

REGISTRATION REPORT

Part A

Risk Management

Product code: MON 76952

Product name: ROUNDUP DYNAMIC

Chemical active substance:

glyphosate, 500 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: MONSANTO SAS

Date: 2020/01/30

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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 DYNAMIC (formulation code: MON 76952), containing 500 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 27/04/2017 to market ROUNDUP DYNAMIC (MON 76952) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation in France and in other Member States (MSs) of the Southern zone.

The present application (2017-1198) 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 DYNAMIC (MON 76952) has been made using endpoints agreed in the EU peer review of glyphosate. It also includes assessment of data and information related to ROUNDUP DYNAMIC (MON 76952) where those data have not been considered in the EU peer review process.

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

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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](#)

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

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This document also describes the specific conditions of use and labelling required for France for the registration of ROUNDUP DYNAMIC (MON 76952).

1.2 Letters of Access

1.3 Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request Justification for submission of tests and studies

According to the applicant: « MON 76952 is a new developed formulation that has not been previously evaluated in the EU according to the Uniform Principles. New studies were conducted with the formulation MON 76952 and similar formulations to fulfil data requirements as stipulated in Regulation 1107/2009.».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ROUNDUP DYNAMIC (MON 76952), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	MON 76952
Product name in MS	ROUNDUP DYNAMIC
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	MONSANTO SAS
Active substance(s) (incl. content)	glyphosate, 500 g/L
Formulation type	Soluble concentrate [SL]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

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2.2 Conclusion DAMM

The evaluation of the application for ROUNDUP DYNAMIC (MON 76952) resulted in the decision **to refuse 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 : no marketing authorisation granted

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

N/A : no marketing authorisation granted.

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

N/A : no marketing authorisation granted .

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁵ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Moreover, for glyphosate-based products, the official statement⁶ 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 2014⁷ provides that:

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

⁶ 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

⁷ <https://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

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- 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 extrapolation⁸ 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 : no marketing authorisation granted .

2.5.2 Specific restrictions linked to the intended uses

N/A : no marketing authorisation granted .

None.

⁸ 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, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

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

When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

PPP (product name/code):	ROUNDUP DYNAMIC (MON 76952)	Formulation type:	SL ^(a, b)	GAP, date: 2020/01/30
Active substance 1:	glyphosate	Conc. of a.s. 1:	500 g/L ^(c)	
Applicant:	MONSANTO SAS	Professional use:	<input checked="" type="checkbox"/>	
Zone(s):	Southern Zone ^(d)	Non-professional use:	<input type="checkbox"/>	
Verified by MS:	Yes			

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(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/Ki nd	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between application s (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/m ax		
Zonal uses (field or outdoor uses, certain types of protected crops)													
6	FR	Inter Crop, Set aside/fallow Crop destruction	F	annual and perennial weeds	spraying	actively growing weeds (Pre plant- pre sowing)	1	-	2.16	1.08	100 - 400	-	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/Ki nd	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between application s (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/m ax		
6	FR	Inter Crop, Set aside/fallow Crop destruction	F	annual and perennial weeds	spraying	actively growing weeds (Pre plant- pre sowing)	1	-	3.84	1.92	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, ^(*))
6	FR	Inter Crop, Set aside/fallow Crop destruction	F	annual and perennial weeds	spraying	actively growing weeds (Pre plant- pre sowing)	1	-	4.8	2.40	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, ^(*) , MRL)
2	FR	Post-plant/pre- emergence	F	annual and perennial weeds	spraying	actively growing weeds (Post-plant, post- sowing/pre- emergence- BBCH 00- 09)	1	-	2.16	1.08	100 - 400	-	Not acceptable (relevant impurity, genotoxic potential, ^(*))
2	FR	Post-plant/pre- emergence	F	annual and perennial weeds	spraying	actively growing weeds (Post-plant, post- sowing/pre- emergence- BBCH 00- 09)	1	-	3.84	1.92	100 - 400	-	Not acceptable (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 ^(f)
					Method/Ki nd	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between application s (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/m ax		
2	FR	Post-plant/pre- emergence	F	annual and perennial weeds	spraying	actively growing weeds (Post-plant, post- sowing/pre- emergence- BBCH 00- 09)	1	-	4.8	2.40	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (**), MRL)
3a	FR	Pre-harvest weed control: cereals	F	annual and perennial weeds	spraying (spot applica- tion only)	actively growing weeds; BBCH 87 < 30 % grain moisture of crop	1	-	4.32	2.16	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, birds, (*), MRL)
3b	FR	Pre-harvest weed control:linseed for fibre production (not for consumption)	F	annual and perennial weeds	spraying	actively growing weeds; BBCH 87 < 30 % grain moisture of crop During the retting	1	-	2.16	1.08	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (*))
7	FR	Pasture, meadow, grassland Weed control	F	annual and perennial weeds	spraying (spot applica- tion only)	actively growing weeds	1	-	2.16	1.08	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (*), MRL)

