ENVIRONMENTAL RISK MANAGEMENT AUTHORITY
NGĀ KAIWHAKATŪPATO WHAKARARU TAIAO

ERMA New Zealand

FORM HS1

Application for approval to

IMPORT OR MANUFACTURE ANY HAZARDOUS SUBSTANCE FOR RELEASE

under section 28 of the Hazardous Substances and New Organisms Act 1996

Name of Substance: **ROUNDUP POWERMAX**

Applicant: **MONSANTO Australia Limited**

Office use only

Application Code: ☐☐☐☐☐☐☐☐ Date received:____/____/____

ERMA NZ Contact: _____ Initial Fees Paid: $

Application Version No: _____.

IMPORTANT

1. Before you fill in this application form, you may find it helpful to consult the *User Guide to Hazardous Substance Applications under the HSNO Act 1996*. This User Guide can either be downloaded from our website or purchased from ERMA New Zealand. The level of information that you need to provide in this application is dependent upon the scale and the significance of the risks and/or whether these risks are well understood and controlled. The User Guide will offer further advice on this.
2. Part B of the User Guide covers applications under Section 28 of the Act and all of the cross references in this application form are to Part B.
3. You can also talk to an applications officer at ERMA New Zealand who can help you scope and prepare your application. We need all relevant information early on in the application process. Quality information up front will speed up the process.
4. This application form may be used to seek approvals for more than one hazardous substance where the substances are related, for example a concentrated compound (active ingredient) and its related formulations or the two parts of an epoxy glue.
5. Any extra material that does not fit in the application form must be clearly labelled, cross-referenced, and included in an Appendix to the application form.
6. Commercially sensitive information must be collated in a separate Appendix.
7. Applicants must sign the form and enclose the correct application fee. The initial application fee can be found in our published *Schedule of Fees and Charges*. Make sure that you have an up to date copy of the Schedule. Please check with ERMA New Zealand staff. We are unable to process applications that do not contain the correct fee.
8. Unless otherwise indicated, all sections of this form must be completed for the application to be progressed. Where an applicant is unable to complete the sections marked optional, this information may be derived by ERMA New Zealand and the costs of doing so will be recovered from the applicant as part of the processing costs.

You can get more information at any time by contacting us. One of our staff members will be able to help you.

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Section One – Applicant Details

See comments under "Section One of Application Form" in the User Guide for guidance.

1.1 Name and postal address in New Zealand of the organisation making the application:

Name:	**NEW ZEALAND AGENT**
	Greg Tower
	Monsanto New Zealand Limited
Address:	c/- Simpson Grierson
	Private Bag 92518
	AUCKLAND
Phone:	09-358 2222
Fax:	09-307 0331
Email:	gbt@sglaw.co.nz

1.2 The applicant's location address in New Zealand (if different from above):

Address:	92 - 96 Albert Street
	AUCKLAND

1.3 Name of the contact person for the application:

This person should have sufficient knowledge to respond to queries and either have the authority to make decisions on behalf of the applicant that relate to processing the application, or have the ability to go to the appropriate authority.

Name:	Megan Shaw
Position:	Regulatory Product Manager
Address:	Monsanto Australia Limited
	(600 St Kilda Road, Melbourne, 3004)
	PO Box 6051
	St Kilda Road Central, VIC 8008
	AUSTRALIA
Phone:	613 9522 7162
Fax:	613 9525 2253
Email:	megan.e.shaw@monsanto.com

Section Two – Application Type and Related Approvals Required

This form is only to be used for an application to import and/or manufacture a hazardous substance for 'release' and if it does not meet the requirements for rapid assessment. Please note that it is the substance(s) which is approved, and thus the approval covers both import and manufacture.

If you are making the application for some other reason, you will need a different form.

2.1 Is the information in this application relevant to import, manufacture or both:
(See comments under "Section 2.1 of Form" in the User Guide)

- Import only? **No**
- Manufacture only? **No**
- Import and manufacture? **Yes**
- If import only, indicate whether or not manufacture is likely in New Zealand **NA**

2.2 If the information in the application relates to manufacture in New Zealand, provide information on the proposed manufacturing process and any alternatives.
(See comments under "Section 2.2 of Form" in the User Guide)

The application is for approval to import and manufacture in New Zealand.
The product is also manufactured in Australia and will be available for importation into NZ. The manufacture in NZ is envisaged to cover the requirements of the NZ market. The manufacturing process will be identical to that carried out in Australia and involves a simple blending process of the technical grade potassium salt of glyphosate in water with a proprietary blend of surfactants with an anti-foaming agent. Packaging and labelling will be localised on the site of the formulator.

2.3 If you have reasons for not providing detailed information in this application, explain what they are and provide some justification.

An example of a reason for not giving detailed information is where an approval has been given by another jurisdiction and information that led to that approval can be referenced or the substance will be used in low risk situations or ways.
(See comments under "Section 2.3 of Form" in the User Guide)

2.4 If this substance(s) needs an approval under any other legislation, has an application for this approval been made?
(Optional) (See comments under "Section 2.4 of Form" in the User Guide)

Name of Approval	Application made
Agricultural Compounds and Veterinary Medicines Act 1997	**Yes**
Other (please specify):	No

Section Three – Information on the Substance(s)

Note all information that is commercially sensitive must be attached as an Appendix. The application form should be cross-referenced to the Appendix but should be able to be read as a stand-alone document which will be publicly available.

You will need to provide a brief description of where the information in the application has been sourced from, eg from; inhouse data, research, technical literature, etc. See the introductory comments under "Section Three of the Form" in the User Guide for more details.

If approval is being sought for more than one hazardous substance, this section must be completed separately for each hazardous substance.

