

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

**Product code: CAL97MO96**

**Product name: COSMIC**

**Chemical active substance(s):**

**glyphosate, 360 g/L**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**  
**(Autorisation renewal according to Art. 43)**

**Applicant: Arysta LifeScience S.A.S.**

**Date: 29/11/2019**

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## PART A

### RISK MANAGEMENT

#### 1 Details of the application

The company ARYSTA LIFESCIENCE SAS has requested a marketing authorisation in France for the product COSMIC (formulation code: CAL97MO96), containing 360 g/L glyphosate<sup>1</sup> as a 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 ARYSTA LIFESCIENCE SAS's application submitted on 14/03/2018 to market COSMIC (CAL97MO96) in France (product uses described under point 2.6). France acted as zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the active substance glyphosate of this product in France and in other Member States (MSs) of the Southern zone.

The present applications (2018-0663 & 2018-0667) were 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 COSMIC (CAL97MO96) has been made using endpoints agreed in the EU peer review of glyphosate. It also includes assessment of data and information related to COSMIC (CAL97MO96) 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

<sup>1</sup> COMMISSION IMPLEMENTING REGULATION (EU) 2017/2324 of 12 December 2017, renewing the approval of the active substance glyphosate in accordance with Regulation (EC) N°1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market, and amending the Annex to commission Implementing Regulation (EU) N°540/2011.

<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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registration of COSMIC (CAL97MO96).

## 1.2 Letters of Access

Arysta LifeScience is part of the Glyphosate Task Force so Arysta LifeScience is co-owner of the protected Glyphosate data used in this application. A letter of acces from Monsanto dated on 14 December 2017 has been provided and is available upon request.

## 1.3 Justification for submission of tests and studies

According to the applicant: « Studies submitted are necessary for the evaluation in accordance with regulation No 544/2011 and No 545/2011 related to data requirements on active substance and plant protection product respectively. ».

## 1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of COSMIC (CAL97MO96), 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	CAL97MO96
COSMIC in MS	COSMIC
Authorisation number	9100650
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	ARYSTA LIFESCIENCE SAS
Active substance(s) (incl. content)	glyphosate, 360 g/L
Formulation type	Soluble concentrate [SL]
Packaging	HDPE <sup>5</sup> (1 L, 5 L, 10 L)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

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<sup>5</sup> High density polyethylene

## 2.2 Conclusion

The evaluation of the application for COSMIC (CAL97MO96) resulted in the **decision to withdraw 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

N/A : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

## 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>6</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, for glyphosate-based products, the official statement<sup>7</sup> of 8 October 2004 provides specific restrictions (applied doses and/or conditions of use) for uses on crops, in non-agricultural or industrial areas or in forestry.

<sup>6</sup> Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>

<sup>7</sup> Avis du 8 octobre 2004 à tous les détenteurs d'autorisations de mise sur le marché pour des spécialités commerciales à base de glyphosate, [https://www.legifrance.gouv.fr/jo\\_pdf.do?id=JORFTEXT00000445445](https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT00000445445)

Finally, the French Order of 26 March 2014<sup>8</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” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>9</sup> is to supply “minor” crops with registered plant protection products.

Therefore the GAP table (Section 2.6) 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**

N/A : marketing authorisation withdrawn.

### **2.5.2                    Specific restrictions linked to the intended uses**

N/A : marketing authorisation withdrawn.

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<sup>8</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

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

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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.  
When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

PPP (COSMIC/code):	COSMIC / CAL97MO96	Formulation type:	GAP rev. 1, date: 2019/11/29
Active substance 1:	glyphosate	Conc. of a.s. 1:	Soluble concentrate [SL] <sup>(a, b)</sup>
Applicant:	ARYSTA LIFESCIENCE SAS	Professional use:	360 g/L <sup>(c)</sup> <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>													
96	France	All crops Intercrops (before sowing and planting) Including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Annual grasses	Spray	-	1	-	3 L/ha	1080		F	Not acceptable (genotoxic potential, (*))

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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		
97	France	All crops Intercrops (before sowing and planting) Including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Annual and biannual broadleaved weeds	Spray	-	1	-	6 L/ha	2160		30	Not acceptable (genotoxic potential, (*))
98a	France	All crops Intercrops (before sowing and planting) Including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Perennials	Spray	-	1	-	7 L/ha	2520		30	Not acceptable (genotoxic potential, exceedance MRL, (**))
98b	France	Non agricultural area (open space before seeding or planta- tion) Ornamentals (non edible, before plant- ing or sowing)	F	Annual grasses Annual and biannual broadleaved weeds	Spray	-	1	-	5 L/ha	1800		F	Not acceptable (genotoxic potential, (*))
98c	France	Non agricultural area (open space before seeding or planta- tion) Ornamentals (non edible, before plant- ing or sowing)	F	Perennials	Spray Only by spot	-	1	-	8 L/ha	Max 2880 g as/ha/y		F	Not acceptable (genotoxic potential, (**))

