Operator exposure risk assessment for MON 78273 under UK use conditions

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Abstract

This report describes a tiered evaluation of the risk associated with the professional handling (mixing, loading and field application) of MON 78273 under UK use conditions.

The operator exposure assessment was based on the UK-POEM model.
The hazard assessment was based on a short-term rabbit teratogenicity study (AOEL = 0.2 mg/kg bw/day) in accordance with the EU-rapporteur's decision.

The risk associated with the professional handling of MON 78273 was assessed according to a tiered or stepwise approach.
In view of access to the dermal penetration data in human skin, no tier 1 assessment was made.

The exposure during tractor-mounted application was estimated at tier 2 level, considering product specific dermal penetration. The risk evaluation based on the UK POEM model shows that where no gloves are worn during any of the exposure events, the systemic exposure exceeded the AOEL. When gGloves are worn at all times (mixing, loading and application) the exposure is reduced to an acceptable level: 60% and 30% of the AOEL for hydraulic nozzles and rotary atomisers respectively.

For hand-held application, the tier 2 was subdivided ~~in two parts:~~ one part (tier 2a) using the default gloves reduction factor as proposed by the model, whereas the second part (tier 2b) takes into consideration a product specific gloves reduction factor.

At the tier 2a level, when considering the default gloves penetration factor ~~as proposed by the model~~, AOEL is exceeded for both types of sprayers (hydraulic nozzles and rotary disc atomisers), even when gloves are worn at all time and impermeable protective clothing during application.

At the tier 2b level, the absorbed dose calculated using the UK-POEM model corresponds to 110% and 100% of the AOEL for hydraulic nozzles and rotary disc atomisers respectively, when gloves are worn at all time and impermeable protective clothing during application.

At tier 3 level, the exposure estimates for application using hand-held hydraulic nozzles were refined based on product specific passive dosimetry studies. Results obtained demonstrate that no health effects are to be expected from professional application using hand-held hydraulic nozzles equipment when gloves are worn at all time (mixing, loading and application).

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Introduction

MON 78273 is a water based, soluble liquid formulation (SL) containing 540 g glyphosate per litre of formulation. The active ingredient is glyphosate potassium salt that will dissociate to free glyphosate acid in the spray liquid.

MON 78273 is a foliar applied translocated herbicide used for the control of annual and perennial grass and broad-leaved weeds and for pre-harvest application in cereals.

In this report, the risk associated with the professional handling (i.e. mixing, loading and field application by farmers and professional applicators) of MON 78273 is assessed according a tiered or stepwise approach. Tractor mounted and hand-held application with both hydraulic nozzles and rotary disc atomizers are evaluated in this report.

In view of access to in-vitro dermal penetration data in human skin, no tier 1 risk assessment was made.

At tier 2 level, product specific data (dermal penetration) are used to refine the exposure estimates. For hand-held evaluation, the tier 2 level is sub-divised in two parts. One part considers the default gloves reduction factor as proposed by the UK-POEM model. The second part takes into consideration a product specific penetration factor through gloves.

The exposure estimates for hand-held hydraulic nozzles equipment are refined at tier 3 level, according to product specific monitoring.

Total absorbed doses of professional workers during mixing, loading and application are estimated based on the UK-POEM exposure model. The scenarios used in the assessment are based on worst-case use conditions in the UK (highest application rate, lowest spray volume, default workload). Total absorbed doses are compared to a systemic "acceptable operator exposure level" (AOEL) in order to evaluate the actual risk.

1. UK-POEM EXPOSURE MODEL

This is a predictive model based on operator exposure studies conducted in Great Britain. These studies were selected according to certain high-level quality criteria and were mainly carried out by industry or initiated by an authority. The surrogate exposure levels derived from these studies were chosen to be 75th percentile values and are expressed in weight/volume of formulation (during mixing and loading) or spray liquid (during application) applied per time unit of activity (in mg/h or mL/h).

The daily mixing and loading time is set to be one hour and the worker is supposed to apply the product during 6 hours/day. The latter corresponds with the application time of a default area of 50 ha/day when spraying downward using tractor mounted equipment.

The calculation of the absorbed dose is performed in three steps. First, the total amount of a.i. deposited onto clothes and uncovered skin is determined using surrogate exposure levels (potential exposure). Then, the total amount of a.i. that comes into contact with skin is calculated from the potential exposure using default permeation factors that are dependent upon the type of formulation, the type of protective clothing (clothing, gloves) and body part (chest, legs). The dermal absorbed (systemic) dose is then derived using a skin absorption of 3% (See end-points list of the review report of Glyphosate). For the estimation of the absorbed dose by inhalation 100 % bioavailability is assumed.

During mixing and loading, hand exposure is the only important route of exposure. In this model it is assumed that there exists a relationship between the number of operations (number of times a container is emptied in the tank) per the day and exposure. Exposure is only dependent on working time and the concentration of the spray liquid in field application. Respiratory exposure is only taken into account for field operations.

2. TRACTOR-MOUNTED APPLICATION OF MON 78273

2.1. TIER 2: Exposure scenarios

2.1.1. Good agricultural practices

Tables 1 summarises the rates and the spray volumes recommended for the application of MON 78273 in UK field conditions using a tractor-mounted equipment. Based on this information, a realistic worst-case scenario is evaluated for each type of sprayer (hydraulic nozzles and rotary atomisers). The maximum application rate and the minimum spray volume are considered for the exposure assessment.

Table 1: Summary of GAP for a tractor mounted application of MON 78273 in UK field conditions

Equipment	Minimum rate (kg a.s./ha)	Maximum rate (kg a.s./ha)	Recommended application volumes (L/ha)
Tractor mounted (with cab) Hydraulic nozzles	0.54	***2.16***	***80*** – 400
Tractor mounted (with cab) Rotary disc atomisers	0.54	***2.16***	***40***

2.1.2. Workload

The default area when spraying downward using a tractor-mounted equipment is 50 ha/day in the UK-POEM model

2.1.3. Protective equipment

Three scenarios are evaluated with regard of protective equipment:

- Scenario 1: with gloves during mixing & loading only
- Scenario 2: with gloves during mixing & loading and during application
- Scenario 3: with gloves during mixing & loading and during application

2.1.4. Dermal uptake

In vitro studies on human skin and in vivo studies on rhesus monkeys were carried out with glyphosate or respective preparations. On the basis of the assessment of all studies available, the rapporteur proposed a value of 3% for the dermal absorption (GlyphosateEuropean Mmonograph, CEE 2002). This value is used in this risk assessment.