3.1 State the unequivocal identification of the substance.

This section should include all information necessary to unequivocally identify the substance(s) and may include:

- Chemical Name (Chemical Abstracts Preferred Index name or IUPAC name)
- Common Name
- Synonyms **MON 78273**
- Trade Names **ROUNDUP POWERMAX**
- CAS Registry Number
- Molecular Formula
- Structural Formula
- Significant impurities

For mixtures, in addition to the above information being provided on the actual mixture, information is also required on the composition of the mixture ie the chemical name, CAS number, function (eg active ingredient, emulsifier, surfactant, filler) and percentages of **ALL** components of the mixture (including non-hazardous components and impurities) should be provided. This information may be best expressed in tabular form. If the composition is variable, please ensure to state the limits.

If there are commercial reasons for not providing full information in the main part of the form, alternative approaches must be discussed with and agreed by ERMA New Zealand. These must include the provision of a unique identifier of some kind.

(See comments under "Section 3.1 of Form" in the User Guide)

For the **CONFIDENTIAL** details of the formulation ingredients, refer to Appendix 1.

Ingredient	CAS number	Function	% w/v
glyphosate potassium salt[10]	70901-12-1	active ingredient	52.0
Compound mixture A[11]			
Compound B[12]			
Compound C[13]			
water	7732-18-5	diluent	

3.2 Provide information on the chemical and physical properties of the substance.

Provide as much information as possible on the chemical and physical properties of the substance(s) [at 20°C and 1 atmosphere unless otherwise stated].

- Appearance **viscous liquid**
- Colour **pale amber**
- Odour **none**
- pH **4.8**
- Density **1.35**
- Boiling point **105^{0}C**
- Flashpoint **> 90^{0}C**
- Solubility in water **soluble**

For mixtures, information is required on the chemical and physical properties of the mixture itself. However, if this information is not available, you should provide information on the chemical and physical properties of EACH hazardous component of the mixture.

3.3 Provide information on the hazardous properties of the substance.

Information should be provided on the hazardous properties of the substance(s) known to the applicant. You must consider each of the six hazardous properties below and provide information on those hazardous properties that trigger any threshold level. If you wish, you may assign the relevant HSNO classification category to each hazardous property that exceeds these threshold levels.

explosiveness	**non-explosive**
flammability	**non-flammable**
oxidising properties	**non-oxidising**
corrosiveness	**non-corrosive**
acute toxicity	**inhalation toxicity**
irritation	**dermal toxicity**
sensitisation	**non-sensitiser**
carcinogenic	**non-mutagenic/carcinogenic**
ecotoxicity	**aquatic toxicity / biocidal activity**

If your substance is a mixture and you cannot provide direct information on its hazardous properties, you can apply mixture rules to the hazardous components of the mixture. If you do this, then you will need to provide information on the hazardous properties of each hazardous component of the mixture, and show your workings.

3.3.1 Explosivity

Roundup PowerMax is not an explosive substance according to the criteria set by the HSNO Act.

3.3.2 Flammability

Roundup PowerMax is not a flammable substance according to the criteria set by the HSNO Act.

3.3.3 Oxidising

Roundup PowerMax does not oxidise and is not an oxidising or self-reacting substance according to the criteria set by the HSNO Act.

3.3.4 Corrosiveness

Roundup PowerMax is above the thresholds for having corrosive properties to metal, skin and eye.

3.3.5 Toxicity[8]

Acute toxicity studies are available for a formulated substance (MON 78270) that is very similar to the substance under evaluation (Roundup PowerMax - MON 78273). The minor difference between the two formulations is covered in Appendix 1, and relates to the inclusion of <0.5% of a common food ingredient in MON 78270. The exclusion of this in the substance MON 78273 under evaluation is considered unlikely to cause any change in adverse effects. Numerous studies have been conducted on both the active ingredient alone (glyphosate acid) and the isopropylamine salt formulation of glyphosate. For the potassium salt of glyphosate (MON 78623)[10] that contains no surfactants (compounds A&B)[11], the toxicity values were very similar for both the IPA and K salts. The very low concentrations of Compounds C and D are unlikely to influence the toxicity of the substance.

The appropriate LD_{50} mg/kg and LC_{50} mg/L values for MON 78270 are summarised in the following table.

Toxicity hazard	MON 78270	Threshold	Classification
acute oral (rat)	>5000 mg/kg [1]	not triggered	
acute oral (mouse)	>5000 mg/kg [2]	not triggered	
acute dermal (rat)	>5000 mg/kg [3]	not triggered	
acute inhalation (rat)	>0.77 <2.21 mg/litre [4]	triggered	6.1D
skin irritation (rabbit)	erythema 1.89 [5]	triggered	6.3B
eye irritation (rabbit)	corneal opacity 0.33[6] conjunctivae 1.33[6]	not triggered not triggered	
sensitisation (guinea pig)	negative [7]	not triggered	

acute oral [1,2]

Ten male/female rats were tested under OECD guidelines with a single dose of 5000 mg/kg of formulated material. There was 10% mortality. The LD_{50} of MON 78270 is indicated to be >5000 mg/kg.

Similar test on mice showed no mortality with an LD_{50} of >5000mg/kg. Both of these values do not trigger the HSNO threshold.

acute dermal [3]

Ten male/female rats were tested under OECD guidelines with a single dose of 5000 mg/kg of formulated material. There were no longterm effects and no mortality. The LD_{50} of MON 78270 is indicated to be >5000 mg/kg. This does not trigger the HSNO threshold.

acute inhalation [4]

Under OECD guidelines, two groups of male/female rats received four-hour nose only inhalation exposure to time weighted average aerosol concentrations of either 0.77mg or 2.21 mg/litre of air. Administration was by aerosol.

There was no mortality at the 0.77 mg/litre concentration. There was 80% mortality at 2.21 mg, the highest dose tested. The LC_{50} of MON 78270 was therefore indicated to be between the lowest and highest concentrations tested of 0.77 and 2.21 mg/litre of air. Based on this range, MON 78270 triggers the inhalation toxicity classification threshold **(HSNO Classification 6.1D).**

skin irritation [5]

Rabbits were tested under US EPA / OECD guidelines and EEC methodology to test the irritant and corrosive effects of a dermal application. Assessments were made at 1, 24, 48 and 72 hours and up to 14 days.