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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		
99	France	Vineyards, Orchards	F	<i>Annual grasses</i>	Spray	-	2	-	4 L/ha	1440 <b>Max 2200 g as/ha/y</b>		21	Not acceptable (genotoxic potential, exceedance MRL for vineyards, (*))
100	France	Vineyards, Orchards	F	<i>Annual and biannual broadleaved weeds</i>	Spray	-	2	-	6 L/ha	2160 <b>Max 2200 g as/ha/y</b>		21	Not acceptable (genotoxic potential, exceedance MRL for vineyards, (*))
101	France	Vineyards, Orchards	F	<i>Perennials</i>	Spray (only by spot)	-	2	-	8 L/ha	<b>Max 2200 g as/ha/y</b>		21	Not acceptable (genotoxic potential, exceedance MRL for vineyards, (*))
102	France	<b>Farm surrounding, building or greenhouse surroundings, paths, headlands, agricultural access</b>	F	<b>Permeable area: Annual and biannual weeds</b>	Spray	-	1	-	5 L/ha	1800		n.a.	Not acceptable (genotoxic potential, (*))
103a	France	<b>Farm surrounding, building or greenhouse surroundings, paths, headlands, agricultural access</b>	F	<b>Permeable area: Perennials</b>	Spray (only by spot)	-	1	-	8 L/ha	2880		n.a.	Not acceptable (genotoxic potential, (*))

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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		
103b	France	Farm surrounding, building or green- house surround- ings, paths, head- lands, agricultural access	F	<b>Impermeable area:</b> <i>All weeds</i>	Spray (only by spot)	-	5	-	<b>8 L/ha</b>	<b>max 1500 g as/ha/y</b> (equivalent to an impermeable surface colonized at 10% to a possibility of 5 treatments max/year)		n.a.	Not acceptable (genotoxic potential, (*))
104	France	Non agricultural area : railways,-industrial zones	F	<i>Perennials</i>	Spray (only by spot)		1		<b>8 L/ha</b>	2880		n.a.	Not acceptable (genotoxic potential operator exposure)
105a	France	Non agricultural area : railways,-industrial zones	F	<b>Permeable area:</b> <i>Annual and biannual weeds</i>	Spray		1		<b>5 L/ha</b>	1800		n.a.	Not acceptable (genotoxic potential operator exposure,)
105b	France	<b>Non agricultural area : cemeteries, paths, pavements (etc)</b>	F	<b>Permeable area:</b> <i>Annual and biannual weeds</i>	Spray		1		<b>5 L/ha</b>	1800		n.a.	Not acceptable (genotoxic potential)
106a	France	<b>Non agricultural area cemeteries, paths, pavements (etc)</b>	F	<b>Impermeable area:</b> <i>Perennials</i>	Spray (only by spot)		1	-	<b>8 L/ha</b>	2880		n.a.	Not acceptable (genotoxic potential)

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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		
106b	France	Non agricultural area cemeteries, paths, pavements (etc)	F	<b>Impermeable area:</b> All weeds	Spray (by spot)		5	-	<b>8 L/ha</b>	<b>max 1500 g as/ha/y</b> (equivalent to an impermeable surface colonized at 10% to a possibility of 5 treatments max/year)		<b>n.a.</b>	Not acceptable (genotoxic potential)

(\*) Risk to diversity and abundance of non-target terrestrial arthropods (other than bees) and vertebrates *via* trophic interactions.

(\*\*) Risk to diversity and abundance of non-target terrestrial arthropods and vertebrates *via* trophic interactions.

**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.

**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<sup>3</sup> 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)

COSMIC (CAL97MO96) is a soluble concentrate (SL). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a colourless liquid. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 506°C. In aqueous solution (1%), it has a pH value of 5.12 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54 °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. Its technical characteristics are acceptable for a suspension concentrate formulation.

The active substance glyphosate contains the relevant impurities formaldehyde and N-nitrosoglyphosate. The relevant impurity formaldehyde is considered as a by-product of the manufacturing process for glyphosate and as such cannot be formed by storage of the formulation. The monitoring of this impurity in the storage studies is not necessary.

Concerning the relevant impurity N-nitrosoglyphosate, based on the conditions of formation of this impurity, it is unlikely that this impurity is formed during the formulation of the preparation.

