

REGISTRATION REPORT

Part A

Risk Management

Product code: MON 79351

Product name: ROUNDUP INNOVERT

Chemical active substance:

glyphosate, 480 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Authorisation renewal according to Art. 43)

Applicant: MONSANTO SAS

Date: 2019/11/29

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PART A

RISK MANAGEMENT

1 Details of the application

The company MONSANTO SAS has requested a marketing authorisation in France for the product ROUNDUP INNOVERT (formulation code: MON 79351), 480 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 application submitted on 29/01/2018 to market ROUNDUP INNOVERT (MON 79351) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the re-registration of authorisation after the renewal of approval of the active substance Glyphosate of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2018-0462) 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 INNOVERT (MON 79351) has been made using endpoints agreed in the EU peer review of glyphosate. It also includes assessment of data and information related to ROUNDUP INNOVERT (MON 79351) where those data have not been considered in the EU peer review process.

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

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

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

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

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

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

This document also describes the specific conditions of use and labelling required for France for the registration of ROUNDUP INNOVERT (MON 79 351).

1.2 Letters of Access

The applicant has provided letters of access for active substance. These 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 INNOVERT (MON 79351).”

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ROUNDUP INNOVERT (MON 79351), 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 79351
Product name in MS	ROUNDUP INNOVERT
Authorisation number	2120035
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	MONSANTO SAS
Active substance(s) (incl. content)	glyphosate, 480 g/L
Formulation type	Soluble concentrate [SL]
Packaging	HDPE ⁵ (1 L, 5 L, 10 L, 15 L, 20 L, 200 L, 640 L, 1000 L)
Coformulants of concern for national authorisations	-

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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Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for ROUNDUP INNOVERT (MON 79351) resulted in the decision to withdraw the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

N/A : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

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

N/A : marketing authorisation withdrawn.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017⁶ provides that:

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

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

⁶ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs 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/AGRG1632554A/jo/texte>

Moreover, for glyphosate-based products, the official statement⁷ of 8 October 2004 provides specific restrictions (applied doses and/or conditions of use) for uses on crops, in non-agricultural or industrial areas or in forestry.

Finally, the French Order of 26 March 2014⁸ provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁹ is to supply “minor” crops with registered plant protection products.

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

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

2.5.1 Restrictions linked to the PPP

N/A : marketing authorisation withdrawn.

2.5.2 Specific restrictions linked to the intended uses

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

None.

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

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

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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.

Use should be crossed out when the applicant no longer supports this use.

GAP, date: 2019/11/29

PPP (product name/code): ROUNDUP INNOVERT (MON 79351)

Formulation type: SL ^(a, b)

Active substance 1: glyphosate

Conc. of a.s. 1: 480 g/L ^(c)

Applicant: MONSANTO SAS

Professional use: ☒Zone(s): Southern Zone ^(d)Non-professional use: ☐

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, 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	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (field or outdoor uses, certain types of protected crops)													

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽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	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
14	FR	Inter crop, fallow land , crop destruc- tion only Non crop area	F	annual weeds, annual broad-leaved, biannuals,	spraying, spot treatment, brushing or wiping with special equipment for selective control	Pre-plant / pre- sowing (actively growing weeds)	3 (max 2 880 g sa/ha/an)	-	3.75	1.80	100		Not acceptable (genotoxic potential, relevant impurity, (*))
14	FR	land , crop destruc- tion only Non crop area	F	perennial weeds	Spot appli- cation only	Pre-plant / pre- sowing (actively growing weeds)	3 (max 2 880 g sa/ha/an)	-	6.00	2.88	500		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 (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	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
	FR	Inter-row in vege- table crops	F	annual weeds	Spraying	actively growing weeds	1	-	2.25	1.08		“bulb/s tem /fruitin g vegeta bles”: 60 d, “legu me/lea fy/puls es vegeta bles, herbs and edible flower s”: 30 d”	Not acceptable (genotoxic potential, MRL compliance for root-vegetables, tuber, cabbage, relevant impurity, (*))
	FR	Inter-row in vegetable crops	F	annual broad-leaved, biannuals,	Spraying	actively growing weeds	1	-	4.5	2,16		-	Not acceptable (genotoxic potential, MRL, relevant impurity, (*))
	FR	Inter-row in vegetable crops	F	perennial weeds	Spraying Spot applicatio n	actively growing weeds	1	-	5.25	2.52		-	Not acceptable (genotoxic potential, MRL, relevant impurity, (*))