The mean Draize toxicity rating scores were -

Category	Mean Draize test score	HSNO threshold
erythema	1.89	1.5
oedema	0.22	1.5

The calculated FIFRA Primary Irritation index was 2.17 and is therefore considered moderately irritating. Under the EEC Evaluation Criteria MON 78270 is classified as an irritant to the skin for erythema and a non-irritant for oedema. Based on the values obtained MON 78270 triggers the skin toxicity classification threshold **(HSNO Classification 6.3B).**

eye irritation [6]

Rabbits were tested under US EPA / OECD guidelines and EEC methodology with a single dose of 0.1ml of substance.

The mean Draize toxicity rating scores were -

Category	Mean Draize test score	HSNO threshold
corneal opacity	0.33	1.0
iris lesion	0.11	1.0
conjunctival redness	1.22	>2.0
conjunctival oedema	1.11	>2.0

Under the EEC guidelines, the material is classified as a non-irritant substance to ocular tissue.

sensitisation [7]

Twenty guinea pigs were treated topically once a week for three weeks. After a two-week rest period, a single topical re-treatment was made. There were no dermal reactions in the challenged animals, with a mean rating score of 0.0.

MON 78270 is not a contact sensitiser and therefore does not trigger the HSNO threshold.

subchronic toxicity

No data is available on the formulated substance. The following table outlines the values in terms of mg/kg/day measured for glyphosate acid, Compound A and AMPA - the major metabolite of glyphosate. There appears to be no data available on Compound B. The very low concentrations of Compounds C and D are unlikely to influence the toxicity of the substance.

Toxicity study NOAEL	**glyphosate acid [14]**	**Compound A[14]**	**AMPA[14]**
oral rat (90 day)	209-1445 mg	36 mg	400 mg
mouse	630-2310 mg		
rat (2 yr)	409 mg		>2.8 mg
dog	>500 mg (12 mths)	<30 mg (14 wk)	263mg (90day)
developmental rat	1000 mg	15 mg	400 mg
rabbit	175 mg		
reproductive rat	694 mg		>4.2 mg
mutagenicity	non-mutagenic		
S. typhimurium	negative		
E. coli	negative		

Summary [14]

Results from several investigations establish that the acute toxicity and irritation potential of (glyphosate IPA formulation) in humans is low. Skin irritation was similar to a baby shampoo and lower than a dishwashing detergent. There was some potential for skin and eye irritation from the undiluted substance, but exposure to the water-diluted spray has rarely resulted in any significant adverse effect. Serious adverse effects such as death occurred only following deliberate ingestion of large amounts of concentrated substance.

The oral absorption of glyphosate is low and eliminated essentially unmetabolised. Dermal penetration is low and it does not appear to bioaccumulate in any animal tissue. No significant toxicity occurred in acute, sub-chronic and chronic studies. Direct dermal exposure may cause irritation. There is no convincing evidence for direct DNA damage and it was concluded that the component glyphosate did not pose a risk for the production of heritable/somatic mutations in humans. Multiple lifetime feeding studies failed to demonstrate any tumorigenic potential for glyphosate. Accordingly, it was concluded that glyphosate is non-carcinogenic, not teratogenic or developmentally toxic. There were no effects on fertility, reproductive parameters, reproductive animal tissues, or any effects indicative of endocrine disruption.[14]

Overall, it is concluded that, under the present and expected conditions of use, the current commercial formulation of the IPA salt of glyphosate containing the POEA surfactant, does not pose a health risk to humans.[14] It is therefore concluded that the toxicity profile of the proposed substance, which is the potassium salt containing a lower concentration of the surfactant, would be little different.

3.3.6 Ecotoxicity

No studies have been conducted on the formulated end use substance for ecotoxic effects. However, a number of studies have been carried out on glyphosate acid and formulations containing glyphosate as the isopropylamine salt (IPA). There are fewer studies for the sodium salt (Na) with a surfactant.

The substance has been designed as a biocide for the non-selective control of a range of annual and perennial broadleaf and grass weeds.

Surfactants

In practice there are generally four types of surfactants used in glyphosate formulations. The main one is POEA which has long carbon chains with C_{16} - C_{20} carbon atoms and poor biodegradability. They also have ocular irritancy and aquatic toxicity properties. The reduction in the concentration of the POEA surfactant in mixture with another surfactant has reduced ocular irritation effects.

The following table outlines the lowest EC_{50} or LC_{50} toxicity values measured for the substance against the most sensitive of the various test species. Comparison is also made with the commercial formulation containing the IPA salt of glyphosate that contains a higher concentration of the polyethoxylated tallow amine (POEA) surfactant than the substance under evaluation.

Toxicity hazard - (glyphosate)	**acid** [15]	**IPA + POEA** [15]	**Na salt + surfact.**	**Threshold**	**Classif. indicated**
aquatic (mg/L)					
fish LC_{50} 96hr	22	5.8 97 (- POEA)		triggered	9.1D
D. magna EC_{50} 48hr	780	9.7 930 (-POEA)		not triggered	
S. capricornutum EC_{50} 96hr	21.8	2.6 72.9(-POEA)		triggered	9.1D
soil (mg/kg)				not triggered	
earthworm NML 14 days	3750	5000	>1250[17]		
NOEC 14 days	118.7	500	270[17]		
DT_{50} days (geometric mean) (arithmetic mean)	2-174	1-197 (17) (32)			
vertebrates (mg/kg)				not triggered	
birds LD_{50} oral	>2000				
birds LC_{50} 8 days diet	>4640	>5620			
invertebrates (µg/bee)				not triggered	
honey bee LD_{50} contact	>100	>100	>25[18]		
biocide	√	√	√	triggered	9.1D

aquatic

The POEA surfactant in the commercial formulation significantly increases the toxicity to aquatic organisms. Glyphosate alone as either the acid or technical IPA salt triggered two of the three HSNO toxicity thresholds that are required for pesticides. There is no data for the surfactant mixture (compounds A and B).

