Asulam sodium

Annex B (Volume 3)

B.6B Toxicology and metabolism – Exposure data

Version history

When	What
2016-04-18	Initial DAR

B.6.14 Exposure data (IIIA 7.2)

During the previous evaluation (EU Review) of asulam sodium, EFSA concluded that operator, bystander/resident and worker exposure estimates should be expressed in terms of asulam rather than asulam sodium. This approach was discussed and agreed at the toxicology expert meeting (PRAPeR 79) held in July 2010. This evaluation follows the same agreed approach in expressing the exposure levels in terms of asulam.

Details of the product 'Asulox'and its supported use are summarised in Table B.6.14.1.

Table B.6.14.1 Proposed use of 'Asulox' and parameters used in exposure estimates

Formulation type	SL formulation containing a nominal 400 g/l asulam (438 g/l asulam sodium)
Use	1. Horticultural herbicide on spinach (pre-emergence) 2. Horticultural herbicide on spinach (post-emergence) 3. Horticultural herbicide for flower bulb production (tulip, hyacinth and lily)
Application method	Tractor-mounted, trailed or self-propelled field crop sprayer
Maximum individual dose	6.0 litres of product/ha (equivalent to 2.4 kg asulam/ha)
Application volume	200 to 600 litres of water/ha
Maximum total dose	1 application *per* crop
Latest time of application	1. Before crop emergence (up to 3 days after sowing) 2. BBCH 12-14 (minimum PHI 28 days) 3. Post-emergence on a hardened, growing crop when the weeds have a height of 4 to 6 cm
Packaging	1, 5 and 10 litre HDPE single trip containers with closure sizes of 36 mm, 50 mm or 63 mm.
Systemic AOEL	0.46 mg/kg bw/day based on the NOAEL of 46 mg/kg bw/day for reproductive effects in the rat multigeneration study and using an assessment factor of 100 with no correction required for incomplete oral absorption (see Section B.6.10).
Dermal absorption	0.5% for 'Asulox' as the concentrate and 3% for the spray solution based on *in vitro* data using human skin (see Section B.6.12).
Classification	Regulation EC 1272/2008: signal word 'Warning;' with the hazard statement H317: 'May cause an allergic skin reaction' (see Section B.6.11). On the basis of this hazard classification alone, it is appropriate for operators to wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate.

B.6.14.1 Operator exposure (IIIA 7.2.1)

B.6.14.1.1 Estimation of operator exposure (IIIA 7.2.1.1)

Operator exposure estimates using the parameters described above have been calculated using the German Model [1] and the UK POEM [2]. These estimates, which use the standard assumptions for each model, are presented in Appendix I at the end of this section and are summarised in Tables B.6.14.2 and B.6.14.3.

UK POEM estimates for the use of field crop sprayers assume a container size of 10 litres (63 mm closure), which results in a higher level of operator contamination during mixing and loading operations than a 5 litre container, when an equivalent amount of product is dispensed. It is unlikely that operators using field crop sprayers would use the smaller containers (1 litre) when treating 50 ha/day (the standard work rate in the UK POEM for the use of field crop sprayers).

Table B.6.14.2 Operator exposure to asulam resulting from the use of 'Asulox' on spinach and ornamentals (German model for tractor-mounted/trailed field crop sprayers)

Dermal exposure mg/person/day		Inhalation exposure mg/person/day		Total systemic exposure *	
Mix/load	Application	Mix/load	Application	mg/kg bw/day**	% of AOEL
No PPE					
115.20	97.92	0.029	0.048	0.0513	11%

* assuming dermal absorption values for asulam in 'Asulox' of 0.5% for the concentrate and 3% for the spray solution
** assuming a body weight of 70 kg (default German model value)
AOEL agreed systemic AOEL of 0.46 mg/kg bw/day

Table B.6.14.3 Operator exposure to asulam resulting from the use of 'Asulox' on spinach and ornamentals (UK POEM for tractor-mounted/trailed field crop sprayers)

Dermal exposure mg/person/day		Inhalation exposure mg/person/day		Total systemic exposure *	
Mix/load	Application	Mix/load	Application	mg/kg bw/day**	% of AOEL
No PPE					
600.00	498.60	negligible	0.72	0.3113	68%

* assuming dermal absorption values for asulam in 'Asulox' of 0.5% for the concentrate and 3% for the spray solution
** assuming a body weight of 60 kg (default POEM value)
AOEL agreed systemic AOEL of 0.46 mg/kg bw/day

The German model estimates summarised above (Table B.6.14.2) indicate that the uses of 'Asulox' through tractor-mounted/trailed equipment without the use of PPE will result in a level of systemic exposure to asulam equivalent to 11% of the agreed systemic AOEL of 0.46 mg/kg bw/day.

The corresponding UK POEM estimate (Table B.6.14.3), based on the standard work rate assumption of 50 ha *per* 6 hour day (which may be excessive for spinach and ornamentals), predicts a level of systemic exposure for an operator without PPE equivalent to 68% of the systemic AOEL of 0.46 mg/kg bw/day.

B.6.14.1.2 Measurement of operator exposure (IIIA 7.2.1.2)

No operator monitoring data have been submitted in support of the proposed use of 'Asulox'.

B.6.14.2 Bystander and resident exposure (IIIA 7.2.2)

In the absence of a harmonised approach to bystander and resident exposure assessment throughout the EU, this evaluation presents calculations using both the UK approach (as presented in the original asulam DAR) and the German approach (as used by the applicant and favoured by some Member States) .