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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/Ki nd	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between application s (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/m ax		
7	FR	Pasture, meadow, grassland Weed control	F	annual and perennial weeds	spraying (spot applica- tion only)	actively growing weeds	1	-	3.84	1.92	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (*), MRL)
7	FR	Pasture, meadow, grassland Weed control	F	annual and perennial weeds	spraying (spot applica- tion only)	actively growing weeds	1	-	4.8	2.40	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (*), MRL)
7	FR	Pasture, meadow, grassland Vegetation cover destruction	F	annual and perennial weeds	spraying	actively growing weeds	1	-	2.16	1.08	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (*))
7	FR	Pasture, meadow, grassland Vegetation cover destruction	F	annual and perennial weeds	spraying	actively growing weeds	1	-	3,84	1.92	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (*))
7	FR	Pasture, meadow, grassland Vegetation cover destruction	F	annual and perennial weeds	spraying	actively growing weeds	1	-	4.8	2.40	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (*))
8	FR	Orchards	F	annual and perennial weeds	spraying, local treatment	actively growing weeds	3 (max 2200 g sa/ha/an)	-	2.88	1.44	100 - 400	Pome fruit, citrus, stone fruit, tree nuts: 21 d Olive: 7 d Kiwi: 90 d	Not acceptable (genotoxic potential, relevant impurity, (*))
8	FR	Orchards	F	annual and perennial weeds	spraying, local treatment	actively growing weeds	3 (max 2200 g sa/ha/an)	-	4.32	2.16	100 - 400	Pome fruit, citrus, stone fruit, tree nuts: 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, 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/Ki nd	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between application s (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/m ax		
8	FR	Orchards	F	annual and perennial weeds	spraying, local treatment (Spot applica- tion only)	actively growing weeds	3 (max 2200 g sa/ha/an)	-	5.76	2.88	100 - 400	Pome fruit, citrus, stone fruit, tree nuts: 21 d Olive: 7 d Kiwi: 90 d	Not acceptable (genotoxic potential, relevant impurity, (*))
9	FR	Vineyards	F	annual and perennial weeds	spraying, shielded spray for local treatment	actively growing weeds	3 (max 2200 g sa/ha/an)	-	2.88	1.44	100 - 400	21 d	Not acceptable (genotoxic potential, relevant impurity, (*))
9	FR	Vineyards	F	annual and perennial weeds	spraying, shielded spray for local treatment	actively growing weeds	3 (max 2200 g sa/ha/an)	-	4.32	2.16	100 - 400	21 d	Not acceptable (genotoxic potential, relevant impurity, (*))
9	FR	Vineyards	F	annual and perennial weeds	spraying, shielded spray for local treatment (spot applica- tion only)	actively growing weeds	3 (max 2200 g sa/ha/an)	-	5.76	2.88	100 - 400	21 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, 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/Ki nd	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between application s (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/m ax		
10	FR	Vegetable In crop inter-row	F	annual and perennial weeds	shielded spray	actively growing weeds	1	-	2.16	1.08	100 - 400	"legume vegetables", "pulses" and "leafy vegetables and herbs and edible flowers": 30 d "bulb vegetables", "stem vegetables" and "fruiting vegetables": 60 d	Not acceptable (genotoxic potential, relevant impurity, (*), MRL for root and tuber vegetables, brassica vegetables)
10	FR	Vegetable In crop inter-row	F	annual and perennial weeds	shielded spray	actively growing weeds	1	-	3.84	1.92	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (*), MRL)
10	FR	Vegetable In crop inter-row	F	annual and perennial weeds	shielded spray	actively growing weeds	1	-	4.8	2.40	100 - 400	-	Not acceptable (genotoxic potential, relevant impurity, (*), MRL)
13a	FR	Devitalisation of stumps,trees and shrumps	F	tree stumps or bushes	Moistenin g, Paint brush, wiping with special equipment for selective control	within 1 h after cutting	1	-	0.24 L/m ² of stump section	120 g/m ² of stump section	-	-	Not acceptable (genotoxic potential, relevant impurity, (*))
13b	FR	Devitalisation of vines and brambles	F	-	spraying in tunnel sprayer	brambles, vines > BBCH 91	1	-	5.76	2.88	-	21	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/Ki nd	Timing/Grow th stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between application s (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/m ax		
17	FR	Alfalfa	F	annual and perennial weeds	spraying	during dormancy of the plant	1	-	0.72	0.36	-	-	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

