

REGISTRATION REPORT

Part A

Risk Management

Product code: MON 79991

Product name: ROUNDUP 720

Chemical active substance:

glyphosate, 720 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal according to art. 43)

Applicant: MONSANTO SAS

Date: 2019-11-29

Table of Contents

1	Details of the application	4
1.1	Application background	4
1.2	Letters of Access	5
1.3	Justification for submission of tests and studies	5
1.4	Data protection claims	5
2	Details of the authorisation decision	5
2.1	Product identity	5
2.2	Conclusion	6
2.3	Substances of concern for national monitoring	6
2.4	Classification and labelling	6
2.4.1	Classification and labelling under Regulation (EC) No 1272/2008	6
2.4.2	Standard phrases under Regulation (EU) No 547/2011	6
2.4.3	Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)	6
2.5	Risk management	6
2.5.1	Restrictions linked to the PPP	7
2.5.2	Specific restrictions linked to the intended uses	7
2.6	Intended uses (only NATIONAL GAP)	8
3	Background of authorisation decision and risk management	18
3.1	Physical and chemical properties (Part B, Section 2)	18
3.2	Efficacy (Part B, Section 3)	18
3.3	Methods of analysis (Part B, Section 5)	19
3.3.1	Analytical method for the formulation	19
3.3.2	Analytical methods for residues	19
3.4	Mammalian toxicology (Part B, Section 6)	20
3.4.1	Acute toxicity	20
3.4.2	Genotoxic potential	20
3.4.3	Operator exposure	22
3.4.4	Worker exposure	23
3.4.5	Bystander and resident exposure	23
3.5	Residues and consumer exposure (Part B, Section 7)	24
	Summary for ROUNDUP 720 (MON 79991)	24
3.6	Environmental fate and behaviour (Part B, Section 8)	25
3.7	Ecotoxicology (Part B, Section 9)	26
3.8	Relevance of metabolites (Part B, Section 10)	26
4	Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)	26

5	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....	27
5.1.1	Post-authorisation monitoring.....	27
5.1.2	Post-authorisation data requirements	27
Appendix 1	Copy of the product authorisation	28
Appendix 2	Copy of the product label	34

PART A

RISK MANAGEMENT

1 Details of the application

The company MONSANTO SAS has requested a renewal authorisation in France for the product ROUNDUP 720 (product code: MON 79991), containing 720 g/kg 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).

Appendix 3 of this document is the list of data considered for national authorisation.

1.1 Application background

The present registration report concerns the evaluation of MONSANTO SAS 's application submitted on 2018/01/29 to market ROUNDUP 720 (MON 79991) 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 activesubstanceglyphosate of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2018-0331) 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 720 (MON 79991) has been made using endpoints agreed in the EU peer review of glyphosate . It also includes assessment of data and information related to ROUNDUP 720 (MON 79991) 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.

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](#)

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.

This document also describes the specific conditions of use and labelling required for France for the registration of ROUNDUP 720 (MON 79991) .

1.2 Letters of Access

The applicant has provided a letter of access for active substance. This letters of access are 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 720 (MON 79991). ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ROUNDUP 720 (MON 79991), 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 79991
Product name in MS	ROUNDUP 720
Authorisation number	2160704
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	MONSANTO SAS
Active substance(s) (incl. content)	glyphosate, 720 g/kg
Formulation type	Water-dispersible granule [WG]
Packaging	Bag LLDPE ⁵ (1 kg, 10 kg)

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 Linear low-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 720 (MON 79991) 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

N/A : marketing authorisation withdrawn.