2.1.5. Data entries for operator exposure assessment for MON 78273 when applied using a tractor-mounted equipment

Table 2: Data entries for the operator exposure assessment for MON 78273 when applied using a tractor-mounted equipment

Formulation	MON 78273 (water based formulation)	
Concentration :	540 a.s./L	
Maximum application dose	4 L/ha (2.16 kg a.s/ha)	
Spray volume **Tractor mounted (with cab) hydraulic nozzles** **Tractor mounted (with cab) rotary atomizer**	 80 L/ha 40 L/ha	
Container size	5 liters	
Body weight (kg/person) [(1)]	60 kg	
Workload	50 ha/day (6 h application)	
Personal protective equipment [(2)]	**Mixing & Loading**	**Application**
	gloves	gloves
Gloves penetration factor (%/100)	0.05	0.10
Penetration through protective clothing (%/100) **UK-POEM** **Hydraulic Nozzles: trunk-level / leg-level** **Rotary disc atomizers: trunk-level / leg-level**	 n.a. n.a.	 0.05 / 0.15 0.05 / 0.05
Skin penetration factor (%/100) [(3)]	0.03	0.03
Bio-availability from inhalation (%/100)	1 (if applicable)	1

[(1)] Default in UK-POEM

[(2)] Three scenarios were evaluated: 1) no gloves during any exposure event, 2) gloves during mixing & loading and 3) gloves during all exposure events.

[(3)] End-points list of the review report of glyphosate

2.2. Exposure results for tractor-mounted application of MON 78273

2.1.1. Potential, actual and absorbed dose calculations

The calculations of the potential, actual and systemic exposure (absorbed dose) according to the UK-POEM were done using Excel spreadsheets. Calculations for tractor-mounted applications are presented into detail in Annex 1. Data entries are based on table 2.

The summaries for the three scenarios (1) no gloves during mixing and loading nor application, 2) gloves during M&L but not during application and 3) gloves during M&L and application), are listed in table 3.

Standard protective garments are worn during all exposure events for the three scenarios.

Table 3: Total absorbed dose calculations for a tractor mounted (with cab) application of MON 78273 according to the UK-POEM model

Gloves during mixing and loading	Gloves during application	Total systemic exposure (mg a.s./kg bw/day)	
		Hydraulic nozzles	Rotary atomisers
No	No	0.70	0.38
Yes	No	0.59	0.28
Yes	Yes	0.12	0.06

3. HAND-HELD APPLICATION OF MON 78273

3.1. Exposure scenarios

3.1.1. TIER 2a

3.1.1.1. Good agricultural practices

Tables 4 summarises the rates and the spray volumes recommended for the application of MON 78273 in UK field conditions using hand-held equipment. Based on this information, a realistic worst-case scenario is evaluated for each type of sprayer (hydraulic nozzles and rotary atomisers).

Table 4: Summary of GAP for hand-held application of MON 78273 in UK field conditions

Equipment	Use	Maximum rate (kg a.s./ha)	Recommended application volumes (L/ha)
Hand-held: Hydraulic nozzles	Natural surfaces not intended to bear vegetation, hard surfaces, green cover on land temporarily out of production	***2.16***	**80** - 300
	Forestry, post-planting	6.6 (Rhododendron)	500
Hand-held: Rotary disc atomisers	Natural surfaces not intended to bear vegetation, hard surfaces, green cover on land temporarily out of production	***2.16***	***40***

3.1.1.2. Workload

The default area when spraying downward using hand-held equipment is 1 ha/day (6 hours/day) in the UK-POEM model

3.1.1.3. Protective equipment

Four scenarios are evaluated with regard of protective equipment:

- Scenario 1: with gloves during mixing & loading only
- Scenario 2: with gloves during mixing & loading and during application
- Scenario 3: with gloves during mixing & loading and during application
- Scenario 4: with gloves during mixing & loading and during application, rubber boots and impermeable coverall

3.1.1.4. Dermal uptake

In vitro studies on human skin and *in vivo* studies on rhesus monkeys were carried out with glyphosate or respective preparations. On the basis of the assessment of all studies available, the rapporteur proposed a value of 3% for the dermal absorption (Glyphosate~~European~~ ~~m~~Monograph~~, CEE 2002~~). This value is used in this risk assessment.

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3.1.1.5. Data entries for operator exposure assessment for MON 78273 when applied using hand-held equipment

Table 5: Data entries for the operator exposure assessment for MON 78273 when applied using hand-held equipment

Formulation	MON 78273 (water based formulation)	
Concentration :	540 a.s./L	
Maximum application dose	4 L/ha (2.16 kg a.s/ha)	
Spray volume **Hand-held hydraulic nozzles** **Hand-held rotary atomizer**	 80 L/ha 40 L/ha	
Container size	5 liters	
Body weight (kg/person) [(1)]	60 kg	
Workload	1 ha/day (6 h application)	
Personal protective equipment [(2)]	**Mixing & Loading**	**Application**
	gloves	gloves
Gloves penetration factor (%/100)	0.05	0.10
Penetration through *permeable* protective clothing (%/100) **UK-POEM** **Hydraulic Nozzles: trunk-level / leg-level** **Rotary disc atomizers: trunk-level / leg-level** **Penetration through *impermeable* protective clothing (%/100)**	 n.a. n.a. n.a.	 0.2 / 0.18 0.05 / 0.2 0.05
Skin penetration factor (%/100) [(3)]	0.03	0.03
Bio-availability from inhalation (%/100)	1 (if applicable)	1

[(1)] Default in UK-POEM
[(2)] Three scenarios were evaluated: 1) no gloves during any exposure event, 2) gloves during mixing & loading and 3) gloves during all exposure events.
[(3)] End-points list of the review report of glyphosate

3.1.2. TIER 2b

The tier 2b approach provides a more realistic exposure assessment, taking into account more accurate data on the protection factors provided by personal protective equipment (PPE).

3.1.2.1. Penetration through protective gloves

The refinement of permeation factor for gloves is based on a permeation testing conducted by Chemrest Company (http://www.chemrest.com).

Chemrest Company tested three different unsupported protective gloves for permeation of Glyphosate from Roundup formulation. Permeation testing was conducted in accordance with ASTM method F739 "Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids and Gases Under Conditions of Continuous Contact. Test method for Permeation of Gases."
For the determination of the breakthrough time, a specimen of the glove was cut and mounted in a dual compartment cell with the outer surface facing up. The outer surface of the specimen was immersed for 8 full hours at 25 degrees C. At time interval, the unexposed "interior" side of the test cell was checked for the presence of permeated chemical and the extent to which it may have permeated the glove material.

It is worth noting that this method represents a very worst-case scenario as a continuous immersion of the glove in the test substance is assumed. In actual field conditions, however, the exposure is expected to be primarily by occasional spills and splashes but not from continuous immersion. In absence of other testing, the results obtained with the above method will be taken into account for the purpose of refining the exposure assessment during mixing, loading and application.

The results for glove material tested using the ASTM method F739 are shown in table 6.

Table 6: Permeation results of Roundup using the ASTM F739

Glove material	Breakthrough time in hours
Viton / butyl	> 8
Nitrile	> 8
Butyl rubber	> 8

Taking into consideration that a daily mixing and loading operation takes less than 1 hour an that the daily workload for application is six hours, the results show that the tested gloves material provide full skin protection against Roundup formulation.
Notwithstanding the fact that no skin exposure occurs during mixing, loading and application when gloves of the above material are worn, ~~still~~ a permeation factor of 0.01 (1%~~/100~~) is taken as refinement in the UK-POEM. This factor takes into account exposure that can occur when putting on and taking off the gloves. This value is well in line with what was observed in the US dosimetry studies (see section 3.2.3). Indeed, hand exposure values (when gloves are worn) in US studies were calculated to be 10 to 100 times lower than the value proposed in UK POEM.