Nevertheless, in order to demonstrate the absence of formation of NNG during the storage, a monitoring of the concentration of this impurity during storage of the preparation has been provided.

**However, the limit of quantification of this analytical method for the impurity in the preparation is higher than the acceptable limit.** Furthermore the content of this impurity during storage is below the limit of detection of the method.

The product COSMIC (CAL97MO96) does not contain POE-tallowamines (CAS n° 61791-26-2).

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

The efficacy level of COSMIC (CAL97MO96) is considered satisfactory for all the claimed uses.

Glyphosate having an herbicidal activity on all types of plants (known as “total weed control”), the preparation COSMIC (CAL97MO96) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green parts of crops or non target plants.

The risks of negative impact on yield, quality and propagation are considered negligible.

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

The risk of negative impact on adjacent crops is considered as acceptable, as long as the preparation does not reach the green parts of adjacent crops. Specific attention should be paid to the spraying conditions close to adjacent crops.

There is a risk of resistance development or appearance to glyphosate for ryegrass (*Lolium multiflorum*, *Lolium perenne* and *Lolium rigidum*), fleabanes (*Conyza* sp.) and common ragweed (*Ambrosia*

*artemisiifolia*) requiring a survey of resistance.

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

#### 3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and the relevant impurities formaldehyde and N-nitrosoglyphosate in the formulation are available and validated. **However, limit of quantification of the analytical method for determination of the relevant impurity N-nitroglyphosate in the preparation is higher than the acceptable limit.**

#### 3.3.2 Analytical methods for residues

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

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

#### Endpoints used in risk assessment

Active Substance: <b>glyphosate</b>			
ADI	0.5 mg kg bw/d	EU (12/16/2017)	
ARfD	0.5 mg/kg bw		
AOEL	0.1 mg/kg bw/d		
Dermal absorption	Based on an in vitro human study performed on formulation according to guidance on dermal absorption (Efsa 2012):	Concentrate (tested) 360 g/L	Diluted formulation (tested) 0.6 g/L
	In vitro (human) %	0.7	3.3
		Concentrate (used in formulation) 360 g/L	Spray dilution (used in formulation) 4.2 g/L
	<b>Dermal absorption endpoints %</b>	<b>0.7</b>	<b>3.3</b>
Oral absorption	<b>20%</b>		

#### 3.4.1 Acute toxicity

COSMIC (CAL97MO96) containing 360 g/L glyphosate 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 sensitiser.

### 3.4.2 Genotoxic potential

In the EC review report for glyphosate (SANTE/10441/2017 Rev 2), the following toxicity studies were requested (see page 6 of the review report):

“As outlined in the EFSA conclusion on glyphosate, the peer review recognised that some genotoxicity studies on formulations presented positive results, and therefore, that the genotoxic potential of formulations should be addressed during renewal or first authorisation of plant protection products.”

According to EFSA scientific opinion on genotoxicity testing strategies (EFSA Journal 2011; 9(9):2379), a combination of two tests is needed to “[fulfil] the basic requirements to cover the three genetic endpoints: the bacterial reverse mutation assay covers gene mutations and the *in vitro* micronucleus test covers both structural and numerical chromosome aberrations”.

To assess the genotoxic potential of the formulation COSMIC (CAL97MO96) an Ames test was performed. The test was negative and the study was considered acceptable. **However no other test was submitted therefore, the genotoxic potential of COSMIC (CAL97MO96) cannot hence be finalized.**

### 3.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G <sup>10</sup>	Equipment Application method	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Orchards Risk envelop	F	Manual Knapsack/ Down-ward spraying	2.880	EFSA 100
Non-agricultural area	F	Manual handheld Down-ward spraying	2.880	French study from UPJ 2009-2010 100

Considering the proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010<sup>11</sup> dedicated to non-agricultural areas and EFSA model<sup>12</sup>:

Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate
Non-agricul-tural area	Manual handheld Downward spraying	Working coverall and gloves during mixing/loading and application.	16.62

<sup>10</sup> Open field or glasshouse

<sup>11</sup> Studies and models that can be used to estimate operator exposure during the use of plant protection products in non-agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

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

	Manual knap-sack Downward spraying	Working coverall and gloves during mixing/loading and application.	1.01
	Vehicle mounted Downward spraying	Working coverall during and gloves during mixing/loading. Working coverall during application.	9.34
Orchards Risk envelop	Manual knap-sack Downward spraying	Working coverall and gloves during mixing/loading and application.	11.06

According to the model calculations, it can be concluded that the risk for the operator using COSMIC (CAL97MO96) is acceptable with a working coverall and gloves during mixing/loading and application.