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽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	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
8	FR	Orchards	F	Annual grasses	Spraying	actively growing weeds	3 (max 2 200 g sa/ha/an)	-	2.25	1.08	100 - 300	Citrus, tree nuts, stone fruits, pome fruits, 21 d Kiwi: 90 d Olives: 7 d	Not acceptable (genotoxic potential, relevant impurity, (*))
8	FR	Orchards	F	Annual broad-leaved, biennials,	Spraying	actively growing weeds	3 (max 2 200 g sa/ha/an)	-	4.5	2.16	100 - 300	Citrus, tree nuts, stone fruits, pome fruits, 21 d Kiwi: 90 d Olives: 7 d	Not acceptable (genotoxic potential, relevant impurity, (*))

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination/purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ⁽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	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/ma x		
8	FR	Orchards	F	perennial weeds	Spraying Spot applicatio	actively growing weeds	3 (max 2 200 g sa/ha/an)	-	6	2.88	100 - 300	Citrus, tree nuts, stone fruits, pome fruits, 21 d Kiwi: 90 d Olives: 7 d	Not acceptable (genotoxic potential, relevant impurity, (**))
13 a	FR	Forest trees devitalisation	F	Tree stumps or bushes	Contact application wiping/ brush	within 1 h after cutting	1	-	0.25 l/m ² of stump section	120 g/m ² of stump section	-	-	Not acceptable (genotoxic potential, relevant impurity, (**))
13b	FR	Brush	F	-	Spraying, with tunnel sprayer	-	-	-	7.5	3.6	-	-	Not accetable (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 ⁽ⁱ⁾
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
14	FR	Non-crop areas	F	annual and perennial weeds	spraying, spot treatment, brushing or wiping with special equipment for selective control	actively growing weeds	3 Permeable areas: 2.88 kg a.s/ha/year For perennials: spot application only Impermeable areas: 1.50 kg a.s/ha/year. Spot application only	-	3,75	1.80	-		Not acceptable (relevant impurity, genotoxic potential, (*))
14	FR	Non-crop areas	F	annual and perennial weeds	Only spot treatment	actively growing weeds	3 Permeable areas: 2.88 kg a.s/ha/year For perennials: spot application only Impermeable areas: 1.50 kg a.s/ha/year. Spot application only		6	2.88	-		Not acceptable (genotoxic potential, relevant impurity, (*))

(*) 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.

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Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/l	(f)	No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.
Remarks columns:	1	Numeration necessary to allow references	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	2	Use official codes/nomenclatures of EU Member States	8	The maximum number of application possible under practical conditions of use must be provided.
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)	9	Minimum interval (in days) between applications of the same product
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application	10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
			13	PHI - minimum pre-harvest interval
			14	Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

ROUNDUP INNOVERT (MON 79351) is a soluble concentrate (SL). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a homogeneous brown liquid, with a caramel odour. It is not explosive and has no oxidising properties. The product is not flammable. It does not have a self-ignition temperature below 600 °C. In aqueous solution, it has a pH value of 4.22 (temperature is missing). There is no effect of low temperature on the stability of the formulation after 7 days at 0°C. Its technical characteristics are acceptable for a soluble concentrate (SL) formulation.

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

Concerning the relevant impurity N-nitrosoglyphosate, based on the conditions of formation of this impurity, it is unlikely that this impurity is formed during the formulation of the preparation. **Nevertheless, in order to demonstrate the absence of formation of NNG during the storage, a monitoring of the concentration of this impurity during storage of the preparation has been provided. However, the limit of quantification of this analytical method for the impurity in the preparation is higher than the acceptable limit.**

The product ROUNDUP INNOVERT (MON 79 351) does not contain POE-tallowamines (CAS n° 61791-26-2).

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- the efficacy level of ROUNDUP INNOVERT (MON 79351) 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 INNOVERT (MON 79351) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed to the green parts of crops.
- the risks of negative impact on yield, quality and propagation are considered negligible.
- The risk of negative impact on succeeding crops is considered negligible.
- The risk of negative impact on adjacent crops is considered acceptable, as long as the preparation does not reach the green parts of adjacent crops. Specific attention should be paid to the spraying conditions close to adjacent crops.

