

REGISTRATION REPORT

Part A

Risk Management

Product code: MON 52276

Product name(s): ROUNDUP PRO 2

Chemical active substance(s):

glyphosate, 360 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Authorisation renewal according to art 43)

Applicant: MONSANTO SAS

Date: 2019/11/29

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PART A

RISK MANAGEMENT

1 Details of the application

The company MONSANTO SAS has requested a marketing authorisation in France for the product ROUNDUP PRO 2 (formulation code: MON 52276), containing 360 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 MONSANTO SAS 's application submitted on 21/02/2018 to market ROUNDUP PRO 2 (MON 52276) 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 in France and in other Member States (MSs) of the Southern zone.

The present application (2018-0594) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of ROUNDUP PRO 2 (MON 52276) has been made using endpoints agreed in the EU peer review of glyphosate. It also includes assessment of data and information related to ROUNDUP PRO 2 (MON 52276) 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](#)

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 ROUNDUP PRO 2 (MON 52276).

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

According to the applicant: « Any new studies submitted in this application are those necessary for the evaluation of the product but not previously evaluated during Annex I renewal of the active substance or during zonal / MS registration of ROUNDUP PRO 2 (MON 52276). ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration ROUNDUP PRO 2 (MON 52276), 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 Details of the authorisation decision

2.1 Product identity

Product code	MON 52276
Product name in MS	ROUNDUP PRO 2
Authorisation number	9300065
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	MONSANTO SAS
Active substance(s) (incl. content)	glyphosate, 360 g/L
Formulation type	Soluble concentrate [SL]
Packaging	HDPE ⁵ bottle (0.5 L, 1 L, 2 L) HDPE container (5 L, 10 L, 15 L, 20 L) HDPE tank (200 L) HDPE tank plus intermediate bulk container in metal (640 L, 1000 L)

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

Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for ROUNDUP PRO 2 (MON 52276) 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

⁶ 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/AGRGI632554A/jo/texte>

appendix 3 of the above-mentioned French Order.

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

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

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/AGRGI407093A/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:

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

GAP rev. 1, date: 2019-11-29

PPP (product name/code): ROUNDUP PRO 2 / MON 52276
Active substance 1: glyphosate
Applicant: MONSANTO SAS
Zone(s): Southern Zone ^(d)
Verified by MS: Yes

Formulation type: SL ^(a, b)
Conc. of a.s. 1: 360 g/L ^(c)
Professional use: ☒
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/Gro wth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, 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/Gro wth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	FR	Pre-plant / pre- sowing Inter crops, fallow, crop destruction	F	Annual and perennial weeds	Spraying	actively growing weeds	1	-	3 L/ha	1080	100 - 300	-	Not acceptable (genotoxic potential, relevant impurity, (*))
1	FR	Pre-plant / pre- sowing Inter crops, fallow, crop destruction	F	Annual and perennial weeds	Spraying	actively growing weeds	1	-	6 L/ha	2160	100 - 300	-	Not acceptable (genotoxic potential, relevant impurity, (*))
1	FR	Pre-plant / pre- sowing Inter crops, fallow, crop destruction	F	Annual and perennial weeds	Spraying	actively growing weeds	1	-	7 L/ha	2520	100 - 300	-	Not acceptable (MRL, relevant impurity, genotoxic potential, (*))
-	FR	Post-sowing /post- emergence Plant cover and regrowth destruction in Crops	F	Annual and perennial weeds	Spraying	actively growing weeds BBCH 00- 09	1	-	3 L/ha	1080	100 - 300	-	Not acceptable (genotoxic potential, relevant impurity, (*))