**No operator exposure data are available for railways, weeding when a weeder train is used. Thus, the risk for the operator cannot be finalised.**

#### 3.4.4 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 13.31% of the AOEL of glyphosate with PPE.

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

#### 3.4.5 Bystander and resident 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 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 EFSA model. An acceptable risk was determined for residents (adult and child) when mitigation measures such as a buffer zone of 3 meters are taken:

Model (AOEM) - All pathways (mean)	% AOEL glyphosate
Resident (children)	34.65% (worst case exposure : orchards)
Resident (adults)	12.47% (worst case exposure:

<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)

	orchards)
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Golf course, turf or other sports lawns: recreational exposure was assessed according to EFSA model. Exposure is estimated to 43.39 % and 15.18 % of the AOEL of glyphosate for children and adults, respectively. It is concluded that there is no unacceptable risk anticipated for recreational exposure.

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

#### 3.5.1 Residues

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for glyphosate as laid down in Reg. (EU) 396/2005 is not expected, providing the application of the mitigation measures.

**However, intended uses on grapes are not supported by available data and the compliance with current MRLs cannot be performed.**

In accordance with the available residue data, a maximum application dose of 6 L/ha is retained for inter-crop uses.

For intended use on non-cultivated / agricultural area, ornamentals, no data is required in this section.

#### 3.5.1 Consumer exposure

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

As far as consumer health protection is concerned, authority, zRMS, agrees with the authorization of the intended uses on inter-crop, orchards, olives.

According to available data, the following specific mitigation measures are recommended:

- **For orchards and olives: “Use application material or agricultural practices to avoid edible parts contact with soil treated with active substance”;**

#### Data gaps

/

#### Information on CAL97MO96

Crop	PHI for CAL97MO96 proposed by applicant	PHI/ Withholding period* sufficiently supported for glyphosate	PHI for CAL97MO96 proposed by zRMS	zRMS Comments (if different PHI proposed)
Orchards Citrus, pome fruits, tree nuts	21	Yes	21	
Grape	This use is not considered as sufficiently supported			
Pre-plant/pre-emergent or Inter-crop	30	Yes	30 (BBCH00-09)	

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Crop	PHI for CAL97MO96 proposed by applicant	PHI/ Withholding period* sufficiently supported for glyphosate	PHI for CAL97MO96 proposed by zRMS	zRMS Comments (if different PHI proposed)
Non- alimentary crop	NR			

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

### Waiting periods before planting succeeding crops

The results of the rotational crop study have shown that neither glyphosate nor AMPA show a potential uptake into follow crops. No specific waiting period is thus required.

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

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

The PEC of glyphosate 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 the FOCUS models or with specific models (e.g. HardSPEC) and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PECsw derived for glyphosate and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

For uses on hard surfaces, the estimation of PECgw is not considered relevant. For other uses, PECgw for glyphosate and AMPA do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000<sup>14</sup>. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT<sub>50</sub> calculation, no significant contamination of the air compartment is expected for the intended uses.

## 3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) N° 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its 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.

<sup>14</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.

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

Risk mitigation measures are required in order to protect aquatic organisms and non-target plants for uses on agricultural area.

The following safety phrase is applied in FR at national level for intended uses in railways: « Avoid spray drift and runoff to nearby plants for uses on non-agricultural areas in railways ».

Concerning the risk assessment to bees and other pollinators, for the intended uses with down-ward application at full dose, the EFSA GD 2013 tier 1 trigger values are not exceeded for application lower and including 2.28 kg a.s./ha. For intended uses in spot applications (<10% of the area), in view of the highest concentration tested in the bee brood semi-field test, the risk can be considered acceptable at doses up to 2.88 kg a.s./ha.

**Concerning the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions (Regulation (EU) 2017/2324), no information has been provided by the notifier to assess this risk. Among the intended uses, this information is not considered necessary for some uses made in highly anthropized area (weed control of railways and of industrial sites).**

### **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)**

N/A : marketing authorisation withdrawn.