Glyphosate does not bioconcentrate in fish or other aquatic animals and no significant bioacumulation is expected.[10] The BCF value for the whole bluegill sunfish was <1.[10] The half-life in aerobic water is <7 days.[10]

Glyphosate and its metabolite AMPA strongly absorb to soil and have a low potential to leach into ground water.[15]

soil

Glyphosate tends to bind strongly to soil and particulate matter and is essentially unavailable to soil organisms. The half-life varies either 1-197[15] or 2-174 days with a K_{oc} of 884-60,000 L/kg.[10] Although there is an absence of data on the formulated product, and in particular the surfactant mixture (compounds A and B), it seems that Roundup PowerMax is unlikely to be significantly different in toxicity compared with the acid and IPA forms of the active ingredient. Therefore it would not appear to trigger the HSNO threshold.

terrestrial vertebrate/ invertebrate

Apart from the active ingredient glyphosate, there is no extensive scientifically generated data for the remaining ingredients in relation to terrestrial invertebrate and vertebrate toxicities. Both glyphosate acid and the commercial IPA salt formulation are practically non-toxic to birds and honey bees. It appears therefore that Roundup PowerMax would not trigger the HSNO thresholds for these two categories.

Summary Table

Hazard property	Threshold	Classification category
Explosiveness	not triggered	
Flammability	not triggered	
Oxidising	not triggered	
Corrosiveness	not triggered	
Toxicity		
acute oral	not triggered	
acute dermal	not triggered	
acute inhalation	triggered	6.1D
skin irritation	triggered	6.3B
eye irritation	not triggered	
sensitisation	not triggered	
mutagenicity	not triggered	
carcinogenicity	not triggered	
Ecotoxicity		
aquatic	triggered	9.1D
soil	not triggered	
terrestrial vertebrate	not triggered	
terrestrial invertebrate	not triggered	
biocide	triggered	9.1 D

3.4 Identification of the default Controls on the substance(s).

A range of default controls are triggered by the hazardous property classification(s) attached to the substance. If you wish, you can list what these default controls are. If you don't provide this information, ERMA New Zealand will do it for you. Regardless, you need to be aware of what the default controls are so that you can take them into account when assessing risks – see Section 4. **(Optional)** (See comments under "Section 3.4 of Form" in the User Guide)

Toxicity:	T 1, 2, 4, 7, 8
Ecotoxicity:	E 1, 2, 6, (E8 ~ T7)
Identification:	I 1, 8, 9, 11, 16 - 21, 28, 29, 30
Packaging:	P 1, 3, 13*
Disposal:	D 4, 5, 6, 7, 8
Emergency Management:	EM 1, 6, 7, 8, 11, 12, 13

3.5 Provide information on what will happen to the substance throughout its whole life from its introduction into New Zealand, its uses, through to disposal.

This information is used in the development of exposure scenarios and the assessment of risks, costs and benefits and should therefore be as expansive as possible.
(See comments under "Section 3.5 of Form" in the User Guide)

Manufacture: The product will be manufactured by Nufarm Limited at their manufacturing sites in Melbourne, Australia and Auckland, New Zealand. Importation into New Zealand in plastic lined bulk containers of 20 thousand litres capacity to the Auckland port. These bulk containers are transported to the specific local manufacturing site for storage prior to repacking and labelling for retail distribution. The specific sites are bunded and adopt GMP and the manufacturer has ISO accreditation. Repacking is carried out according to the Resource Management, Health and Safety to Employee and other relevant Acts.

Storage: The product is labelled and the smaller size containers are packed in multiple units in cardboard boxes for despatch to the retailer for storage along with other such products that are currently used for weed and pest control. The storage and repacking facility has prominent signage denoting the HAZCHEM code appropriate for the substances in storage. These repacked retail containers are then despatched to retail outlets and home garden centres etc, to be stored on shelves for sale to the commercial and domestic end-user.

Packaging: The containers are constructed of HDPE plastic and are very commonly used to contain pesticides. The labelled containers are either packed in cardboard boxes or shrink wrapped on pallets for transportation in bulk to the distributor/retailer for sale as individual units. The pack sizes may include capacities of 200ml, 500ml, 1, 5, 20, 50, 100, 400 and 1000 litres. The imported container is 20,000 litres in capacity.

Usage: The product is diluted with water It is intended for commercial and home garden use for the control of a wide range of annual and perennial broadleaf and grass weeds. Little or no contamination of the local air, soil or water environment is likely as the spraying is directed to the vegetative parts of the undesirable plants. The claims, instructions and general directions for use are outlined on the container label.

Disposal: The container is unlikely to be disposed of until empty. The large 20 thousand litre bulk container will be returned empty and unrinsed to the manufacturer in Australia. Similarly, the empty 1000 litre container, generally used by forestry contractors for weed control, will be returned to the supplier unrinsed for refilling and reuse. It is not proposed to refill or reuse the smaller empty container packs. These are likely to be triple-rinsed with water and disposed of safely by crushing and burning, if circumstances such as wind direction permit, or buried in a suitable landfill. The small containers for home garden use can be disposed of when empty by either recycling or disposal in domestic garbage.

Section Four: Risks, Costs and Benefits

These are the positive and adverse effects referred to in the HSNO Act. It is easier to regard risks and costs as being adverse (or negative) and benefits as being positive. In considering risks, cost and benefits, it is important to look at both the likelihood of occurrence (probability) and the potential magnitude of the consequences, and to look at distribution effects (who bears the costs, benefits and risks).