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method/Kind	Timing/Gro wth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
-	FR	Post-sowing /post-emergence Plant cover and regrowth destruction in Crops	F	Annual and perennial weeds	Spraying	actively growing weeds BBCH 00- 09	1	-	6 L/ha	2160	100 - 300	-	Not acceptable (genotoxic potential, relevant impurity, (*))
-	FR	Post-sowing /post-emergence Plant cover and regrowth destruction in Crops	F	Annual and perennial weeds	Spraying	actively growing weeds BBCH 00- 09	1	-	7 L/ha (Spot appli- cation only)	2520	100 - 300	-	Not acceptable (MRL, relevant impurity, genotoxic potential, (*))
-	FR	Vegetables, interrow weed control	F	Annual and perennial weeds	Spraying	actively growing weeds	1	-	3 L/ha	1080	100 - 300	“legume vegetables”, “pulses” and “leafy vegetables and herbs and edible flowers”: 30 d “bulb vegetables”, “stem vegetables” and “fruiting vegetables”: 60 d	Not acceptable (MRL for root vegetables, tuber vegetables, cabbage, relevant impurity, genotoxic potential, (*))
-	FR	Vegetables, interrow weed control	F	Annual and perennial weeds	Spraying	actively growing weeds	1	-	6 L/ha	2160	100 - 300	-	Not acceptable (MRL, relevant impurity, genotoxic potential, (*))

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁽ⁱ⁾)
					Method/Kind	Timing/Gro wth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
-	FR	Vegetables, interrow weed control	F	Annual and perennial weeds	Spraying	actively growing weeds	1	-	7 L/ha (Spot appli- cation only)	2520	100 - 300	-	Not acceptable (MRL, relevant impurity, genotoxic potential, (*)
8	FR	Orchards: Citrus, pome fruit, stone fruit, tree nuts, kiwi, olives, tropical and sub-tropical fruit	F	Annual and perennial weeds	Spraying hand-held ground treatment, overall spraying over weeds under trees, shielded spray for spot or local treatment	actively growing weeds Spring, summer and autumn	3	-	4 L/ha	1440 Max 2200 g as/ha/y	100 - 300	Pome fruits, citrus, stone fruit, tree nuts, , tropical and sub-tropical fruit: 21 d Olive: 7 d Kiwi: 90 d	Not acceptable (genotoxic potential, relevant impurity, (*)
8	FR	Orchards: Citrus, pome fruit, stone fruit, tree nuts, kiwi, olives, , tropical and sub- tropical fruit	F	Annual and perennial weeds	Spraying hand-held ground treatment, overall spraying over weeds under trees, shielded spray for spot or local treatment	actively growing weeds Spring, summer and autumn	3	-	6 L/ha	2160 Max 2200 g as/ha/y	100 - 300	Pome fruits, citrus, stone fruit, tree nuts, , tropical and sub-tropical fruit: 21 d Olive: 7 d Kiwi: 90 d	Not acceptable (genotoxic potential, relevant impurity, (*)
8	FR	Orchards: Citrus, pome fruit, stone fruit, tree nuts, kiwi, olives, , tropical and sub- tropical fruit	F	Annual and perennial weeds	Spraying hand-held ground treatment, overall spraying over weeds under trees, shielded spray for spot or local treatment	actively growing weeds Spring, summer and autumn	3	-	8 L/ha (Spot appli- cation only)	2880 Max 2200 g as/ha/y	100 - 300	Pome fruits, citrus, stone fruit, tree nuts, , tropical and sub-tropical fruit: 21 d Olive: 7 d Kiwi: 90 d	Not acceptable (genotoxic potential, relevant impurity, (*)

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, 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/Gro wth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
9	France	Vineyards	F	Annual and perennial weeds	Spraying, hand- held Shielded spray for local treatment	actively growing weeds Spring, summer and autumn	3	-	4 L/ha	1440 Max 2.2 kg as/ha/y	100 - 300	21 d	Not acceptable (genotoxic potential, relevant impurity, (*))
9	France	Vineyards	F	Annual and perennial weeds	Spraying, hand- held Shielded spray for local treatment	actively growing weeds Spring, summer and autumn	3	-	6 L/ha	2160 Max 2200 g as/ha/y	100 - 300	21 d	Not acceptable (genotoxic potential, relevant impurity, (*))
9	France	Vineyards	F	Annual and perennial weeds	Spraying, hand- held Shielded spray for local treatment	actively growing weeds Spring, summer and autumn	3	-	8 L/ha (spot application only)	2880 Max 2.2 kg as/ha/y	100 - 300	21 d	Not acceptable (genotoxic potential, relevant impurity, (*))
12a, 12b	France	Forestry (incl. pre-plant , inter- row, spot application, nurseries, christmas trees and fire break)	F	Annual and perennial weeds	overall spraying, shielded spray for spot or local treatment	actively growing weeds	1	-	3 L/ha	1080	100 - 300	-	Not acceptable (genotoxic potential, relevant impurity, (*))

