



UNEP



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**Rotterdam Convention on the Prior Informed  
Consent Procedure for Certain Hazardous  
Chemicals and Pesticides in International Trade  
Chemical Review Committee**

Third meeting

Rome, 20–23 March 2007

Item 5 (b) (iii) of the provisional agenda\*

**Listing of chemicals in Annex III of the Rotterdam Convention:  
review of notifications of final regulatory actions to ban  
or severely restrict a chemical: endosulfan**

## **Endosulfan**

### **Note by the Secretariat**

The Secretariat has the honour to provide, in the annex to the present note, additional documentation received from the European Commission to support its notification of final regulatory action on endosulfan.

Further supporting information has already been circulated in the annex to document UNEP/CRC.3/10/Add.1. In addition, the following documentation will be made available at the current meeting: European Commission – Peer Review Programme – ECCO Meetings – Endosulfan-Volume 1, December 1999; European Commission – Peer Review Programme – ECCO Meetings – Endosulfan-Volume 3, Annex B, December 1999.

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\* UNEP/FAO/RC/CRC.3/1.

## **Annex**

- Annex B – Endosulfan – Addendum B-6: Toxicology and Metabolism (May 2001)
- Annex B – Endosulfan – Addendum B-6: Toxicology and Metabolism (November 2003)

## **ADDENDUM TO ANNEX B**

# **ENDOSULFAN**

### **B - 6 : TOXICOLOGY AND METABOLISM**

**B.6.14 Exposure data (IIIA, 7.2)**

**B.6.14.1 Excel applicant**

**Operator exposure**

Operator exposure, in the context of this section, refers to potential exposure to the person or persons involved in mixing, loading and/or spray application of a plant protection product.

Endocel 35 EC is applied using field crop sprayers and hand held sprayers.

▪ **ESTIMATES OF OPERATOR EXPOSURE UK MODEL**

**Hand held sprayers- no PPE**

**A. PRODUCT DATA**

1.	Name	Endocel 35 EC
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	2 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	1 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	2 litres product/ha
3.	Work rate	1 ha/day
4.	Number of operations	4/day
5.	Hand contamination	0.04 ml/day
6.	Protective clothing	NONE
7.	Transmission to skin	100%
8.	Dermal exposure to formulation	0.04 ml/day

**C. EXPOSURE DURING SPRAY APPLICATION**

1.	Application technique	
2.	Application volume	350 l spray/ha

3.	Volume of surface contamination	50 ml/h		
		Hands	Trunk	Legs
4.	Distribution	25%	25%	50%
5.	Clothing	None	Perm.	Perm.
6.	Penetration	100%	20%	18%
7.	Dermal exposure	10	2.5	4.5
8.	Duration of exposure		6 h	
9.	Total dermal exposure to spray	102 ml/day		

D. ABSORBED DOSE

		Mix/load	Application
1.	Dermal exposure	0.04 ml/day	102 ml/day
2.	Concentration of as	350 mg/ml	2 mg/ml
3.	Dermal exposure to as	14 mg/day	204 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	2.8 mg/day	40.8 mg/day

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.02 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	2 mg/ml
4.	Inhalational exposure to as	0.24 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.24 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	43.84 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>0.731 mg/kg bw/day</b>

**Hand held sprayers- with PPE (Gloves for mixer/loader and applicator)**

**A. PRODUCT DATA**

1.	Name	Endocel 35 EC
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	2 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	1 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	2 litres product/ha
3.	Work rate	1 ha/day
4.	Number of operations	4/day
5.	Hand contamination	0.04 ml/day
6.	Protective clothing	Gloves
7.	Transmission to skin	1%
8.	Dermal exposure to formulation	0.0004 ml/day

**C. EXPOSURE DURING SPRAY APPLICATION**

1.	Application technique				
2.	Application volume	350 l spray/ha			
3.	Volume of surface contamination	50 ml/h			
			Hands	Trunk	Legs
4.	Distribution	25%	25%	50%	
5.	Clothing	Gloves	Perm.	Perm.	
6.	Penetration	1%	20%	18%	
7.	Dermal exposure	0.125	2.5	4.5	
8.	Duration of exposure		6 h		
9.	Total dermal exposure to spray	42.75 ml/day			