B.6.14.2.1 Bystander and resident exposure to vapour (UK approach)

Bystander exposure to asulam resulting from the proposed use of 'Asulox' is likely to result primarily from spray drift as asulam is of low volatility (vapour pressure 5 x 10^{-7} Pa at 45 °C). However, as a worst case, the level of bystander exposure to asulam vapour following the use of 'Asulox' can be estimated using a surrogate value for residues in air adjacent to treated crops, derived from Californian Environmental Protection Agency studies [3]. In these studies, a 24 ha orange orchard was treated with chlorpyrifos (vapour pressure 1.43 x 10^{-3} Pa at 20°C) using broadcast air-assisted sprayers. During application, wind speeds ranged from 2 to 20 km/h and the maximum temperature was 42 °C. Chlorpyrifos residues in air adjacent to the orchard were monitored over 72 hours. The highest 24 hour time-weighted average residue in air was 15 µg/m^3.
Bystander exposure to vapour can be calculated using these surrogate values and assuming:

- a body weight of 60 kg for an adult (based on the 50th percentile value for females aged 16 to 24 years in 1995-7 Health Surveys for England);
- a body weight of 15 kg for a small child (based on the average value for male and female children aged 2 and 3 years in 1995-7 Health Surveys for England);
- a respired volume of 15.2 m^3/day (based on mean values for the long term inhalation rate for adult males aged 19 to >65 years published in the United

States Environmental Protection Agency (US EPA) Exposure Factors Handbook); and

- a respired volume of 8.3 m^3/day (based on mean values for the long term inhalation rate for children aged 3 to 5 years published in the US EPA Exposure Factors Handbook).

On this basis, potential exposure to vapour is estimated to be 0.0038 mg/kg bw/day for an adult and 0.0083 mg/kg bw/day for a child. The higher of these values is equivalent to 2% of the systemic AOEL of 0.46 mg/kg bw/day for asulam.

As this calculation assumes a 24-hour duration of exposure which is repeated on a daily basis, this approach is relevant and precautionary for both bystanders and residents.

B.6.14.2.2 Bystander and resident exposure to spray drift (UK approach)

Estimates of bystander exposure to spray drift are based on direct measurements of simulated bystander exposure for field crop sprayers in a UK study [4]. In this study, a single pass of the sprayer resulted in a mean potential dermal exposure (PDE) of 0.1 ml of spray solution on a bystander positioned 8 m downwind from the edge of the treatment area. Mean potential inhalation exposure (PIE) was 0.006 ml of spray solution.

Bystander exposure to spray drift can be calculated using these measurements and assuming that:

- 'Asulox' is applied at the maximum proposed concentration of 12 mg asulam *per* ml of spray solution;
- there is no exposure reduction from clothing;
- there is 3% dermal absorption of asulam from the spray solution and 100% absorption and retention of potential inhalation exposure; and
- the bystander has a body weight of 60 kg.

On this basis, total systemic bystander exposure to asulam is calculated to be:

$$\frac{(\text{ml spray dermal} \times \text{mg/ml} \times \text{\% absorbed}) + (\text{ml inhaled} \times \text{mg/ml})}{\text{kg bw}} = \frac{(0.1 \times 12 \times 3) + (0.006 \times 12)}{60}$$

= 0.0018 mg/kg bw (equivalent to 0.4% of the systemic AOEL of 0.46 mg/kg bw/day).

Although this estimate is based on a situation in which acute exposure to the spray solution occurs, as the level of systemic exposure is compared with an AOEL considered appropriate for assessing the risks associated with repeated exposures for

operators, this exposure assessment is also relevant to situations of repeated bystander exposure to spray drift (for example, the exposure of residents in property adjoining sprayed crops).

B.6.14.2.3 Bystander and resident exposure to drift fallout (UK approach)

The following calculations predict the amount of asulam likely to be deposited in gardens next to a spinach or flower bulb crop treated with 'Asulox' (due to fallout from spray drift) and the level of exposure likely to result when children playing in the garden are exposed through dermal, hand-to-mouth and object-to-mouth routes. These estimates are based on the spray drift fallout values for field crop sprayers used for the aquatic risk assessment [5] and US EPA values for residential exposure resulting from contact with treated lawns [6].

Spray drift fallout

Allowing for an untreated headland of 1 m, the level of fallout from spray drift at the boundary with a neighbouring area is predicted to be equivalent to 2.77% of the applied dose. This level of fallout deposit is predicted to decline to 0.57% at a distance of 5 m from the boundary. By integration, the average level of fallout over the whole area from the boundary to a point 3 m outside is estimated to be about 1%.

Children's dermal exposure

A child's systemic exposure to asulam resulting from dermal contact with a lawn contaminated by spray drift during the application of 'Asulox' is calculated as follows.

SE(d) = (AR x DF x TTR x TC x H x DA) / BW

Where:
SE(d) = systemic exposure *via* the dermal route
AR = total dose of 2.4 kg asulam/ha = 24 µg asulam/cm^2
DF = drift fallout value of 1% of the applied dose for applications to field crops
TTR = turf transferable residue value of 5% (EPA default value)
TC = transfer coefficient of 5200 cm^2/h (standard EPA value for this situation)
H = duration of exposure of 2 hours *per* day (standard EPA value based on 75th percentile data)
DA = dermal absorption of 3% for asulam (higher value for the spray solution)
BW = body weight of 15 kg

SE(d) = (24 µg a.s./cm^2 x 1% x 5% x 5200 cm^2/h x 2h/d x 3%) / 15 kg bw
= 0.2496 µg/kg bw/d

Children's hand-to-mouth exposure

Additional systemic exposure to asulam resulting from ingestion of turf residues of 'Asulox' transferred from contaminated hands to the mouth is calculated as follows.