You will need to consider the effects on the environment and human health and welfare, including any social effects.

In each section set out below, it might be easier for you, and most useful for ERMA New Zealand, if the information is set out under the following three sub sections:

- Costs and benefits which can be stated in monetary (dollar) terms
- Non-monetary risks and costs
- Non-monetary benefits.

Complete this section as far as you can. If the analysis provided is incomplete, then it will be completed by ERMA New Zealand. However, the costs of doing this will be chargeable.

You will need to provide a brief description of where the information in the application has been sourced from, eg from; inhouse research, independent research, technical literature, community or other consultation.
(See comments under "Section 4 of Form" in the User Guide)

4.1 Identify all of the potential risks, costs and benefits of the substance(s)

Identification is the first step in assessing risks, costs and benefits. The introductory part of "Section 4 of Form" in the user Guide provides detailed guidance on what kinds of costs, risks and benefits should be thought about. It is important to think about the source of the risk, ie the way in which the risk is created (the exposure pathway), and then the consequences and likelihood of exposure.

You should try to think as widely as possible about every potential risk, cost and benefit and give a brief description. The range of matters that you will need to think about is discussed in the User Guide. You must also decide how significant that risk, cost or benefit is likely to be. If the risk, cost, or benefit is obviously not significant (and you can give reasons), then there is no need to further assess that risk, cost, or benefit.
(See comments under "Section 4.1 of Form" in the User Guide)

RISKS - Identification

Source	*Lifecycle*	*Event*
Spillage	Transport Storage Use	Accident during transport and handling - on ship, at port, factory site, in land vehicle, to and from storage during life cycle. Opening container, measurement of quantity, pouring into spray tank, and disposal of used container.
Spray application	Use Disposal	Contamination of workers, users, the local public; the soil, water and air environments from - the use of un-calibrated spray equipment, adverse wind causing spray drift to off-target areas, and disposal of unrinsed containers.

Hazardous property	*Impact*	*Exposure pathway*	*Adverse effect*
Toxicity	Worker and User health	*skin* contact *inhalation*	moderate irritation or reddening. irritation of respiratory tract
Ecotoxicity	Environment	*water* - from spillage run-off, rinsing and disposal of empty container. *vegetation* - off-target site	effect on aquatic organisms biocidal

1. **Primary risk is to Human exposure and its consequences during occupational use.**
   The risks to human health from exposure to the undiluted substance relates largely to -
   - *Skin contact*. Mild irritation with reddening of the skin, especially from contact with the undiluted substance.
   - *Inhalation*. Inhalation, particularly of the undiluted substance when misted, may give rise to irritation of the mucous membranes and respiratory tract.

2. **Secondary risk is to contamination of the Environment.**
   The risks to the environment from exposure would relate to the contamination of -
   - *Water*. Slight toxic effects on some fish and aquatic vegetation.
   - *Air*. Biocidal effects on off-target areas.

Source of the Risks:

Spillage: Accidental spillage may occur during storage at or transport between the ship, port, manufacturing site, warehouse, distributor/retailer and the end-user. Accidents in storage situations could arise from forklift use or improper and unrealistic stacking of containers. Other possible spillage situations could arise during transportation involving vehicular accidents on public roads or rail. The physical handling of smaller containers in any situation could also lead to spillage. Spillage is possible at end-user level during the opening of the container, measuring and pouring the correct amount of the liquid substance into the spray tank that is partly filled with water. Splashes or wind drift of undiluted substance could occur in these circumstances.

Spray Drift: Application to unwanted vegetative plant growth is either by hand operated hand gun, mistblower and knapsack sprayers, weed wiper, or vehicle operated ground boom sprayer or aircraft. All boom spraying equipment would be calibrated to apply specific volumes of diluted spray per

hectare. Spray drift occurs when adverse wind conditions arise during application, or equipment is improperly calibrated and spraying pressure is higher than desired. This creates small fine droplets that disperse and drift more readily rather than the larger droplets that deposit by gravitational force on to the surfaces of trees and vines.

BENEFITS - Identification

The major benefit of the substance is the improved toxicity profile in respect of occupational safety to end-users and the aquatic environment. This follows the use of a proprietary blend of surfactants that reduces the level of the POEA surfactant normally used which is more ecotoxic with poor biodegradability. The usually high concentration of POEA alone gives rise to ocular irritation and aquatic toxicity.

4.2 Provide an assessment of those risks, costs, and benefits identified in Section 4.1 which might be significant.

This section excludes risks, costs, and benefits which relate specifically to Māori taonga or to international agreements. See Sections 4.3 and 4.4 below for those aspects.

Assessments only need to be done for those risks, costs and benefits which Section 4.1 shows might be significant. Section 4.2 in the User Guide provides a detailed explanation of how to do an assessment. Remember that assessments can be qualitative ie based on judgements, if there is no analytical information available. But it is essential that a firm conclusion is drawn about the size and likelihood of the risks, costs or benefits, and also about the certainty of the assessment.

In assessing risks especially, it is important to take account of the extent to which risks will be reduced by the default or other controls (see Section 3.4 above and 4.5 below).
(See comments under "Section 4.2 of Form" in the User Guide)

RISKS - Assessment

The potentially significant risks with toxic hazardous properties with possible adverse effects on human health and the environment are considered.

Source of risk	Lifecycle	Occurrence likelihood	Impact	Magnitude
spillage	transport and storage	unlikely	occupational health and environment	minimal
	use	unlikely	occupational health and environment	minimal
spray application	use	unlikely	environment	low
	disposal	unlikely	occupational health and environment	low

The magnitude of all the risks identified are considered minimal, as they are localised in relation to the distribution of effects. Application is generally target specific rather than broadcast. Overall, the risks are considered insignificant. The individual manufactured units will be contained on pallets shrink-wrapped to minimise loss or removal and thus minimise damage and spillage. The geographical locations are restricted to specific sites whether as the result of any accidental spillage or by use on

specific weedy areas or individual plants in the home garden. The workers responsible for the handling, transport and use of the substance are relatively few but are usually qualified and experienced in such occupational use. Apart from the deliberate inhalation of the concentrated substance, all risk exposures are involuntary but can be and are currently managed by controls on packaging, labelling and education. The long term use of numerous similar glyphosate-based products, both commercially and domestically, has not given rise to any adverse effects.

