

**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**

**(New application after re-registration)**

**Applicant: MONSANTO S.A.S**

**Date: 04/05/2023**

**Updated version:**

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# PART A

## RISK MANAGEMENT

### 1 Details of the application

The company MONSANTO S.A.S has requested a marketing authorisation in France for the product ROUNDUP INNOVERT (formulation code: MON 79351), 480 g/L glyphosate<sup>1</sup> 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 S.A.S application submitted on 29/01/2018 to market ROUNDUP INNOVERT 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 updated version concerns the evaluation of new data submitted by MONSANTO S.A.S on 07/01/2021 for the Physical and chemical section (relevant impurity) and the Toxicology section (genotoxic potential) (application 2020-3345).**

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 1107/2009<sup>2</sup>, 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”)<sup>3</sup>. 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 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 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

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<sup>1</sup> 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.

<sup>2</sup> 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

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

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B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011<sup>4</sup>, 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.

## 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 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. Details of the authorisation decision

## 1.5 Product identity

Product code	MON 79351
Product name in MS	ROUNDUP INNOVERT
Authorisation number	N/A : no marketing authorisation granted
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	MONSANTO S.A.S
Active substance(s) (incl. content)	glyphosate, 480 g/L
Formulation type	Soluble concentrate [SL]
Packaging	HDPE <sup>5</sup> (1 L, 5 L, 10 L, 15 L, 20 L, 200 L, 640 L, 1000 L)
Coformulants of concern for national authorisations	-

<sup>4</sup> 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

<sup>5</sup> High density polyethylene

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

## 1.6 Conclusion

The evaluation of the application for PRODUCT NAME resulted in the decision to refuse the authorisation.


## 1.7 Substances of concern for national monitoring

Refer to 5.1.1.

## 1.8 Classification and labelling

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

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	<b>No classification for human health.</b> Hazardous to the aquatic environment - Chronic Hazard, category 2
Hazard pictograms:	 SGH09
Signal word:	Warning
Hazard statement(s):	<b>No classification for human health.</b> H411: Toxic to aquatic life with long lasting effects.
Precautionary statement(s):	<i>For the P phrases, refer to the existing legislation</i>

See Part C for justifications of the classification and labelling proposals.

### 1.8.2 Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted

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

None.

## 1.9 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 2017<sup>6</sup> provides that:

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

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

Moreover, for glyphosate-based products, the official statement<sup>7</sup> 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 12 April 2021<sup>8</sup> 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 extrapolation<sup>9</sup> 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.

### **1.9.1 Restrictions linked to the PPP**

N/A : no marketing authorisation granted

### **1.9.2 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 1.9.1 (mandatory labelling):

None.

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<sup>6</sup> 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>

<sup>7</sup> 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](https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000000445445)

<sup>8</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

<sup>9</sup> 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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### 1.10 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 12 April 2021 (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 rev. 2, date: 04/05/2023

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

Formulation type: SL <sup>(a, b)</sup>

Active substance 1: glyphosate

Conc. of a.s. 1: 480 g/L <sup>(c)</sup>

Applicant: MONSANTO S.A.S

Professional use:

Zone(s): Southern Zone <sup>(d)</sup>

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. <sup>(e)</sup>	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 <sup>(f)</sup>
					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		
<b>Zonal uses (field or outdoor uses, certain types of protected crops)</b>													



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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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 ( <sup>(f)</sup> )
					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		
14	FR	<b>Inter crop, fallow land , crop destruc- tion</b>  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	-	<b>Not finalised</b> (relevant impurity, genotoxic potential, (*))
14	FR	<b>land , crop destruc- tion</b>  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	-	<b>Not acceptable</b> (relevant impurity, genotoxic potential, (*))

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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 ( <sup>(f)</sup> )
					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	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”	<b>Not acceptable</b> (MRL compliance for root- vegetables, tuber, cabbage relevant impurity, <b>genotoxic potential</b> , (*)
	FR	Inter-row in vegetable crops	F	annual broad-leaved, biannuals,	Spraying	actively growing weeds	1	-	4.5	2.16		-	<b>Not acceptable</b> (MRL, relevant impurity, <b>genotoxic potential</b> , (*))
	FR	Inter-row in vegetable crops	F	perennial weeds	Spraying  Spot applicatio n	actively growing weeds	1	-	5.25	2.52		-	<b>Not acceptable</b> (MRL, relevant impurity, <b>genotoxic potential</b> , (*))