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.

(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.

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)

The formulation ROUNDUP DYNAMIC (MON 76952) 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 of brown orange, clear homogeneous liquid, free from visible suspended matter and sediment, with a slight chemical odour. It is not explosive and has no oxidizing properties. The product is not flammable. It has a self-ignition temperature 520 °C. In aqueous solution (1%), it has a pH value 4.86 at 21°C. 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 appearance, active ingredient content nor the technical properties were changed.

The active substance glyphosate contains two 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 ROUNDUP DYNAMIC (MON 76952) does not contain POE-tallowamines (CAS n° 61791-26-2).

The formulation is not classified for the physico-chemical aspect.

3.2 Efficacy (Part B, Section 3)

Considering the submitted data :

- The efficacy level of ROUNDUP DYNAMIC (MON 76952) 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 DYNAMIC (MON 76952) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green parts of crops.
- 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.
- For cereals at the stage of maturity before harvest, the risks of negative impact on bread making is considered acceptable. In the absence of data allowing the assessment of the risk of negative impact on cereal brewing and malting and seed production, the preparation should not be used on cereals intended to brewing/malting and seed production.
- For alfalfa seed production, in view of the quality requirement (analytical purity) for harvested alfalfa seeds, the selectivity level of ROUNDUP DYNAMIC (MON 76952) and the risk of impact on yield and quality are considered acceptable in the conditions of use specific to this use (mentioned below).

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- 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 glyphosate and its relevant impurities formaldehyde and N-Nitrosoglyphosate in the formulation are available. **However, limit of quantification of the analytical method for determination of the relevant impurity N-nitroglyphosate in the preparation is higher than the acceptable limit.**

3.3.2 Analytical methods for residues

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

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: Glyphosate		
ADI	0.5 mg kg bw/d	EU (2017)
ARfD	0.5 mg/kg bw	
AOEL	0.1 mg/kg bw/d	
AAOEL	not applicable	
Dermal absorption	Based on an in vitro human study performed on formulation:	
	Concentrate (tested) 500 g/L	Diluted formulation (tested) 1 g/L
In vitro (human) %	0.17	0.33
	Concentrate (used in formulation) 500 g/L	Spray dilution (used in formulation) 1 g/L
Dermal absorption endpoints %	1	1
Oral absorption	20%	

3.4.1 Acute toxicity

ROUNDUP DYNAMIC (MON 76952) containing 500 g/L glyphosate has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin 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”.

Genotoxicity studies performed with ROUNDUP DYNAMIC (MON 76952) are available. An *in vitro* micronucleus assay in mammalian cells and a bacterial reverse mutation assay are available.

Bacterial reverse mutation assay :

The AMES test performed with ROUNDUP DYNAMIC (MON 76952) is acceptable.

Some limitations were identified:

- 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.*

Under the experimental conditions, ROUNDUP DYNAMIC (MON 76952) doesn't induce gene mutations in bacteria.

In vitro micronucleus assay in mammalian cells:

The study is considered not acceptable.

