

REGISTRATION REPORT

Part A

Risk Management

Product code: 1 31063 01

Product name(s): BUGGY GREENLINE

Chemical active substance(s):

glyphosate, 240 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

**(authorisation renewal according to art 43 and label
extension)**

Applicant: PHYTEUROP

Date: 29/11/2019

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PART A

RISK MANAGEMENT

1 Details of the application

The company PHYTEUROP has requested a renewal and a label extension of marketing authorisation in France for the product BUGGY GREENLINE (formulation code: 1 31063 01), containing 240 g/L glyphosate¹ 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 PHYTEUROP's application submitted on 15/03/2018 (authorisation renewal), 28/06/2017 (major label extension) and 27/02/2017 (minor label extension) to market BUGGY GREENLINE (1 31063 01) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the active substance glyphosate of this product as well as for the extension of major and minor uses in France and in other Member States (MSs) of the Southern zone.

The present applications (2018-0766, 2017-1850 and 2017-0809) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of BUGGY GREENLINE has been made using endpoints agreed in the EU peer review of glyphosate. It also includes assessment of data and information related to BUGGY GREENLINE where those data have not been considered in the EU peer review process.

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

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

¹ COMMISSION IMPLEMENTING REGULATION (EU) 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.

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

³ SANCO document "risk envelope approach", European Commission (14 March 2011). [Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5](#)

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No 546/2011⁴, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of BUGGY GREENLINE.

1.2 Letters of Access

The applicant has provided a letter of access for active substance. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

The dossier was evaluated according to the data requirement in place at the time of the applications.

1.4 Data protection claims

2 Where protection for data is being claimed for information supporting registration of BUGGY GREENLINE (1 31063 01), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. Details of the authorisation decision

2.1 Product identity

Product code	1 31063 01
Product name in MS	BUGGY GREENLINE
Authorisation number	2160960
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	PHYTEUROP
Active substance(s) (incl. content)	glyphosate, 240 g/L
Formulation type	Soluble concentrate [SL]
Packaging	10 L, 20 L, 100 L, 600 L (HDPE ⁵)
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

⁵ High density polyethylene

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Recommended tank mixtures	None
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2.2 Conclusion

The evaluation of the application for BUGGY GREENLINE (1 31063 01) 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 2017⁶ 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.

⁶ 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 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGR1632554A/jo/texte>

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Moreover, for glyphosate-based products, the official statement⁷ 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.

Finally, the French Order of 26 March 2014⁸ 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 extrapolation⁹ is to supply “minor” crops with registered plant protection products.

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

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

N/A : marketing authorisation withdrawn.

2.5.2 Specific restrictions linked to the intended uses

N/A : marketing authorisation withdrawn.

⁷ 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=JORFTEXT000000445445

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

⁹ 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 (product name/code): BUGGY GREENLINE/ 1 31063 01 GAP rev. 1, date: 2019/11/29
 Active substance 1: glyphosate Formulation type: soluble concentrate (SL) ^(a, b)
 Applicant: PHYTEUROP Conc. of a.s. 240 g/L ^(c)
 Zone(s): Southern Zone ^(d) Professional use:
 Verified by MS: Yes Non-professional use:

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

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Zonal uses (field or outdoor uses, certain types of protected crops) – Re-registration													
1	France	Between crops (After harvest / before the following sowing) All crops Inter-crops (before sowing and planting) Including crop destruction (all crops except forest) (all seeded and transplanted crops)	F	Annual grass	Down-ward spraying	-	1	-	4.5	1080	50-200	F	Not acceptable (genotoxic potential, resident child exposure, bystander child exposure, (*))
				Annual and bisannual dicots		-	1	-	9	2160	50-200	F	Not acceptable (genotoxic potential, resident child exposure, bystander child exposure, (*))
				Perennial weeds		-	1	-	10.5	2520	50-200	F	Not acceptable (genotoxic potential, resident child exposure, bystander child exposure, MRL, (**))
2	France	Cereals before harvest Except cereals for seed production	F	-	Down-ward spraying	BBCH 87-89	1	-	9 by spot	2160	50-200	7 (cereals)	Not acceptable (genotoxic potential, MRL, birds, (*))
3	France	Fallow (growth and fructification control)	F	White mustard	Down-ward spraying	-	1	-	0.75	180	50-200	-	Not acceptable (genotoxic potential, resident child exposure, bystander child exposure, (*))
				Phacelia / italian ryegrass		-	1	-	0.9	216	50-200	-	Not acceptable (resident child exposure, bystander child exposure) sed (genotoxic potential, (*))
				Forage radish		-	1	-	1.2	288	50-200	-	Not acceptable (genotoxic potential, resident child exposure, bystander child, exposure (*))
				Alta fescue / English ryegrass / Carnation clover / Purple clover / common vetch		-	1	-	1.3	312	50-200	-	Not acceptable (genotoxic potential, resident child exposure,