⁷ Avis du 8 octobre 2004 à tous les détenteurs d'autorisations de mise sur le marché pour des spécialités commerciales à base de glyphosate, https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000000445445

⁸ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

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

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant,
When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

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

PPP (product name/code): ROUNDUP 720 / MON 79991
Active substance 1: glyphosate
Applicant: MONSANTO SAS
Zone(s): Southern Zone ^(d)
Verified by MS: Yes

Formulation type: WG ^(a, b)
Conc. of a.s. 1: 720 g/kg ^(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/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g 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)													

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

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/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
1	FR	Intercrop Pre-plant/ Pre-sowing all crops (YACKR)	F	- annual grasses ,	spraying, handheld equipment , shielded applicatio n, spot applicatio n	Pre-plant/ Pre- sowing (actively growing weeds)	2 (Max dose rate: 2.88 kg/ha/year)	-	1.45	1044	100 - 300		Not acceptable (genotoxic potential, (**))
1	FR	Intercrop Pre-plant/ Pre-sowing all crops (YACKR)	F	- annual broad-leaved , biannuals ,	spraying, handheld equipment , shielded applicatio n, spot applicatio n	Pre-plant/ Pre- sowing (actively growing weeds)	1	-	3.0	2160	100 - 300		Not acceptable (genotoxic potential, (**))
1	FR	Intercrop Pre-plant/ Pre-sowing all crops (YACKR)	F	- perennial weeds	spraying, handheld equipment , shielded applicatio n, spot applicatio n	Pre-plant/ Pre- sowing (actively growing weeds)	1	-	3.5	2520	100 - 300		Not acceptable (genotoxic potential, MRL)(**))
2	FR	Post-plant/pre-emer- gence (e.g. BEAVA, BEAVC, fodder and sugar beet , SOLTU, potato ...)	F	annual grasses ,	spraying	BBCH 00-09 - after sowing/planting - before crop emergence (actively growing weeds)	2 (Max dose rate: 2.88 kg as/ha/year)	-	1.45	1044	100 - 300		Not acceptable (genotoxic potential, (**))

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

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/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
	FR	Post-plant/pre-emergence (e.g. BEAVA, BEAVC, fodder and sugar beet, SOLTU, potato ...)	F	- annual broad-leaved, biennials	spraying	BBCH 00-09 – after sowing/planting - before crop emergence (actively growing weeds)	1	-	3.0	2160	100 - 300		Not acceptable (genotoxic potential, (*))
	FR	Post-plant/pre-emergence (e.g. BEAVA, BEAVC, fodder and sugar beet, SOLTU, potato ...)	F	- perennial weeds	Spraying Spot application	BBCH 00-09 - after sowing/planting - before crop emergence (actively growing weeds)	1	-	3.5	2520	100 - 300		Not acceptable (genotoxic potential, MRL(*))
12	FR	Crop interrow (e.g. CUMSA cucumber, CUUPE pumpkin, BRSOL cabbage, DAUCS carrot, ALLCE onion, ASPOF asparagus, ALLPO leek, BEAVA, BEAVC fodder and sugar beet, ...)	F	- annual grasses	shielded spray	actively growing weeds	2 (max 2.88 kg as/ha/year)	-	1.45	1044	100 - 300	“bulb/stem /fruiting vegetables”: 60d, “legume/leafy/pulses vegetables, herbs and edible flowers”: 30 d”	Not acceptable (genotoxic potential, LMR only for root vegetable, tuber vegetable and cabbage(*))

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

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/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
12	FR	Crop interrow (e.g. CUMSA cucumber, CUUPE pumpkin, BRSOL cabbage, DAUCS carrot, ALLCE onion, ASPOF asparagus, ALLPO leek, BEAVA, BEAVC fodder and sugar beet, ...)	F	- annual broad-leaved, biannuals	shielded spray	actively growing weeds	1	-	3.0	2160	100 - 300	-	Not acceptable (genotoxic potential, MRL(*))
12	FR	Crop interrow (e.g. CUMSA cucumber, CUUPE pumpkin, BRSOL cabbage, DAUCS carrot, ALLCE onion, ASPOF asparagus, ALLPO leek, BEAVA, BEAVC fodder and sugar beet, ...)	F	- perennial weeds	shielded spray Spot application	actively growing weeds	1	-	3.5	2520	100 - 300	-	Not acceptable (genotoxic potential, MRL(*))
3a	FR	Pre-harvest weed control: cereals (TRZAW, TRZAS, TTLWI, TTLSS, HORVS, HORVW, SECCW, SECCS, TRZSP, AVESA)	F	Annual and perennial weeds	Spraying Spot application	grain moisture <30% BBCH 87	1	-	3.0	2160	100 - 300	-	Not acceptable (genotoxic potential, MRL(*))