Some deviations were identified:

- No analyses was performed to determine the concentration, uniformity and stability of the test substance dose formulations.
- According to the new HCD (restricted to same gender and vehicle that those used in the study), even if there are no overlap in the positive and negative historical control ranges (min –max) in the 3 test conditions, there is an overlap between the maximum negative values and the minimum positive values in the 95% CL, 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

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Kirsch-Volders, 1992).

Considering the major deviation observed with the HCD, the study is not acceptable.

As a conclusion, only the bacterial reverse mutation assay is acceptable, the genotoxic potential of ROUNDUP DYNAMIC (MON 76952) cannot hence be finalized.

3.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/ G ⁹		Equipment <i>Application method</i>	Maximum application rate kg as /ha	Minimum vol- ume water (L/ha)
Devitalisation of vines and brambles (max. 5.76 L product/ha)	F	Crop area	Vehicle mounted <i>Downward spraying</i> [EFSA model]	2.88 kg sa/ha	400
GRAPES (max. 5.76 L product/ha)	F	Crop area	Manual Knapsack/Hand held <i>Downward spraying</i> [EFSA model]	2.88 kg sa/ha	100
LOW CROPS* (max. 4.80 L product/ha)	F	Crop area	Vehicle mounted <i>Downward spraying</i> [EFSA model]	2.4 kg sa/ha	100
		Non crop area**	Vehicle mounted <i>Downward spraying</i> Manual Knapsack/Hand held <i>Downward and upward spraying</i> [MODOP ZNA]		
Devitalization of stumps, trees, shrubs	F	Crop and non-crop area	Paintbrush [Consumer product painting model]	0.24 L product/m ²	-

* includes crop and non-crop areas

** Pasture, meadow, grassland and forest clearing

Considering proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010¹⁰ dedicated to non-agricultural areas, the Consumer product painting model¹¹ and the EFSA model¹²:

⁹ Open field or glasshouse

¹⁰ Studies and models that can be used to estimate operator exposure during the use of plant protection products in non-agricultural areas. Report from expert group « produits phytosanitaires : substances et préparations chimiques » Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011

¹¹ Consumer product painting model: ACP - SC 11000 - consumer exposure to non-agricultural pesticide products (Ann. Occ. Hyg. 44(6):421-426, 2000)

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

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Model	Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate
EFSA	GRAPES (max. 5.76 L product/ha)	Manual Knap-sack <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	4.5
		Hand held <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	15
	LOW CROPS (max. 4.80 L product/ha)	Vehicle mounted <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	2.11
ZNA MO-DOP	LOW CROPS (max. 4.80 L product/ha)	Vehicle mounted <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	3.0
		Hand held <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	6.6
		Manual Knap-sack <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	0.4
		Hand held <i>Upward spraying</i>	Working coverall and gloves during mixing/loading and application	4.6
Biocide model [Consumer product painting model]	Devitalization of stumps, trees, shrubs	Paintbrush	Working coverall during mixing/loading and application	98.2

According to the model calculations, it can be concluded that the risk for the operator using ROUNDUP DYNAMIC (MON 76952) 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

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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% of the AOEL of glyphosate with PPE (work wear).

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

3.4.5 Bystander and resident exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹³.

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): “*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure.*”

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child):

Model (AOEM) - All pathways (mean)	% AOEL Glyphosate
Resident (children)	13
Resident (adults)	4

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” “cereals” 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 4.3 L/ha and of 2.2 L/ha is retained for respectively inter-crop uses, 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.

¹³ 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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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.

Summary for ROUNDUP DYNAMIC (MON 76952)

Table: Information on ROUNDUP DYNAMIC (MON 76952) (KCA 6.8)

Crop	PHI for ROUNDUP DYNAMIC (MON 76952) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for ROUNDUP DYNAMIC (MON 76952) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate		
Citrus	21days	Yes	21 days	
Pome fruits	21 days	Yes	21 days	
Stone fruits	21 days	Yes	21 days	
Tree nuts	21 days	Yes	21 days	
Kiwi	90 days	Yes	90 days	
Olives	7 days	Yes	7 days	
Grapes		Yes	21 days	
Inter-row treated vegetables “legume vegetables”, “pulses”, “leaf vegetables, herbs and edible flowers”	30 days	Yes	30 days	
Inter-rows treated vegetable “bulb vegetables”, “stem vegetables”, “fruiting vegetables”	30 days	No	60 days	Trials performed at PHI 60 days
Inter-row treated vegetables “root and tuber vegetables”, “brassica vegetables”, “fungi”, “oilseeds”, “cereals”, “berries and small fruits”, “tea, coffee, and herbal infusions”, “hops” and “spices”	30 days	-		This use is not recommended in France as not sufficient residue trials are available.
Inter-crop uses	(30 days for vegetables)	Yes	F	

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).