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												bystander child exposure, (*))	
4	France	Orchards (citrus, stone fruit, tree nuts; pome fruit, kiwi, olive)	F	Annual grass	Down- ward spraying	BBCH 00-85 BBCH 89-97	1	-	6	1440	50-250	Citrus, stone fruit and tree nuts: 21 days ; pome fruit: 28 days, kiwi: 90 days, olive: 7 days	Not acceptable (genotoxic potential, operator exposure for hand-held applications; resident and bystander child exposure for manual hand-held and manual knapsack applications, (*))
				Annual and bisannual dicots			1	-	9	2160	50-250		
				Perennial weeds			3	-	12 Spot applica- tion	2880 Max 2200 g as/ha/y	50-250		
5	France	Grapevine	F	Annual grass	Down- ward spraying	BBCH 00-85 BBCH 89-97	1	-	6	1440	50-250	21	Not acceptable (genotoxic potential, operator exposure for hand-held applications; resident and bystander child exposure for manual hand-held and manual knapsack applications, (*))
				Annual and bisannual dicots			1	-	9	2160	50-250		
				Perennial weeds			3	-	12 Spot applica- tion	2880 Max 2200 g as/ha/y	50-250		
Zonal uses (field or outdoor uses, certain types of protected crops) – Extension of minor uses													
6	France	Seed bearing alfalfa	F	weeds	Down- ward spraying	During vegeta- tive rest state (December- Jan- uary)	1	-	1.5	360	50-200	-	Not acceptable, genotoxic potential, (*))
7	France	Fibre flax	F	weeds	Down- ward spraying	On uprooted flax	1	-	4.5	1080	50-200	-	Not acceptable, genotoxic potential, (*))
Zonal uses (field or outdoor uses, certain types of protected crops) – Extension of major uses													
8	France	After sowing-before crop emergence	F	Annual grass	Down- ward spraying	BBCH 00-09	1	-	4.5	1080	50-200	F	Not acceptable (genotoxic potential, resident child exposure, bystander child resident exposure, (*))
		Destruction of vegeta- tion cover in post sow- ing / pre-emergence of		Annual and bisannual dicots		BBCH 00-09	1	-	9	2160	50-200		

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		the crop (maize, sun-flower, sugar beets, rapeseed, cereals, peas, potatoes, alfalfa)		Perennial weeds		BBCH 00-09	1	-	10.5	2520	50-200		Not acceptable (genotoxic potential, resident child exposure, bystander child exposure, MRL, (**))
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(*) 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)	(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.
Remarks columns:	1 Numeration necessary to allow references	7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2 Use official codes/nomenclatures of EU Member States	8 The maximum number of application possible under practical conditions of use must be provided.
	3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9 Minimum interval (in days) between applications of the same product
	4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10 For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench 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)**

BUGGY GREENLINE is a soluble concentrate (SL). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a amber-brown liquid limpid, with a characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self- ignition temperature of 463 °C. In aqueous solution, it has a pH value of 4.7 at 22°C. Its technical characteristics are acceptable for a soluble concentrate formulation. 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. The formulation is not classified for the physico-chemical aspect.

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.