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (^(f))
					Method/Kind	Timing/Gro wth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applicatio ns (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
12a, 12b	France	Forestry (incl. pre-plant , inter-row, spot application, nurseries, christmas trees and fire break)	F	Annual and perennial weeds	overall spraying, shielded spray for spot or local treatment	actively growing weeds	1	-	6 L/ha	2160	100 - 300	-	Not acceptable (genotoxic potential, relevant impurity, (*))

(*) 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, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references

2 Use official codes/nomenclatures of EU Member States

3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)

4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.

6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

8 The maximum number of application possible under practical conditions of use must be provided.

9 Minimum interval (in days) between applications of the same product

10 For specific uses other specifications might be possible, e.g.: g/m³ 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)

ROUNDUP PRO 2 (MON 52276) 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 that of a clear yellow homogeneous liquid free from visible suspended matter and sediment, with odour of amine. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 440 °C. In 1% aqueous, it has a pH value of 4.83 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 significantly.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in glass bottle.

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 formulation is not classified for the physico-chemical aspect.

The product ROUNDUP PRO 2 (MON 52276) does not contain POE-tallowamines (CAS n° 61791-26-2).

3.2 Efficacy (Part B, Section 3)

Considering the submitted data :

the efficacy level of ROUNDUP PRO 2 (MON 52276) is considered satisfactory for all the claimed uses.

Glyphosate having an herbicidal activity on all types of plants (known as “total weed killer”), the preparation ROUNDUP PRO 2 (MON 52276) cannot therefore be considered selective. **Given the foliar penetration of glyphosate, the preparation should not be directed to the green parts of crops.**

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 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 this dossier and validated for the determination of residues of glyphosate in plants, food of animal origin, soil, water (surface and drinking) and air.

An analytical method is available in this dossier and validated for the determination of residues of glyphosate in tissues and body fluids.

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 an <i>in vitro</i> human study performed on formulation:			
		Concentrate (tested) 360 g/L	Diluted formulation (tested)	
			28.8 g/L	2.4 g/L
	In vitro (human) %	0.1%	0.2%	0.3%
		Concentrate (used in formulation) 360 g/L	Spray dilution (used in formulation) min: 0.9 g/L	

	Dermal absorption endpoints %	1%*	1%*
Oral absorption	20%		EU 2017

*the dermal absorption study performed on ROUNDUP PRO 2 (MON 52276) was assessed during the EU review of glyphosate (ROUNDUP PRO 2 (MON 52276) is the representative formulation of glyphosate). The dilution have no impact on the dermal absorption, so a pro rata correction is not appropriate. The dermal absorption value retained at EU level was used for the non-dietary risk assessment of ROUNDUP PRO 2.

3.4.1 Acute toxicity

ROUNDUP PRO 2 (MON 52276) containing 360 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 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”.

Genotoxicity studies performed with ROUNDUP PRO 2 (MON 52276) are available. An *in vitro* micronucleus assay in mammalian cells and a bacterial reverse mutation assay are available.

Bacterial reverse mutation assay :

The study is acceptable with some limitations.

Identified deviations were:

- No analysis was performed to determine the concentration, uniformity and stability of the test substance dose formulations;
- For several strains, there is an overlap between the maximum negative values and the minimum positive values. Nevertheless, the negative HCD are in the expected ranges as recommended in Gatehouse’s publication (Gatehouse, D.G., and all, 1990, Bacterial Mutation Assays. In: Basic Mutagenicity Tests : UKEMS Part 1 Revised).
- The maximal dose tested is questionable. Indeed, the maximal dose of 5000 µg/plate described in the OECD guideline 471 is recommended for substances, not for mixtures: “Testing above the concentration of 5 mg/plate or 5 µl/plate may be considered when evaluating substances containing substantial amounts of potentially mutagenic impurities.”