**D. ABSORBED DOSE**

		Mix/load	Application
1.	Dermal exposure	0.0004 ml/day	42.75 ml/day
2.	Concentration of as	350 mg/ml	2 mg/ml
3.	Dermal exposure to as	0.14 mg/day	85.5 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	0.028 mg/day	17.1 mg/day

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.02 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	2 mg/ml
4.	Inhalational exposure to as	0.24 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.24 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	17.368 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>0.289 mg/kg bw/day</b>

**Estimates of operator exposure-German model****Endocel 35 EC, calculation of exposure for mixer/loader and spray application by tractor. No PPE**

Maximum Application Rate (kg ai/ha) : 0.7

Specific Exposure and Work Rate

<b>Mixing and Loading (mg/person x kg ai)</b>	<b>Spray Application (mg/person x kg ai)</b>	<b>Work Rate (ha/day)</b>
$I_M^* = 0.0006$ $D_{M(H)}^* = 2.4$	$I_A^* = 0.001$ $D_{A(C)}^* = 0.06$ $D_{A(H)}^* = 0.38$ $D_{A(B)}^* = 1.6$	20

Expected Inhalation Exposure:

$$I_M = I_M^* \times R \times A = 0.0006 \times 0.7 \times 20 = 0.0084 \text{ mg/person/day}$$

$$I_A = I_A^* \times R \times A = 0.001 \times 0.7 \times 20 = 0.014 \text{ mg/person/day}$$

Expected Dermal Exposure:

$$D_{M(H)} = D_{M(H)}^* \times R \times A = 2.4 \times 0.7 \times 20 = 33.6 \text{ mg/person/day}$$

$$D_{A(H)} = D_{A(H)}^* \times R \times A = 0.38 \times 0.7 \times 20 = 5.32 \text{ mg/person/day}$$

$$D_{A(C)} = D_{A(C)}^* \times R \times A = 0.06 \times 0.7 \times 20 = 0.84 \text{ mg/person/day}$$

$$D_{A(B)} = D_{A(B)}^* \times R \times A = 1.6 \times 0.7 \times 20 = 22.4 \text{ mg/person/day}$$

**Inhalation exposure = 0.0084 + 0.014 mg ai/person = 0.0224 mg ai/person**

**Total dermal exposure = 62.16 mg ai/person**

**Total dermal exposure based on dermal absorption in humans of 20% = 12.432 mg ai/person**

Total systemic exposure = inhalation + dermal exposure = 12.454 mg ai/person

**Total systemic exposure for a 70 kg person = 0.178 mg ai/kg/day**



**With PPE (Gloves 1% mixing/loading 1%; gloves during application 1%; protection cloth during application 5% and hear protection during application 50% ):**

Dermal exposure:

$$D_{M(H)} = 0.336 \text{ mg/person/day (1\%)}$$

$$D_{A(H)} = 0.0532 \text{ mg/person/day (1\%)}$$

$$D_{A(C)} = 0.42 \text{ mg/person/day (50\%)}$$

$$D_{A(B)} = 1.12 \text{ mg/person/day (5\%)}$$

**Total dermal exposure = 1.9292 mg ai/person**

**Total dermal exposure based on dermal absorption in humans of 20% = 0.386 mg ai/person**

Total systemic exposure = inhalation + dermal exposure = 0.408 mg ai/person

**Total systemic exposure for a 70 kg person = 0.006 mg ai/kg/day**

▪ **ESTIMATES OF OPERATOR EXPOSURE UK MODEL**

**Tractor mounted boom (with cab) with hydraulic nozzles- no PPE**

**A. PRODUCT DATA**

1.	Name	Endocel 35 EC
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	2 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	1 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	2 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	100/day
5.	Hand contamination	1 ml/day
6.	Protective clothing	NONE
7.	Transmission to skin	100%
8.	Dermal exposure to formulation	1 ml/day

C. EXPOSURE DURING SPRAY APPLICATION

1.	Application technique			
2.	Application volume	350 l spray/ha		
3.	Volume of surface contamination	10 ml/h		
			Hands	Trunk
				Legs
4.	Distribution	65%	10%	25%
5.	Clothing	None	Perm.	Perm.
6.	Penetration	100%	50%	15%
7.	Dermal exposure	6.5	0.5	0.375
8.	Duration of exposure		6 h	
9.	Total dermal exposure to spray	44.25 ml/day		