3.1.2.2. Exposure scenarios evaluated

One scenario was evaluated with regards to protective equipment:

- with gloves during mixing & loading and during application, rubber boots and impermeable coverall

3.1.3. TIER 3

At tier 3 level, the results obtained from US passive dosimetry studies (Cowell J.E., 1990 MSL-9655 and MSL-9656) were used to refined the specific exposure values defined in the UK-POEM when spraying with hand-held equipment.
In these US studies, only hand-held equipment with hydraulic nozzles was evaluated. Therefore, it was only possible to refine the exposure assessment for the hand-held hydraulic nozzles application. Exposure was not calculated for hand-held RDA at tier 3 level.

3.1.3.1. US passive dosimetry and biomonitoring studies

From 1986 to 1988, the USDA forestry service and Monsanto have sponsored studies (Cowell J.E and Steinmetz J.R., 1990 MSL-9655 and MSL 9656) to determine the exposure of forest nursery and forest workers to glyphosate while performing backpack foliar application of Roundup (SL formulation containing 360 g glyphosate acid/L). The systemic exposure was quantified using passive dosimetry (patch test and hand rinses). The total absorbed dose was evaluated by determination of glyphosate in urine.
It is worth noting that those studies illustrate a worst-case for exposure during backpack application. Indeed, the vegetation height is generally greater in forestry area than in field area and thus increase the exposure of the legs during spraying.

The forest Nursery study (MSL-9655) presents the results from two pine seedling nurseries: Ashe, Mississipi and Elkton, Oregon. In this study three types of worker functions were investigated:
Tractor applicators: Mixed/loaded glyphosate into the spray tank and applied the mixture to various roadsides, ditch, bank and fallow nursery bed
Weeders: Only at Ashe, Mississipi, used hand-held sprayers with shielded nozzles to selectively apply glyphosate to weeds in and around pine seedling beds. One of the weeders in addition to spraying also mixed spray solutions and filled sprayers for the other sprayers.
Scouts: Scanned pine seedling nursery beds to estimate the pest populations/damage.
Only the weeders exposure during application is considered here, illustrating a hand-held application of glyphosate.

The forest study (MSL-9656) was conducted at three sites maintained by the USDA forestry service near Clayton, Georgia, the Savannah River Plant, South Carolina, and Edgefield, South Carolina. gGlyphosate was used to control vegetative growth around pine seedlings planted in clear-cut forest areas. The operation monitored was the backpack sprayer application of glyphosate. One of the workers at each site, in addition to spraying, also measured and mixed the solution for the others of the work crew.

The exposure values derived from these studies are later expressed in ml/hr spray solution applied so that they can be extrapolated to the UK worst-case conditions.

A. Application conditions

- MSL-9655: Forest Nursery study

Hand-held applications were monitored. Applications were made with hand-held sprayers with shielded nozzles using directed spray, spot treatment application technique. Workers wore normal protective clothing: cotton clothing, rubber boots and gloves.
Spray operatorsWeeders worked for 8 hours and applied 1,89 L of 9 g a.e./L solution per trip. Four trips were made each day for a total of 68.04 g glyphosate handled each day.
One of the workerweeders also mixed and filled the sprayers for all the other operatorsweeders. The exposure monitored for this workerweeder represents the exposure occurring during, mixing, loading and application.
Only the exposure values during application will be considered further for extrapolation to the UK worst-case conditions.

- MSL-9656: Forest study

Backpack applications were monitored. Roundup herbicide was applied using a backpack sprayer: Ssolo model 475 diaphragm pump backpack with a spraying system model 30 Gunjet, or a wand tip No TP2503. Workers wore normal protective clothing: cotton clothing, rubber boots and gloves.
Workers worked for 8 hours/day. The concentration for the spray solution was 10.8 g a.e./L.

B. *Sampling techniques*

- MSL-9655: Forest Nursery study

- Clothing and skin deposition sampling
The deposition on the hand was monitored by the use of hand rinses. Hand rinses were taken from each worker at the end of the day of each worker. A solution of ethanol/water (1:9) was placed in a large plastic bag, the hands were then inserted and shaken. The rinsing solution was then analysed for glyphosate residues.

The deposition onto or under clothing was monitored using gauze patches of 10 cm x 10 cm. The parts of the body where patches were placed on the outside of the applicator's are described in table 7.

Table 7: Patches location (MSL-9655)

Location of Patches	Body region represented
Ankle pads combined left and right	Lower leg
Thigh pads combined left and right	Thigh
Forearm pads combined left and right	Forearm
Chest pad	Chest/stomach/ front of neck
Back pad	Back/back of neck
Head pad	Head

One patch was placed under clothing on right and left forearm.
Only the data on the deposition of Glyphosate on outside de clothing are used for this risk assessment.

- MSL-9656: Forest study

- Clothing and skin deposition sampling
The deposition on the hand was monitored by the use of hand rinses. Hand rinses at each break food is to be consumed and at the end of the work shift. A solution of 1% Liqui-Nox was placed in a large plastic bag, the hands were then inserted and shaken. The hand-wash samples were then analysed for glyphosate residues.

The deposition onto or under clothing was monitored using gauze patches of 10 cm x 10 cm. The parts of the body where patches were placed on the outside of the applicator's clothing are detailed in the table 8.

Table 8: Patches locations (MSL-9656)

Location of Patches	Body region represented
Mean of Shin and calf (left and right)	Lower leg
Mean of Thigh (left and right)	Thigh
Mean of Forearm (left and right)	Forearm
Shoulder (left and right)	Upper arm
Chest	Chest/stomach/ front of neck
Back	Back/back of neck
Mean of shoulder, back and chest	Head

The parts of the body where patches were placed under the clothing are right forearm, left thigh and chest. Only the data on the deposition of glyphosate on outside de clothing are used for this risk assessment.

- Air sampling

Glass fibre air filters were attached at the end of a tube which was attached to personal, battery operated air pump attached to the waist of the subject. The air filter was attached to the shoulder near the subject's breathing area.

C. Method of determination

The gauze pads worn by the test subjects and the air filters were analysed for Glyphosate residues using an analytical method which consist of water extraction, direct injection or concentration by evaporation, and quantification by HPLC/OPA post column reactor with fluorescence detection.
Hand rinses were analysed by direct injection first and concentrated by evaporation if below direct injection validation limits. Quantification was also performed by HPLC/OPA post column reactor with fluorescence detection.

The mean recoveries and the limit of quantification (LOQ) for the different media used in the study are presented in table 9.

Table 9: Recovery and LOQ derived from fortification studies

Sampling technique		**Study MSL-9655**		**Study MSL-9656**	
		Recovery (%)	**LOQ**	**Recovery (%)**	**LOQ**
Air	Glass air filter	NA	NA	99.1	0.5 µg/filter
Dermal	Gauze pads	97.4	1 µg/pad	96.9	1 µg/pad
	Hand rinses	99.8	0.02 µg/ml	83.5	0.02 µg/ml

3.2. Exposure results for handheld application of MON 78273

3.2.1. TIER 2a

3.2.1.1. Potential, actual and absorbed dose calculations

The calculations of the potential, actual and systemic exposure (absorbed dose) according to the UK-POEM were done using Excel spreadsheets. Calculations for hand-held applications are presented into detail in Annex 2 and Annex 3 for hydraulic nozzles and rotary atomisers respectively. Data entries are based on table 5.