It could be concluded under the experimental conditions, ROUNDUP PRO 2 (MON 52276) is not considered as mutagenic.

In vitro micronucleus assay in mammalian cells:

The study is not considered acceptable.

Identified deviations were:

- No analysis was performed to determine the concentration, uniformity and stability of the test substance dose formulations.
- The maximal dose tested without cytotoxicity is questionable for a mixture.
- There is an overlap between the maximum negative values and the minimum positive values (both in the min-max range and in the 95% LC), which causes a real problem for the interpretation of the results and does not enable the interpretation of any biological increases. Moreover, positive HCD are very low, below the value of 16/1000 that is considered as a possible threshold value for negative controls (Van Hummelen and Kirsch-Volders, 1992).

Based on these data, the study is not acceptable. The assessment of the mutagenic potential of ROUNDUP PRO 2 (MON 52276) cannot be finalised.

As a conclusion, only the bacterial reverse mutation assay is acceptable, **the genotoxic potential of ROUNDUP PRO 2 (MON 52276) cannot hence be finalized.**

3.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ¹⁰	Equipment <i>Application method</i>	Maximum application rate kg as /ha	Model (Minimum volume water (L/ha))
bare soil, grassland and lawns	F	Vehicle mounted <i>Downward spraying</i>	7L ROUNDUP PRO 2 (MON 52276) /ha 2.52 kg glyphosate/ha	EFSA (100 L/ha)
Orchards, grapes, forestry	F	Vehicle mounted <i>Downward spraying</i>	8L ROUNDUP PRO 2 (MON 52276) /ha 2.88 kg glyphosate/ha	EFSA (100 L/ha)
		Manual hand-held <i>Downward spraying</i>	8L ROUNDUP PRO 2 (MON 52276) /ha 2.88 kg glyphosate/ha	EFSA (100 L/ha)
		Manual knapsack <i>Downward spraying</i>	8L ROUNDUP PRO 2 (MON 52276) /ha 2.88 kg glyphosate/ha	EFSA (100 L/ha)

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

Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate (0.1 mg/kg bw/d)
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¹⁰ Open field or glasshouse

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

bare soil, grassland and lawns	Vehicle mounted <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	2.2%
Orchards, grapes, forestry	Vehicle mounted <i>Downward spraying</i>		1.2%
	Manual hand-held <i>Downward spraying</i>		15%
	Manual knapsack <i>Downward spraying</i>		4.5%

According to the model calculations, it can be concluded that the risk for the operator using ROUNDUP PRO 2 (MON 52276) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.4.4 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 4.0% of the AOEL of glyphosate with work wear.

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 set¹².

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.”

¹² Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

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Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child) without mitigation measures:

Bare soil Downward spraying, vehicle-mounted		Glyphosate	
ZNT : 2-3 mètres w/o 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 glyphosate/ha	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Sum (mean)	0.0092	9.2%
Resident adult Body weight: 60 kg	Sum (mean)	0.0030	3.0%

Orchards, grapes Downward spraying, vehicle-mounted, manual hand-held, manual knapsack		Glyphosate	
ZNT : 2-3 mètres w/o 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 glyphosate/ha	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Sum (mean)	0.0105	11%
Resident adult Body weight: 60 kg	Sum (mean)	0.0035	3.5%

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 MRL (Reg. 293/2013) for glyphosate as laid down in Reg. (EU) 396/2005 is not expected except for olives in contact with soil providing the application of the mitigation measures.