D. ABSORBED DOSE

		Mix/load	Application
1.	Dermal exposure	1 ml/day	44.25 ml/day
2.	Concentration of as	350 mg/ml	2 mg/ml
3.	Dermal exposure to as	350 mg/day	88.5 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	70 mg/day	17.7 mg/day

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.01 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	2 mg/ml
4.	Inhalational exposure to as	0.12 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.12 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	87.82 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>1.464 mg/kg bw/day</b>

**Tractor mounted boom (with cab) with hydraulic nozzles- with PPE (Gloves for mixer/loader and applicator)**

**A. PRODUCT DATA**

1.	Name	Endocel 35 EC
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	2 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	1 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	2 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	100/day
5.	Hand contamination	1 ml/day
6.	Protective clothing	Gloves
7.	Transmission to skin	1%
8.	Dermal exposure to formulation	0.01 ml/day

**C. EXPOSURE DURING SPRAY APPLICATION**

1.	Application technique				
2.	Application volume	350 l spray/ha			
3.	Volume of surface contamination	10 ml/h			
			Hands	Trunk	Legs
4.	Distribution	65%	10%	25%	
5.	Clothing	Gloves	Perm.	Perm.	
6.	Penetration	1%	50%	15%	
7.	Dermal exposure	0.065	0.5	0.375	
8.	Duration of exposure		6 h		
9.	Total dermal exposure to spray	5.64 ml/day			

**D. ABSORBED DOSE**

		Mix/load	Application
1.	Dermal exposure	0.01 ml/day	5.64 ml/day
2.	Concentration of as	350 mg/ml	2 mg/ml
3.	Dermal exposure to as	3.5 mg/day	11.28 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	0.7 mg/day	2.256 mg/day

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.01 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	2 mg/ml
4.	Inhalational exposure to as	0.12 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.12 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	3.076 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>0.051 mg/kg bw/day</b>

**B.6.14.1b Calliope applicant**

**Operator exposure**

The following assumptions have been used in calculation operator exposure:

<u>Maximum application rate</u>	610 g of a.i./ha, corresponding with 1,74 l of product/ha
<u>Spray volume</u>	Projected spray 400-1000 l/ha
	Pneumatic systems 80-150 l/ha
<u>Maximum in-use a.i. concentration</u>	Projected spray 1,53 mg/ml
	Pneumatic systems 7,63 mg/ml
<u>Container size</u>	5 litres (63 mm neck diameter)
<u>Application techniques</u>	Tractor mounted boom (with cab) with hydraulic nozzles
	Tractor mounted boom (with cab) with rotary discs
	Tractor mounted (without cab) air assisted: application volume 100l/ha

**Estimates of operator exposure-German model**

**Callistar, calculation of exposure for mixer/loader and spray application by tractor - No PPE**

Maximum Application Rate (kg ai/ha): 0.61

Specific Exposure and Work Rate

Mixing and Loading (mg/person x kg ai)	Spray Application (mg/person x kg ai)	Work Rate (ha/day)
$I_M^* = 0.0006$ $D_{M(H)}^* = 2.4$	$I_A^* = 0.001$ $D_{A(C)}^* = 0.06$ $D_{A(H)}^* = 0.38$ $D_{A(B)}^* = 1.6$	20

Expected Inhalation Exposure:

$$I_M = I_M^* \times R \times A = 0.0006 \times 0.61 \times 20 = 0.00732 \text{ mg/person/day}$$

$$I_A = I_A^* \times R \times A = 0.001 \times 0.61 \times 20 = 0.0122 \text{ mg/person/day}$$

Expected Dermal Exposure:

$$D_{M(H)} = D_{M(H)}^* \times R \times A = 2.4 \times 0.61 \times 20 = 29.28 \text{ mg/person/day}$$

$$D_{A(H)} = D_{A(H)}^* \times R \times A = 0.38 \times 0.61 \times 20 = 4.636 \text{ mg/person/day}$$

$$D_{A(C)} = D_{A(C)}^* \times R \times A = 0.06 \times 0.61 \times 20 = 0.732 \text{ mg/person/day}$$

$$D_{A(B)} = D_{A(B)}^* \times R \times A = 1.6 \times 0.61 \times 20 = 19.52 \text{ mg/person/day}$$