## **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 : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

## Appendix 1 Copy of the product authorisation



### Décision relative à une demande de renouvellement de l'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 règlement d'exécution (UE) 2017/2324 de la Commission du 12 décembre 2017 renouvelant l'approbation de la substance active « glyphosate » conformément au règlement (CE) no 1107/2009 du Parlement européen et du Conseil concernant la mise sur le marché des produits phytopharmaceutiques et modifiant l'annexe du règlement d'exécution (UE) no 540/2011 de la Commission,*

*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 de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active glyphosate, la demande d'extension d'usage mineur et les données complémentaires fournies suite à une exigence post-autorisation du produit phytopharmaceutique COSMIC*

de la société ARYSTA LIFESCIENCE  
enregistrées sous les n°2018-0633, 2018-0667, 2016-3339 et 2019-1004

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

*Considérant que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit,*

*Considérant qu'un effet génotoxique ne peut être exclu,*

*Considérant que les conditions mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont donc pas respectées,*

*L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après n'est pas renouvelée en France.*

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Informations générales sur le produit	
<b>Nom du produit</b>	COSMIC
<b>Type de produit</b>	Produit de référence
<b>Titulaire</b>	ARYSTA LIFESCIENCE Route d'Artix BP80 64150 NOGUERES France
<b>Formulation</b>	Concentré soluble (SL)
Contenant	486 g/L - glyphosate sel d'isopropylamine (équivalent à 360 g/L de glyphosate)
<b>Numéro d'intrant</b>	9100650
<b>Numéro d'AMM</b>	9100650
<b>Fonction</b>	Herbicide
<b>Gamme d'usage</b>	Professionnel

A Maisons-Alfort le, 29 NOV. 2019

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



**Liste des usages refusés**

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11015904 Usages non agricoles * Désherb. total	5 L/ha	1/an	Non applicable
<b>Motivation du refus :</b> L'usage revendiqué, correspondant au nouveau libellé « Traitements Généraux * Désherbage * Zones non cult. », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.			
L'usage est également refusé à la dose de 8 L/ha au même motif.			
11015903 Usages non agricoles * Désherbage * All. PJT, Cimet, Voies	8 L/ha	1/an	Non applicable
<b>Motivation du refus :</b> L'usage revendiqué, correspondant aux nouveaux libellés « Usages non agricoles * Désherb.total * Sites Indust. et autres infrastructures » et « Usage non agricole * Désherbage * Voies ferrées », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.			
11015903 Usages non agricoles * Désherbage * All. PJT, Cimet, Voies	5 L/ha	1/an	Non applicable
<b>Motivation du refus :</b> L'usage revendiqué, correspondant au nouveau libellé « Usages non agricoles * Désherbage * PJT », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.			
L'usage est également refusé à la dose de 8 L/ha au même motif.			



**Liste des usages retirés**

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
<b>00201024</b> Cultures fruitières * Désherbage * Cult. Installées	4 L/ha	2/an	21	6 mois à compter de la présente décision	12 mois à compter de la présente décision
<b>Motivation du retrait :</b> L'usage revendiqué est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.					
	3 L/ha	1/an	F	6 mois à compter de la présente décision	12 mois à compter de la présente décision
<b>11015924</b> Traitements généraux * Désherbage * Avt Mise Cult.					
<b>Motivation du retrait :</b> L'usage revendiqué, correspondant au nouveau libellé « Traitements Généraux * Désherbage * Interculture, jachères et destruction de culture », est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.					
L'usage est également retiré aux doses de 5 L/ha, 6 L/ha, 7 L/ha et 8 L/ha au même motif et pour les doses supérieures à 6 L/ha au motif que les données fournies ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus.					
<b>11015921</b> Traitements généraux * Désherbage * Zones Cult. Avt Plantat.	3 L/ha	1/an	F	6 mois à compter de la présente décision	12 mois à compter de la présente décision
<b>Motivation du retrait :</b> L'usage revendiqué, correspondant au nouveau libellé « Traitements Généraux * Désherbage * Interculture, jachères et destruction de culture », est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.					
L'usage est également retiré à la dose de 5 L/ha au même motif.					



**Liste des usages retirés**

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
12705902  Vigne * Désherbage * Cult. Instalées	4 L/ha	2/an	21	6 mois à compter de la présente décision	12 mois à compter de la présente décision

**Motivation du retrait :**  
 L'usage revendiqué est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.  
 L'usage est également retiré au motif que le respect des limites maximales de résidus n'a pas pu être vérifié en raison d'un manque d'essais résiduels.  
 L'usage est aussi retiré aux doses de 6 L/ha et 8 L/ha aux mêmes motifs.

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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.



**COSMIC / CAL97MO96**  
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**PREMIERS SOINS**

Consignes générales : Eloigner la personne atteinte de la zone de travail. La conduire dans un endroit bien aéré et la protéger de l'hypothermie. Ne rien administrer par voie orale et ne pas tenter de la faire vomir, contacter le centre antipoison ou un médecin.

Munissez vous de l'étiquette ou de cette fiche de sécurité si possible.

Après inhalation : Aérer au maximum le sujet. Alerter les secours en cas de difficultés respiratoires, de mal-être ou de maux de tête persistants.