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

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

Considering the data submitted:

- The efficacy level of BUGGY GREENLINE 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 BUGGY GREENLINE cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green parts of crops.
- In the specific case of the limitation of crop growth and/or fruiting on fallows and intermediate crops, the crop is treated directly with the product. The selectivity is considered acceptable under the specific conditions for this use (reduced dose, application growth stage...).
- For all claimed uses except specific cases of weed control for alfalfa seed production and weed control for cereals at the stage of maturity before harvest, the risks of negative impact on yield, quality and propagation are considered negligible.

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- For cereals at the stage of maturity before harvest, the risks of negative impact on transformation processes (bread making and malting/brewing) is considered acceptable. In the absence of data allowing the assessment of the risk of negative impact on cereal seed production, the preparation should not be used on cereals intended to seed production.
- For alfalfa seed production, in view of the quality requirement (analytical purity) for harvested alfalfa seeds, the selectivity level of BUGGY GREENLINE (1 31063 01) and the risk of impact on yield and quality are considered acceptable in the conditions of use specific to this use (mentioned above in the point 2.5.1).
- The risk of negative impact on succeeding crops is considered negligible.
- The risk of negative impact on adjacent crops is considered 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)

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.**

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: glyphosate			
ADI	0.5 mg kg bw/d	EU (2017)	
ARfD	0.5 mg/kg bw		
AOEL	0.1 mg/kg bw/d		
AAOEL	none		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):	Concentrate (used in formulation) 240 g/L	Spray dilution (used in formulation) min: 0.9 g/L
		Dermal absorption endpoints %	20%
Oral absorption	20%		UE (2017)

3.4.1 Acute toxicity

BUGGY GREENLINE (1 31063 01) containing 240 g/L of glyphosate has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitisier.

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”.

These studies have not been submitted in this dossier. As a conclusion, the genotoxic potential of BUGGY GREENLINE (1 31063 01) cannot hence be finalized.

3.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ¹⁰	Equipment Application method	Maximum application rate kg as /ha	Model (Minimum volume water (L/ha))
Cereals, fallow, al-falfa, flax, bare soil	F	Vehicle mounted <i>Downward spraying</i>	10.5 L/ha 2.52 glyphosate/ha	EFSA (50 L/ha)
orchards, grapes	F		9 L/ha 2.16 glyphosate/ha	
orchards, grapes	F	Manual hand-held <i>Downward spraying</i>	12 L/ha 2.88 glyphosate/ha	
orchards, grapes	F	Manual knapsack <i>Downward spraying</i>	12 L/ha 2.88 glyphosate/ha	

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model¹¹:

Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate (0.1 mg/kg bw/d)

¹⁰ Open field or glasshouse

¹¹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

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Cereals, fallow, alfalfa, flax, bare soil	Vehicle mounted <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	35%
orchards, grapes	Vehicle mounted <i>Downward spraying</i>		9.7%
orchards, grapes	Manual hand-held <i>Downward spraying</i>		235%
orchards, grapes	Manual knapsack <i>Downward spraying</i>		59%

According to the model calculations, it can be concluded that the risk for the operator using 1 31063 01/BUGGY GREENLINE is acceptable with a working coverall and gloves during mixing/loading and application for vehicle-mounted applications and knapsack application and **unacceptable for hand-held applications**.

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

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. Results are presented in table below:

Model data	Level of PPE	Glyphosate		
		Total absorbed dose (mg/kg/day)	% of systemic AOEL	
Orchards, Grapes, grassland, cereals and oilseeds				
Number of applications and application rate: 1 x 2.52 kg glyphosate/ha				
2 hours/day ⁽¹⁾ , TC: 12500 cm ² /person/h ⁽²⁾ (total potential exposure) TC: 1400 cm ² /person/h ⁽²⁾ (arms, body and legs covered) Body weight: 60 kg	Potential exposure Work wear	0.7875 0.0882	788% 88%	
Orchards, Grapes				
Number of applications(interval) and application rate: 3 (1) x 0.96 kg glyphosate/ha				
2 hours/day ⁽¹⁾ , TC: 12500 cm ² /person/h ⁽²⁾ (total potential exposure) TC: 1400 cm ² /person/h ⁽²⁾ (arms, body and legs covered) Body weight: 60 kg	Potential exposure Work wear	0.7037 0.0788	704% 79%	

(1) e.g. 8 h/day for professional applications for maintenance or 2 h/day for professional applications for inspection or irrigation activities.