Spillage -

Accidental spillage during transport and storage is considered unlikely to occur under normal conditions. Transportation of dangerous goods/hazardous substances is by designated and experienced carriers such as Chemcourier Services. The use of public passenger or private transport is not envisaged. Transportation by the end-user from the retailer is unlikely to be private domestic vehicles. To minimise the possibility of any spillage, the container packaging meets the requirements of Dangerous Goods for the stability of contents and robustness during handling and storage. The drum tops have a tamper-proof seal that has a two-fold purpose. One is to be alert to the possibility of contamination and possible spillage and the other to make it more difficult to access by children. The major risk of spillage could occur during use by the applicator during the process of measurement and mixing prior to the spray application. The deliberate act of opening the container by the end-user, and the consequent measuring/decanting of the correct amount and pouring it into the partly filled spray tank of water, is likely to cause some spillage to a greater or lesser extent.

Impact on Occupational health - spillage during transport or storage would have minimal adverse effects on individual workers involved. The exposure pathway of the inhalation risk is unlikely to occur. The low magnitude of any risk to worker health and safety is controlled by the use of suitable protective clothing such as goggles and rubber gloves. Any exposure to inhalation of the substance is likely to be of very short duration and therefore of low significance.

Impact on the Environment - spillage during transport is unlikely and in any consequence would be by nature localised. Current containment procedures would ensure minimal or no contamination of waterways or drains, and contaminated soil removed to an appropriate approved landfill. Warehouse storage facilities are generally bunded to ensure containment of any spillage. The spillage can be absorbed into inert material and disposed of into an appropriate landfill. Some storage facilities may have underground storage tanks suitable for biological/chemical degradation of waste and spillage.

The spray applications are not made to bodies of water, and any run-off to such from spray drift/ ground deposition would be negligible. Spray applications are made to the point of run-off.

Spray drift -

Spray drift is equally likely and unlikely to occur, as it is dependent upon the weather conditions prevailing at and during the spray application. Ground broadcast boom applications are recommended using low water volumes applied at 200-280 kPa pressure to avoid fine mist droplets. These small droplets have the propensity to drift, instead of gravitational deposition upon the target area. Applications using hand-operated equipment may generate some fine droplets but these are applied direct to target area. There could be phytotoxic effects from the application to vegetation on the boundary of treated areas. Home garden applications are directed specifically and deliberately to the unwanted vegetation and not applied indiscriminately into the air, onto the ground or towards non-target areas.

Personnel competency -

All personnel involve in transportation, storage, and warehousing as well as end-use have the knowledge and experience in the handling requirements of hazardous substances previously known as dangerous goods. Retailers and growers are likely to be GROWSAFE certified with the requisite knowledge and responsibility in the handling, storage and use of these types of substances.

BENEFITS - assessment

Benefits-

The introduction of Roundup PowerMax for release into NZ provides an alternative glyphosate-based herbicide from the originators of glyphosate herbicides. Glyphosate in the form of a different salt formulated with surfactants of lower toxicity will give a wider choice where toxicity is a factor. The risk of adverse effects to occupational health and the aquatic environment is therefore reduced.

Costs-

As a consequence of any spillage during transportation or storage, containment and disposal costs of contaminated soil and water would occur. The cost of these would depend on quantities of material involved and the locality of the spillage and the site of an appropriate landfill.

4.3 Provide an assessment of any particular risks, costs and benefits which arise from the relationship of Māori and their culture and traditions with their taonga, or which are, for other reasons, of particular relevance to Māori.

We have asked for a separate response in this area because these requirements are different to other risks, costs and benefits. These are explained in more detail in Section 4.3 of the User Guide. Please note that if there are potentially significant risks in this area, it will almost certainly be necessary to consult with Māori in preparing an assessment.
(See comments under "Section 4.3 of Form" in the User Guide)

Overall, the importation and use of Roundup PowerMax will not adversely affect the natural resources of indigenous maori flora, fauna, waterways, land and culture. Any effect is minimal and of low magnitude and is no greater than that pertaining to non-Maori. The controls to be put in place in the management of the substance would also be applicable in relation to the current health, safety and culture of maori generally.

The risks are known and understood by Maori by reason of knowledge and experience in the transport handling, storage and use of glyphosate-based herbicides. Those employed by contractors in the use of similar types of products would have the appropriate experience and certification of competency to carry out such duties.

Although virtually all of the risks are involuntary, the distribution of such are localised geographically and are identical to those described for New Zealanders generally under 4.1.

Glyphosate-based herbicides are widely used for the control of unwanted vegetation and used in non-selective situations, and applied directly to the weed or area infested with weeds. Therefore, it is unlikely there would be any adverse effects on native flora or traditional food sources such as shellfish, freshwater fish or herbaceous plants from any incidental or accidental off-target spray or drift. There does not appear to have been any impact to Maori since the introduction of glyphosate herbicides that have been in use in NZ for about 30 years.

The introduction of RoundupPowerMax would not violate or impact upon the principles of the Treaty of Waitangi.