The summaries for the four scenarios (1) no gloves during mixing and loading nor application, 2) gloves during M&L but not during application and 3) gloves during M&L and application, 4) gloves during M&L and application, rubber boots and impermeable coverall are listed in table 10.

Table 10: Total absorbed dose calculations for a handheld application of MON 78273 according to the UK-POEM model

Gloves during mixing and loading	Gloves during application	Total systemic exposure (mg a.s./kg bw/day)	
		Hydraulic nozzles	Rotary atomisers
Permeable coverall			
No	No	1.44	0.95
Yes	No	1.43	0.94
Yes	Yes	0.72	0.65
Impermeable coverall			
Yes	Yes	0.31	0.23

3.2.2. TIER 2b exposure results for hand-held application of MON 78273

3.2.2.1. Potential, actual and absorbed dose calculations

The calculations of the potential, actual and systemic exposure (absorbed dose) according to the UK-POEM were done using Excel spreadsheets. Tier 2b ~~c~~Calculations for hand-held applications (Hydraulic nozzles and RDA) are presented into detail in Annex 4. The assumptions used at tier 2b ~~level~~ are described in detail in section 3.1.2.
The results are shown in table 11.

Table 11: Total absorbed dose calculation for a hand-held application of MON 78273 according to the UK POEM model: gloves at all time + boots + impermeable coverall

Gloves during mixing and loading	Gloves during application	Total systemic exposure (mg a.s./kg bw/day)	
		Hydraulic nozzles	Rotary atomisers
Yes	Yes	0.22	0.20

3.2.3. TIER 3 exposure results for hand-held application of MON 78273

3.2.3.1. Specific exposure values derived from passive dosimetry studies

Specific exposure values (expressed in ml/hr of spray solution) were derived from the exposure data obtained in the two US passive dosimetry studies. Only the application phase was evaluated.
Specific exposure values (in ml/hr) were calculated for trunk, head, legs, hands and inhalation for each of the selected workers. Detailed calculations are given in annex 5 of this report. The 75th percentile exposure value was selected for this risk assessment. Table 12 summarises the 75th percentile exposure values calculated for each body parts.

Table 12: 75th percentile specific exposure values (ml/hr)

Body part	**Specific exposure (ml/hr) – 75th percentile**
Dermal	
Hands	0.014
Trunk	0.4
Head	0.034
Legs	3.33
Inhalation	
Inhalation	0.001

3.2.3.2. Hand-held hydraulic nozzles: calculation of the absorbed dose

Absorbed dose during mixing and loading was calculated using the default assumptions described in the UK POEM model. Absorbed dose during application was calculated based on the specific exposure value derived from the two US monitoring studies (MSL-9655 and MSL-9656).
An overview of the assumptions used at tier 3 ~~level~~ is given in table 13.

Table 13: assumptions used to calculate and extrapolate tier 3 exposure estimates based on the US monitoring studies

Parameter	Value	Source
Applicator weight	60 kg	Default UK-POEM
Bioavailability factor for inhalation	1	
Gloves permeation concentrated formulation	0.01	Chemrest study
Clothing permeation factor at trunk: Permeable coverall Impermeable coverall	 0.2 0.05	Default – UK POEM
Clothing permeation factor at legs: Permeable coverall Impermeable coverall	 0.18 0.05	Default - UK POEM
Skin penetration factor concentrated and diluted formulation	0.03	List of end points of the EU review report of glyphosate
Application rate	2.16 kg a.s./ha	Product label
Volume of spray solution (L/ha)	80 L/ha	Product label

Two scenarios were evaluated with regards to protective equipment:

- Scenario 1: with gloves during mixing & loading and during application, permeable coverall
- Scenario 2: with gloves during mixing & loading and during application, rubber boots and impermeable coverall

Results are presented in tables 14 and 16.

- Mixing and loading

Table 14: Calculation of the absorbed dose during mixing and loading at tier 3 level

Body part	Specific dermal exposure (ml/operation)	Number of operation / day	Gloves permeation factor	Skin penetration factor	Absorbed dose (mg/day)
Hands	0.01	5	0.01	0.03	0.00015

- Application

- ***Permeable coverall***

Table 15: Calculation of absorbed dose during field application at tier 3 level – permeable coverall

Body part	Specific exposure (ml/h)	UK daily workload (h/day)	Concentration of solution (mg/ml)	Clothing permeation factor	Skin penetration factor	Absorbed dose (mg/day)
	A	B	C	D	E	AxBxCxDxE
Dermal						
Hands	0.014	6	27	NA	0.03	0.068
Trunk	0.4	6	27	0.2	0.03	0.388
Head	0.034	6	27	NA	0.03	0.165
Legs	3.33	6	27	0.18	0.03	2.913
Inhalation						
Inhalation	0.001	6	27	NA	1	0.162
Total						3.696

- ***Impermeable coverall***

Table 16: Calculation of absorbed dose during field application at tier 3 level – impermeable coverall

Body part	Specific dermal exposure (ml/h)	UK daily workload (h/day)	Concentration of solution (mg/ml)	Clothing permeation factor	Skin penetration factor	Absorbed dose (mg/day)
	A	B	C	D	E	AxBxCxDxE
Dermal						
Hands	0.014	6	27	NA	0.03	0.068
Trunk	0.4	6	27	0.05	0.03	0.097
Head	0.034	6	27	NA	0.03	0.165
Legs	3.33	6	27	0.05	0.03	0.8092
Inhalation						
Inhalation	0.001	6	27	NA	1	0.162
Total						1.3012

Total absorbed dose

The total absorbed dose for glyphosate is the sum of the dose absorbed through dermal contact and the dose absorbed through inhalation during mixing and loading and field application:

- ***Scenario 1: Permeable coverall***

  0.00015 mg/day + 3.696 mg/day = 3.696015 mg/day

  For a 60 kg person applying 1ha/day, the total absorbed dose is **0.061 mg/kg bw/day.**

- ***Scenario 2: Impermeable coverall***

  0.00015 mg/day + 1.3012mg/day = 1.3014 mg/day

  For a 60 kg person applying 1ha/day, the total absorbed dose is **0.021 mg/kg bw/day.**

4. HAZARD ASSESSMENT : The Acceptable operator exposure level (AOEL)

The AOEL is based on a (short term) Teratogenicity study in rabbits (Tasker 1980)
Artificially inseminated Dutch Belted rabbits were administred glyphosate technical as an 0.5% aqueous suspension in Methocel® at a constant dosing volume of 1 ml/kg once daily from gestation days 6 through 27 by oral gavage. The dose levels where 0; 75; 175 and 350 mg/kg bw/day. The maternal body weight was not affected.
According to the study report definite signs of maternal toxicity as an increase of frequency of soft stool, diarrhea and nasal discharge were observed at the highest dose level and to a lesser extent at 175 mg/kg bw/day.
Intercurrent deaths were confined to the treated groups with a total number of 1, 2 and 10 rabbits in the low, mid and high dose group, respectively. The cause of death could not be elicted and one can't exclude that these deaths were treatment related. Thus the low dose of 75 mg/kg bw/day was assumed to represent the NOEL for maternal effects. A NOEL of 350 mg/kg bw/ day was established for developmental toxicity.