**Inhalation exposure = 0.00732 + 0.0122 mg ai/person = 0.01952 mg ai/person**

**Total dermal exposure = 54.168 mg ai/person**

**Total dermal exposure based on dermal absorption in humans of 20% = 10.834 mg ai/person**

Total systemic exposure = inhalation + dermal exposure = 10.853 mg ai/person

**Total systemic exposure for a 70 kg person = 0.155 mg ai/kg/day**

**With PPE (Gloves during mixing/loading 1%; gloves during application 1%; protection cloth during application 5% and hear protection during application 50%):**

Dermal exposure:

$$D_{M(H)} = 0.293 \text{ mg/person/day (1\%)}$$

$$D_{A(H)} = 0.04636 \text{ mg/person/day (1\%)}$$

$$D_{A(C)} = 0.366 \text{ mg/person/day (50\%)}$$

$$D_{A(B)} = 0.976 \text{ mg/person/day (5\%)}$$

**Total dermal exposure = 1.681 mg ai/person**

**Total dermal exposure based on dermal absorption in humans of 20% = 0.3362 mg ai/person**

Total systemic exposure = inhalation + dermal exposure = 0.356 mg ai/person

**Total systemic exposure for a 70 kg person = 0.005 mg ai/kg/day**

▪ **ESTIMATES OF OPERATOR EXPOSURE UK MODEL**

**Tractor mounted boom (with cab) with hydraulic nozzles- no PPE**

**A. PRODUCT DATA**

1.	Name	Callistar
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	1.53 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	5 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	1.74 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	18/day
5.	Hand contamination	0.18 ml/day
6.	Protective clothing	NONE
7.	Transmission to skin	100%
8.	Dermal exposure to formulation	0.18 ml/day

C. EXPOSURE DURING SPRAY APPLICATION

1.	Application technique			
2.	Application volume	400 l spray/ha		
3.	Volume of surface contamination	10 ml/h		
			Hands	Trunk
				Legs
4.	Distribution	65%	10%	25%
5.	Clothing	None	Perm.	Perm.
6.	Penetration	100%	50%	15%
7.	Dermal exposure	6.5	0.5	0.375
8.	Duration of exposure		6 h	
9.	Total dermal exposure to spray	44.25 ml/day		

D. ABSORBED DOSE

		Mix/load	Application
1.	Dermal exposure	0.18 ml/day	44.25 ml/day
2.	Concentration of as	350 mg/ml	1.53 mg/ml
3.	Dermal exposure to as	63 mg/day	67.70 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	12.6 mg/day	13.54 mg/day

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.01 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	1.53 mg/ml
4.	Inhalational exposure to as	0.092 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.092 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	26.232 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>0.437 mg/kg bw/day</b>



**Tractor mounted boom (with cab) with hydraulic nozzles- with PPE (Gloves for mixer/loader and applicator)**

**A. PRODUCT DATA**

2.	Name	Callistar
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	1.53 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	5 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	1.74 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	18/day
5.	Hand contamination	0.18 ml/day
6.	Protective clothing	Gloves
7.	Transmission to skin	1%
8.	Dermal exposure to formulation	0.0018 ml/day

**C. EXPOSURE DURING SPRAY APPLICATION**

1.	Application technique				
2.	Application volume	400 l spray/ha			
3.	Volume of surface contamination	10 ml/h			
			Hands	Trunk	Legs
4.	Distribution	65%	10%	25%	
5.	Clothing	Gloves	Perm.	Perm.	
6.	Penetration	1%	50%	15%	
7.	Dermal exposure	0.065	0.5	0.375	
8.	Duration of exposure		6 h		
9.	Total dermal exposure to spray	5.64 ml/day			

**D. ABSORBED DOSE**

		Mix/load	Application
1.	Dermal exposure	0.0018 ml/day	5.64 ml/day
2.	Concentration of as	350 mg/ml	1.53 mg/ml
3.	Dermal exposure to as	0.63 mg/day	8.63 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	0.126 mg/day	1.726 mg/day

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.01 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	1.53 mg/ml
4.	Inhalational exposure to as	0.092 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.092 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	1.944 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>0.0324 mg/kg bw/day</b>