4.4 Provide an assessment of any risks, costs or benefits to New Zealand's international obligations.

This is a specialist area which ERMA New Zealand will handle. However, any information you are able to provide on relevant international agreements would help us and save time and cost.
(Optional) (See comments under "Section 4.4 of Form" in the User Guide)

4.5 Provide information on the proposed management of the substance.

This section should provide information on managing the effects identified and assessed in Sections 4.1 - 4.4 above. The starting point for this is the range of default controls triggered by the hazardous property classification(s) attached to the substance (see Section 3.4). You should describe how these controls would be implemented and indicate other mean of managing risks.. The information provided must be specific to the substance(s) and cover all areas of intended use. Reference should be made to Codes of Practice or standard operating procedures that will be followed. If changes to the default controls triggered by the substance classification are proposed, the reasons for these changes should be provided.

Please note that you will find it easiest to complete this section in conjunction with section 4.2. That is because the management of risks will influence their residual level.
(See comments under "Section 4.5 of Form" in the User Guide)

Identification

- The secondary identifiers required to be available within 10 seconds will include a description of the hazardous substance, the hazard risks, safety and health warnings and precautions, first aid, disposal of empty container and rinsate. These will be prominently displayed at the top of the back panel of the container label. The name, addresses and phone numbers etc for contact will also be printed on the label.
- The container will be labelled before supply for sale, and the label durable for outdoor conditions, firmly affixed to the container, with text in English that is easily read and understood by a teenager. The label will have good contrast between background colour and typeface clarity. The active ingredient and concentration of the substance will be described in generic terms. The rates of application and conditions under which they are permitted to be applied will be expressed on the label.
- The specific workplace information required within 10 minutes by personnel involved in transportation, storage, supply, end-use and emergency management is the NZ Material Safety Data sheet. The data sheet will include information and controls required for the identification, description, emergency management and disposal requirements of the substance. The product will be stored where signage already exists for the storage of agricultural chemicals with the appropriate HAZCHEM rating code. Advertising will indicate the substance is toxic, causing skin irritation upon contact and must be kept away from children.

Toxicity

- The specific requirements of the protective clothing necessary for the handling and use of the substance will be contained in the precautionary statements at the top of the back panel of the label. As the quantities required for the proposed uses are significant, and the product has toxic and ecotoxic properties, it will not be transported by private domestic or public passenger transport but by specific specialist carriers of hazardous goods.
- The application equipment will be calibrated.

Ecotoxicity

- The appropriate precautionary statement will be made on the container label for the avoidance of contamination of any water supply with the chemical or empty container. Disposal of container will be in an approved landfill if not previously crushed and burned.

Packaging

- The substance will be packed in robust containers for the purpose of secure containment during the transport by sea from Australia, rail/road within NZ and storage conditions during the product life cycle.

Emergency Management

- The Level 1 information required for managing the risk of any exposure to persons or the environment is outlined on the container label under Precautions, First Aid and Container disposal. Additional information relating to contamination from spillage is contained in the Material Safety data sheet (MSDS).
- The Level 2 information required to manage any risk during storage and transportation, in addition to the container label, will include the MSDS.
- The Level 3 information required for warehouse and other storage facilities will have the appropriate signage relative to the quantities stored including the HAZCHEM rating. The emergency response plan for each storage facility will be that approved by the appropriate body for the storage of agricultural chemicals and other deemed hazardous substances. This could include the local Regional Authority and requirements under the Resource Management Act.

Disposal

- The substance is not used undiluted. Dilution is with water only. Rinsate from the triple-rinsing of the empty containers with water are to be returned to the spray tank. This shall be outlined on the container label.
- The disposal of the rinsed empty container is outlined in bold on the label and conforms to the general requirements currently accepted under the ACVM Act 1997.
- Additional information and documentation requirements in the management of the disposal of large quantities of undiluted or diluted substance from spillage or expiry will be outlined in the MSDS.

Spillage

- Spills should be absorbed with inert material and packed in waste containers. Spills should be prevented from entering waterways and sewers. Spillage areas should then be washed with water and the contaminated water and material absorbed with inert material. Disposal of waste and waste containers must be in accordance with local by-laws. For containment and management of a large spillage, the Fire Service should be informed immediately and then the local health protection officer of the local District Health Board or hospital. Details of emergency management are outlined in the Material Safety Data sheet and also the Agrichemical Hazard Response Handbook that has been adopted by the NZ Fire Service.

Summary: The overall management of the substance subsequent to importation or manufacture for release with controls, in respect of transport, storage, application use and container disposal will be in compliance with the Code of Practice for the Management of Agrichemicals NZS 8409:1999. The information and documentation to facilitate this will include the ready availability of relevant documentation such as the container label and Material Safety Data sheet.

4.6 Provide an overall evaluation of the combined impact of all of the risks, costs and benefits set out in sections 4.2, 4.3 and 4.4.

Doing this overall evaluation is the main task of the Authority. However, you may wish to express a view on the relative importance of the different risks, costs and benefits and how they should be brought together in making a decision.
(Optional) (See comments under "Section 4.6 of Form" in the User Guide)

There are no significant risks in relation to -

Toxicity

Glyphosate is of relatively low oral, dermal and inhalation toxicity. The risk of irritation effects, particularly skin, from exposure can be managed by appropriate protective clothing such as goggles and gloves. Studies showed glyphosate did not give rise to mutations or carcinogenic effects. Some slight effects occurred in developmental studies at very high dose rates. Similarly in kidneys of male rats at high doses in reproductive studies, but was not mutagenic. Almost all the glyphosate is excreted as parent compound, with very little absorbed in tissues and organs, and less reaches the bone marrow.

Dietary exposure

The EPA concluded that chronic dietary risk posed by glyphosate food uses is minimal. A reference dose or estimate of daily exposure that would not cause adverse effects throughout a lifetime of 2 mg/kg/day has been proposed. This is based on the developmental toxicity studies.[14] Human dietary exposure and risk is therefore minimal.

Occupational exposure

Exposure to workers is generally expected to pose no undue risks, due to its low acute toxicity. However, splashes during measuring and mixing may cause eye and skin irritation. Protective clothing would minimise the effect of this exposure risk.