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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 ( <sup>(f)</sup> )
					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	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	<b>Not acceptable</b> (relevant impurity, genotoxic potential, (*))
8	FR	Orchards	F	Annual broad-leaved, biannuals,	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	<b>Not acceptable</b> (relevant impurity, genotoxic potential, (*))

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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 ( <sup>(i)</sup> )
					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	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	<b>Not acceptable</b> (relevant impurity, genotoxic potential, (*))
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 <sup>2</sup> of stump section	120 g/m <sup>2</sup> of stump section	-	-	<b>Not acceptable</b> (relevant impurity, genotoxic potential, (*))
13b	FR	Brush	F	-	Spraying, with tunnel sprayer	-	-	-	7.5	3.6	-	-	<b>Not acceptable</b> (relevant impurity, genotoxic potential, (**))

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. <sup>(e)</sup>	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 ( <sup>(f)</sup> )
					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		
14	FR	Non-crop areas	F	annual and perennial weeds	spraying, spot treatment, brushing or wiping with special equip- ment 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	-		<b>Not acceptable</b> (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		6.0	2.88	-		<b>Not acceptable</b> (relevant impurity, 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.

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<b>Remarks table heading:</b>	<ul style="list-style-type: none"> <li>(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</li> <li>(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008</li> <li>(c) g/kg or g/l</li> </ul>	<ul style="list-style-type: none"> <li>(d) Select relevant</li> <li>(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1</li> <li>(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.</li> </ul>
<b>Remarks columns:</b>	<ul style="list-style-type: none"> <li>1 Numeration necessary to allow references</li> <li>2 Use official codes/nomenclatures of EU Member States</li> <li>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)</li> <li>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</li> <li>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.</li> <li>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.</li> </ul>	<ul style="list-style-type: none"> <li>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</li> <li>8 The maximum number of application possible under practical conditions of use must be provided.</li> <li>9 Minimum interval (in days) between applications of the same product</li> <li>10 For specific uses other specifications might be possible, e.g.: g/m<sup>3</sup> in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.</li> <li>11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).</li> <li>12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".</li> <li>13 PHI - minimum pre-harvest interval</li> <li>14 Remarks may include: Extent of use/economic importance/restrictions</li> </ul>

## 2 Background of authorisation decision and risk management

### 2.1 Physical and chemical properties (Part B, Section 2)

ROUNDUP INNOVERT is a soluble concentrate (SL). 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 two relevant impurities, formaldehyde and N-nitrosoglyphosate.

The relevant impurity formaldehyde is a starting material of the manufacturing process for glyphosate and as such cannot be formed during the storage of the formulation. The monitoring of this impurity in the storage studies is not necessary.

The relevant impurity N-nitrosoglyphosate is likely to form during the process formulation and storage of the product.

In the accelerated stability study (Rages, D., 2013), the content of NNG before and after storage (0.239ppm and 0.223ppm respectively) is in the acceptable limit (0.376 mg/kg). The analytical method (AG-ME-1681-01) for its determination is validated with an LOQ of 0.205ppm.

In the ambient shelf life study (Park,A., 2017 Park Anne 2018 MSL0029507), the content of NNG is below the acceptable limit before storage but above the acceptable limit after 1 and 2 years (0.40ppm and 0.40ppm respectively). Moreover the LOQ of the analytical method (HPLC-UV method ME-2070-01) (LOQ= 0.86ppm) used for its determination is above the acceptable limit.

No new studies have been provided by the applicant.

The product is therefore not considered to be stable based on the data provided under the conditions tested.

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

### 2.2 Efficacy (Part B, Section 3)

Considering the data submitted:

- the efficacy level of ROUNDUP INNOVERT 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 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.