▪ **ESTIMATES OF OPERATOR EXPOSURE UK MODEL**

Tractor mounted boom (with cab) with rotary discs- No PPE

A. PRODUCT DATA

3.	Name	Callistar
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	7.63 mg/ml

B. EXPOSURE DURING MIXING AND LOADING

1a.	Container size	5 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	1.74 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	18/day
5.	Hand contamination	0.18 ml/day
6.	Protective clothing	NONE
7.	Transmission to skin	100%
8.	Dermal exposure to formulation	0.18 ml/day

C. EXPOSURE DURING SPRAY APPLICATION

1.	Application technique	
2.	Application volume	80 l spray/ha
3.	Volume of surface contamination	2 ml/h
		Hands    Trunk    Legs

4.	Distribution	75%	15%	10%
5.	Clothing	None	Perm.	Perm.
6.	Penetration	100%	5%	5%
7.	Dermal exposure	1.5	0.015	0.01
8.	Duration of exposure		6 h	
9.	Total dermal exposure to spray	9.15 ml/day		

#### D. ABSORBED DOSE

		Mix/load	Application
1.	Dermal exposure	0.18 ml/day	9.15 ml/day
2.	Concentration of as	350 mg/ml	7.63 mg/ml
3.	Dermal exposure to as	63 mg/day	69.81 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	12.6 mg/day	13.962 mg/day

#### E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.005 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	7.63 mg/ml
4.	Inhalational exposure to as	0.2289 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.2289 mg/day

#### F. PREDICTED EXPOSURE

1.	Total absorbed dose	26.791 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>0.447 mg/kg bw/day</b>

### Tractor mounted boom (with cab) with rotary discs- - with PPE (Gloves for mixer/loader and applicator)

#### A. PRODUCT DATA

4.	Name	Callistar
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	7.63 mg/ml

#### B. EXPOSURE DURING MIXING AND LOADING

1a.	Container size	5 litre
1b.	Hand contamination/operation	0.01 ml

2.	Application dose	1.74 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	18/day
5.	Hand contamination	0.18 ml/day
6.	Protective clothing	Gloves
7.	Transmission to skin	1%
8.	Dermal exposure to formulation	0.0018 ml/day

C. EXPOSURE DURING SPRAY APPLICATION

1.	Application technique			
2.	Application volume	80 l spray/ha		
3.	Volume of surface contamination	2 ml/h		
			Hands	Trunk
				Legs
4.	Distribution	75%	15%	10%
5.	Clothing	Gloves	Perm.	Perm.
6.	Penetration	1%	5%	5%
7.	Dermal exposure	0.015	0.015	0.01
8.	Duration of exposure		6 h	
9.	Total dermal exposure to spray	0.24 ml/day		

D. ABSORBED DOSE

		Mix/load	Application
1.	Dermal exposure	0.0018 ml/day	0.24 ml/day
2.	Concentration of as	350 mg/ml	7.63 mg/ml
3.	Dermal exposure to as	0.63 mg/day	1.83 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	0.126 mg/day	1.566 mg/day

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.005 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	7.63 mg/ml
4.	Inhalational exposure to as	0.2289 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.2289 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	1.9209 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>0.032 mg/kg bw/day</b>

**B.6.14.1c AgrEvo applicant****Operator exposure**

The exposure to endosulfan in Thiodan-EC35 is predicted according to the German BBA-Model and the UK Model

**Scenario 1: Tractor mounted boom sprayers in field crops**

The maximum application rate in maize is 1.05 Kg a.s/ha (equivalent to 3.0 l product/ha) applied in 400 to 1000 l of water (depending on the growth stage of the crop).

**Scenario 2: Airblast spraying in high crops with tractor –mounted equipment**

The worst case for this scenario is airblast spraying in citrus orchards with a maximum application rate of 1.05 kg a.s./ha (equivalent to 3.0 l of product/ha) and a water volume of 1000 to 3000 l/ha.