(2) Modified from EUROPOEM II (2002) considering US EPA 2012. EUROPOEM II, 2002, Post-Application Exposure of

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Workers to Pesticides in Agriculture or
 US-EPA policy paper [EPA, Science Advisory Council for Exposure; Agricultural Transfer Coefficients, Policy # 3.]. TC:
 Transfer coefficient

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

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

3.4.5 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.

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. Result of resident exposure is presented in the tables below:

Bare soil Downward spraying, vehicle-mounted		glyphosate	
ZNT = 10m Drift reduction technology			
	DT ₅₀ (days)	30	
	DFR (µg/cm ² /kg a.s./ha)	3	
	Application rate (kg a.s./ha)	1 x 2.52 kg/ha	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Sum (mean)	0.1111	111%
Resident adult Body weight: 60 kg	Sum (mean)	0.0458	46%

grassland, cereals and oilseeds Downward spraying, vehicle-mounted		glyphosate	
ZNT = 10m Drift reduction technology			
	DT ₅₀ (days)	30	
	DFR (µg/cm ² /kg a.s./ha)	3	
	Application rate (kg a.s./ha)	1 x 2.16 kg/ha	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Sum (mean)	0.0954	95%
Resident adult Body weight: 60 kg	Sum (mean)	0.0393	39%

Orchards, grapes Downward spraying, vehicle-mounted		glyphosate	
ZNT = 10m Drift reduction technology			
	DT ₅₀ (days)	30	
	DFR (µg/cm ² /kg a.s./ha)	3	

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	Application rate (kg a.s./ha)	1 x 2.16 kg/ha	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Sum (mean)	0.0984	98%
Resident adult Body weight: 60 kg	Sum (mean)	0.0406	41%

Orchards, grapes Downward spraying, manual hand-held and manual knapsack		glyphosate	
ZNT = 10m Drift reduction technology	DT ₅₀ (days)	30	
	DFR (µg/cm ² /kg a.s./ha)	3	
	Application rate (kg a.s./ha)	1 x 2.88 kg/ha	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Sum (mean)	0.1833	183%
Resident adult Body weight: 60 kg	Sum (mean)	0.0649	65%

With manual hand-held and manual knapsack application, an unacceptable risk was determined for residents (child) when drift reduction technology and mitigation measures (buffer zone of 10 meters) are taken.

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 for glyphosate as laid down in Reg. (EU) 396/2005 is not expected providing the application of the mitigation measures, **except for pre-harvest uses on cereals**.

In accordance with the available residue data, **a maximum application dose of 9.00 L/ha is retained for inter-crop/pre-emergence uses**. Furthermore, a PHI type F is retained for inter-crop/pre-emergence uses. 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, France agrees with the authorization of the intended inter-crop/pre-emergence uses (including fallows), uses on orchards, grapevine, seed bearing alfalfa and fiber flax.

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

- For uses in orchards, kiwi, grapevine and olives: “Use application material or agricultural practices to avoid edible parts contact with active substance or with soil treated with active substance”
- By-products of alfalfa and flax should not be used for food or feed.

Data gaps

None

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Information on BUGGY GREENLINE (KCA 6.8):

Crop	PHI for 1 31063 01 proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for 1 31063 01 proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate		
Intercrop uses	NR	Yes	F	
Cereal before harvest	This use is not recommended, considering a possibility of exceedance of current MRL on grain.			
Orchards Citrus fruits	21 days	Yes	21 days	
Orchards Stone fruits	21 days	Yes	21 days	
Orchards Tree nuts	21 days	Yes	21 days	
Orchards Pome fruits	28 days	Yes	28 days	
Orchards Kiwi	90 days	Yes	90 days	
Orchards Olives	7 days	Yes	7 days	
Grape	21 days	Yes	21 days	
Pre-emer- gence	30 days (vegetable crops)	Yes	F – application pre emergence	

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 following 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 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.

PECgw for glyphosate and its metabolite do not occur at levels exceeding those mentioned in regulation EC 1107/2009. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) 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.