Après un contact avec les yeux : Rincer immédiatement et abondamment à grande eau, pendant au moins 10 à 15 minutes. Écarter les paupières des globes oculaires afin que le rinçage soit efficace. Consulter un spécialiste si une douleur ou une rougeur persiste.

Après un contact avec la peau : Retirer les vêtements souillés et bien nettoyer la zone affectée avec de l'eau et du savon.

Après ingestion : NE PAS faire vomir et NE RIEN donner à boire.

Alerter les secours et leur montrer l'étiquette.

**INFORMATIONS REGLEMENTAIRES**

Nom commercial : COSMIC N° D.A.M.M. : 9100650 Détenteur de A.M.M. : ARYSTA LIFESCIENCE SAS BP 80 - route d'Artix - 64150 Noguères - tél 05.59.60.92.92 Type d'action du produit : Herbicide	Formulation : SL (concentré soluble) Composition : Glyphosate (sel d'isopropylamine) 360 g éq. acide/L (30.8% p / p éq.acide) Usage : Professionnel
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Usage	Adventices	Dose homologuée	Dose maximale Applicable/an
Traitements généraux(1)* Désherbage*Avant mise en culture Après récolte ou avant semis ou plantation en zones agricoles	Graminées annuelles	3 L/ha	8 L/ha/an
	Dicotylédones annuelles ou bisannuelles	6 L/ha	
	Vivaces	7 L/ha	
Traitements généraux* Désherbage*Avant mise en culture Avant semis ou plantation en zones non agricoles et production horticole	Annuelles et bisannuelles	5 L/ha	8L/ha/an en zone perméable et 4 L/ha/an en zone imperméable***
	Vivaces (uniquement par taches)	8 L/ha	
	Graminées annuelles	4 L/ha	
Cultures fruitières(1)* Désherbage*Cultures installées Vigne*Désherbage*Cultures installées	Dicotylédones annuelles ou bisannuelles	6 L/ha	6 L/ha/an**
	Vivaces (uniquement par taches)	8 L/ha	
	Par taches : vivaces, annuelles et bisannuelles en zones imperméables	8 L/ha	
Usages non agricoles*Désherb. Total	Annuelles et bisannuelles en zones perméables	5 L/ha	Equivalent, pour une surface imperméable colonisée à hauteur de 10 %, à une possibilité de 5 traitements maximum par an
Usages non agricoles*Désherb. Total	Annuelles et bisannuelles en zones perméables	5 L/ha	1 application par an
Usages non agricoles*Désherbage*All. PJT, Cimet, Voies	Annuelles et bisannuelles en zones perméables	5 L/ha	1 application par an
Usages non agricoles*Désherbage*All. PJT, Cimet, Voies	Par taches : vivaces, annuelles et bisannuelles en zones imperméables	8 L/ha	Equivalent, pour une surface imperméable colonisée à hauteur de 10 %, à une possibilité de 5 traitements maximum par an

(1) sauf fruits à noyaux, kiwi, bananes

\*\*équivalent, pour un traitement à 6L produit/ha localisé sur le rang correspondant à une surface de 33%, à une possibilité de 3 traitements maximum par an.

\*\*\* équivalent, pour une surface imperméable colonisée à hauteur de 10%, à une possibilité de 5 traitements maximum par an.

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Les doses indiquées ne nécessitent pas l'adjonction d'adjungants extemporanés.  
 Pour les limites maximales de résidus, se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database>.

Les conditions d'utilisation de la préparation, compte-tenu des bonnes pratiques agricoles critiques proposées, permettent de respecter la limite maximale de résidus en recommandant un délai avant récolte de 21 jours pour l'ensemble des cultures fruitières sauf kiwi, banane et fruits à noyaux et de 30 jours pour le désherbage en zones cultivées et cultures potagères.

**MELANGES**

Les mélanges extemporanés doivent être mis en oeuvre conformément à la réglementation en vigueur

**MODE D'ACTION**

COSMIC est un herbicide non sélectif à action foliaire et systémique. Il pénètre par les parties vertes des plantes, par les stomates, les blessures, et la cuticule. Ensuite, COSMIC est véhiculé par la sève vers les zones méristématiques, et notamment jusqu'à l'extrémité des racines.

Il intervient alors sur le métabolisme des plantes en provoquant des perturbations de la croissance et du développement. Il détruit alors totalement les mauvaises herbes (feuilles, tiges, racines, rhizomes).