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

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and the relevant impurity formaldehyde 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 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	0.5mg/kg bw			
AOEL	0.1 mg/kg bw/d			
AAOEL	none			
Dermal absorption	Based on an <i>in vitro</i> human study performed on formulation:			
		Concentrate (tested) 480 g/L	Diluted formulation (tested)	
			28.7 g/L	2.4 g/L
	In vitro (human) %	0.3	0.5	2.4
		Concentrate (used in formulation) 480 g/L	Spray dilution (used in formulation) min 1.2 g/L	
	Dermal absorption endpoints %	0.3	5%*	
Oral absorption	20%		UE 2017	

*pro rata correction

3.4.1 Acute toxicity

ROUNDUP INNOVERT (MON 79351) containing 480 g/L of glyphosate has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitizer.

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 INNOVERT (MON 79351) are available. An Ames (bacterial reverse mutation assay) test and an *in vitro* micronucleus test are available.

Ames test:

The study is acceptable with some limitations. The identified deviations are:

- No analysis is 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 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.”*

Based on these data, ROUNDUP INNOVERT (MON 79351) is not mutagenic in the condition of this assay.

Micronucleus assay:

The study is not acceptable. Deviations below are identified:

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

Considering the major deviation observed for HCD, the study is not acceptable. The assessment of the mutagenic potential of ROUNDUP INNOVERT (MON 79351) cannot be finalized.

As a conclusion, the genotoxic potential of ROUNDUP INNOVERT (MON 79351) cannot hence be finalized.

3.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ¹⁰	Equipment <i>Application method</i>	Maximum application rate kg as /ha	Model (Minimum volume wa- ter (L/ha))
bare soil	F	Vehicle mounted <i>Downward spraying</i>	6 L MON 79351/ha 2.88 kg glyphosate/ha	EFSA (100 L/ha)
		Manual hand-held <i>Downward spraying</i>	6 L MON 79351/ha 2.88 kg glyphosate/ha	EFSA (100 L/ha)
		Manual knapsack <i>Downward spraying</i>	6 L MON 79351/ha 2.88 kg glyphosate/ha	EFSA (100 L/ha)
Orchards		Vehicle mounted <i>Downward spraying</i>	4.5L MON 79531/ha 2.16 kg glyphsaote/ha	EFSA (100 L/ha)
		Manual hand-held <i>Downward spraying</i>	6L MON 79531/ha 2.88 kg glyphsaote/ha	EFSA (100 L/ha)
		Manual knapsack <i>Downward spraying</i>	6L MON 79531/ha 2.88 kg glyphsaote/ha	EFSA (100 L/ha)
devitalization of brambles, non-agri- cultural area, for- estry		Vehicle mounted <i>Downward spraying</i>	7.5 L MON 79351/ha 3.6 kg glyphosate/ha	Modop ZNA (UPJ 2009-2010 dedicated to non-agricul- tural areas)
		Manual knapsack <i>Downward spraying</i>	7.5 L MON 79351/ha 3.6 kg glyphosate/ha	
		Manual hand-held <i>Downward spraying</i>	7.5 L MON 79351/ha 3.6 kg glyphosate/ha	

¹⁰ Open field or glasshouse

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Considering proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010¹¹ dedicated to non-agricultural areas and the EFSA model¹²:

Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate (0.1 mg/kg bw/d)
bare soil	Vehicle mounted <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	2.3%
	Manual hand-held <i>Downward spraying</i>		61%
	Manual knapsack <i>Downward spraying</i>		16%
Orchards	Vehicle mounted <i>Downward spraying</i>		1.5%
	Manual hand-held <i>Downward spraying</i>		61%
	Manual knapsack <i>Downward spraying</i>		16%
Non-agricultural area, forestry	Vehicle mounted <i>Downward spraying</i>		17%
	Manual knapsack <i>Downward spraying</i>		1.8%
devitalization of brambles, non-agricultural area, forestry	Manual hand-held <i>Downward spraying</i>		29%

According to the model calculations, it can be concluded that the risk for the operator using ROUNDUP INNOVERT (MON 79351) is acceptable with a working coverall and gloves during mixing/loading and application.

¹¹ 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

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

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 % of the AOEL of glyphosate with 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) without mitigation measure:

Bare soil Downward spraying,		Glyphosate	
ZNT : 2-3 mètres w/o drift reduction technology			
	DT ₅₀ (days)	30	
	DFR (µg/cm ² /kg a.s./ha)	3	
	Application rate (kg a.s./ha)	1 x 2.88 kg glyphosate/ha	
	Pathways (percentile)	Total absorbed dose (mg/kg bw/day)	% AOEL
Resident child Body weight: 10 kg	Sum (mean)	0.0441	44%
Resident adult Body weight: 60 kg	Sum (mean)	0.0161	16%

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 olives in contact with soil.