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

For the chronic risk assessment to birds, the intended use in cereals pre-harvest, the scenario ‘BBCH 71-89’ - small insectivorous bird “passerine” do not meet the trigger value of 5. Therefore the risk for the insectivorous birds following applications of BUGGY GREENLINE (1 31063 01) for pre-harvest weed control in cereals cannot be finalised. Consequently, for the intended use in cereals zRMS proposed to not apply BUGGY GREENLINE (1 31063 01) at pre-harvest (BBCH 71-89). Indeed application in cereals could be considered in pre-planting of crops (GAP n°1) or post-sowing at application rate of 2.52 kg a.s./ha, since an acceptable risk is demonstrated.

Risk mitigation measures are required in order to protect aquatic organisms and non-target plants.

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.

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)

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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

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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, les demandes d'extension d'usages majeurs et mineurs et les données complémentaires fournies suite à une exigence post-autorisation du produit phytopharmaceutique BUGGY GREENLINE

<i>de la société</i>	<i>PHYTEUROP</i>
<i>enregistrées sous les</i>	<i>n°2018-0766, n°2018-1517, n°2017-1850 et n°2017-0809</i>

Vu les conclusions de l'évaluation de l'Anses du 25 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,

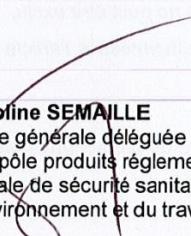
L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas renouvelée** en France.

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Informations générales sur le produit	
Noms du produit	BUGGY GREENLINE TAMROK GREENLINE DEVIT SKATE
Type de produit	Produit de référence
Titulaire	PHYTEUROP 55, rue Raspail - CS 80105 92594 Levallois-Perret cedex France
Formulation	Concentré soluble (SL)
Contenant	323,6 g/L - glyphosate sel d'isopropylamine (équivalent à 240 g/L de glyphosate)
Numéro d'intrant	933-2013.01
Numéro d'AMM	2160960
Fonction	Herbicide
Gamme d'usage	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)



ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
10995905 Porte graine - Légumineuses fourragères* Désherbage	1,5 L/ha	1/an	Non applicable
	4,5 L/ha	1/an	30
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Traitements généraux* Destruction des couverts et des repousses dans les cultures », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.			
11015932 Traitements généraux* Désherbage* Cult. Installées			
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Lin*Désherbage*Pendant rouissage », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.			



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
15105921 Céréales*Désherbage* Avt Récolte	9 L/ha	1/an	7	6 mois à compter de la présente décision	12 mois à compter de la présente décision
Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.					
00201024 Cultures fruiteres*Désherbage* Cult. Installées	6 L/ha	1/an	90	6 mois à compter de la présente décision	12 mois à compter de la présente décision
Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.					
15415932 Jachères et cultures intermédiaires* Ttr Part.Aer.* Limit. Pousse Fructif.	0,75 L/ha	1/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.					



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
11015924 Traitements généraux* Désherbage* Avt Mise Cult.	4,5 L/ha	1/an	F	6 mois à compter de la présente décision	12 mois à compter de la présente décision
Motivation du retrait : 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 en raison d'un risque d'effet nocif pour les résidents enfants et les personnes présentes enfants. L'usage est également retiré aux doses de 9 L/ha et 10,5 L/ha, aux mêmes motifs. L'usage est également retiré aux doses supérieures à 9 L/ha au motif que les données fournies ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus.					
12705902 Vigne*Désherbage* Cult. installées	6 L/ha	1/an	21	6 mois à compter de la présente décision	12 mois à compter de la présente décision
Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.					
L'usage est également retiré en raison d'un risque d'effet nocif pour les opérateurs pour une application manuelle, pour les résidents enfants et les personnes présentes enfants. L'usage est également retiré aux doses de 9 L/ha et 12 L/ha, aux mêmes motifs.					

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.