SE(h) = (AR x DF x TTR x (SE/100) x SA x Freq x H) / BW

Where:
SE(h) = systemic exposure *via* the hand-to-mouth route
AR = total dose of 2.4 kg asulam/ha = 24 µg asulam/cm^2
DF = drift fallout value of 1% of the applied dose for applications to grapevines
TTR = turf transferable residue value of 5% (EPA default value for wet hands)
SE = saliva extraction factor of 50% (EPA default value)
SA = surface area of the hands in contact with the mouth (the value of 20 cm^2/event represents the palmar surface of three fingers)
Freq = frequency of hand to mouth events/hour (the value of 20 events/hour is the 90th percentile of observations ranging from 0 to 70 events/hour)
H = duration of exposure of 2 hours *per* day (standard EPA value based on 75th percentile data)
BW = body weight of 15 kg

SE(h) = (24 µg a.s./cm^2 x 1% x 5% x 50% x 20 cm^2 x 20/h x 2h/d) / 15 kg bw
= 0.32 µg/kg bw/d

Children's object-to-mouth exposure
Additional systemic exposure to asulam resulting from ingestion of turf residues of 'Asulox' transferred from contaminated objects to the mouth is calculated as follows.

SE(o) = (AR x DF x TTR x IgR)/BW

Where:
SE(o) = systemic exposure *via* mouthing activity
AR = total dose of 2.4 kg asulam/ha = 24 µg asulam/cm^2
DF = drift fallout value of 1% of the applied dose for applications to grapevines
TTR = turf transferable residue value of 20% (EPA default value for object-to-mouth assessments)
IgR = ingestion rate for mouthing of 25 cm^2 grass/day (EPA default value)
BW = body weight of 15 kg

SE(o) = (24 µg a.s./cm^2 x 1% x 20% x 25 cm^2) / 15 kg bw
= 0.08 µg/kg bw/d

Children's total exposure

On the basis of the above estimates, the total systemic exposure to asulam for a child playing on a lawn contaminated by spray drift during the application of 'Asulox' is calculated to be 0.00065 mg/kg bw/day. This is equivalent to 0.14% of the systemic AOEL of 0.46 mg/kg bw/day.

Although this estimate assumes a 2-hour exposure duration, as the level of systemic exposure is compared with an AOEL considered appropriate for assessing the risks associated with repeated exposures for operators, this exposure assessment is relevant to situations where residents in property adjoining treated crops may be exposed to drift fallout on a daily basis.

B.6.14.2.4 Bystander and resident exposure (German approach)

Bystander and resident exposure estimates using the German approach [7] are presented in Appendix I at the end of this section and are summarised in Table B.6.14.4.

In line with the BfR approach, these estimates are based on the following assumptions:

- Bystanders and residents will be lightly clothed adults (body weight 60 kg) and children (body weight 16.15 kg).
- Bystanders are located at the edge of the area being treated at a distance 10 m downwind from the sprayer and will be directly exposed to spray drift through dermal and inhalation routes.
- The spray equipment will take 5 minutes to pass the bystander.
- The level of spray drift reaching bystanders is 0.29% of the applied dose for field crop sprayers based on published deposition data
- Bystander inhalation exposure will be no greater than that experienced by an unprotected sprayer operator, adjusted for the duration of exposure.
- Residential exposure will result from dermal contact with surfaces previously exposed to spray drift (2 hour exposure for adults and children in contact with a contaminated lawn), the inhalation of vapour (over 24 hours) and, for children aged between 2 years and 5 years, oral uptake by hand-to-mouth contact and by object-to-mouth contact.

Table B.6.14.4 Bystander and resident exposure to asulam resulting from the use of 'Asulox' through field crop (boom) sprayers (German approach)

Group	Route-specific external exposure (mg/person/day)			Total systemic exposure *	
	Dermal	Inhalation	Oral	mg/kg bw/day**	% of AOEL
Bystander Adult	0.01160	0.000011	not applicable	0.000359	0.08%
Bystander Child	0.00905	0.000024	not applicable	0.000295	0.06%
Resident Adult	0.00085	0.000276	not applicable	0.000302	0.07%
Resident Child	0.00112	0.000515	0.000108	0.000656	0.14%

* assuming a dermal absorption values for asulam in 'Asulox' of 3% for the spray solution
** assuming a body weight of 60 kg for an adult and 16.15 kg for a child (default BfR values)
AOEL agreed systemic AOEL of 0.46 mg/kg bw/day

The above estimates predict that the proposed uses of 'Asulox' will result in levels of systemic bystander and resident exposure to asulam no greater than 0.000656 mg/kg bw/day. This is equivalent to 0.14% of the systemic AOEL of 0.46 mg/kg bw/day.

B.6.14.3 Worker exposure (IIIA 7.2.3)

Although the commercial production of flower bulbs is likely to involve mechanical harvesting operations, the production process may be associated with cut flower production and, as a precautionary approach, this evaluation considers the harvesting and bundling of ornamentals.

Levels of worker exposure to asulam when harvesting spinach and ornamentals for flower bulb production treated with 'Asulox' have been estimated using the EUROPOEM Worker Re-entry Model [8].

These estimates are based on the following assumptions.