Intended interrow uses on groups “root and tuber vegetables” and “brassica vegetables”, 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 2.25 L/ha is retained

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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for 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-row uses (“bulb vegetables”, “stem vegetables”, “fruiting vegetables”, “legume vegetables”, “pulses”, “leafy vegetables and herbs and edible flowers”) and uses on orchards.

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

- **For uses on orchards, 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 INNOVERT (MON 79351)

Table 14: Information on ROUNDUP INNOVERT (MON 79351) (KCA 6.8)

Crop	PHI for ROUNDUP INNOVERT (MON 79351) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for ROUNDUP INNOVERT (MON 79351) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate		
Citrus	21 days	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	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”, “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.

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

PEC soil and PEC_{sw} derived for glyphosate and its metabolites are used for the ecotoxicological risk assessment.

For uses on hard surfaces, the estimation of PEC_{gw} is not considered relevant. For other uses, 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, except for devitalization on brambles.

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.

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

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.

ROUNDUP INNOVERT (MON 79351)
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Appendix 1 Copy of the product authorisation

ROUNDUP INNOVERT (MON 79351)
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Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique

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

Vu le règlement d'exécution (UE) 2017/2324 de la Commission du 12 décembre 2017 renouvelant l'approbation de la substance active «glyphosate» conformément au règlement (CE) n° 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) n° 540/2011 de la Commission,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et réglementaire,

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

de la société **MONSANTO SAS**

enregistrées sous les **n°2018-0462, 2019-0456, 2014-0140, 2015-0485 et 2019-4413**

Vu les conclusions de l'évaluation de l'Anses du 21 octobre 2019,

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

Considérant qu'un effet génotoxique ne peut être exclu,

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

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

ROUNDUP INNOVERT (MON 79351)
Part A - National Assessment
FRANCE



Informations générales sur le produit	
Nom du produit	ROUNDUP INNOVERT
Type de produit	Produit de référence
Titulaire	MONSANTO SAS Eden Park - Bâtiment B 1 rue Buster Keaton 69800 ST PRIEST FRANCE
Formulation	Concentré soluble (SL)
Contenant	588,1 g/L - glyphosate sel de potassium (équivalent à 480 g/L de glyphosate)
Numéro d'intrant	2100194
Numéro d'AMM	2120035
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	
00401014 Forêt*Dévitalisation	120 g/m ²	-	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.					
11015924 Traitements généraux* Dés herbage* Avr Mise Cult.	3,75 L/ha	3/an	F	6 mois à compter de la présente décision	12 mois à compter de la présente décision	
	Motivation du retrait : L'usage revendiqué correspondant au nouveau libellé « Traitements Généraux * Dés herbage * Interculture, jachères et destruction de culture », est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré à la dose de 6 L/ha au même motif.					
11015932 Traitements généraux* Dés herbage* Cult. Installées	4,5 L/ha	1/an	90	6 mois à compter de la présente décision	12 mois à compter de la présente décision	
	Motivation du retrait : L'usage revendiqué correspondant aux nouveaux libellés « Cultures fruitières*Dés herbage*Cult. Installées » et « Cultures légumières * Dés herbage * Inter-rang » est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré à la dose de 6 L/ha et pour des délais avant récolte de 7 jours sur olivier, 21 jours sur agrumes, fruits à coque, fruits à pépins et fruits à noyaux, 30 jours sur cultures légumières et 90 jours sur kiwi au même motif. L'usage est retiré pour les doses supérieures à 2,25 L/ha sur légumes-bulbes, légumes-tiges, légumes-fruits, légumes potagères, légumineuses séchées et légumes feuilles, fines herbes et fleurs comestibles en raison d'un risque de dépassement des limites maximales de résidus. L'usage est également retiré sur légumes-racines et légumes-tubercules et choux en raison d'un risque de dépassement des limites maximales de résidus.					

ROUNDUP INNOVERT
AMM n°2120035

ROUNDUP INNOVERT (MON 79351)
Part A - National Assessment
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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
11015911 Traitements généraux* Dévital. Broussaillies	7,5 L/ha Motivation du retrait : L'usage revendiqué correspondant au nouveau libellé « Traitement Généraux * Débroussaillage », est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit.	-	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
11015904 Usages non agricoles* Desherb. total	3,75 L/ha Motivation du retrait : L'usage revendiqué correspondant au nouveau libellé « Traitement Généraux * Désherbage * Zones non cult. », est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré à la dose de 6 L/ha au même motif.	3/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
11015903 Usages non agricoles* Désherbage* All. P.JT, Cimet., Voies	3,75 L/ha Motivation du retrait : L'usage revendiqué correspondant au nouveau libellé « Usages non agricoles * Désherbage * P.JT », est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré à la dose de 6 L/ha au même motif.	3/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision

ROUNDUP INNOVERT
AMM n°2120035

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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.