BUGGY® GREENLINE®							
Sans Classement						SIGNALISEZ-LE	
NOM HOMOLOGUE : BUGGY® GREENLINE®	N° D'AMM : 2160960	DETENTEUR DE L'AMM : Phyteurop - 55 rue Raspail 92300 Levallois Perret	TYPE D'ACTION : Herbicide (HRAC G)	FORMULATION : Concentré soluble (SL)	COMPOSITION : 240 g/L (21,2%) de glyphosate acide équivalent à 324 g/L (28,7%) de sel d'isopropylamine		
Distribué par : PHYTEUROP - 55 rue Raspail 92300 Levallois-Perret Tél.: 01 47 59 77 00 - Fax: 01 47 37 54 52 - www.phyteurop.com	P260 Ne pas respirer les aérosols.	SP1 Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.]	SPe3 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.	SPe3 Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente pour les usages sur jachère et cultures intermédiaires, traitements généraux avant mise en culture, cultures fruitières installées, vignes installées et en céréales.	EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.		
Usages ¹	Catégories ¹	Dose	Nombre maximum d'applications	Spécifications d'usage ²	DAR	ZNT aquatique	
Intercultures (uniquement avant mise en culture de cultures potagères, industrielles et grandes cultures)	Adventices annuelles	4,5 L/ha	1/ton	2880 g s.a./ha/ton	Non applicable	5 m	
	Dicotylédones annuelles et bisannuelles	9 L/ha				5 m	
	Adventices vivaces	10,5 L/ha				5 m	
Céréales avant récolte ³		9 L/ha	1/ton Entre les stades BBCH87 et BBCH89	-	7 jours	5 m	
Jachères et cultures intermédiaires Limitation de la pousse et de la fructification	Moutarde blanche Phacélie Ray-grass italien Radis fourrager Fétuque élevée Ray-grass anglais Trèfle incarne Trèfle violet Vesce commune	0,75 L/ha 0,9 L/ha 0,9 L/ha 1,2 L/ha 1,3 L/ha 1,3 L/ha 1,3 L/ha 1,3 L/ha	1/ton	-	-	5 m	
Cultures fruitières** (Cultures installées)	Adventices annuelles	6 L/ha	1/ton	2200 g s.a./ha/ton 3 applications maximum		5 m	
	Dicotylédones annuelles et bisannuelles	9 L/ha				5 m	
	Adventices vivaces	12 L/ha (traitement par tache)	3/ton		21 jours	5 m	
Vigne (Cultures installées)	Adventices annuelles	6 L/ha	1/ton	2200 g s.a./ha/ton		5 m	
	Dicotylédones annuelles et bisannuelles	9 L/ha				5 m	
	Adventices vivaces	12 L/ha (traitement par tache)	3/ton			5 m	
L'utilisation de ce produit sur ses usages autorisés n'est recommandée que sur les cultures et cibles indiquées dans le tableau ci-dessus.							
PHYTEUROP décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou pour des cibles non recommandées.							
* Ne pas appliquer ce produit ou tout autre produit contenant du glyphosate au-delà des doses maximum définies dans l'Avis à tous les détenants d'autorisation de mise sur le marché pour des spécialités commerciales à base de glyphosate (Journal Officiel du 8 octobre 2004).							
* Ne pas appliquer sur céréales à paille destinées à la production de semences et à la brasserie. Uniquement sur céréales à paille pour le désherbage avant moisson, sur adventices vivaces (par tache).							
** Les fruits récoltés ne doivent pas avoir été en contact direct avec le sol.							
* 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 mélanges doivent être mis en œuvre conformément à la réglementation en vigueur.							
* Délai de rentrée : 6 heures.							
RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL							
Consulter ce livret avant toute utilisation							
® Marque déposée PHYTEUROP							
							
PHYTEUROP <i>un éclairage différent</i>							
EMB : 49215 F <small>Date de fabrication : voir sur l'emballage.</small>							
Volume net : 10 L							