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

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/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
8	FR	Orchards (e.g. NNNOK, CIDLI, CIDLC, NNNOS, IUGRE, PIAVE, MUBPA, ATICH, ELYCA, ...),	F	- annual grasses	spraying, handheld equipment , shielded applicatio n, spot applicatio n	actively growing weeds	3 (applications directed on max 33% of the total area, for each application)	-	2.0	1440	100 - 300	Pome fruits: 28 d Citrus, tree nuts, stone fruits, trop- ical fruits (except ba- nana): 21 d Kiwi: 90 d Olives: 21 d Banana: 1 d	Not acceptable (genotoxic potential, (*))
8	FR	Orchards (e.g. NNNOK, CIDLI, CIDLC, NNNOS, IUGRE, PIAVE, MUBPA, ATICH, ELYCA, ...),	F	- annual broad-leaved, biannuals		actively growing weeds	3 (applications directed on max 33% of the total area, for each application)	-	2.8	2020	100 - 300	Pome fruits: 28 d Citrus, tree nuts, stone fruits, trop- ical fruits (except ba- nana): 21 d Kiwi: 90 d Olives: 21 d Banana: 1 d	Not acceptable (genotoxic potential, (*))

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

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/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
8	FR	Orchards (e.g. NNNOK, CIDLI, CIDLC, NNNOS, IUGRE, PIAVE, MUBPA, ATICH, ELYCA, ...),	F	- perennial weeds	spot applica- tion	actively growing weeds	3 (applications directed on max 33% of the total area, for each application)	-	3.0 (only olive) 4.0 (others crops)	2160 2880	100 - 300	Pome fruits: 28 d Citrus, tree nuts, stone fruits, trop- ical fruits (except ba- nana): 21 d Kiwi: 90 d Olives: 21 d Banana: 1 d	Not acceptable (genotoxic potential, (*))
9	FR	Vineyards (VITSS)	F	- annual grasses	spraying, handheld equipment , shielded applicatio n	actively growing weeds	3 Max dose rate: 2.20 kg as/ha/year (applications directed on max 33% of the total area, for each application)	-	2.0	1440	100 - 300	21 d	Not acceptable (genotoxic potential, (*))

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

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/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
9	FR	Vineyards (VITSS)	F	- annual broad-leaved, biannuals	spraying, handheld equipment , shielded applicatio n	actively growing weeds	3 Max dose rate: 2.20 kg as/ha/year (applications directed on max 33% of the total area, for each application)	-	3.0	2160	100 - 300	21 d	Not acceptable (genotoxic potential, (*))
9	FR	Vineyards (VITSS)	F	- perennial weeds	spraying, handheld equipment , shielded applicatio n, spot applicatio n	actively growing weeds	3 Max dose rate: 2.20 kg as/ha/year (applications directed on max 33% of the total area, for each application)	-	4.0	2880	100 - 300	21 d	Not acceptable (genotoxic potential, (*))
13b	FR	Devitalization of vines (e.g. VITSS, ...)	F	-	spraying in tunnel sprayer, wiping Spot applica- tion only	actively growing weeds, vines > BBCH 91	1	-	4.0	2880	200 - 400	-	Not acceptable (genotoxic potential, (*))