Use	Maximum total dose (kg a.s./ha)	Latest time of application	Re-entry task	Transfer coefficient (cm^2/h)
Spinach	2.4	BBCH 14 28 days before harvest	Harvesting	2500
Flower bulb production	2.4	No restriction based on growth stage	Harvesting	5000

In accordance with the EUROPOEM worker re-entry model, the following worst-case assumptions have been used:

Application rate (R): As above

Initial dislodgeable foliar residue (DFR): 3 $\mu g/cm^2$ x R

Task-related transfer coefficient (TC): As above

Duration of task (A):
Harvesting 8 h/day

On this basis, the potential dermal exposure (D = DFR x TC x A) and systemic exposure (assuming a dermal absorption value for dry transferred foliar residues of asulam of 3% and a worker body weight of 60 kg) are estimated to be as follows for an unprotected worker.

Use	Dermal exposure (µg/person)	Systemic exposure (mg/kg bw/day)	% of AOEL*
Spinach	144000	0.072	16%
Flower bulb production	288000	0.144	31%

*AOEL = 0.46 mg/kg bw/day

These estimates predict that the proposed uses of 'Asulox' on spinach and ornamentals for flower bulb production will result in an acceptable level of systemic exposure to asulam for a worker carrying out harvesting operations without PPE.

B.6.14.4 Summary of risk to operators, bystanders and workers

The situations summarised below are estimated to result in an acceptable level of exposure for operators (Table B.6.14.5), bystanders/residents (Table B.6.14.6) and workers entering treated crops (Table B.6.14.7).

Table B.6.14.5 Operator exposure to asulam resulting from the proposed use of 'Asulox': summary of estimates indicating an acceptable exposure level

Proposed use	Application method	Model/data	Operator protection	% of AOEL
Spinach and ornamentals	Tractor-mounted/trailed field crop sprayer	German	Mix: none Apply: none	11%
		UK POEM	Mix: none Apply: none	68%

On the basis of these estimates and considering the hazard classification of the formulation, the proposed use of 'Asulox' is considered to be acceptable subject to the following operator protection requirement.

- Operators must wear suitable protective clothing (coveralls) and suitable protective gloves when handling the concentrate.

Table B.6.14.6 Bystander/resident exposure to asulam resulting from the proposed use of 'Asulox': summary of estimates indicating an acceptable exposure level for unprotected bystanders

Proposed use	Application method	Model/data	% of AOEL
Spinach and ornamentals	Tractor-mounted/trailed field crop sprayer	UK approach. Vapour exposure (worst case CA EPA data).	2%
		UK approach. Drift exposure (simulated bystander exposure measurements, Lloyd and Bell)	0.4%
		UK approach. Children's exposure to fallout from spray drift (Rautmann *et al* and US EPA)	0.14%
		German approach. Adult bystander	0.08%
		German approach. Child bystander	0.06%
		German approach. Resident adult	0.07%
		German approach. Resident child	0.14%

On the basis of these estimates, the level of exposure for unprotected bystanders and residents resulting from the proposed use of 'Asulox' is considered to be acceptable.

Table B.6.14.7 Worker exposure to asulam resulting from the proposed use of 'Asulox': summary of estimates indicating an acceptable exposure level for unprotected workers

Proposed use	Model/data	% of AOEL
Spinach	EUROPOEM Worker Re-entry model	16%
Ornamentals		31%

On the basis of this estimate, the level of exposure for unprotected workers entering and handling crops treated with 'Asulox' is considered to be acceptable.

References used in assessment of data.

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6. USA EPA (1998). Occupational and residential exposure test guidelines: Group B, Post-application exposure monitoring test guidelines. Series 875 v 5.4.

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7. Martin, S., Westphal, D., Erdtmann-Vourliotis, M., Dechet, F., Schulze-Rosario, C., Stauber, F., Wicke, H. and Chester, G. (2008). Guidance for exposure and risk evaluation for bystanders and residents exposed to plant protection products during and after application. J. Verbr. Lebensm. 3 (2008):272-281

8. van Hemmen *et al* (2002). Post-application exposure of workers to pesticides in agriculture. Report of the re-entry working group, EUROPOEM II project: FAIR3-CT96-1406

APPENDIX 1: EXPOSURE ESTIMATES

OPERATOR EXPOSURE ESTIMATES

The following exposure estimates were calculated using the German Model and the UK Predictive Operator Exposure Model (POEM).

Estimate	Model	Use	Application method	Operator protection	
				Mix/load	Apply
1	German Model	Spinach Flower bulbs	Field crop sprayer	None	None
2	UK POEM	Spinach Flower bulbs	Field crop sprayer	None	None

The following assumptions were used:

i) a work rate of 20 ha *per* day for field crop sprayers in the German Model (standard assumption) and a work rate of 50 ha *per* 6 hour day for field crop sprayers in the UK POEM (standard assumption);

ii) the use of a wide-necked (63 mm ECPA standard) 10 litre container is assumed in the UK POEM estimates for tractor-mounted/trailed field crop sprayers on the basis of the area treated, giving a hand contamination value of 0.05 ml of concentrate *per* decanting operation;

iii) dermal absorption values for asulam in 'Asulox' of 0.5% for the concentrate and 3% for the spray solution;

iv) an operator body weight of 70 kg in the German Model and 60 kg in the UK POEM;

v) any assumptions not detailed above will be as given in document SC 8001 (POEM) or the published German model.

Although some values in the exposure estimates are expressed as unrounded figures, this level of precision is not generally justified when considering the various assumptions on which the calculations are based.

Estimate 1: German Model. No PPE. Tractor-mounted/trailed field crop sprayers.