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

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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 AMPA 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) No 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, except for devitalization on brambles. Risk mitigations are required to protect birds, aquatic organisms and non-target plants.

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.

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

N/A : no marketing authorisation granted .

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 : no marketing authorisation granted.

5.1.2 Post-authorisation data requirements

N/A : no marketing authorisation granted .

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Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le 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 d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique ROUNDUP DYNAMIC

de la société MONSANTO SAS

enregistrées sous les n° 2017-1207, 2017-1198, 2017-1856, 2018-3600, 2019-0463, et 2019-6576

Vu les conclusions de l'évaluation de l'Anses du 4 décembre 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,

La mise sur le marché du produit phytopharmaceutique désigné ci-après n'est pas autorisée en France.

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Informations générales sur le produit	
Noms du produit	ROUNDUP DYNAMIC ROUNDUP POWERFLEX ROUNDUP PLATINUM
Type de produit	Produit de référence
Titulaire	MONSANTO SAS 16 Rue Jean Marie Leclair 69009 LYON FRANCE
Formulation	Concentré soluble (SL)
Contenant	612,5 g/L - glyphosate sel de potassium (équivalent à 500 g/L de glyphosate)
Numéro d'intrant	369-2017.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort le,

30 JAN. 2020


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

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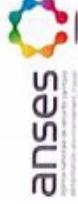
ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
00201024 Cultures fruitières* Désherbage* Cult. Installées	2,88 L/ha	3/an	21
Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé aux doses de 4,32 L/ha et 5,76 L/ha au même motif.			
12015901 Kiwi*Désherbage* Cult.. Installées	2,88 L/ha	3/an	90
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Cultures fruitières * Désherbage * Cult. Installées », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé aux doses de 4,32 L/ha et 5,76 L/ha au même motif.			
15455911 Légumineuses fourragères* Désherbage	0,72 L/ha	1/an	Non applicable
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Porte-Graine * Légumineuses fourragères * Désherbage » est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.			
12505901 Olivier*Désherbage* Cult. Installées	2,88 L/ha	3/an	7
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Cultures fruitières * Désherbage * Cult. Installées », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé aux doses de 4,32 L/ha et 5,76 L/ha au même motif.			
15705914 Prairies* Désherbage	2,16 L/ha	1/an	Non applicable
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Prairies * Désherbage » et « Prairies * Destruction du couvert végétal » est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé à la dose de 3,84 L/ha et 4,8 L/ha au même motif.			

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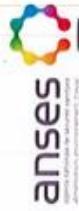


Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
11015924 Traitements généraux* Désherbage* Avt Mise Cuit.	2,16 L/ha	1/an	30
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Traitements Généraux * Désherbage * Interculture, jachères et destruction de culture » est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé à la dose de 3,84 L/ha au même motif. L'usage est également refusé pour les doses supérieures à 3,84 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	2,16 L/ha	1/an	Non applicable
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.	4,32 L/ha	1/an	7
11015932 Traitements Généraux * Désherbage * Cult. Installées	2,16 L/ha	1/an	30
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Céréales * Désherbage * Avt Récolte » est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé en raison d'un risque de dépassement des limites maximales de résidus.	4,32 L/ha	1/an	7
11015932 Traitements Généraux * Désherbage * Cult. Installées	2,16 L/ha	1/an	30
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Traitements Généraux * Désherbage * Interv-rang des cult. Installées » et « 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. L'usage est également refusé à la dose de 3,84 L/ha au même motif. L'usage est également refusé pour les doses supérieures à 3,84 L/ha au motif que les données fournies ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus.	4,32 L/ha	1/an	30
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Cultures légumières * Désherbage Interv-rang » est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé pour les usages sur légumes-racines, légumes tuberculeux 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.	4,32 L/ha	1/an	30