**Estimates of operator exposure-German model**

**Scenario 1: Tractor-mounted boom sprayers in field crop**

Maximum Application Rate (kg ai/ha): 1.05

Specific Exposure and Work Rate

Mixing and Loading (mg/person x kg ai)	Spray Application (mg/person x kg ai)	Work Rate (ha/day)
$I_M^* = 0.0006$ $D_{M(H)}^* = 2.4$	$I_A^* = 0.001$ $D_{A(C)}^* = 0.06$ $D_{A(H)}^* = 0.38$ $D_{A(B)}^* = 1.6$	20

Expected Inhalation Exposure:

$$I_M = I_M^* \times R \times A = 0.0006 \times 1.05 \times 20 = 0.0126 \text{ mg/person/day}$$

$$I_A = I_A^* \times R \times A = 0.001 \times 1.05 \times 20 = 0.021 \text{ mg/person/day}$$

Expected Dermal Exposure:

$$D_{M(H)} = D_{M(H)}^* \times R \times A = 2.4 \times 1.05 \times 20 = 50.4 \text{ mg/person/day}$$

$$D_{A(H)} = D_{A(H)}^* \times R \times A = 0.38 \times 1.05 \times 20 = 7.98 \text{ mg/person/day}$$

$$D_{A(C)} = D_{A(C)}^* \times R \times A = 0.06 \times 1.05 \times 20 = 1.26 \text{ mg/person/day}$$

$$D_{A(B)} = D_{A(B)}^* \times R \times A = 1.6 \times 1.05 \times 20 = 33.6 \text{ mg/person/day}$$

**Inhalation exposure = 0.0126 + 0.021 mg ai/person = 0.0336 mg ai/person**

**Total dermal exposure = 93.24 mg ai/person**

**Total dermal exposure based on dermal absorption in humans of 20% = 18.648 mg ai/person**

Total systemic exposure = inhalation + dermal exposure = 18.682 mg ai/person

**Total systemic exposure for a 70 kg person = 0.267 mg ai/kg/day**

**With PPE (Gloves 1% during mixing/loading/application, protection cloth during application 5% and hear protection during application 50%):**

Dermal exposure:

$$D_{M(H)} = 0.504 \text{ mg/person/day (1\%)}$$

$$D_{A(H)} = 0.0798 \text{ mg/person/day (1\%)}$$

$$D_{A(C)} = 0.63 \text{ mg/person/day (50\%)}$$

$$D_{A(B)} = 1.68 \text{ mg/person/day (5\%)}$$

**Total dermal exposure = 2.894 mg ai/person**

**Total dermal exposure based on dermal absorption in humans of 20% = 0.579 mg ai/person**

Total systemic exposure = inhalation + dermal exposure = 0.612 mg ai/person

**Total systemic exposure for a 70 kg person = 0.009 mg ai/kg/day**

▪ **ESTIMATES OF OPERATOR EXPOSURE UK MODEL**

**Tractor mounted boom (with cab) with hydraulic nozzles- no PPE**

**A. PRODUCT DATA**

5.	Name	Thiodan EC 35
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	2.625 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	1 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	3 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	150/day
5.	Hand contamination	1.5 ml/day
6.	Protective clothing	NONE
7.	Transmission to skin	100%

8.      Dermal exposure to formulation      1.5 ml/day

C. EXPOSURE DURING SPRAY APPLICATION

1.	Application technique			
2.	Application volume	400 l spray/ha		
3.	Volume of surface contamination	10 ml/h		
		Hands	Trunk	Legs
4.	Distribution	65%	10%	25%
5.	Clothing	None	Perm.	Perm.
6.	Penetration	100%	50%	15%
7.	Dermal exposure	6.5	0.5	0.375
8.	Duration of exposure		6 h	
9.	Total dermal exposure to spray	44.25 ml/day		

D. ABSORBED DOSE

		Mix/load	Application
1.	Dermal exposure	1.5 ml/day	44.25 ml/day
2.	Concentration of as	350 mg/ml	2.625 mg/ml
3.	Dermal exposure to as	525 mg/day	116.16 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	105 mg/day	23.232 mg/day

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.01 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	2.625 mg/ml
4.	Inhalational exposure to as	0.158 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.158 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	128.39 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>2.14 mg/kg bw/day</b>



**Tractor mounted boom (with cab) with hydraulic nozzles- with PPE (Gloves for mixer/loader and applicator)**

**A. PRODUCT DATA**

6.	Name	Thiodan EC 35
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	2.625 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	1 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	3 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	150/day
5.	Hand contamination	1.5 ml/day
6.	Protective clothing	Gloves
7.	Transmission to skin	1%
8.	Dermal exposure to formulation	0.015 ml/day