The AOEL was based on the NOEL of 75 mg/kg bw/day as this is the dose at which no signs of maternal toxicity were observed in rabbits. Using an assessment factor (AF) of 100, an oral AOEL of 0.75 mg/kg bw/day could be established. In order to derive a systemic AOEL 30% oral absorption was taken into account. The approximate systemic AOEL becomes : **0.2 mg/kg bw/day.**

5. RISK EVALUATION

The total absorbed dose obtained through UK-POEM model is compared against the systemic AOEL of 0.2 mg/kg bw/day for risk characterisation. The percentage of AOEL calculated for tractor-mounted and hand-held application are shown in tables 17 and 18 respectively.

5.1. Tractor mounted (with cab) application

Table 17: Absorbed dose data and % of AOEL obtained for tractor-mounted applications

Exposure scenario	Hydraulic nozzles		Rotary disc atomizers	
	Absorbed dose (mg/kg bw/day)	% of systemic AOEL	Absorbed dose (mg/kg bw/day)	% of systemic AOEL
No gloves	0.70	***350***	0.38	***190***
Gloves during mix & load	0.59	***295***	0.28	***140***
Gloves at all time	0.12	***60***	0.06	***30***

5.2. Hand-held application

An overview of the absorbed doses that have been calculated for the three tier levels is given in table 18. These absorbed doses are then compared against the systemic AOEL of 0.2 mg/kg bw/day.

Table 18: Absorbed dose data and % of AOEL obtained for hand-held applications at the three tier levels

Tier Level	Exposure scenario	Hydraulic nozzles		Rotary disc atomizers	
		Absorbed dose (mg/kg bw/day)	% of systemic AOEL	Absorbed dose (mg/kg bw/day)	% of systemic AOEL
Tier 2a	No gloves	1.44	***720***	0.95	***475***
	Gloves during mix & load	1.43	***715***	0.94	***470***
	Gloves at all time	0.72	***360***	0.65	***325***
	Gloves at all time Rubber boots Impermeable coverall	0.31	***155***	0.23	***115***
Tier 2b	Gloves at all time Rubber boots Impermeable coverall	0.22	***110***	0.2	***100***
Tier 3	Gloves at all time Permeable coverall	0.06	***30***	NA	NA
	Gloves at all time Rubber boots Impermeable coverall	0.02	***10***	NA	NA

6. DISCUSSION AND CONCLUSION

The risk associated with the professional handling of MON 78273 was assessed according to a tiered or stepwise approach.
In view of access to the dermal penetration data in human skin, no tier 1 assessment was made.

The exposure during tractor-mounted application was estimated at tier 2 ~~level~~, considering product specific dermal penetration. The risk evaluation based on the UK POEM model shows that where no gloves are worn during any of the exposure events, the systemic exposure exceeded the AOEL. When Gloves are worn at all times (mixing, loading and application) the exposure is reduced to an acceptable level: 60% and 30% of the AOEL for hydraulic nozzles and rotary atomisers respectively.

For hand-held application, the tier 2 was subdivided in two parts: one part (tier 2a) using the default gloves reduction factor as proposed by the model whereas the second part (tier 2b) takes into consideration product specific gloves reduction factor.

At the tier 2a level, when considering the default gloves penetration factor as proposed by the model, AOEL is exceeded for both types of sprayers (hydraulic nozzles and rotary disc atomisers), even when gloves are worn at all time and impermeable protective clothing during application.

At the tier 2b level, the absorbed dose calculated using the UK-POEM model corresponds to 110% and 100% of the AOEL for hydraulic nozzles and rotary disc atomisers respectively, when gloves are worn at all time and impermeable protective clothing during application.

At tier 3 level, the exposure estimates for application using hand-held hydraulic nozzles were refined based on product specific passive dosimetry studies. Results ~~obtained~~ demonstrate that no health effects are to be expected from professional application using hand-held hydraulic nozzles equipment when gloves are worn at all time (mixing, loading and application).

Based on the risk evaluation, the label recommendations will be the following:

- Wear suitable protective gloves when handling the concentrate and the diluted product.
- Wear suitable protective clothing (water-proof jacket & trousers), suitable gloves and rubber boots when using hand held sprayers fitted with low volume hydraulic nozzles and when using ~~in~~ hand-held rotary atomisers

References

Cowell J.E. and Steinmetz J.R. (1990). Assessment of forestry nursery workers exposure to Glyphosate during normal operations. Monsanto report MSL-9655.

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Pesticides safety Directorate (1986). UK Predictive Exposure Model (POEM): Estimation of exposure and absorption of pesticides by spray operators. UK scientific subcommittee on presticides & British agrochemical association. Joint Medical Panel.PS 4221, SC8001.

ANNEX I : Results for tractor mounted (with cab) application

AI.1. HYDRAULIC NOZZLES

AI.1.1. Tractor-mounted Hydraulic nozzles : Scenario 1 - No gloves

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*27*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*50*	ha / day
4.	No of operations per day :	*40*	/ day
5.	Contamination / day :	*0.4*	ml / day
6.	Protective clothing :	*0*	
7.	Penetration of gloves :	*100*	%
8.	Dermal exposure to formulation	*0.4*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1	Application technique :	*Vehicle Mounted (with Cab) Hydraulic Nozzles.*					
2.	Application volume :			*80*	litres spray / ha		
3.	Volume of surface contamination :			*10*	ml/h		
		HANDS		TRUNK		LEGS	
4.	Distribution :	*65*	%	*10*	%	*25*	%
5.	Clothing :	*0*		*permeable*		*permeable*	
6.	Penetration :	*100*	%	*5*	%	*15*	%
7.	Dermal exposure :	*6.5*	ml/h	*0.05*	ml/h	*0.375*	ml/h
8.	Duration of exposure :	*6*	hours				
9.	Total dermal exposure to spray :	*41.55*	ml / day				

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.4*	ml / day	*41.55*	ml/day
2.	Concentration of ai	*540*	mg/ml	*27*	mg/ml
3.	Dermal Exposure to ai	*216*	mg/day	*1121.85*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*6.48*	mg/day	*33.6555*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.01*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*27*	mg/ml
4.	Inhalation exposure to ai :	*1.62*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*1.62*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*41.76*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.695925*	mg / kg body weight /day

AI.1.2. Tractor-mounted Hydraulic nozzles: Scenario 2 - Gloves during M&L

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*27*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*50*	ha / day
4.	No of operations per day :	*40*	/ day
5.	Contamination / day :	*0.4*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.02*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1 Application technique : *Vehicle Mounted (with Cab) Hydraulic Nozzles.*