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INTERCULTURE Préconisation par adventice					BUGGY® GREENLINE®				
Nom commun	Dic. Gram.	Ann. Viv.	BUGGY GREENLINE® Dose (L/ha) / adventice		Nom commun	Dic. Gram.	Ann. Viv.	BUGGY GREENLINE® Dose (L/ha) / adventice	
			Stade Dép.	Stade Jeune				Stade Dép.	Stade Jeune
Agrotis jouet du vent	G	A	2,0	1,8	Métrioïne camomille	D	A	4,0	3,3
Agrotis stolonifère	G	V	4,5	-	Menthe	D	V	10,0	-
Agrotis vulgaire	G	V	4,5	-	Mercouale enuelle	D	A	5,5	2,25
Amaranthe réflectrice	D	A	3,3	2,25	Morelle	D	A	5,5	2,8
Ambroïse feuille d'amoïse	D	A	4,0	3,3	Mouron des oiseaux	D	A	2,9	1,8
Amoïse	D	V	10,0	-	Mouron rouge	D	A	5,5	2,25
Amroche étalée	D	A	3,75	2,25	Moutarde des champs	D	A	4,5	2,25
Amroche hastée	D	A	4,0	2,5	Orge des rats	G	A	3,0	2,0
Avoine à chevelu	G	V	5,5	-	Orge grande orfe	D	V	10,0	-
Brome de toits	G	A	4,0	2,5	Penic pied de coq	G	A	4,2	2,5
Brome stérile	G	A	4,5	3,0	Pétunia annuel	G	A	3,75	2,25
Capselle boursier-pasteur	D	A	2,9	1,8	Pennée des champs	D	A	5,5	2,25
Chardon des champs	D	V	5,5	-	Pissenlit	D	V	6,0	-
Chenopode blanc	D	A	3,75	1,8	Plantain	D	V	6,0	-
Chenopent pied de poule	G	V	10,0	-	Potentille rampante	D	V	10,0	-
Chenopent rampant	G	V	5,0	-	Pétale	D	V	10,5	-
Coquelicot	D	A	4,0	1,8	Revenelle	D	A	5,5	2,25
Dactyle aggrégé	G	A	5,0	-	Reyngrass anglais	G	V	6,0	-
Delice stérile	D	A	5,5	3,75	Ray-grass bâton	G	A	3,75	1,8
Digitaire	G	A	4,5	2,5	Renouée amphibia	D	V	10,0	-
Diplodice	D	A	3,0	2,25	Renouée des oiseaux	D	A	5,5	3,3
Epiaire	D	A	5,5	-	Renouée liseron	D	A	7,5	2,9
Euphorbe des moissans	D	A	4,0	2,0	Renouée persique	D	A	4,0	2,25
Euphorbe réveil matin	D	A	4,0	1,8	Roseau masselle	G	V	10,0	-
Faule	G	V	6,0	-	Rumex (bulbes nophores)	D	V	5,5	-
Folie avoine	G	A	3,5	2,0	Génégos jacobée	D	V	8,5	-
Fumeterre	D	A	2,9	1,8	Sénégol commun	D	A	2,8	1,8
Gelée	D	A	4,0	2,25	Sétaire glauque	G	A	4,2	3,3
Geranium découpé	D	A	7,5	3,3	Sorgho d'Alép	G	V	10,0	-
Geranium à feuilles rondes	D	A	7,5	3,3	Souci des champs	D	A	3,75	2,25
Gesse lubreuse	D	V	9,0	-	Trefles	D	V	10,0	-
Gende cornouade	D	V	10,0	-	Tussilage	D	V	10,0	-
Houlique molle	G	V	10,0	-	Veronique de Perse	D	A	3,75	2,25
Jonc	G	V	10,0	-	Veronique agreste	D	A	3,75	2,25
Leturon des champs	D	V	6,0	-	Vesce culture	D	A	6,0	3,75
Leturon (nuée et mésophile)	D	A	4,0	2,0	Vulpin des champs	G	A	4,2	1,8
Lemier amplexicaule	D	A	4,0	1,8	Repousses de céréales	G	A	2,0	1,5
Lemier pourpre	D	A	4,0	1,8	Repousses de colza	D	A	6,5	3,5
Luron des champs	D	V	10,0	-	Repousses de pomme de terre	D	A	9,0*	6,0*
Luron des haies	D	V	10,0	-	Repousses de tourmalé	D	A	3,0	2,5
Luzerne	D	A	7,0	5,5					

* : en présence de tubercules ** : avant tubérisation

IDEML ETIQUETTE