## 2.3 Methods of analysis (Part B, Section 5)

### 2.3.1 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.

### 2.3.2 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.

## 2.4 Mammalian toxicology (Part B, Section 6)

### Endpoints used in risk assessment

Active Substance: <b>glyphosate</b>			
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	
	<b>Dermal absorption endpoints %</b>	<b>0.3</b>	<b>5%*</b>
Oral absorption	<b>20%</b>		<b>UE 2017</b>

\*pro rata correction



### 2.4.1 Acute toxicity

ROUNDUP INNOVERT 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 sensitiser.

### 2.4.2 Genotoxic potential

Based on the results of the Ames test and the second *in vitro* micronucleus performed on ROUNDUP INNOVERT, ROUNDUP INNOVERT is not mutagenic, not aneugenic nor clastogenic under the study conditions. Thus, the assessment of genotoxicity of ROUNDUP INNOVERT can be finalised.

### 2.4.3 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G <sup>10</sup>	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)
devitalization of vines and brambles, non-agricultural area, forestry	F	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	

Considering proposed uses, operator systemic exposure was estimated using the French study from UPJ 2009-2010<sup>11</sup> dedicated to non-agricultural areas and the EFSA model<sup>12</sup>:

<sup>10</sup> Open field or glasshouse

<sup>11</sup> 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

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

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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%
Non-agricultural area, forestry	Vehicle mounted <i>Downward spraying</i>		17%
	Manual knapsack <i>Downward spraying</i>		1.8%
devitalization of vines and 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 MON 79351 is acceptable with a working coverall and gloves during mixing/loading and application.

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

#### 2.4.4 Worker exposure

Not applicable for the intended uses.

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

#### 2.4.5 Bystander and resident exposure

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

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

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

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

## 2.5 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”, “brassica vegetables”, “fungi”, “oilseed”, “cereals”, “berries and small fruits”, “tea, coffee, and herbal infusions”, “hops” and “spices” are not supported by available data and the compliance with current MRLs cannot be performed.

In accordance with the available residue data, a maximum application dose of 2.25 L/ha is retained 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

**Table 1: Information on ROUNDUP INNOVERT (KCA 6.8)**

Crop	PHI for ROUNDUP INNOVERT proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for ROUNDUP INNOVERT proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate		
Citrus	21 days	Yes	21 days	
Pome fruits	21 days	Yes	21 days	

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Crop	PHI for ROUNDUP INNOVERT proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for ROUNDUP INNOVERT proposed by zRMS	zRMS Comments (if different PHI proposed)
		Glyphosate		
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.

## 2.6 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<sub>sw</sub> derived for glyphosate and its metabolites are used for the ecotoxicological risk assessment.

For uses on hard surfaces, the estimation of PEC<sub>gw</sub> is not considered relevant. For other uses, PEC<sub>gw</sub> 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 DT<sub>50</sub> calculation, no significant contamination of the air compartment is expected for the intended uses.

## **2.7 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 ».

## **2.8 Relevance of metabolites (Part B, Section 10)**

Not relevant.

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

The active substance glyphosate is not approved as a candidate for substitution, however a comparative assessment according to Art. 50(2) is undertaken.

## **4 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”.

#### **4.1.1 Post-authorisation monitoring**

The survey of resistance to glyphosate should be continued based on analysis of field efficacy failures (one monitoring for all products based on glyphosate), and especially on ryegrass (*Lolium multiflorum*, *Lolium perenne* and *Lolium rigidum*), fleabanes (*Conyza sp.*) and common ragweed (*Ambrosia artemisiifolia*). Any new information which would change the resistance risk analysis should be provided to Anses. In all cases, a report on the results of the survey put in place should be provided at the time of the next renewal of glyphosate.

#### **4.1.2 Post-authorisation data requirements**

The following data would have been required to update the dossier:

- An accelerated storage stability study and a shelf life study with the content of NNG before and after the storage should be provided. The NNG should be determined with a validated method with a limit of quantification in accordance with the maximum concentration limit of this NNG impurity in the preparation.