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	Asulox		Active substance		asulam
Formulation type	Liquid		a.s. concentration		400 g/l
Dermal absorption from product	0.5	%	Dermal absorption from spray		3 %
RPE during mix/loading	None		RPE during application		None
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	6	l product/ha	Work rate/day		20 ha

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2.4	mg/kg a.s.
Hand contamination/day	115.2	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	115.2	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0006	mg/kg a.s.
Inhalation exposure/day	0.0288	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0288	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	2.88	18.24	76.8	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	97.92	mg/day		

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.048	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.048	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	115.2	mg/day	97.92	mg/day
Percent absorbed	0.5	%	3	%
Absorbed dose (dermal route)	0.576	mg/day	2.9376	mg/day
Inhalation exposure to a.s.	0.0288	mg/day	0.048	mg/day
Total systemic exposure	0.6048	mg/day	2.9856	mg/day

PREDICTED EXPOSURE

Total systemic exposure	3.5904	mg/day
Operator body weight	70	kg
Operator exposure	0.051291429	mg/kg bw/day

Estimate 2: UK POEM. No PPE. Tractor-mounted/trailed field crop sprayers.

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	Asulox		Active substance	asulam
Formulation type	water-based		a.s. concentration	400 mg/ml
Dermal absorption from product	0.5	%	Dermal absorption from spray	3 %
Container	10 litres 63 mm closure			
PPE during mix/loading	None		PPE during application	None
Dose	6	l/ha	Work rate/day	50 ha
Application volume	200	l/ha	Duration of spraying	6 h

EXPOSURE DURING MIXING AND LOADING

Container size	10	litres
Hand contamination/operation	0.05	ml
Application dose	6	litres product/ha
Work rate	50	ha/day
Number of operations	30	/day
Hand contamination	1.5	ml/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to formulation	1.5	ml/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Application volume	200	spray/ha		
Volume of surface contamination	10	ml/h		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		

ABSORBED DERMAL DOSE

	Mix/load		Application	
Dermal exposure	1.5	ml/day	41.55	ml/day
Concen. of a.s. product or spray	400	mg/ml	12	mg/ml
Dermal exposure to a.s.	600	mg/day	498.6	mg/day
Percent absorbed	0.5	%	3	%
Absorbed dose	3	mg/day	14.958	mg/day

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure	0.01	ml/h
Duration of exposure	6	h
Concentration of a.s. in spray	12	mg/ml
Inhalation exposure to a.s.	0.72	mg/day
Percent absorbed	100	%
Absorbed dose	0.72	mg/day

PREDICTED EXPOSURE

Total absorbed dose	18.678	mg/day
Operator body weight	60	kg
Operator exposure	0.3113	mg/kg bw/day

BYSTANDER AND RESIDENT EXPOSURE ESTIMATES (BfR APPROACH)

Estimation of bystander exposure during/after application in Field Crops, Tractor Mounted

Input parameters considered for the estimation of bystander exposure:

Intended use(s):	Spinach and flower bulbs		**Drift (D):**	0.29	% (FCTM, 10 m)
Application rate (AR):	2.4	kg a.s./ha	**Exposed Body Surface Area (BSA):**	1	m² (adults)
				0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I*A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.00057	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	3.00	% ('worst case')	**Area Treated (A):**	20	ha/d (based on Field Crops, Tractor Mounted (FCTM))
Inhalation absorption (IA):	100	%	**Exposure duration (T):**	5	min
AOEL:	0.46	mg/kg bw/d			

Bystander exposure towards Asulam					
Adults			**Children**		
Bystander: Dermal exposure after application in Spinach and flower bulbs (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(240 x 0.29% x 1 x 3%) / 60			(240 x 0.29% x 0.21 x 3%) / 16.15		
External exposure	0.696	mg/person	External exposure	0.14616	mg/person
External exposure	0.0116	mg/kg bw/d	External exposure	0.00905015	mg/kg bw/d
Absorbed dose:	**0.0003480**	**mg/kg bw/d**	**Absorbed dose:**	**0.0002715**	**mg/kg bw/d**
Bystander: Inhalation exposure after application in Spinach and flower bulbs					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0,000 / 360 x 2.4 x 20 x 5 x 100%) / 60			(0,000 / 360 x 2.4 x 20 x 5 x 100%) / 16.15		
External exposure	0.00066667	mg/person	External exposure	0.00038314	mg/person
External exposure	1.1111E-05	mg/kg bw/d	External exposure	2.3724E-05	mg/kg bw/d
Absorbed dose:	**0.0000111**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000237**	**mg/kg bw/d**
Total systemic exposure: SE_B = SDE_B + SIE_B			Total systemic exposure: SE_B = SDE_B + SIE_B		
Total systemic exposure (absorbed dose)	0.02154667	mg/person	Total systemic exposure (absorbed dose)	0.00476794	mg/person
Total systemic exposure (absorbed dose)	**0.0003591**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0002952**	**mg/kg bw/d**
% of AOEL:	**0.08**	**%**	**% of AOEL:**	**0.06**	**%**

Estimation of resident exposure after application in Field Crops, Tractor Mounted (FCTM)

Input parameters considered for the estimation of resident exposure:

Intended use(s):	Spinach and flower bulbs		**Drift (D):**	0.29	% (FCTM, 10 m)
Application rate (AR):	2.4	kg a.s /ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
				2600	cm^2/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	0.001	mg/m3
Dermal absorption (DA):	3.00	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults),
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA)	100	%	**Saliva Extraction Factor (SE):**	50	%
AOEL	0.46	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm^2
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards Asulam					
Adults			**Children**		
Residents: Dermal exposure after application in Spinach and flower bulbs (via deposits caused by spray drift)					
SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW			SDE_R = (AR x NA x D x TTR x TC x H x DA) / BW		
(0.024 x 1 x 0.29% x 5% x 7300 x 2 x 3%) / 60			(0.024 x 1 x 0.29% x 5% x 2600 x 2 x 3%) / 16.15		
External exposure	0.050808	mg/person	External exposure	0.018096	mg/person
External exposure	0.0008468	mg/kg bw/d	External exposure	0.0011205	mg/kg bw/d
Absorbed dose:	**0.0000254**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000336**	**mg/kg bw/d**
Residents: Inhalation exposure to vapour					
SIE_R = (AC_V x IR x IA) / BW			SIE_R = (AC_V x IR x IA) / BW		
(0.001 x 16.57 x 100%) / 60			(0.001 x 8.31 x 100%) / 16.15		
External exposure	0.01657	mg/person	External exposure	0.00831	mg/person
External exposure	0.00027617	mg/kg bw/d	External exposure	0.00051455	mg/kg bw/d
Absorbed dose:	**0.0002762**	**mg/kg bw/d**	**Absorbed dose:**	**0.0005146**	**mg/kg bw/d**
			Residents: Oral exposure (hand-to-mouth transfer)		
			SOE_H = (AR x NA x D x TTR x SE x SA x Freq x H x OA) /		
			(0.024 x 1 x 0.29% x 5% x 50% x 20 x 20 x 2 x 100%) / 16.15		
			External exposure	0.001392	mg/person
			External exposure	8.6192E-05	mg/kg bw/d
			Absorbed dose	**0.0000862**	**mg/kg bw/d**
			Residents: Oral exposure (object-to-mouth transfer)		
			SOE_O = (AR x NA x D x DFR x IgR x OA) / BW		
			(0.024 x 1 x 0.29% x 20% x 25 x 100%) / 16.15		
			External exposure	0.000348	mg/person
			External exposure	2.1548E-05	mg/kg bw/d
			Absorbed dose	**0.0000215**	**mg/kg bw/d**
Total systemic exposure: SE_R = SDE_R + SIE_R			Total systemic exposure: SE_R = SDE_R + SIE_R + SOE_H + SOE_O		
Total systemic exposure (absorbed dose)	0.01809424	mg/person	Total systemic exposure (absorbed dose)	0.01059288	mg/person
Total systemic exposure (absorbed dose)	**0.0003016**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0006559**	**mg/kg bw/d**
% of AOEL:	**0.07**	**%**	**% of AOEL:**	**0.14**	**%**

B.6.15 Literature search

UPL submitted a literature review in support of the renewal of mesotrione via the consultancy firm, JSC. The RMS (UK) considers that the search and relevance criteria applied by the report author for their literature review in the mammalian toxicology and non dietary human exposure areas, and the reliability assessment applied to relevant studies, are acceptable and no issues were identified that would not be expected based on the available regulatory test data and the exposures experienced in the published studies. A detailed assessment can be found in section B.6.8.2.

B.6.16 References relied on

In every chapter (B.1, B.2, etc.) in Volume 3 (AS) the reference relied on heading should start with a paragraph indicating how the literature search was carried out and if this is considered acceptable. It should also be indicated if the RMS can agree with the justifications given by the notifier (especially for non-relevant literature).This is not expected to be a detailed study-by-study consideration. Relevant literature would be evaluated and assessed in the normal way within each section.

For (draft) renewal assessment reports the reference lists at the end of each section/chapter (sorted by data requirement) should include the newly submitted data relied upon as well as those original submitted tests and studies that are still considered relevant to support the application for renewal. However these studies should be clearly identified in the reference list as well as in the individual study sections. This could be done by consistent use of a statement for each study:
Previous evaluation: responded "N.A". for NAS, "Submitted for the purpose of renewal", or "In DAR (year)", "In addendum to DAR (year)" or any other appropriate