[illegible]

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FR_Rupinnovert_1L_Bklt_12741030 Page 2



Les bonnes pratiques du désherbage à adopter

- ★ Désherber avec le bon équipement: gants imperméables, chaussures de jardinage, eau propre et pulvérisateur dédié au désherbant non-sélectif.
- ★ Ne pas traiter sur un terrain risquant un entraînement vers un point d'eau (ruisseau, étang, mare, puit...) en particulier si le terrain est en pente.
- ★ Ne pas traiter aux abords d'un fossé, d'une grille d'évacuation d'eau ou d'une bouche d'égout.
- ★ Traiter un jour sans pluie, sans vent et à température modérée (12-25°C).
- ★ Ne pas réaliser plus d'une application en plein (traitement complet d'une surface recouverte de mauvaises herbes) et 3 applications en tache par an (traitement localisé de touffes de mauvaises herbes).
- ★ Ne pas laisser de préparation prête à l'emploi dans le pulvérisateur.
- ★ Éliminer les emballages, avec ou sans reliquat de produit, dans une déchetterie.

REMARQUES
MONSANTO garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché du Ministère de l'Agriculture. Ne peut être reformulé ou reconditionné. Aucune licence attribuée explicitement ou implicitement sous un brevet américain.

MONSANTO 

CHARDON	RONCE	ORTIE	LISSON	CHIENDENT pied de poule	renouée à griffes	ZONES CULTIVÉES
CHARDON Traitez de préférence : de mai à août et de juin à début septembre. Stade de traitement : bouton fermé ou chardon en fleur. Hauteur de la plante : 15-30 cm Dose de Roundup INNOVERT : 40 ml dose 5 l d'eau	RONCE Traitez de préférence : à l'automne (en dehors des périodes de gel). Traitements nécessaires sur plusieurs années. Laisser agir jusqu'au printemps suivant. Dose de Roundup INNOVERT : 40 ml dose 5 l d'eau	ORTIE Traitez de préférence : à l'automne et laissez agir 3 mois sans arracher. Dose de Roundup INNOVERT : 40 ml dose 5 l d'eau	LISSON Traitez de préférence : de fin mai à début juin sur la plante en fleur. Dose de Roundup INNOVERT : 50 ml dose 5 l d'eau	CHIENDENT pied de poule Traitez de préférence : de septembre à octobre. Ne pas retourner le sol avant traitement (éviter la préférence du chien de pied de poule). Dose de Roundup INNOVERT : 50 ml dose 5 l d'eau	renouée à griffes Traitez de préférence : au printemps ou à l'automne un mois avant le nouveau semis pour éliminer votre peuplier et se semer une nouvelle. Dose de Roundup INNOVERT : 47,5 à 60 ml dose 5 l d'eau	ZONES CULTIVÉES Traitez de préférence : d'août à novembre pour désherber avant la mise en culture. Laissez agir le produit 15 jours avant de semer ou de travailler le sol. Dose de Roundup INNOVERT : 47,5 à 60 ml dose 5 l d'eau
						

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18-Jul-17

Les différentes étapes du traitement – Précautions d'emploi

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'intoxication animale, contactez votre vétérinaire.

AVANT LE TRAITEMENT :

Traiter en dehors des heures chaudes et des périodes de gel.
Traiter de février à novembre (pour les ronces, plutôt en automne; pour les chardons, plutôt à la floraison).
Pas de pluie (pendant le traitement et 6h après) pour éviter le lessivage.
Pas de vent, pour éviter les projections.
Traiter entre 12 et 25°C. Roundup INNOVERT permet le maintien d'un

bon niveau d'efficacité dès 1°C et jusqu'à 30°C.

- Avec le bon équipement : gants imperméables, chaussures de jardinage, eau propre et pulvérisateur dédié au désherbant non-sélectif.
- Vérifier le bon état de fonctionnement des buses et du pulvérisateur de manière générale.

STOCKAGE DU PRODUIT

Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux. Conserver hors de la portée des enfants et des personnes non qualifiées.