Intended uses on alfalfa and interrow uses on groups “root and tuber vegetables”, “brassica vegetables”, “fungi”, “oilseed”, “cereals” “berries and small fruits”, “tea, coffee, and herbal infusions”, “hops” and “spices” 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 6.00 kg/ha and of 3.00 kg/ha is retained for respectively inter-crop uses and olives, and inter-row uses on “bulb vegetables”, “stem vegetables”, “fruiting vegetables”, “legume vegetables”, “pulses” and “leafy vegetables and herbs and edible flowers”. Furthermore a PHI of 60 days is retained for inter-row uses on “bulb vegetables”, “stem vegetables” and “fruiting vegetables” and a PHI type F for inter-crop uses.

3.5.2 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, zRMS France, agrees with the authorization of the intended inter-crop/pre-emergence uses (including also stubble), inter-row uses (“bulb vegetables”, “stem vegetables”, “fruiting vegetables”, “legume vegetables”, “pulses”, “leafy vegetables and herbs and edible flowers”) and uses on orchards and vineyards.

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 PEC_{sw} derived for glyphosate and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{gw} for glyphosate and AMPA do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000¹³. 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 with risk mitigations are acceptable for the intended uses.

¹³ 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.

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

Concerning the risk assessment to bees and other pollinisators, 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)

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 les demandes de renouvellement de l'autorisation de mise sur le marché suite au renouvellement de l'approbation de la substance active glyphosate, de modification des informations déclarées, et les données complémentaires fournies suite à une exigence post-autorisation du produit phytopharmaceutique **ROUNDUP PRO 2***

de la société MONSANTO SAS

enregistrées sous les n°2018-0594, 2019-4403 et 2019-0441

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 respectées,

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



Informations générales sur le produit	
Nom du produit	ROUNDUP PRO 2
Type de produit	Deuxième gamme
Titulaire	MONSANTO SAS Eden Park - Bâtiment B 1 rue Buster Keaton 69800 ST PRIEST France
Formulation	Concentré soluble (SL)
Contenant	485.8 g/L - glyphosate sel d'isopropylamine (équivalent à 360 g/L de glyphosate)
Numéro d'intrant	9300065
Numéro d'AMM	9300065
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 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.	3 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 » 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 6 L/ha et pour des délais avant récolte de 30 jours sur cultures légumières et 7 jours sur grandes cultures, au même motif. L'usage est également retiré 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.				
11015932 Traitements généraux* Désherbage* Cult. Installées	3 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 revendiqué correspondant au nouveau libellé « Traitements Généraux * Destruction des couverts et des repousses dans les cultures » 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 6 L/ha aux mêmes motifs. L'usage est également retiré 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.				

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
11015932 Traitements généraux* Désherbage* Cult. Installées	3 L/ha	1/an	30	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 « Cultures légumières*Désherbage Inter-rang » 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 3 L/ha sur légumes-racines, légumes-tubercules et choux au motif que le respect des limites maximales de résidus n'a pas pu être vérifié en raison d'un manque d'essais résidus. L'usage est également retiré pour les doses supérieures à 3 L/ha pour les groupes de cultures légumes-bulbes, légumes-tiges, légumes-fruits, légumes potagères, légumineuses séchées et légumes feuilles, fines herbes et fleurs comestibles au motif que les données fournies ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus.				
	4 L/ha	3/an	21 jours	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 « Vigne*Désherbage*Cult. Installées » 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 6 L/ha et 8 L/ha au même motif.				
	4 L/ha	3/an	21	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 « Cultures fruitières*Désherbage*Cult. Installées » 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 6 L/ha et 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
11015932 Traitements généraux* Désherbage* Cult. Installées	3 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 revendiqué correspondant au nouveau libellé « Forêt*Dégagement », 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 6 L/ha au même motif.				
	4 L/ha	3/an	90	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 « Cultures fruitières*Désherbage*Cult. Installées » 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 6 L/ha et 8 L/ha au même motif.				
	4 L/ha	3/an	7	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 « Cultures fruitières*Désherbage*Cult. Installées » 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 6 L/ha et 8 L/ha au même motif.				