**RECOMMANDATIONS D'EMPLOI**

- Volume d'eau : entre 150 et 300 L/ha. Ne pas dépasser 400 L/ha.
- Préparation : remplir la cuve aux 2/3, ajouter COSMIC sous agitation, puis compléter en eau.
- Traiter sur des mauvaises herbes vertes en conditions poussantes.
- Traiter par temps calme et éviter toute pulvérisation ou embruns sur le feuillage des cultures voisines.
- Traiter avec une température optimale de 8°C à 22°C.
- Traiter avec une hygrométrie comprise entre 60 et 90%.

Délai de ré-entrée : 6 heures après traitement.

**GRANDES CULTURES (Interculture)**

- Préparation des semis au printemps : destruction de toutes les mauvaises herbes annuelles et vivaces
- Après récolte : destruction de toutes les mauvaises herbes annuelles et vivaces
- Recommandations : en cas de présence de vivaces, attendre 7 jours pour travailler le sol.

COSMIC assure ainsi une destruction de toutes les annuelles et vivaces afin de permettre une meilleure levée.

**VIGNE ET ARBORICULTURE**

- Trois périodes de traitement sont possibles :
- 1ère période de février à avril avant débourrement : COSMIC est efficace contre toutes les mauvaises herbes levées sur annuelles et vivaces.
- 2ème période de mai à juillet : COSMIC est efficace contre toutes annuelles estivales.
- 3ème période de novembre à décembre : COSMIC est efficace contre les annuelles d'hiver et contre les ronces.
- Traiter sur vigne de plus de 2 ans, et arbres à pépins de plus de 3 ans.
- Eviter tout contact avec les parties vertes et non aotées de la culture ainsi qu'avec les plaies non cicatrisées (vignes : attendre 10 à 15 jours après épamprage, rognage, relevage, attachage pour traiter)

**PRECAUTIONS D'EMPLOI**

- Ne pas laisser la bouillie prête à l'emploi dans le pulvérisateur.
- Porter des gants pendant les phases de mélanges, chargement et application de la préparation.
- Porter un vêtement de protection approprié pendant la phase d'application pour les traitements avec un pulvérisateur à dos et une lance (traitement par tâches).
- Dans le cadre des bonnes pratiques d'utilisation, l'usage de buses à dérive limitée et/ou d'adjungants appropriés possédant la mention « limitation de la dérive » est recommandé.
- Eviter tout contact avec les feuilles et les tiges non aotées de la vigne.
- Ne pas traiter en plein au dessus des vignes même avant débourrement.
- Ne pas traiter sur rosée, gelée blanche et en cas de risque de pluie imminente. Ne pas traiter aux heures chaudes et en période de gel.
- Éviter toute dérive de pulvérisation et de ruissellement vers les plantes voisines.
- Eviter tout traitement à base de glyphosate sur les fossés en eaux ou à proximité de points d'eau.
- Pour protéger les organismes aquatiques, respecter une zone tampon non traitée de 5 m par rapport aux masses d'eau de surface.

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**MANIPULATION ET STOCKAGE**

- Ne pas manger, boire, téléphoner ou fumer lors de l'utilisation du produit
- Éviter que le produit, qu'il soit neuf ou usagé, ne vienne en contact avec la peau, les yeux ou les vêtements.
- Se laver les mains après toute manipulation/utilisation/intervention dans une parcelle préalablement traitée
- Ne pas laver les vêtements de travail avec le linge domestique.
- Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non autorisées
- Conserver dans le récipient original bien fermé, dans un endroit frais et bien ventilé.
- Stocker sous abri, dans un local approprié, à l'écart de la chaleur et des sources d'ignition, à une température < 35 °C.
- Ne pas stocker dans un endroit clos à une température inférieure à -5°C.
- Porter des gants pendant les phases de mélange / chargement et un vêtement imperméable pendant l'application