**C. EXPOSURE DURING SPRAY APPLICATION**

1.	Application technique				
2.	Application volume	400 l spray/ha			
3.	Volume of surface contamination	10 ml/h			
			Hands	Trunk	Legs
4.	Distribution	65%	10%	25%	
5.	Clothing	Gloves	Perm.	Perm.	
6.	Penetration	1%	50%	15%	
7.	Dermal exposure	0.065	0.5	0.375	
8.	Duration of exposure		6 h		
9.	Total dermal exposure to spray	5.64 ml/day			

**D. ABSORBED DOSE**

		Mix/load	Application
1.	Dermal exposure	0.015 ml/day	5.64 ml/day
2.	Concentration of as	350 mg/ml	2.625 mg/ml
3.	Dermal exposure to as	5.25 mg/day	14.81 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	1.05 mg/day	2.962 mg/day

**E. INHALED EXPOSURE DURING SPRAY APPLICATION**

1.	Inhalation exposure	0.01 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	2.625 mg/ml
4.	Inhalational exposure to as	0.158 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.158 mg/day

**F. PREDICTED EXPOSURE**

1.	Total absorbed dose	4.17 mg/day
2.	Operator body weight	60 kg
3.	Operator exposure	<b>0.07 mg/kg bw/day</b>

**Estimates of operator exposure-German model**

**Scenario 2: Airblast spraying in high crops with tractor-mounted equipment**

Maximum Application Rate (kg ai/ha): 1.05

Specific Exposure and Work Rate

Mixing and Loading (mg/person x kg ai)	Spray Application (mg/person x kg ai)	Work Rate (ha/day)
$I_M^* = 0.0006$ $D_{M(H)}^* = 2.4$	$I_A^* = 0.018$ $D_{A(C)}^* = 1.2$ $D_{A(H)}^* = 0.7$ $D_{A(B)}^* = 9.6$	8

Expected Inhalation Exposure:

$$I_M = I_M^* \times R \times A = 0.0006 \times 1.05 \times 8 = 0.00504 \text{ mg/person/day}$$

$$I_A = I_A^* \times R \times A = 0.018 \times 1.05 \times 8 = 0.1512 \text{ mg/person/day}$$

Expected Dermal Exposure:

$$D_{M(H)} = D_{M(H)}^* \times R \times A = 2.4 \times 1.05 \times 8 = 20.16 \text{ mg/person/day}$$

$$D_{A(H)} = D_{A(H)}^* \times R \times A = 0.7 \times 1.05 \times 8 = 5.88 \text{ mg/person/day}$$

$$D_{A(C)} = D_{A(C)}^* \times R \times A = 1.2 \times 1.05 \times 8 = 10.08 \text{ mg/person/day}$$

$$D_{A(B)} = D_{A(B)}^* \times R \times A = 9.6 \times 1.05 \times 8 = 80.64 \text{ mg/person/day}$$

**Inhalation exposure = 0.00504 + 0.1512 mg ai/person = 0.15624 mg ai/person**

**Total dermal exposure = 116.76 mg ai/person**

**Total dermal exposure based on dermal absorption in humans of 20% = 23.352 mg ai/person**

**Total systemic exposure** = inhalation + dermal exposure = 23.508 mg ai/person

**Total systemic exposure** for a 70 kg person = **0.336 mg ai/kg/day**

**With PPE (Gloves during mixing/loading/application 1%.; protection cloth during application 5%.; during application 20% and hear protection during application 50%):**

Inhalation exposure = **0.0313 mg ai/person** (20%)