Appendix 2 Copy of the product label

1. VIGNE ET VERGER (suite)

Nom Commun	Dic. Gram. Mono.	An. Viv.	Doses Roundup PRO2 (l/ha)	Stade Dvpé	Stade Jeune	Période de traitement	Remarques
Laiteron (rude et marichet)	D	A	3,5	2,5		Février-avril	
Laitue scarole	D	A	3,5	3		Février-avril	
Lamier pourpre	D	A	4	2,5		Février-avril	
Liseron	D	V	7			Juin-août	Optimum de traitement: pleine floraison Traitement par tache uniquement
Luzerne lupuline	D	A	4,5	3		Février-avril	
Maive	D	V	7			Mai-juin	Optimum de traitement: pleine floraison Traitement par tache uniquement
Maive (annuelle)	D	A	4	3		Février-mars	Levées issues de germination d'automne
Millipertuis perforé	D	V	4			Mars-avril	Traitement par tache uniquement
Morelle	D	A	4	2,5		Mai-juillet	
Mouron des oiseaux	D	A	3	2		Février-avril	
Mouron rouge	D	A	4	3		Février-avril	
Orpe des Rats	G	A	3	1,5		Février-avril	
Penic pied de coq	G	A	4	2		Mai-juillet	
Passerage drave	D	V	4			Mars-avril	Traitement par tache uniquement
Pétun annuel	G	A	3	2		Février-avril	
Picote	D	A	4	3		Mars-avril	
Pissenlit	D	V	5			Mars-avril	Traitement par tache uniquement
Plantain	D	V	4			Mars-avril	Traitement par tache uniquement
Poireau des vignes	M	V	5			Nov-février	Traitement par tache uniquement
Ray-grass anglais	G	V	6			Février-avril	Traitement par tache uniquement
Ray-grass d'Italie	G	A	4	2,5		Février-avril	Traitement de préférence avant montaison
Ranonce persicaire	D	A	4	2,5		Mai-juillet	
Ronce	D	V	8			Sept.-oct.	Traitement par tache uniquement
Rumex (toutes espèces)	D	V	4,5			Mars-avril	3 l/ha sur semis Traitement par tache uniquement
Séneçon vulgaire	D	A	3	2		Février-avril	
Sorgho d'alep	G	V	7			Mai-juillet	Traitement optimal: 30/40 cm de haut - sur levées de graines: 3,5 l/ha Traitement par tache uniquement

Dicotylédones jeunes = jusqu'au stade 6-8 feuilles, Graminées jeunes = avant tallage, D = dicotylédone,
G = graminée, M = monocotylédone, A = annuelle ou bisannuelle, V = vivace ou pluriannuelle

1. VIGNE ET VERGER (suite)

Nom Commun	Dic. Gram.	An. Viv.	Doses Roundup PRO2 (l/ha)	Stade Dvpé	Stade Jeune	Période de traitement	Remarques
Trèfle	D	V	7			Février-avril	Traitement par tache uniquement
Tussilage	D	V	7			Mai-juillet	Traitement par tache uniquement
Valériane potagère	D	A	5	3		Février-avril	
Véronique de persa	D	A	3	2		Février-avril	
Véronique feuille de terre	D	A	3,5	2,5		Février-avril	

Dicotylédones jeunes = jusqu'au stade 6-8 feuilles, Graminées jeunes = avant tallage, D = dicotylédone,
G = graminée, M = monocotylédone, A = annuelle ou bisannuelle, V = vivace ou pluriannuelle

2. INTERCULTURE (cultures arables)

En interculture: ne pas dépasser la quantité maximale annuelle de 2880 g
m.a./ha/an (m.a.: matière active)

Nom Commun	Dic. Gram.	An. Viv.	Doses Roundup PRO2 (l/ha)	Stade Dvpé	Stade Jeune	Remarques
Agrostis puet du vent	G	A	1,5	1		
Agrostis stolonifère	G	V	3,5			Sur levées de graines: 2 l/ha
Amarante hybride	D	A	2,5	1,5		
Amarante réfléchi	D	A	2	1,5		
Ambroisie feuille d'armoise	D	A	2,5	2		
Armoise	D	V	7			
Arroche étiolée	D	A	2,5	1,5		
Arroche hastée	D	A	3	1,5		
Avoine à chapelet	G	V	4			Sur levées de graines: 2 l/ha
Brome mou	G	A	3	1,5		
Brome stérile	G	A	2,5	2		
Capselle	D	A	2,5	1		
Chardon des champs	D	V	3,5			Sur levées de graines de printemps: 2 l/ha
Chénopode	D	A	2,5	1		
Chiendent pied de poule	G	V	7			