2. Application volume : *80* litres spray / ha

3. Volume of surface contamination : *10* ml/h

		HANDS		TRUNK		LEGS	
4.	Distribution :	*65*	%	*10*	%	*25*	%
5.	Clothing :	*0*		*permeable*		*permeable*	
6.	Penetration :	*100*	%	*5*	%	*15*	%
7.	Dermal exposure :	*6.5*	ml/h	*0.05*	ml/h	*0.375*	ml/h

8.	Duration of exposure :	*6*	hours
9.	Total dermal exposure to spray :	*41.55*	ml / day

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.02*	ml / day	*41.55*	ml/day
2.	Concentration of ai	*540*	mg/ml	*27*	mg/ml
3.	Dermal Exposure to ai	*10.8*	mg/day	*1121.85*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.324*	mg/day	*33.6555*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.01*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*27*	mg/ml
4.	Inhalation exposure to ai :	*1.62*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*1.62*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*35.60*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.593325*	mg / kg body weight /day

AI.1.3. Tractor-mounted Hydraulic nozzles: Scenario 3 - Gloves during M&L and application

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*27*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*50*	ha / day
4.	No of operations per day :	*40*	/ day
5.	Contamination / day :	*0.4*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.02*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1 Application technique : *Vehicle Mounted (with Cab) Hydraulic Nozzles.*

2.	Application volume :	*80*	litres spray / ha
3.	Volume of surface contamination :	*10*	ml/h

	HANDS	TRUNK	LEGS
4. Distribution :	*65* %	*10* %	*25* %
5. Clothing :	*gloves*	*permeable*	*permeable*
6. Penetration :	*10* %	*5* %	*15* %
7. Dermal exposure :	*0.65* ml/h	*0.05* ml/h	*0.375* ml/h

8.	Duration of exposure :	*6*	hours
9.	Total dermal exposure to spray :	*6.45*	ml / day

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.02*	ml / day	*6.45*	ml/day
2.	Concentration of ai	*540*	mg/ml	*27*	mg/ml
3.	Dermal Exposure to ai	*10.8*	mg/day	*174.15*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.324*	mg/day	*5.2245*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.01*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*27*	mg/ml
4.	Inhalation exposure to ai :	*1.62*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*1.62*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*7.17*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.119475*	mg / kg body weight /day

AI.2. ROTARY DISC ATOMIZERS

AI.2.1. Tractor-mounted RDA - Scenario 1 : No gloves

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*54*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*50*	ha / day
4.	No of operations per day :	*40*	/ day
5.	Contamination / day :	*0.4*	ml / day
6.	Protective clothing :	*0*	
7.	Penetration of gloves :	*100*	%
8.	Dermal exposure to formulation	*0.4*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1 Application technique : *Vehicle Mounted (with Cab) Rotary Disc Atomizers.*

2.	Application volume :	*40*	litres spray / ha
3.	Volume of surface contamination :	*2*	ml/h

		HANDS		TRUNK		LEGS	
4.	Distribution :	*75*	%	*15*	%	*10*	%
5.	Clothing :	*0*		*permeable*		*permeable*	
6.	Penetration :	*100*	%	*5*	%	*5*	%
7.	Dermal exposure :	*1.5*	ml/h	*0.015*	ml/h	*0.01*	ml/h

8.	Duration of exposure :	*6*	hours
9.	Total dermal exposure to spray :	*9.15*	ml / day

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.4*	ml / day	*9.15*	ml/day
2.	Concentration of ai	*540*	mg/ml	*54*	mg/ml
3.	Dermal Exposure to ai	*216*	mg/day	*494.1*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*6.48*	mg/day	*14.823*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.005*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*54*	mg/ml
4.	Inhalation exposure to ai :	*1.62*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*1.62*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*22.92*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.38205*	mg / kg body weight /day

AI.2.2 Tractor-mounted RDA - Scenario 2 :Gloves during M&L

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*54*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*50*	ha / day
4.	No of operations per day :	*40*	/ day
5.	Contamination / day :	*0.4*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.02*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1 Application technique : *Vehicle Mounted (with Cab) Rotary Disc Atomizers.*

2.	Application volume :	*40*	litres spray / ha
3.	Volume of surface contamination :	*2*	ml/h

		HANDS		TRUNK		LEGS	
4.	Distribution :	*75*	%	*15*	%	*10*	%
5.	Clothing :	*0*		*permeable*		*permeable*	
6.	Penetration :	*100*	%	*5*	%	*5*	%
7.	Dermal exposure :	*1.5*	ml/h	*0.015*	ml/h	*0.01*	ml/h

8.	Duration of exposure :	*6*	hours
9.	Total dermal exposure to spray :	*9.15*	ml / day

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.02*	ml / day	*9.15*	ml/day
2.	Concentration of ai	*540*	mg/ml	*54*	mg/ml
3.	Dermal Exposure to ai	*10.8*	mg/day	*494.1*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.324*	mg/day	*14.823*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.005*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*54*	mg/ml
4.	Inhalation exposure to ai :	*1.62*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*1.62*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*16.77*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.27945*	mg / kg body weight /day

AI.2.3. Tractor-mounted RDA - Scenario 3 : Gloves during mixing and loading

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*54*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*50*	ha / day
4.	No of operations per day :	*40*	/ day
5.	Contamination / day :	*0.4*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.02*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1 Application technique : *Vehicle Mounted (with Cab) Rotary Disc Atomizers.*

2. Application volume : *40* litres spray / ha

3. Volume of surface contamination : *2* ml/h

		HANDS		TRUNK		LEGS	
4.	Distribution :	*75*	%	*15*	%	*10*	%
5.	Clothing :	*gloves*		*permeable*		*permeable*	
6.	Penetration :	*10*	%	*5*	%	*5*	%
7.	Dermal exposure :	*0.15*	ml/h	*0.015*	ml/h	*0.01*	ml/h

8.	Duration of exposure :	*6*	hours
9.	Total dermal exposure to spray :	*1.05*	ml / day

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.02*	ml / day	*1.05*	ml/day
2.	Concentration of ai	*540*	mg/ml	*54*	mg/ml
3.	Dermal Exposure to ai	*10.8*	mg/day	*56.7*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.324*	mg/day	*1.701*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.005*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*54*	mg/ml
4.	Inhalation exposure to ai :	*1.62*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*1.62*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*3.65*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.06075*	mg / kg body weight /day

ANNEX II : Tier 2a EXPOSURE RESULTS – HANDHELD EQUIPMENT HYDRAULIC NOZZLES

AII.1. TIER 2a: Scenario 1 : No gloves

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*27*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*5*	/ day
5.	Contamination / day :	*0.05*	ml / day
6.	Protective clothing :	*0*	
7.	Penetration of gloves :	*100*	%
8.	Dermal exposure to formulation	*0.05*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1	Application technique :	*Hand held Outdoors Hydraulic Nozzles : Low level Application.*					
2.	Application volume :			*80*	litres spray / ha		
3.	Volume of surface contamination :			*50*	ml/h		
		HANDS		TRUNK		LEGS	
4.	Distribution :	*25*	%	*25*	%	*50*	%
5.	Clothing :	*0*		*permeable*		*permeable*	
6.	Penetration :	*100*	%	*20*	%	*18*	%
7.	Dermal exposure :	*10*	ml/h	*2.5*	ml/h	*4.5*	ml/h
8.	Duration of exposure :	*6*	hours				
9.	Total dermal exposure to spray :	*102*	ml / day				

