 14307:2006)				
BOTTES certifiées EN 13 832-3:2006				

**APPLICATION AVEC**

LANCE / CULTURES BASSES (< 50 cm)		LANCE / CULTURES HAUTES (> 50 cm)		PULVÉRISATEUR À DOS	
SANS CONTACT AVEC LA VÉGÉTATION	CONTACT INTENSE AVEC LA VÉGÉTATION	SANS CONTACT AVEC LA VÉGÉTATION	CONTACT INTENSE AVEC LA VÉGÉTATION	Réutilisables	A usage unique
					
					
					
					
					
					
					
					
					
				<img alt="Icon of a lance" data-bbox="418 569	

CA2157 / FUSILADE MAX  
Part A - National Assessment  
FRANCE

160 mm

127 mm

190 mm

180 mm

**FUSILADE MAX®**

**PROTECTION DE L'OPERATEUR PENDANT LES PHASES DE:**

Caractéristiques des EPI	NETTOYAGE				PROTECTION DU TRAVAILLEUR
	LANCE Uniquement extérieur en plein champ	PULVÉRISATEUR À DOS - uniquement autorisé en plein champ	AUTOMATE Usage sous abris	PULVÉRISATEUR À RAMPE	
GANTS EN NITRILE NF EN ISO 374-1(A1) Réutilisables NF EN 352-1 à A1 (Type A ou C) ou à usage unique (NFEN 374-2 types A,B ou C)	Réutilisables	Réutilisables	Réutilisables	Réutilisables	
EPI VESTIMENTAIRE conforme à la norme NF EN ISO 27065/41	EPI vestimentaire		EPI vestimentaire	EPI vestimentaire	
EPI PARTIEL blouson ou tablier à manches longues catégorie III type PB3	ET EPI partiel		ET EPI partiel	ET EPI partiel	
COMBINAISON DE PROTECTION CHIMIQUE catégorie III type 3 ou 4	Type 3 ou 4	Type 4			

\*Dans le cas d'une intervention sur le matériel 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.

Rapporter les équipements de protection individuelle (EPI) usagés dans un sac translucide, à votre distributeur partenaire ECO EPI ou faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

**Nettoyage du pulvérisateur et gestion des fonds de cuve**

A la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses, ...) doit être rincée à l'eau claire. Le rinçage du pulvérisateur, l'épandage ou la vidange du fond de cuve et l'élimination des effluents doivent être réalisés conformément à la réglementation en vigueur.

**Elimination du produit, de l'emballage**

**REEMPLOI DE L'EMBALLAGE INTERDIT.**

Lors de l'utilisation du produit, bien vider et rincer le bidon à l'eau claire (rinçage manuel à 3 reprises en agitant le bidon rempli au 1/3 ou rinçage mécanique d'une durée minimale de 30 secondes) en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Apporter les emballages ouverts, rincés et égouttés à votre distributeur partenaire d'A.D.I.V.A.L.O.R. ou à un autre service de collecte spécifique. Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.V.A.L.O.R. ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

**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.

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<p><b>miller</b> GRAPHICS GROUP</p> <p>Miller Graphics Limoges 10 -12, rue Léon Walras Z.I de Magrè - 87006 Limoges FRANCE Tél. 05 55 30 04 55 <a href="http://www.millergraphics.com">www.millergraphics.com</a></p> <p></p>	<p><b>CLIENT</b> NUFARM SAS</p> <p><b>REFERENCE</b> FUSILADE MAX 510011318-022023-FUSILADE MAX-Verso L-dg-e-CCL 2202044 50/100/100-02/03/2023</p> <p><b>ORDER N°</b> 00675068-001-001</p> <p><b>BARCODE N°</b> 03485260028570</p> <p><b>CSR</b> Marion Champelievier</p> <p><b>OPERATOR</b> GRC</p> <p><b>PROOF / DATE</b> Approval N°2 - 10-Feb-23</p>	<p><b>M</b> 330 x 70 mm</p> <p><b>Y</b> 345 x 70 mm</p> <p><b>K</b> 3220 x 70 mm</p> <p><b>VERNIS UV</b> 100%</p>	<p><b>UNIT SIZE</b> 150 H x 160 L mm</p> <p><b>INK NUMBER</b> 3</p> <p><b>SH2</b></p> <p><b>DEVELOPMENT</b> 0</p> <p><b>PLATE</b></p> <p><b>SCREEN RULING</b> 120</p> <p><b>PRINTING SIDE</b> surface</p> <p><b>PLAN</b></p>	<p>This proof is used to control the document (size, text, barcode).</p> <p>After your approval we will proceed to the next step of production. Please return us this proof once signed.</p> <p><b>CUSTOMER'S SIGNATURE</b></p> <p>Date: _____</p> <p><b>OK</b> THE DOCUMENT IS CORRECTLY DISPLAYED</p> <p></p>
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