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

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/Ki nd	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
7	FR	Pasture, meadow, grassland (NNNFW)	F	- annual grasses	spraying,	actively growing weeds	1	-	1.45	1044	100 - 300		Not acceptable (genotoxic potential, MRL (*))
7	FR	Pasture, meadow, grassland (NNNFW)	F	- annual broad-leaved, biannuals	spraying,	actively growing weeds	1	-	3.0	2160	100 - 300	-	Not acceptable (genotoxic potential, MRL (*))
7	FR	Pasture, meadow, grassland (NNNFW)	F	- perennial weeds	spraying, spot appli- cation	actively growing weeds	1	-	3.5	2520	100 - 300	-	Not acceptable (genotoxic potential, MRL(*))
12a	FR	Forestry: pre-plant (YACKR)	F	- annual grasses	spraying, shielded appli- cation	actively growing weeds	1	-	1.45	1044	100 - 300	-	Not acceptable (genotoxic potential, (*))
12a	FR	Forestry: pre-plant (YACKR)	F	- annual broad-leaved, biannuals and perennial weeds	spraying, shielded appli- cation	actively growing weeds	1	-	2.8	2020	100 - 300	-	Not acceptable (genotoxic potential, (*))
12b	FR	Forestry: inter row (e.g. NNNWW, YAUF0, YPFLG)	F	- annual grasses	spraying, shielded appli- cation	actively growing weeds	1	-	1.45	1044	100 - 300	-	Not acceptable (genotoxic potential, (*))
12b	FR	Forestry: inter row (e.g. NNNWW, YAUF0, YPFLG)	F	- annual broad-leaved, biannuals	spraying, shielded appli- cation	actively growing weeds	1	-	2.8	2020	100 - 300	-	Not acceptable (genotoxic potential, (*))

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

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/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
12b	FR	Forestry: inter row (e.g. NNNWW, YAUFO, YPFLG)	F	perennial weeds	spraying, shielded applica- tion	actively growing weeds	1	-	3	2160	100 - 300	-	Not acceptable (genotoxic potential, (*)
13a	FR	Devitalization of stumps, trees and shrubs (e.g. NNNOG, NNNWL, NNNWN, NNNHS...)	F	tree stumps or bushes	Spraying, wiping, spot applicatio n	treatment of stump surface immediately after cutting	1	-	0.17 kg/m² of stump section.	120 g/m² of stump section.	- -	-	Not acceptable (genotoxic potential, (*)
17	FR	Alfalfa weeding , Parasite control (MEDVA)	F	annual and perennial weeds	spraying	during dormancy of the plant - on alfalfa crops of more than 1 year, - when winter conditions are sufficient to block completely the growth of alfalfa	1	-	0.50	360	100 - 200	-	Not acceptable (genotoxic potential, (*)

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

(**) Risk to diversity and abundance of non-target terrestrial arthropods (other than bees) 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.

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
		Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	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 720 (MON 79991) is an herbicide (SG). 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 free-flowing ivory, cream granules free from visible extraneous matter and hard lumps. It is not explosive and has no oxidising properties. It is not self-ignitable. In aqueous solution, it has a pH value around 4.2. There is no effect of low or 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 had changed significantly. The product was also found to be fully acceptable after 6 years storage at ambient temperatures. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in SP001 film packaging. The technical characteristics of ROUNDUP 720 (MON 79991) are acceptable for a SG formulation.

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

Concerning the relevant impurity N-nitrosoglyphosate, based on the conditions of formation of this impurity, it is unlikely that this impurity is formed during the formulation of the preparation. The absence of NNG formation during the storage has been demonstrated through a monitoring of the concentration of this impurity during storage of the preparation.

The product ROUNDUP 720 (MON 79991) 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 720 (MON 79991) is considered satisfactory for all the claimed uses.
- Glyphosate having a herbicidal activity on all types of plants (known as “total weed killer”), the preparation cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green part 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 as negligible.
- The risks of negative impact on transformation process (bread making and brewing) are considered as acceptable. In absence of data on the impact on propagation, the preparation should not be applied to cereals intended to seed production.

- For the weed control for alfalfa intended for seed production, in view of the quality requirement (analytical purity) for harvested alfalfa seeds, the selectivity level and the risk of impact on yield and quality are considered acceptable in the conditions of use specific to this use (mentioned below).
- The risk of negative impact on succeeding crops is considered as negligible.
- The risk of negative impact on adjacent crops is considered as acceptable on the condition that the preparation do not reach the green parts of adjacent crops. Specific attention should be paid to the condition of use of the preparation 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 its relevant impurities NNG and formaldehyde is available and validated.