Mauvaises herbes jeunes jusqu'au stade 3 feuilles (ou tallage pour les graminées)
D = dicotylédone, G = graminée, A = annuelle ou bisannuelle, V = vivace ou pluriannuelle

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2. INTERCULTURE (cultures arables) (suite)

Nom Commun	Dic. Gram.	An. Viv.	Doses Roundup PRO2 (l/ha)		Remarques
			Stade Dypé	Stade Jeune	
Chiendent rampant	G	V	3,5		
Coquelicot	D	A	3	1,5	
Datura stramonium	D	A	4	2,5	
Digitaire	G	A	3	1,5	
Dipsacis (annuelle)	D	A	2	1,5	
Euphorbe des moissons	D	A	2,5	1	
Euphorbe réveil matin	D	A	3	1	
Folle avoine	G	A	2,5	1,5	
Fumeterre	D	A	2,5	1	
Gaillet	D	A	3	1,5	
Géranium (toutes espèces)	D	A	6	3	
Grande consoude	D	V	7		
Laiteron des champs	D	V	4		
Laiteron (rude et maraîcher)	D	A	3	1,5	
Lamier pourpre	D	A	3	1,5	
Lamier amplexicaule	D	A	4	1,5	
Liseron des haies	D	V	6		
Liseron des champs	D	V	7		
Métricaire	D	A	3	2,5	
Mercouriale	D	A	4	1,5	
Morelle	D	A	3	1,5	
Mouron des oiseaux	D	A	2	1	
Mouron rouge	D	A	3,5	1,5	
Orge des rizières	D	A	2	1,5	
Panic pied de coq	G	A	3	1,5	
Pâleurin annuel	G	A	2,5	1,5	
Pensée des champs	D	A	5	1,5	
Pissenlit	D	V	5		
Plantain	D	V	4		
Ravenelle	D	A	4	1,5	
Ray-grass anglais	G	V	5		

Mauvaises herbes jeunes jusqu'au stade 3 feuilles (ou tallage pour les graminées)
D= dicotylédons, G= graminée, A= annuelle ou bisannuelle, V= vivace ou pluriannuelle

2. INTERCULTURE (cultures arables) (suite)

Nom Commun	Dic. Gram.	An. Viv.	Doses Roundup PRO2 (l/ha)		Remarques
			Stade Dypé	Stade Jeune	
Ray-grass d'Italie	G	A	3	1	
Renouée amphibie	D	V	7		
Renouée des oiseaux	D	A	4	2	
Renouée léonon	D	A	5	2	
Renouée persicaire	D	A	2,5	1,5	
Rumex crépu	D	V	3,5		
Rumex (toutes espèces)	D	V	4		3 l/ha sur rumex issus de semis
Séneçon vulgaire	D	A	2	1	
Sétaire	G	A	3	2	
Sorgho d'élev	G	V	7		Sur levées de graines: 1,5 l/ha
Trèfle rampant	D	V	7		
Tussilage	D	V	7		
Véronique	D	A	2,5	1,5	Plaine végétation: 3,5 l/ha
Vesce cultivée	D	A	5	2,5	
Vulpin des champs	G	A	2,5	1	
Reposes de céréales	G	A	1,5	1	Orge développé 2 l/ha
Reposes de colza	D	A	6	2,5	3,5 l/ha au stade montaison
Reposes de tournesol	D	A	3	1,5	

Mauvaises herbes jeunes jusqu'au stade 3 feuilles (ou tallage pour les graminées)
D= dicotylédons, G= graminée, A= annuelle ou bisannuelle, V= vivace ou pluriannuelle

APPLICATION DE ROUNDUP PRO2

PAR PULVÉRISATION

Une bonne pulvérisation doit assurer la meilleure répartition possible des gouttelettes sur la surface foliaire des herbes visées. Les gouttelettes ne doivent être ni trop petites (risque de dérive), ni trop grosses (risque de ruissellement). Recommandations pour la pulvérisation de ROUNDUP PRO2

Préparation de la bouillie:
Utiliser un volume d'eau compris entre 100 et 300 l/ha. Ne pas dépasser 400 l/ha pour éviter le ruissellement.