Caractéristiques des EPI	MÉLANGE/ CHARGEMENT	PROTECTION DE L'UTILISATEUR PENDANT LES PHASES DE :						PROTECTION DU TRAVAILLEUR
		APPLICATION AVEC :				NETTOYAGE		
		PULVÉRISATEUR PORTE OU TRAINE A RAMPE, PNEUMATIQUE OU ATOMISEUR ; PULVÉRISATION VERS LE BAS TRACTEUR AVEC CABINE	TRACTEUR SANS CABINE	LANCE / CULTURES BASSES (< 50 cm)	PULVÉRISATEUR À DOS			
<b>GANTS EN NITRILE</b> réutilisables (certifiés EN 374-3) ou à usage unique (certifiés EN 374-2)	 Réutilisables		 À usage unique	 Réutilisables	 Réutilisables	 Réutilisables	 Réutilisables	 Réutilisables
<b>EPI VESTIMENTAIRE</b> 65 % polyester / 35 % coton à 230 g/m <sup>2</sup> + traitement déperlant <b>EPI PARTIEL</b> blouse ou tablier à manches longues catégorie III type PB3 certifié EN 14605-A1	 EPI vestimentaire ET EPI partiel  OU Type 3 ou 4				 Type 3	 Type 4	 Type 3	 Type 3 ou 4
<b>COMBINAISON DE PROTECTION CHIMIQUE</b> catégorie II type 3 ou 4 certifiée EN 14605-A1/2009	 OU							
<b>LUNETTES ou ÉCRAN FACIAL</b> certifiées EN 166:2002 (CE, stigla 3)	 OU							
<b>PROTECTION RESPIRATOIRE</b> demi-masque ou masque (EN 149:1998) équipé d'un filtre P3 (EN 14320:00) ou A2P3 (EN 14387:2006)	 OU							
<b>BOTTES</b> certifiées EN 13 832-3:2006	 OU							

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 de produits dangereux

**APRES APPLICATION**

À la fin de la période d'application du produit, l'intégralité de l'appareil (cuve, rampe, circuit, buses...) doit être rinçée 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

Réemploi 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.VALOR 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.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux

Les vêtements de protection peuvent être lavés avec un détergent classique

Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds de bidon non utilisés et les eaux de lavage du pulvérisateur

**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



Détail des doses efficaces sur les principales mauvaises herbes annuelles et vivaces (stade plantules développées) en grandes cultures :

Nom Commun	Gram/Dicot	An/Viv	Doses L/Ha
Amarante réfléchie	Dicot	An	4
Brômes	Gram	An	2,5
Chardons	Dicot	Viv	4
Chiendent pied de poule	Gram	Viv	7
Chiendent rampant	Gram	Viv	4
Géraniums	Dicot	An	5
Laliterons	Dicot	An	4
Liseron	Dicot	Viv	7
Mercuriale annuelle	Dicot	An	4
Morelle noire	Dicot	An	4
Ray Grass Italien	Gram	An	2,5
Renouée des oiseaux	Dicot	An	4
Repousses de céréales	Gram	An	1,5
Repousses de colza	Dicot	An	5
Rumex	Dicot	Viv	4
Trèfles	Dicot	Viv	7
Vulpin	Gram	An	3

**COSMIC / CAL97MO96**  
**Part A - National Assessment**  
**FRANCE**

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Détails des doses efficaces sur les principales mauvaises herbes annuelles et vivaces (stade plantules développées) en vigne et arboriculture fruitière :

Nom commun	Graminées/ Dicotylédones	Annuelles/ Vivaces	Doses L/Ha	Périodes
Amarantes	Dicot	A	4	Mai-juillet
Chénopodes	Dicot	A	4	Mai-juillet
Chiendent pied de poule	Gram	V	8 par tâches	Juin-août
Crépis	Dicot	A	4	Février-avril
Digitaire sanguine	Gram	A	4	Mai-juillet
Epilobes	Dicot	V	7 par tâches	Avril-juin (floraison)
Erigérons	Dicot	A	4	Février-avril
Gaillet	Dicot	A	4	Février-avril
Lamiers	Dicot	A	4	Février-avril
Liserons	Dicot	V	7 par tâches	Juin-août (floraison)
Mauves	Dicot	V	7 par tâches	Février-mars (floraison)
Morelle noire	Dicot	A	4	Mai-juillet
Panic pied de coq	Gram	A	4	Mai-juillet
Paturin annuel	Gram	A	3	Février-avril
Picris	Dicot	A	4	Mars-Avril
Pissenlit	Dicot	V	4,5	Mars-Avril
Ray Grass anglais	Gram	V	6	Février-avril
Ray Grass italien	Gram	A	4	Février-avril
Renouées	Dicot	A	4	Mai-juillet
Rumex	Dicot	V	4,5	Mars-Avril
Séneçons	Dicot	A	3	Mai-juillet
Sétaire	Dicot	A	3	Mai-juillet
Véroniques	Dicot	A	3	Février-avril





**360g éq.acide/L (30.8 % p/p) de Glyphosate  
 Concentré Soluble (SL)**

**Herbicide Foliaire Systémique**  
 Cosmic s'utilise en vigne, arboriculture et en interculture des grandes cultures, cultures fruitières et vigne.  
 Utilisation sur mauvaises herbes annuelles, bi-annuelles et vivaces et Désherbage total des zones non plantées : allées de parcs, jardins publics, trottoirs..

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N° de lot, date de fabrication : voir sur le bidon

FR-G36-019-02 (03/18)

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