3.3.2 Analytical methods for residues

Analytical methods are available in this dossier or in the RAR and are validated for the determination of residues of glyphosate in plants, food of animal origin, soil, water (surface and drinking), air 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	not applicable		
Dermal absorption	Based on an in vitro human study performed on formulation:		
		Concentrate (tested) 720 g/kg	Diluted formulation (tested) 3.6 g/L
	In vitro (human) %	0.1	1
		Concentrate (used in formulation) 720 g/L	Spray dilution (used in formulation) 0.9 g/L
	Dermal absorption endpoints %	0.1	4*
Oral absorption	20%		

*pro rata correction

3.4.1 Acute toxicity

ROUNDUP 720 (MON 79991) containing 720 g/kg 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 720 (MON 79991) are available. An *in vivo* micronucleus assay in mammalian cells and a bacterial reverse mutation assay are available.

In vivo micronucleus assay:

The micronucleus assay performed with ROUNDUP 720 (MON 79991) is acceptable and the systemic exposure of glyphosate acid is considered clearly demonstrate according to the observable concentrations of glyphosate acid in the plasma and bone marrow at the dose level used in the *in vivo* micronucleus assay in mice. However, shortcomings in the analytic method provided (e.g. the LOQ of glyphosate acid in bone marrow, the repeatability and the recovery of the analytic method), has been highlighted by the zRMS.

In conclusion, the *in vivo* micronucleus assay performed with ROUNDUP 720 (MON 79991) cannot be interpreted in absence of a complete method of analysis provided to support the demonstration that exposure of the bone marrow/plasma occurred.

Bacterial reverse mutation assay :

The AMES test performed with ROUNDUP 720 (MON 79991) is considered acceptable.

However, two deviations/GLP have been highlighted in this study:-

- No analyse was performed to determine the concentration, uniformity and stability of the test substance dose formulations.
- The maximal dose tested is questionable. Indeed, the maximal dose of 5000 µg/plate described in the OECD guideline 471 is preconized 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 that under the experimental conditions (limitation of the maximal tested dose of glyphosate acid at 3580 µg/plate instead of 5000 µg/plate), ROUNDUP 720 (MON 79991) doesn't induce gene mutations in bacteria

As a conclusion, only the bacterial reverse mutation assay is acceptable, **the genotoxic potential of ROUNDUP 720 (MON 79991) 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	Minimum volume wa- ter (L/ha)
Devitalisation of vines and brambles (max. 4 kg product/ha) GAP 13b	F	Vehicle mounted <i>downward spraying</i> [EFSA model]	2.88 kg sa/ha	200
LOW CROPS (max. 3.5 kg product/ha) (GAPs 1,2, 3a, 5, 7, 8, 9, 12a, 12b)	F	Vehicle mounted Knapsack/Hand held <i>Downward spraying</i> [EFSA model]	2.52 kg sa/ha	100
GRAPES, orchards (max. 4kg product/ha) GAPs 8, 9, 12a, 12b	F	Vehicle mounted/Manual Knapsack/Hand held <i>Downward spraying</i> [EFSA model]	2.88 kg sa/ha	100
Devitalization of stumps, trees, shrubs GAP 13a	F	Paintbrush [Consumer product paint- ing model]	0.120 kg/m ²	-

Considering proposed uses, operator systemic exposure was estimated using the consumer product painting model and the EFSA model¹¹:

Crop	Equipment	PPE and/or working coverall	% AOEL Glyphosate
LOW CROPS (max. 3.5 kg product/ha)	Vehicle mounted <i>Downward spraying</i> [EFSA model]	Working coverall and gloves during mixing/loading and application	3.8
GRAPES * (max. 4kg product/ha)	Vehicle mounted downward [EFSA model]	Working coverall and gloves during mixing/loading and application	3.1
	Manual Knapsack downward [EFSA model]	Working coverall and gloves during mixing/loading and application	13.1