PENDANT LE TRAITEMENT :

LA PRÉPARATION

- Rincer le pulvérisateur avant emploi.
- Mesurer la surface à traiter pour ne préparer que la quantité nécessaire (exemple: 8 mètres de longueur x 5 mètres de largeur = 40m²).
- Calculer la dose nécessaire en fonction de la surface et du type de mauvaises herbes.
- Verser un peu d'eau propre dans le pulvérisateur.
- Doser le volume nécessaire dans le pulvérisateur puis compléter avec le volume d'eau indiqué.
- Ne pas surdoser. Respecter les doses d'emploi indiquées sur l'étiquette.

L'APPLICATION

- Pulvériser à une distance de 20 à 30 cm sur les mauvaises herbes développées ou en croissance. Roundup INNOVERT étant un désherbant non sélectif qui détruit tout végétal traité, éviter les projections sur les plantes à conserver et utiliser un cache herbicide si nécessaire.
- Couper les feuilles des végétaux à conserver si elles ont reçu une éclaboussure de produit.
- Ne jamais traiter à moins de 5 mètres d'un point d'eau (ruisseaux, puits, fossé, grille d'évacuation d'eau, bouche d'égout...), sur un terrain en pente pouvant entraîner un ruissellement vers un point d'eau ou sur un terrain saturé en eau.
- Pour le désherbage des massifs, ornements ou bordures de pelouse, il est conseillé d'utiliser un cache de protection pour éviter toute projection sur la végétation à préserver ainsi que le ruissellement sur les mauvaises herbes.
- Éviter toute pulvérisation ou embruns sur le feuillage des cultures ou plantations voisines, en particulier en été ou en automne pour les plantations arborescentes. En cas de projection accidentelle sur le feuillage des plantes à préserver, rincer abondamment et immédiatement avec de l'eau.

APRÈS LE TRAITEMENT :

- Rincer le pulvérisateur après traitement.
- Ne pas entrer dans la zone traitée avant le séchage complet. Attendre 1 semaine avant de replanter.
- Ne jamais jeter à l'évier ou à l'égout les fonds de bidon et de pulvérisateur : rincer 3 fois le pulvérisateur à l'eau propre et appliquer les eaux de rinçage sur une zone perméable enherbée (friches) ou dans le cadre de dispositif de gestion et de traitements des effluents (ex Phytobac®, Osmofim® etc.).
- Pour une efficacité optimale, respecter un délai pour replanter ou retravailler le sol de 7 jours, pour permettre au produit d'assurer la destruction complète des mauvaises herbes.
- Conserver Roundup INNOVERT dans son emballage d'origine et à l'abri du gel, dans votre local phytosanitaire.
- Réemploi de l'emballage interdit.

EN CAS DE DEVERSEMENT

ACCIDENTEL

Se protéger (EPI) et sécuriser la zone. Prévenir les pompiers (18) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens.
Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse. Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.

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18-JUL-17



*** Propriétés et Période d'utilisation**

- Roundup INNOVERT est un désherbant systémique non sélectif. Il détruit la plupart des mauvaises herbes annuelles (amarantes, chénopodes), biennales (rumex) et vivaces (pissenlits, chiendent, isarons).
- Roundup INNOVERT peut s'utiliser toute l'année, mais préférentiellement de février à novembre.

*** Conditions d'emploi :**

1. Estimer votre surface à traiter
2. Calculer la dose
3. Verser 1/2 du volume de l'eau
4. Doser
5. Verser dans le pulvérisateur
6. Rincer le doseur
7. Verser l'eau de rinçage
8. Compléter avec de l'eau
9. Traiter
10. En fin de traitement, stocker le matériel avant de l'application

DOSES D'EMPLOI



= 100 m² nettoyés

USAGES	Catégorie des mauvaises herbes	Doses recommandées en ml/100m ²
Usages non agricoles des désherbages allées, parcs, jardins et trottoirs, chemins et voies de circulation	Adventices annuelles et bien nées	De 22.5 à 37.5 ml/100 m ²
	Adventices vivaces	60 ml/100 m ² par tache uniquement
Usages non agricoles des désherbages talus	Adventices annuelles et bien nées	De 22.5 à 37.5 ml/100 m ²
	Adventices vivaces	60 ml/100 m ² par tache uniquement
Traitement préleveur, désherbages avant mise en culture	Adventices annuelles et bien nées	De 22.5 à 37.5 ml/100 m ²
	Adventices vivaces	