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## **Appendix 1 Copy of the product authorisation**



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

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

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

<i>de la société</i>	<b>MONSANTO SAS</b>
<i>enregistrées sous les</i>	<b>n°2018-0462, 2019-0456, 2014-0140, 2015-0485 et 2019-4413</b>

*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.**



MON 79 351/ ROUNDUP INNOVERT  
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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	
<b>00401014</b> Forêt*Dévitalisation	120 g/m <sup>2</sup> <b>Motivation du retrait :</b> L'usage 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	
<b>11015924</b> Traitements généraux* Désherbage* Avt Mise Cult.	3,75 L/ha <b>Motivation du retrait :</b> L'usage revendiqué correspondant au nouveau libellé « Traitements Généraux * Désherbage * Interculture, jachères et destruction de culture », est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré à la dose de 6 L/ha au même motif.	3/an	F	6 mois à compter de la présente décision	12 mois à compter de la présente décision	
<b>11015932</b> Traitements généraux* Désherbage* Cult. Installées	4,5 L/ha <b>Motivation du retrait :</b> L'usage revendiqué correspondant aux nouveaux libellés « Cultures fruitières*Désherbage*Cult. Installées » et « Cultures légumières * Désherbage * Inter-rang » est retiré au motif que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit. L'usage est également retiré à la dose de 6 L/ha et pour des délais avant récolte de 7 jours sur oivier, 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.	1/an	90	6 mois à compter de la présente décision	12 mois à compter de la présente décision	

ROUNDUP INNOVERT  
AMM n°2120035




### 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
<b>11015911</b> Traitements généraux* Dévital. Broussaillies	7,5 L/ha <b>Motivation du retrait :</b> 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
<b>11015904</b> Usages non agricoles* Dés herb. total	3,75 L/ha <b>Motivation du retrait :</b> 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
<b>11015903</b> Usages non agricoles* Dés herbage* All. PJT, Cimet., Voies	3,75 L/ha <b>Motivation du retrait :</b> L'usage revendiqué correspondant au nouveau libellé « Usages non agricoles * Désherbage * PJT », 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

### Appendix 2 Copy of the product label

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

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## Roundup<sup>®</sup> INNOVERT

**HERBICIDE foliaire systémique non sélectif**  
Concentré soluble (SL) contenant 480 g/l (35,74% p/p) de glyphosate acide

**RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL**  
Lire les instructions ci-jointes avant l'emploi

- Formulation brève tée
- Efficacité prouvée
- Contre les mauvaises herbes
- Destruction des feuilles jusqu'aux racines
- Permet de replanter

• Déserbages en zone cultivée ou d'es allées de parcs, jardins, trottoirs  
• Usage possible pour les cours de ferme

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

Puis signaler une anomalie au numéro Printzone, N° Vert : 0 800 807 607 (appel gratuit depuis tous pays).

**Monsanto**

### La technologie Roundup<sup>®</sup> INNOVERT

- ★ Une formulation brevétée à l'efficacité démontrée
- ★ Destruction des feuilles jusqu'aux racines
- ★ Contre les mauvaises herbes
- ★ Permet de replanter
- ★ Cours de ferme

TRAITEMENT	CADRE D'USAGE DE MAUVAISES HERBES	SPÉCIFICITÉ DU DURAGE	DOSAGE CADRE D'USAGE
Usage en agriculture (travaux entre, parcs, jardins, trottoirs, allées de parcs, trottoirs, zones de circulation)	Adapté aux mauvaises herbes annuelles et vivaces	375°Cla Efficace par pulvérisation	200 g par m <sup>2</sup> de terrain 200 g par m <sup>2</sup> de terrain
Usage en agriculture (travaux entre)	Adapté aux mauvaises herbes annuelles et vivaces	375°Cla Efficace par pulvérisation	200 g par m <sup>2</sup> de terrain 100 g par m <sup>2</sup> de terrain
Usage en agriculture (travaux entre)	Adapté aux mauvaises herbes annuelles et vivaces	375°Cla Efficace par pulvérisation	200 g par m <sup>2</sup> de terrain