Traiter avec un pulvérisateur adapté, en bon état de fonctionnement et fournissant une pulvérisation régulière.

Type de buse

Buse à fente (exemples):

APG Albuz orange, Spraying System (8002/11002)

Pression 2 à 3 bars

Angle du jet 80° à 100°

Buse miroir (exemples):

Albuz APM orange, Spraying system TK2, Lurmark Bleu clair

Pression 1 à 1,5 bar

Angle du jet 120° à 140°

IMPORTANT

Respectez les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements, selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers, concernant votre exploitation; tels que: la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces... Monsanto garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché du Ministère de l'Agriculture. Ne peut être reformulé ou reconditionné. Aucune licence attribuée explicitement ou implicitement sous brevet américain.

Nom commercial: ROUNDUP® PRO 2

Type d'action du produit: HERBICIDE

Numéro AMM: 9300065 délivrée le 10 septembre 2008

Substance active: 360 g/L (30,8 % p/p) de glyphosate acide
(équivalent à 486 g/L (41,5 % p/p) de sel d'isopropylamine de glyphosate)

- P234 :** Conserver uniquement dans le récipient d'origine.
P273 : Eviter le rejet dans l'environnement.
P280 : Porter des gants de protection.
EUH 401 : Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
SP1 : Ne pas polluer l'eau avec le produit ou son emballage.
SPa3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m par rapport aux points d'eau.

Délai de rentrée sur la parcelle: 6 heures

Usage	Substances	Dose maximale	Délai de rentrée	Dose maximale	Conditions d'emploi	Délai de rentrée
Traitement précoce, désherbage des zones cultivées, pulvérisation précoce	Graines annuelles	3 l/ha	2000 g n. active/l	-	Culture précoce: 30 jours	6 heures
	Graines annuelles et bisannuelles	6 l/ha				
	Adventices vivaces	7 l/ha				
Traitement précoce, désherbage des zones cultivées, pulvérisation précoce	Graines annuelles	3 l/ha	2000 g n. active/l	-	200 l/ha	6 heures
	Graines annuelles et bisannuelles	6 l/ha				
	Adventices vivaces	6 l/ha				
Adventices vivaces, désherbage, maintenance précoce	Graines annuelles	4 l/ha	2000 g n. active/l	3 applications maximum par an et par ha	21 jours avant récolte (30 jours avant récolte si 17 jours)	6 heures
	Graines annuelles et bisannuelles	6 l/ha				
	Adventices vivaces	8 l/ha (par bêche)				
Vignes, désherbage, maintenance précoce	Graines annuelles	4 l/ha	2000 g n. active/l	-	21 jours	6 heures
	Graines annuelles et bisannuelles	6 l/ha				
	Adventices vivaces	8 l/ha (par bêche)				

Travail: minimum 48 heures et par

Monsanto ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, décline toute responsabilité concernant son utilisation à d'autres usages tels que prévus par le catalogue des usages en vigueur.

L'avis maximal de résidus: se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse: <http://ec.europa.eu/food/plant/pesticides/vet-pesticides-database>

Fiche de données de sécurité disponible sur: www.quichfda.com

EN CAS D'URGENCE
Composer le 15 ou le 112 ou contacter le centre anti poison le plus proche

Puis signaler vos symptômes au réseau PhytoPharma N° Vert: 0 800 807 887 (Appel gratuit depuis un poste fixe).
Numéro d'urgence 24 h / 24 h: 0 800 807 887

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MON 52276 / ROUNDUP PRO 2
Part A - National Assessment
FRANCE