¹⁰ Open field or glasshouse

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

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

	Manual Hand-held sprayer, downward (EFSA model)	Working coverall and gloves during mixing/loading and application	50.3
Devitalization of stumps, trees, shrubs	Paintbrush [Consumer product painting model]	Working coverall during mixing/loading and application	61.1

* Worst case regarding the use of the preparation. It covers the use on:

- Arable crops, cereals, vegetables (pre-plant/pre-sowing, post plant/pre-emergence/ post-harvest/stubble),
- Orchards (worst case, 4 kg product/ha)
- Devitalisation of vines and brambles (max. 4kg product/ha)

According to the model calculations, it can be concluded that the risk for the operator using ROUNDUP 720 (MON 79991) is acceptable with a working coverall and gloves during mixing/loading and application.

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 20,2% of the AOEL of glyphosate with PPE (coverall).

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.”*

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

Model (AOEM) - All pathways (mean)	% AOEL Glyphosate
Resident (children)	41
Resident (adults)	15

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)

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

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 providing the application of the mitigation measures, **except for pre-harvest uses on cereals (wheat and barley), the uses on pasture (linked to MRL exceedance in livestock commodities) and olives in contact with soil.**

Intended interrow uses on groups “root and tuber vegetables”, “cereals”, “berries and small fruits” 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 3.00 kg/ha and of 1.50 kg/ha is retained for respectively inter-crop/pre-emergence uses (including also stubble) 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/pre-emergence uses.

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

As far as consumer health protection is concerned, 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, alfalfa and vineyards.

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

- For uses on orchards, grapevine and olives and inter-row uses: “Use application material or agricultural practices to avoid edible parts contact with active substance or with soil treated with active substance”

Summary for ROUNDUP 720 (MON 79991)

Crop	PHI for ROUNDUP 720 (MON 79991) proposed by applicant	PHI/ Withhold-ing period* suf-ficiently sup-ported for	PHI for ROUNDUP 720 (MON 79991) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate		
Wheat (pre-har-vest)	7 days	-	-	This use is not recommended in France, considering a possibility of exceedance of the current MRL on grain in NEU and on livestock commodities.
Barley (pre-har-vest)	7 days	-	-	This use is not recommended in France, considering a possibility of exceedance of the current MRL on grain and on livestock commodi-ties.
Citrus	21 days	Yes	21 days	
Pome fruits	28 days	Yes	28 days	
Stone fruits	21 days	Yes	21 days	
Tree nuts	21 days	Yes	21 days	.

MON 79991 / ROUNDUP 720
Part A - National Assessment
FRANCE

Crop	PHI for ROUNDUP 720 (MON 79991) proposed by ap- plicant	PHI/ Withhold- ing period* suf- ficiently sup- ported for	PHI for ROUNDUP 720 (MON 79991) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate		
Bananas	1 day	Yes	1 day	
Kiwi	90 days	Yes	90 days	
Olives	7 days	Yes	7 days	
Grapes	21 days	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”, “cereals”, “berries and small fruits”	30 days	-		This use is not recommended in France as not sufficient residue tri- als are available.
Inter-crop/pre- emergence uses	- (30 days for veg- etables)	Yes	F	
Pasture, meadow, grassland	7 days	-		This use is not recommended in France considering a possibility of exceedance of the current MRL on livestock commodities
Alfalfa	-	-	-	In France the use is only recom- mended for seed production

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).

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

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

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

The PEC of glyphosate and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models 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.

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

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

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) 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 with risk mitigations are acceptable for the intended uses.