Active substance

*details to be added during Peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA, 5.1.1/01	[redacted]	1989	Asulam biokinetics and metabolism in the male and female rat [redacted] GLP, Unpublished **Study required to elucidate ADME of the test article**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA, 5.1.1/02	[redacted]	1995	Asulam - Tissue distribution and kinetic study in the rat [redacted] GLP, Unpublished **Study required to elucidate tissue distribution and kinetics of the test article**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 5.1.3/01	[redacted]	1989	Asulam biokinetics and metabolism in the male and female rat [redacted] GLP, Unpublished **Study required to elucidate ADME of the test article** ⇒ CA 5.1.1/01	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.2.1/01	[redacted]	1987a	FR 1398/1: Acute oral toxicity study in the rat [redacted] GLP, Unpublished **Study required to determine acute oral toxicity of the test article**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA, 5.2.1/02	[redacted]	1988	Acute peroral (rat) and percutaneous (rabbit) toxicity studies Asulam sodium salt [redacted] GLP, Unpublished **Study required to determine acute oral /dermal toxicity of the test article from a difference source**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.2.2/01	[redacted]	1987b	FR 1398/1: Acute percutaneous toxicity study in the rat [redacted] GLP, Unpublished **Study required to determine acute dermal toxicity of the test article**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.2.2/02	[redacted]	1988	Acute peroral (rat) and percutaneous (rabbit) toxicity studies Asulam sodium salt [redacted] GLP, Unpublished **Study required to determine acute oral /dermal toxicity of the test article from**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			a difference source ⇒ CA 5.2.1/02					
CA, 5.2.3/01	[redacted]	1988	Asulam (sodium salt) - Acute dust aerosol inhalation toxicity test in rats [redacted] GLP, Unpublished **Study required to determine acute inhalatory toxicity of the test article**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.2.4/01	[redacted]	1987a	FR 1398/1: Acute dermal irritation/corrosion test in the rabbit [redacted] GLP, Unpublished **Study required to determine acute dermal irritation potential of the test article**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.2.5/01	[redacted]	1987b	FR 1398/1: Acute eye irritation/corrosion test in the rabbit [redacted] GLP, Unpublished **Study required to determine acute**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			ocular irritation potential of the test article					
CA, 5.2.6/01	[redacted]	1987c	FR 1398/1: Delayed contact hypersensitivity study in guinea-pigs [redacted] GLP, Unpublished **Study required to determine skin sensitisation potential of the test article**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 5.3.2.1/01	[redacted]	1989a	Eight-week range-finding dietary toxicity study in mice [redacted] GLP, Unpublished **Study required to provide information for dose selection for the chronic mouse study**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.3.2.2/01	[redacted]	2000	Asulam: 90-day toxicity study in the rat by dietary administration [redacted]	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			[redacted] GLP, Unpublished **Study required to assess the sub-chronic toxicity of the test article in the rat**					
CA, 5.3.3/01	[redacted]	1980	Asulam: six month oral toxicity study in beagles [redacted] Not GLP, Unpublished **Study required to assess the sub-chronic toxicity of the test article in the dog**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.3.4/01	[redacted]	2004	52-week toxicity study by oral route (gavage) in beagle dogs (asulam) [redacted] GLP, Unpublished **Study required to assess the chronic toxicity of the test article in the dog**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 5.3.7/01	[redacted]	1989b	21-day repeated dose dermal toxicity study in rabbit [redacted]	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			[redacted] GLP, Unpublished **Study required to assess the sub-acute dermal toxicity of the test article in the rabbit**			(EC) No 1107/2009		
CA 5.4.1/01	van der Wijngaard, M.J.M	2008	Bacterial reverse mutation test with Asulam United Phosphorus Limited report no.: not assigned TNO, Zeist, The Netherlands. Unpublished report No.: V7905/05 GLP, Unpublished **Study required to elucidate *in vitro* genotoxic potential in bacteria from an alternative source**	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 5.4.1/02	Tendulkar, K.E.	2013	Bacterial reverse mutation test of asulam sodium (50% w/v) aqueous concentrate using *Salmonella typhimurium* United Phosphorus Limited report no.: not assigned Jai Research Foundation, India Unpublished report No.: 481-1-06-6691 GLP, Unpublished **Study required to elucidate *in vitro* genotoxic potential in bacteria from an alternative source**	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009		
CA 5.4.2/01	Galloway, S.M. & Myhr, B.C.	1984	Mutagenicity Evaluation of Asulam Technical (dried)	N	Y	Data protection is claimed	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			Batch : PN 85, in an in vitro cytogenetic assay measuring chromosome aberration frequencies in human lymphocytes Litton Bionetics, Inc., Maryland, USA Unpublished report no.: 20990 Company report No.: R001262 GLP, Unpublished **Study required to elucidate *in vitro* clastogenic potential in mammalian cells**			in accordance with Article 59 of Regulation (EC) No 1107/2009		
CA, 5.4.3/01	Steenwinckel, M-J. S.T.	2009	Gene mutation test at the TK-locus of L5178Y cells with Asulam United Phosphorus Limited report no.: not assigned TNO, Zeist, The Netherlands. Unpublished report No.: V7903/02 GLP, Unpublished **Study required to elucidate *in vitro* gene mutation potential in mammalian cells**	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.4.4/01	[redacted]	2004	AE F102789 00 SG80 A102 (project asulam) micronucleus-test on the male mouse [redacted] GLP, Unpublished **Study required to assess the *in vivo***	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			genotoxic potential of the test article in the rat					
CA, 5.5.2/01	[redacted]	1981	Asulam - toxicity and tumorigenicity in prolonged dietary administration to rats and addendum to final report [redacted] Not GLP, Unpublished **Study required to assess the chronic/carcinogenic potential of the test article in the rats**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
	[redacted]	1981	Asulam - toxicity and tumorigenicity in prolonged dietary administration to rats [redacted] Not GLP, Unpublished **Study required to assess the chronic/carcinogenic potential of the test article in the rats**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
	[redacted]	1987	Background data related to [redacted] Asulam - toxicity and tumorigenicity in prolonged dietary	Y	Y	Data protection is claimed in accordance with Article 59 of	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			[redacted]			Regulation (EC) No 1107/2009		
CA, 5.5.3/01	[redacted]	1992	2-year dietary oncogenicity study in mice [redacted] GLP, Unpublished **Study required to assess the chronic/carcinogenic potential of the test article in mice**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
	[redacted]	1996	[redacted] historical control selected neoplastic data. Male CD-1 mouse – [redacted]	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.6.1/01	[redacted]	1981	Asulam: two generation reproduction study in the rat [redacted] Not GLP, Unpublished **Study required to**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			assess reproductive toxic potential of the test article					
CA, 5.6.10/01	[redacted]	1982	Asulam: teratology study in the rat [redacted] GLP, Unpublished **Study required to assess developmental toxic potential of the test article in the rat**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.6.11/01	[redacted]	1981	Asulam: tetratogenicity study by the oral route in the rabbit [redacted] GLP, Unpublished **Study required to assess developmental toxic potential of the test article in a second species (rabbit)**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 5.8/01	[redacted]	2011	[redacted] Acute oral toxicity in the rat – fixed dose method [redacted]	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			GLP, Unpublished **Study required to assess the acute toxicity of the metabolite**					
CA 5.8/02	[redacted]	2011	[redacted] Seven day repeated dose oral (gavage) range-finding study in the rat [redacted] GLP, Unpublished **Range-finder study required to assess the toxicity of the metabolite**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 5.8/03	[redacted]	2012	[redacted] twenty-eight day repeated dose oral (gavage) toxicity study in the rat [redacted] GLP, Unpublished **Study required to assess the sub-acute toxicity of the metabolite**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 5.8/04	May, K.	2011	[redacted] Bacterial reverse mutation test Huntingdon Life Sciences, Suffolk, UK Unpublished report no.: YRK0016 Company report No.: not assigned GLP, Unpublished **Study required to**	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			elucidate *in vitro* genotoxic potential in bacteria of the metabolite					
CA 5.8/05	Brown, R.W.	2012	[redacted] L5178Y TK+/- mouse lymphoma assay Harlan Laboratories Ltd., Derbyshire, UK Unpublished report no.: 41101395 Company report No.: not assigned GLP, Unpublished **Study required to elucidate *in vitro* clastogenic potential in mammalian cells of the metabolite**	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 5.8/06	Morris, A. & Lacey, F.E.	2012	Chromosome aberration test in human lymphocytes *in vitro* Harlan Laboratories Ltd., Derbyshire, UK Unpublished report no.: 41101392 Company report No.: not assigned GLP, Unpublished **Study required to elucidate *in vitro* clastogenic potential in mammalian cells of the metabolite**	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA 5.8/07	Bowen, D.E	2011	[redacted] Toxicological relevance as a metabolite of the active substance asulam JSC International, North Yorkshire, UK Unpublished report no.: UPL 10/01 Company report No.: not assigned Non-GLP, Unpublished	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CA 5.9.1/01	Jana, S	2013	Medical surveillance statement United Phosphorus Limited, West Bengal, India Non-GLP, Unpublished Confidential information	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CA, 5.10.2/01	Doerge, D.R., Decker, C.J.	1994	Inhibition of peroxidase-catalyzed reactions by Arylamines: mechanism for the anti-thyroid action of sulfamethazine Division of Biochemical Toxicology, National Center for Toxicological Research, Jefferson, USA & Burroughs Wellcome Co., Research Triangle Park, North Carolina, USA *Chemical Research & Toxicology*, **7**, pp 164-169 Not GLP, published	Y	N	-	Public	
CA, 5.10.2/02	Capen, C.C.	1998	Correlation of mechanistic data and histopathology in the evaluation of selected endpoints of the endocrine system Department of Veterinary Biosciences, The Ohio State University, Ohio, USA; *Toxicology Letters*; **102-103**; pp 405 to 409 Not GLP, published	Y	N	-	Public	
CA, 5.10.2/03	McClain, R.M.	1995	Mechanistic considerations for the	Y	N	-	Public	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
			relevance of animal data on thyroid neoplasia to human risk assessment Hoffmann-La Roche. Inc, Department of Toxicology and Pathology, New Jersey, USA *Mutation Research*, **333**, pp 131-142 Not GLP, published					
CA, 5.10.2/04	Poirer, L.A., Doerge, D.R., Gaylor, D.W., Miller, M.A., Lorentzen, R.J., Casciano, D.A., Kadlubar, F.F., Schwetz, B.A.	1999	An FDA review on sulfamethazine toxicity Division of Molecular Epidemiology, NCTR, Arkansas, USA *Regulatory Toxicology & Pharmacology*, **30**, pp 217-222 Not GLP, published	Y	N	-	Public	