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
L'usage est également refusé pour les doses supérieures à 2,16 L/ha au motif que les données fournies ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus.			
11015921 Traitements généraux* Désherbage* Zones Cult. Avt Plantat.	2,16 L/ha	1/an	30
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Traitements Généraux » Désherbage * Interculture, jachères et destruction de culture », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé à la dose de 3,84 L/ha au même motif. L'usage est également refusé pour les doses supérieures à 3,84 L/ha au motif que les données fournies ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus.			
11015911 Traitements généraux* Dérital. Broussailles	5,76 L/ha	1/an	Non applicable
Motivation du refus : L'usage revendiqué correspondant au nouveau libellé « Traitement Généraux » Débroussailage », est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.			
11015910 Traitements généraux* Dévitalisation* Arb. sur pied Souches	0,24 L/m ²	1/an	Non applicable
Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.			
12705502 Vigne*Désherbage* Cult. Installées	2,88 L/ha	3/an	21
Motivation du refus : L'usage est refusé au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également refusé aux doses de 4,32 L/ha et 5,76 L/ha au même motif.			

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Appendix 2 Copy of the product label

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

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Informations réglementaires

Nom commercial : Roundup Dynamic

Détenteur de l'autorisation de mise sur le marché :

Monsanto SAS, Eden Park, 1 Rue Buster Keaton, 69800 St-Priest

Numéro AMM:

Substance Active: 500 g/L de sel de potassium de glyphosate

Formulation: concentré soluble

Type d'action du produit : Herbicide

Fabriqué en Belgique par Monsanto Europe S.A., certifié ISO 9001

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

SPe3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 m par rapport aux points d'eau

Réserve à un usage strictement professionnel

La fiche de données de sécurité est disponible sur le site www.quickfds.com

Usages	Catégories	Doses maximales	Conditions d'emploi			
			Délai avant récolte (DAR)	Quantité maximale annuelle	Spécifications d'usage	Délai de réentrée
11015031 Traitements	Graminées	2,15 L/ha				

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<i>Toutes espèces fruitières sauf banane</i>	Dicotylédone s annuelles et biannuelles	4,32 L/ha	jours	*	par an et par ha	
12505901 Olivier*Désherbage*Cultures installées	Adventices Vivaces	5,76 L/ha (par tache)				
12015901 Kiwi*Désherbage*Cultures installées						
12705902 Vigne*Désherbage*Cultures installées	Graminées annuelles	2,88 L/ha	21 jours	2200 g m.a/ha/an *	-	
	Dicotylédone s annuelles et biannuelles	4,32 L/ha				
	Adventices Vivaces	5,76 L/ha (par tache)				
11015911 Traitements généraux*Dévitalisation des broussailles	-	5,76 L/ha	-	-	Pulvérisation en plein avec panneaux récupérateurs	
11015910 Traitements généraux*Dévitalisation* Arbres sur pied, souches	-	0,24 L/m ² de section de souche ou de terrières	-	-	Volume de bouillie de 1 L/m ² de section de souche ou de terrière	

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15455911 Légumineuses fourragères*Désherbage <i>Luzerne porte-graines</i>	Uniquement luzerne porte-graines de plus d'un an, en dormance	0,72 L/ha	-	-	Uniquement si les conditions hivernales sont suffisamment rigoureuses pour bloquer totalement la croissance de la plante	
11015932 Traitements généraux*Désherbage*Cultures installées <i>Lin Fibre</i>	-	2,16 L/ha	-	-	1 application maximale par an et par ha	

* m.a/ha/an : matière active par hectare et par an

ZNT par rapport aux points d'eau et aux zones non cultivées adjacentes : 5 m

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 Phyt'Attitude, N° Vert : 0 800 887 887 (Appel gratuit depuis un poste fixe) »

- Premiers soins

« S'éloigner de la zone dangereuse.

En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste.

En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical.

Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

EN CAS D'URGENCE

Composer le 15 ou le 112 ou contacter le centre anti poison le plus proche

En cas d'intoxication animale, contactez votre vétérinaire. »