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

Concerning the risk assessment to bees and other pollinisators, for the intended uses with downward 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 et la demande associée

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

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 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 les demandes de renouvellement de l'autorisation de mise sur le marché et de modification des informations déclarées, suite au renouvellement de l'approbation de la substance active glyphosate, et les données complémentaires fournies suite à une exigence post-autorisation du produit phytopharmaceutique **ROUNDUP 720***

de la société MONSANTO SAS

enregistrées sous les n°2018-0331, n°2018-2698, n°2019-0462 et n°2019-4419

Vu les conclusions de l'évaluation de l'Anses du 17 octobre 2019,

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

Considérant qu'un effet génotoxique ne peut être exclu,

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

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



Informations générales sur le produit	
Noms du produit	ROUNDUP 720 ROUNDUP EXTRADRY
Type de produit	Produit de référence
Titulaire	MONSANTO SAS Eden Park - Bâtiment B 1 rue Buster Keaton 69800 ST PRIEST France
Formulation	Granulé soluble dans l'eau (SG)
Contenant	792,4 g/kg - glyphosate sel d'ammonium (équivalent à 720 g/kg de glyphosate)
Numéro d'intrant	935-2012.01
Numéro d'AMM	2160704
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
15105912 Blé*Dés herbage	3 kg/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 « Céréales*Dés herbage*Avt Récolte » est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré en raison d'un risque de dépassement des limites maximales de résidus.				
00201024 Cultures fruitières*Dés herbage* Cult. Installées	2 kg/ha	1/an	90	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré aux doses de 2,8 kg/ha, 3 kg/ha et 4 kg/ha, et pour des délais avant récolte de 7 jours sur olivier, 21 jours sur agrumes, fruits à coque, fruits à noyau, fruits tropicaux (sauf banane) et 28 jours sur fruits à pépins, au même motif.				
	2 kg/ha	1/an	1	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 « Bananier*Dés herbage » 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 2,8 kg/ha et 4 kg/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
00401017 Forêt*Dégagement	1,45 kg/ha	1/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré aux doses de 2,8 kg/ha et 3 kg/ha au même motif.				
00401013 Forêt*Dés herbage *Avt Plantation	1,45 kg/ha	1/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré à la dose de 2,8 kg/ha au même motif.				
00401014 Forêt*Dévitilisation	0,17 g/m ²	1/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.				
15455911 Légumineuses fourragères* Dés herbage	0,5 kg/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 « Porte-graine – Légumineuses fourragères*Dés herbage » est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.				

Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
15105913 Orge*Désherbage	3 kg/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 « Céréales*Désherbage*Avt Récolte », est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré en raison d'un risque de dépassement des limites maximales de résidus.					
15705914 Prairies*Désherbage	1,45 kg/ha	1/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré en raison d'un risque de dépassement des limites maximales de résidus pour les denrées d'origine animale. L'usage revendiqué correspondant au nouveau libellé « Prairie*Déstruction du couvert végétal », est également retiré aux doses de 1,45 kg/ha, 3 kg/ha et 3,5 kg/ha, aux mêmes motifs.					
11015924 Traitements généraux* Désherbage* Avt Mise Cult.	1,45 kg/ha	2/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 « Traitements généraux*Désherbage*Interculture et jachères », 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 3 kg/ha et 3,5 kg/ha au même motif. L'usage est également retiré à la dose de 3,5 kg/ha au motif que le respect des limites maximales de résidus n'a pas pu être vérifié en raison d'un manque d'essais résidus.					

ROUNDUP 720
AMM n°2160704

Page 5 sur 6

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	1,45 kg/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 « 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 aux doses de 3 kg/ha et 3,5 kg/ha au même motif.				
	L'usage est également retiré à la dose de 3,5 kg/ha au motif que le respect des limites maximales de résidus n'a pas pu être vérifié en raison d'un manque d'essais résidus.				
	1,45 kg/ha	1/an	30	6 mois à compter de la présente décision	12 mois à compter de la présente décision
11015910 Traitements généraux* Dévitalisation* Arb. sur pied Souches	Motivation du retrait : L'usage revendiqué correspondant au nouveau libellé « Cultures légumières* Désherbage » (pour du désherbage inter-rang), est retiré 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 et au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré aux doses de 3 kg/ha et 3,5 kg/ha aux mêmes motifs.				
	4 kg/ha	1/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.				
12705902 Vigne* Désherbage* Cult. Installées	2 kg/ha	1/an	21	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré aux doses de 3 kg/ha et 4 kg/ha au même motif.				

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.