Environmental exposure

Glyphosate is absorbed strongly to soil and does not appear to move below the 15cm soil layer, with residues expected to be immobile in the soil. It is readily degraded by soil microbes to the metabolite AMPA that in turn is degraded to carbon dioxide. It is not readily broken down by water and sunlight.

Glyphosate is not toxic to birds, earthworms and honey bees, but is classified (under HSNO) as slightly toxic to some fish species. The risk of exposure to aquatic organisms can be managed and minimised by ensuring disposal of container rinsate into spray tank and the subsequent burning or burial of empty containers in a landfill.

Maori

Providing the substance is used according to current and proposed label instructions, there is unlikely to be any adverse effects on the flora, fauna and other taonga associated with Maori.

Section Five – International Considerations

5.1 **ERMA New Zealand is interested in whether this substance (or any of its components) has been considered by any other regulatory authority in New Zealand or by any other country. If you are aware of this, please provide details of the results of such consideration. (Optional)** (See comments under "Section 5.1 of Form" in the User Guide)

New Zealand

Other commercial formulations containing glyphosate as the active ingredient have been considered by the Ministry of Agriculture both under The Agricultural Chemicals Act 1959 and the subsequent Pesticides Act 1979. Of the 63 currently registered products to date containing glyphosate, a selection of some of these products with the active ingredient in a soluble concentrate formulation, is outlined in the following table.

This comparison is made with the proposed soluble concentrate formulation of Roundup PowerMax containing 40% glyphosate (540g/litre).

Trade name	Registrant	Active content (g/litre)	Register No.	Date registered
Roundup Ultra	Monsanto Australia Limited	510	P5844	Oct 2001
Roundup Renew Xtra	Monsanto Australia Limited	490	P5628	March 2000
Roundup Herbicide	Monsanto Australia Limited	360	P5014	Oct 1998

Australia

The registration of the identical formulation by the NRA in Australia is pending. The application is under the same trade name Roundup PowerMax (CRIS 55687).

USA

Glyphosate was discovered by Monsanto and developed commercially in about 1972.

The US EPA have previously considered and approved the sodium salt of glyphosate under the trade name of Polado. The registration was for use as a plant growth regulator on sugar cane. The US EPA have registered a similar formulation (MON78270) under the trade name Roundup WeatherMax herbicide.

Section Six – Miscellaneous

6.1 Provide a glossary of scientific and technical terms used in the application.
(See comments under "Section 6.1 of Form" in the User Guide)

AMPA	amino methyl phosphonic acid (metabolite of glyphosate)
GMP	Good Manufacturing Practice
HAZCHEM code	Hazardous Chemical Emergency Response code
HDPE	high density polyethylene
ISO	International Standards Organisation
NML	no-mortality level
POEA	polyethoxylated tallow amine (surfactant)
SAR	Structure Activity Relationship

6.2 Provide here any other information you consider relevant to this application not already included.
(See comments under "Section 6.2 of Form" in the User Guide)

Nil

Section Seven – Summary of Public Information

The information provided in this section may be used in the Authority's public register of substances required under Section 20 of the HSNO Act.

This summary information will be used to provide information for those people and agencies (eg Ministry for the Environment, Department of Conservation, Regional Councils, etc), who will be notified of the application, and for potential submitters who request information. This information will also be used to prepare the public notice of the application.

For these reasons, applicants should ensure that this summary information does not contain any commercially sensitive material.

7.1 Name of the substance for the public register:

Roundup PowerMax

7.2 Purpose of the application for the public register:

The purpose of the application is to obtain approval to import and manufacture for release of Roundup PowerMax for use as a herbicide for the control of weeds in non-selective situations. The inhalation toxicity, dermal irritation and ecotoxic/biocidal activity triggers the HSNO thresholds for a hazardous substance.

7.3 Use Categories of the substance:

ERMA New Zealand has adopted the system of use categories developed by the European Union, which identify various functional uses of substances. This information is pertinent to the assessment of exposure scenarios and the determination of risk and is also useful for building up a profile of the substance. There are three sets of use categories. Within each of these, applicants should state which use categories are relevant to all intended uses of the substance.

- **Main category:** **4** Wide dispersive use - spraying of a pesticide.
- **Industry category:** **1** Agricultural industry - plant protection product.
- **Function/Use category:** **38** Pesticide - destroy undesirable plants

7.4 Executive Summary:

In this section, the applicant should provide a summary of information contained in this application, including:

- the identification of the substance, its hazardous properties and intended uses
- an assessment of the risks, costs and benefits
- the methods implemented to manage the risks, particularly in relation to emergency management and disposal.

This is an application to import and manufacture Roundup PowerMax for release in NZ for use as a herbicide. The product contains glyphosate as the active ingredient in a soluble concentrate formulation for dilution with water. The active ingredient is of low acute toxicity and is not mutagenic or carcinogenic. The substance is classified as hazardous by reason of its low inhalation toxicity, skin irritation and aquatic toxicity. It is designed as a biocide for use by farmers, commercial horticultural growers and foresters for the control of a range of annual and perennial broadleaf and grass weeds.

The large empty imported bulk container will be returned to the manufacturer. The smaller retail containers, when empty, will be triple rinsed, crushed and burned or buried in a suitable landfill.

The concentration of active ingredient in the water-based formulation will have little or no adverse effect to handlers and users during transport, storage and end use, or to the air and soil environments around the treated plants.

Glyphosate is not active long term in the soil or plant environments.

It poses little risk to humans when the material is handled and used according to the label instructions. This is confirmed by the widespread usage of the substance in various formulations since its introduction into New Zealand in the early 1970's.

CHECKLIST

Mandatory sections filled out	**Yes**
Appendices enclosed	**Yes**
Fee enclosed	**Yes**
Application signed and dated	**Yes**
Electronic copy emailed to ERMA NZ	**Yes**

Signed **Date**