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.05*	ml / day	*102*	ml/day
2.	Concentration of ai	*540*	mg/ml	*27*	mg/ml
3.	Dermal Exposure to ai	*27*	mg/day	*2754*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.81*	mg/day	*82.62*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.02*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*27*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*86.67*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*1.4445*	mg / kg body weight /day

AII.2. TIER 2a - Scenario 2 : Gloves during M&L

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*27*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*5*	/ day
5.	Contamination / day :	*0.05*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.0025*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1	Application technique :	*Hand held Outdoors Hydraulic Nozzles : Low level Application.*					
2.	Application volume :					*80*	litres spray / ha
3.	Volume of surface contamination :					*50*	ml/h
		HANDS		TRUNK		LEGS	
4.	Distribution :	*25*	%	*25*	%	*50*	%
5.	Clothing :	*0*		*permeable*		*permeable*	
6.	Penetration :	*100*	%	*20*	%	*18*	%
7.	Dermal exposure :	*10*	ml/h	*2.5*	ml/h	*4.5*	ml/h
8.	Duration of exposure :	*6*	hours				
9.	Total dermal exposure to spray :	*102*	ml / day				

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.0025*	ml / day	*102*	ml/day
2.	Concentration of ai	*540*	mg/ml	*27*	mg/ml
3.	Dermal Exposure to ai	*1.35*	mg/day	*2754*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.0405*	mg/day	*82.62*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.02*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*27*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*85.90*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*1.431675*	mg / kg body weight /day

AII.1.3. TIER 2a - Scenario 3 : Gloves at all time

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*27*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*5*	/ day
5.	Contamination / day :	*0.05*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.0025*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1	Application technique :	*Hand held Outdoors Hydraulic Nozzles : Low level Application.*					
2.	Application volume :					*80*	litres spray / ha
3.	Volume of surface contamination :					*50*	ml/h
		HANDS		TRUNK		LEGS	
4.	Distribution :	*25*	%	*25*	%	*50*	%
5.	Clothing :	*gloves*		*permeable*		*permeable*	
6.	Penetration :	*10*	%	*20*	%	*18*	%
7.	Dermal exposure :	*1.25*	ml/h	*2.5*	ml/h	*4.5*	ml/h
8.	Duration of exposure :			*6*	hours		
9.	Total dermal exposure to spray :			*49.5*	ml / day		

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.0025*	ml / day	*49.5*	ml/day
2.	Concentration of ai	*540*	mg/ml	*27*	mg/ml
3.	Dermal Exposure to ai	*1.35*	mg/day	*1336.5*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.0405*	mg/day	*40.095*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.02*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*27*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*43.38*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.722925*	mg / kg body weight /day

AII.4. TIER 2a - Scenario 4: Gloves at all time, rubber boots + impermeable coverall

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*water*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*27*	mg/ml

EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*5*	/ day
5.	Contamination / day :	*0.05*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.0025*	ml / day

EXPOSURE DURING SPRAY APPLICATION

1	Application technique :	*Hand held Outdoors Hydraulic Nozzles : Low level Application.*					
2.	Application volume :					*80*	litres spray / ha
3.	Volume of surface contamination :					*50*	ml/h
		HANDS		TRUNK		LEGS	
4.	Distribution :	*25*	%	*25*	%	*50*	%
5.	Clothing :	*gloves*		*impermeable*		*impermeable*	
6.	Penetration :	*10*	%	*5*	%	*5*	%
7.	Dermal exposure :	*1.25*	ml/h	*0.625*	ml/h	*1.25*	ml/h
8.	Duration of exposure :		*6*	hours			
9.	Total dermal exposure to spray :		*18.75*	ml / day			

SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.0025*	ml / day	*18.75*	ml/day
2.	Concentration of ai	*540*	mg/ml	*27*	mg/ml
3.	Dermal Exposure to ai	*1.35*	mg/day	*506.25*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.0405*	mg/day	*15.1875*	mg/day

INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.02*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*27*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

PREDICTED EXPOSURE

1	Total dose absorbed	*18.47*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.308*	mg / kg body weight /day

ANNEX III : TIER 2a EXPOSURE RESULTS – HAND-HELD EQUIPMENT ROTARY DIS ATOMIZERS

AIII.1. TIER 2a: Scenario 1: no gloves

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*54*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*3*	/ day
5.	Contamination / day :	*0.03*	ml / day
6.	Protective clothing :	*0*	
7.	Penetration of gloves :	*100*	%
8.	Dermal exposure to formulation	*0.03*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1	Application technique :	*Hand held Outdoors Rotary Disc Atomizers: Low level Application.*	
2.	Application volume :	*40*	litres spray / ha
3.	Volume of surface contamination :	*20*	ml/h

	HANDS		TRUNK		LEGS	
4. Distribution :	*10*	%	*5*	%	*85*	%
5. Clothing :	*0*		*permeable*		*permeable*	
6. Penetration :	*100*	%	*5*	%	*20*	%
7. Dermal exposure :	*2*	ml/h	*0.05*	ml/h	*3.4*	ml/h

8.	Duration of exposure :	*6*	hours
9.	Total dermal exposure to spray :	*32.7*	ml / day

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.03*	ml / day	*32.7*	ml/day
2.	Concentration of ai	*540*	mg/ml	*54*	mg/ml
3.	Dermal Exposure to ai	*16.2*	mg/day	*1765.8*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.486*	mg/day	*52.974*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.01*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*54*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*56.70*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.945*	mg / kg body weight /day

AIII.2. Tier 2a : Scenario 2: Gloves during M&L

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*54*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*3*	/ day
5.	Contamination / day :	*0.03*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.0015*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1 Application technique : *Hand held Outdoors Rotary Disc Atomizers: Low level Application.*

2. Application volume : *40* litres spray / ha

3. Volume of surface contamination : *20* ml/h

	HANDS		TRUNK		LEGS	
4. Distribution :	*10*	%	*5*	%	*85*	%
5. Clothing :	*0*		*permeable*		*permeable*	
6. Penetration :	*100*	%	*5*	%	*20*	%
7. Dermal exposure :	*2*	ml/h	*0.05*	ml/h	*3.4*	ml/h

8. Duration of exposure : *6* hours

9. Total dermal exposure to spray : *32.7* ml / day

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.0015*	ml / day	*32.7*	ml/day
2.	Concentration of ai	*540*	mg/ml	*54*	mg/ml
3.	Dermal Exposure to ai	*0.81*	mg/day	*1765.8*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.0243*	mg/day	*52.974*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.01*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*54*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*56.24*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.937305*	mg / kg body weight /day

AIII.3. Tier 2a : Scenario 3 – Gloves at all time

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

A. PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*0*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*54*	mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*3*	/ day
5.	Contamination / day :	*0.03*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.0015*	ml / day

C. EXPOSURE DURING SPRAY APPLICATION

1	Application technique :	*Hand held Outdoors Rotary Disc Atomizers: Low level Application.*	
2.	Application volume :	*40*	litres spray / ha
3.	Volume of surface contamination :	*20*	ml/h