**Informations réglementaires**

Nom commercial: Roundup INNOVERT  
Noms de vente: 2020204 et 2020205  
Date de mise sur le marché: 14/02/2012  
N° d'autorisation de mise sur le marché: 1402 02 00 2474 (p)  
N° d'autorisation de mise sur le marché: 1402 02 00 2474 (p)  
N° d'autorisation de mise sur le marché: 1402 02 00 2474 (p)  
N° d'autorisation de mise sur le marché: 1402 02 00 2474 (p)

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FR\_Hupinnovert\_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	ROUÏE	ORTIE	TRIFOLIUM	CHIENDENT BLEU DE POULE	RAI-COUE À PRINTEMPS	ZONES CULTIVÉES
<p>Traitez de préférence : de mai à avril et de juin à début septembre.</p> <p>Stade de traitement : bouton fermé ou chardon en fleur.</p> <p>Hauteur de la plante : 15-30 cm</p> <p>Dose de Roundup INNOVERT : 40 ml dans 5 l d'eau</p>	<p>Traitez de préférence : à l'automne (en dehors des périodes de gel).</p> <p>Traitement nécessaire sur plusieurs années.</p> <p>Laissez agir jusqu'au printemps suivant.</p> <p>Dose de Roundup INNOVERT : 40 ml dans 5 l d'eau</p>	<p>Traitez de préférence : à l'automne et laissez agir 3 mois sans arracher.</p> <p>Dose de Roundup INNOVERT : 40 ml dans 5 l d'eau</p>	<p>Traitez de préférence : de fin mai à début juin sur la plante en fleur.</p> <p>Dose de Roundup INNOVERT : 50 ml dans 5 l d'eau</p>	<p>Traitez de préférence : de septembre à octobre.</p> <p>Ne pas retourner le sol avant traitement (éviter la prolifération du chiendent pied de poule).</p> <p>Dose de Roundup INNOVERT : 50 ml dans 5 l d'eau</p>	<p>Traitez de préférence : au printemps ou à l'automne un mois avant le nouveau semis pour limiter votre peuloux et se semer une nouvelle fois.</p> <p>Dose de Roundup INNOVERT : 47,5 à 60 ml dans 5 l d'eau</p>	<p>Traitez de préférence : d'avril à novembre pour désherber avant la mise en culture. Laissez agir le produit 15 jours avant de semer ou de travailler le sol.</p> <p>Dose de Roundup INNOVERT : 47,5 à 60 ml dans 5 l d'eau</p>

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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 ronciers, 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 PREPARATION**

- 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 = 40m<sup>2</sup>).
- 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'égoût...), 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.
- Eviter toute pulvérisation ou embruns sur le feuillage des cultures ou plantations voisines, en particulier en été ou en automne pour les plantations arbustives. 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'égoût 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 traitements des effluents (ex Phytobac®, Osmofit<sup>®</sup> 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 VERSEMENT 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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**★ 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, Isérons).
- 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 10 dl du volume de l'eau
- 4 Doser
- 5 Verser dans le pulvérisateur
- 6 Rincer le doseur
- 7 Verser l'eau de rinçage
- 8 Complétez avec de l'eau
- 9 Traiter
- 10 En fin de traitement, rincer le matériel avec soin à l'application



**DOSES D'EMPLOI**



**USAGES**

USAGES	Catégorie des mauvaises herbes	Doses recommandées en ml/100m <sup>2</sup>
Usages non agricoles : désherbage des allées, parcs, jardins et trottoirs, cimetières et voies de communication	Adventices annuelles et biennales Adventices vivaces	De 22,5 à 37,5 ml/100 m <sup>2</sup> 60 ml/100 m <sup>2</sup> par tache unitairement
Usage non agricole : désherbage de talus	Adventices annuelles et biennales Adventices vivaces	De 22,5 à 37,5 ml/100 m <sup>2</sup> 60 ml/100 m <sup>2</sup> par tache unitairement
Traitement préventif : désherbage des cultures en culture	Adventices annuelles et biennales Adventices vivaces	De 22,5 à 37,5 ml/100 m <sup>2</sup>

DOSEUR de Roundup INNOVERT pour 5 litres d'eau (100 ml de désherbant)

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