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*details to be added during Peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CP, 7.1.1/01	[redacted]	2002a	AE F074383 00 SL33 A103 (EXP 04668 A): Acute oral toxicity in rats [redacted] GLP, Unpublished **Study conducted to support formulation**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP, 7.1.2/01	[redacted]	2002b	AE F074383 00 SL33 A103 (EXP 04668 A) - acute dermal toxicity in rats [redacted] GLP, Unpublished **Study conducted to support formulation**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP, 7.1.4/01	[redacted]	2002c	AE F074383 00 SL33 A103 (EXP 04668 A): Acute dermal irritation in rabbits [redacted] GLP, Unpublished **Study conducted to support formulation**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	*Previous evaluation
CP, 7.1.5/01	[redacted]	2002d	AE F074383 00 SL33 A103 (EXP 04668 A): Acute eye irritation in rabbits [redacted] GLP, Unpublished **Study conducted to support formulation**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP, 7.1.6/01	[redacted]	2003	AE F074383 00 SL33 A103 (EXP 04668 A): Skin sensitisation test in guinea pigs (modified Buehler test: nine applications) [redacted] GLP, Unpublished **Study conducted to support formulation**	Y	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	
CP, 7.3.3/01	Odin-Feurtet, M.	2006	Asulox® *In-vitro* dermal absorption study using human skin Bayer CropScience, Sophia Antipolis, France Unpublished report no.: SA 06280 Company report no.: M-280980-01-1 GLP, Unpublished **Study conducted to assess the dermal absorption of the representative formulation**	N	Y	Data protection is claimed in accordance with Article 59 of Regulation (EC) No 1107/2009	UPL	