	HANDS	TRUNK	LEGS
4. Distribution :	*10* %	*5* %	*85* %
5. Clothing :	*gloves*	*permeable*	*permeable*
6. Penetration :	*10* %	*5* %	*20* %
7. Dermal exposure :	*0.2* ml/h	*0.05* ml/h	*3.4* ml/h

8.	Duration of exposure :	*6*	hours
9.	Total dermal exposure to spray :	*21.9*	ml / day

D. SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.0015*	ml / day	*21.9*	ml/day
2.	Concentration of ai	*540*	mg/ml	*54*	mg/ml
3.	Dermal Exposure to ai	*0.81*	mg/day	*1182.6*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.0243*	mg/day	*35.478*	mg/day

E. INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.01*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*54*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

F. PREDICTED EXPOSURE

1	Total dose absorbed	*38.74*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.645705*	mg / kg body weight /day

AIII.4. Scenario 4: Gloves at all time, rubber boots and impermeable coverall

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*water*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*54*	mg/ml

EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*3*	/ day
5.	Contamination / day :	*0.03*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*5*	%
8.	Dermal exposure to formulation	*0.0015*	ml / day

EXPOSURE DURING SPRAY APPLICATION

1 Application technique : *Hand held Outdoors Rotary Disc Atomizers: Low level Application.*

2.	Application volume :	*40*	litres spray / ha
3.	Volume of surface contamination :	*20*	ml/h

	HANDS		TRUNK		LEGS	
4. Distribution :	*10*	%	*5*	%	*85*	%
5. Clothing :	*gloves*		*impermeable*		*impermeable*	
6. Penetration :	*10*	%	*5*	%	*5*	%
7. Dermal exposure :	*0.2*	ml/h	*0.05*	ml/h	*0.85*	ml/h

8.	Duration of exposure :	*6*	hours
9.	Total dermal exposure to spray :	*6.6*	ml / day

SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.0015*	ml / day	*6.6*	ml/day
2.	Concentration of ai	*540*	mg/ml	*54*	mg/ml
3.	Dermal Exposure to ai	*0.81*	mg/day	*356.4*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.0243*	mg/day	*10.692*	mg/day

INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.01*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*54*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

PREDICTED EXPOSURE

1	Total dose absorbed	*13.96*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.233*	mg / kg body weight /day

ANNEX IV : TIER 2b EXPOSURE RESULTS – HAND-HELD EQUIPMENT HYDRAULIC NOZZLES AND ROTARY DIS ATOMIZERS

AIV.1. HYDRAULIC NOZZLES

AIV.1.1. Tier 2b: Gloves at all time + rubber boots + impermeable coverall

With a permeation factor = 0.01 for gloves

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*water*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*27*	mg/ml

EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*5*	/ day
5.	Contamination / day :	*0.05*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*1*	%
8.	Dermal exposure to formulation	*0.0005*	ml / day

EXPOSURE DURING SPRAY APPLICATION

1	Application technique :	*Hand held Outdoors Hydraulic Nozzles : Low level Application.*					
2.	Application volume :					*80*	litres spray / ha
3.	Volume of surface contamination :					*50*	ml/h
		HANDS		TRUNK		LEGS	
4.	Distribution :	*25*	%	*25*	%	*50*	%
5.	Clothing :	*gloves*		*impermeable*		*impermeable*	
6.	Penetration :	*1*	%	*5*	%	*5*	%
7.	Dermal exposure :	*0.125*	ml/h	*0.625*	ml/h	*1.25*	ml/h
8.	Duration of exposure :			*6*	hours		
9.	Total dermal exposure to spray :			*12*	ml / day		

SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.0005*	ml / day	*12*	ml/day
2.	Concentration of ai	*540*	mg/ml	*27*	mg/ml
3.	Dermal Exposure to ai	*0.27*	mg/day	*324*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.0081*	mg/day	*9.72*	mg/day

INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.02*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*27*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

PREDICTED EXPOSURE

1	Total dose absorbed	*12.97*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.216*	mg / kg body weight /day

AIV.1. ROTARY DISC ATOMISERS

AIV.1.1. Tier 2b: Gloves at all time + rubber boots + impermeable coverall

With a permeation factor = 0.01 for gloves

ESTIMATION OF SPRAY OPERATOR EXPOSURE - PERCENT ABSORPTION METHOD

PRODUCT DATA

1.	Name :	*MON 78273*	
2a	Active Ingredient :	*glyphosate*	
2b	Concentration :	*540*	mg/ml
3.	Formulation Type :	*SL*	
4a	Main Solvent :	*water*	
4b	Concentration of solvent :	*0*	% w/w
5.	Maximum in-use ai concentration :	*54*	mg/ml

EXPOSURE DURING MIXING AND LOADING

1a	Container Size :	*5*	litres
1b	Hand contamination/operation :	*0.01*	ml / operation
2.	Application rate :	*4*	litres product / ha
3.	Work rate :	*1*	ha / day
4.	No of operations per day :	*3*	/ day
5.	Contamination / day :	*0.03*	ml / day
6.	Protective clothing :	*gloves*	
7.	Penetration of gloves :	*1*	%
8.	Dermal exposure to formulation	*0.0003*	ml / day

EXPOSURE DURING SPRAY APPLICATION

1	Application technique :	*Hand held Outdoors Rotary Disc Atomizers: Low level Application.*	
2.	Application volume :	*40*	litres spray / ha
3.	Volume of surface contamination :	*20*	ml/h

		HANDS		TRUNK		LEGS	
4.	Distribution :	*10*	%	*5*	%	*85*	%
5.	Clothing :	*gloves*		*impermeable*		*impermeable*	
6.	Penetration :	*1*	%	*5*	%	*5*	%
7.	Dermal exposure :	*0.02*	ml/h	*0.05*	ml/h	*0.85*	ml/h

8.	Duration of exposure :	*6*	hours
9.	Total dermal exposure to spray :	*5.52*	ml / day

SYSTEMIC EXPOSURE

		mixing and loading		spray application	
1	Dermal exposure	*0.0003*	ml / day	*5.52*	ml/day
2.	Concentration of ai	*540*	mg/ml	*54*	mg/ml
3.	Dermal Exposure to ai	*0.162*	mg/day	*298.08*	mg/day
4.	Percent Absorption	*3*	%	*3*	%
5.	Absorbed Dose	*0.00486*	mg/day	*8.9424*	mg/day

INHALATION EXPOSURE DURING SPRAY APPLICATION

1	Inhalation exposure :	*0.01*	ml/h
2.	Duration of exposure :	*6*	hours
3.	Concentration of ai :	*54*	mg/ml
4.	Inhalation exposure to ai :	*3.24*	mg/day
5.	Percent absorbed :	*100*	%
6.	Absorbed Dose	*3.24*	mg/day

PREDICTED EXPOSURE

1	Total dose absorbed	*12.19*	mg / day
2.	Operator body weight	*60*	kg
3.	Operator Exposure	*0.203*	mg / kg body weight /day

ANNEX V : Calculation of specific exposure values based on the two US passive dosimetry studies.

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