Dermal exposure:

$$D_{M(H)} = 0.2016 \text{ mg/person/day (1\%)}$$

$$D_{A(H)} = 0.0588 \text{ mg/person/day (1\%)}$$

$$D_{A(C)} = 5.04 \text{ mg/person/day (10\%)}$$

$$D_{A(B)} = 4.032 \text{ mg/person/day (5\%)}$$

**Total dermal exposure = 9.3324 mg ai/person**

**Total dermal exposure based on dermal absorption in humans of 20% = 1.866 mg ai/person**

Total systemic exposure = inhalation + dermal exposure = 1.898 mg ai/person

**Total systemic exposure for a 70 kg person = 0.027 mg ai/kg/day**

▪ **ESTIMATES OF OPERATOR EXPOSURE UK MODEL**

**Tractor mounted (whitout cab) air assisted: application volume 1000l/ha- No PPE**

**A. PRODUCT DATA**

7.	Name	Thidan EC 35
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	1.05 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	1 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	3 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	150/day
5.	Hand contamination	1.5 ml/day
6.	Protective clothing	NONE
7.	Transmission to skin	100%
8.	Dermal exposure to formulation	1.5 ml/day

C. EXPOSURE DURING SPRAY APPLICATION

1.	Application technique			
2.	Application volume	1000 l	spray/ha	
3.	Volume of surface contamination	400 ml/h		
		Hands	Trunk	Legs
4.	Distribution	10%	65%	25%
5.	Clothing	None	Perm.	Perm.
6.	Penetration	100%	2%	5%
7.	Dermal exposure	10	5.2	5
8.	Duration of exposure		6 h	
9.	Total dermal exposure to spray	121.2 ml/day		

D. ABSORBED DOSE

		Mix/load	Application
1.	Dermal exposure	1.5 ml/day	121.2 ml/day
2.	Concentration of as	350 mg/ml	1.05 mg/ml
3.	Dermal exposure to as	525 mg/day	127.26 mg/day
4.	Percent absorbed	20%	20%
5.	Absorbed dose	105 mg/day	25.452 mg/day

E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.05 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	1.05 mg/ml
4.	Inhalational exposure to as	0.315 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.315 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	130.767 mg/day
2.	Operator body weight	60 kg
3.	<b>Operator exposure</b>	<b>2.179 mg/kg bw/day</b>

**Tractor mounted (whitout cab) air assisted: application volume 1000l/ha- - with PPE (Gloves for mixer/loader and applicator)**

**A. PRODUCT DATA**

8.	Name	Thiodan Ec 35
2a.	Active Ingredient	Endosulfan
2b.	Concentration	350 mg/ml
3.	Formulation type	EC
4a.	Main solvent	
4b.	Concentration of solvent	
5.	Maximum in-use as concentration	1.05 mg/ml

**B. EXPOSURE DURING MIXING AND LOADING**

1a.	Container size	1 litre
1b.	Hand contamination/operation	0.01 ml
2.	Application dose	3 litres product/ha
3.	Work rate	50 ha/day
4.	Number of operations	150/day
5.	Hand contamination	1.5 ml/day
6.	Protective clothing	Gloves
7.	Transmission to skin	1%
8.	Dermal exposure to formulation	0.015 ml/day

**C. EXPOSURE DURING SPRAY APPLICATION**

1.	Application technique				
2.	Application volume	1000 l spray/ha			
3.	Volume of surface contamination	400 ml/h			
			Hands	Trunk	Legs
4.	Distribution	10%	65%	25%	
5.	Clothing	Gloves	Perm.	Perm.	
6.	Penetration	1%	2%	5%	
7.	Dermal exposure	0.4	5.2	5	
8.	Duration of exposure		6 h		
9.	Total dermal exposure to spray	63.6 ml/day			

**D. ABSORBED DOSE**

		Mix/load	Application
1.	Dermal exposure	0.015 ml/day	63.6 ml/day
2.	Concentration of as	350 mg/ml	1.05 mg/ml
3.	Dermal exposure to as	5.25 mg/day	66.78 mg/day
4.	Percent absorbed	20%	20%

5.	Absorbed dose	1.05 mg/day	13.356 mg/day
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E. INHALED EXPOSURE DURING SPRAY APPLICATION

1.	Inhalation exposure	0.05 ml/h
2.	Duration of exposure	6 h
3.	Concentration of as	1.05 mg/ml
4.	Inhalational exposure to as	0.315 mg/day
5.	Percent absorbed	100%
6.	Absorbed dose	0.315 mg/day

F. PREDICTED EXPOSURE

1.	Total absorbed dose	14.721 mg/day
2.	Operator body weight	60 kg
3.	<b>Operator exposure</b>	<b>0.245 mg/kg bw/day</b>

**B.5.14.d Summary of predicted exposure**

Predicted total systemic exposures from a representative sample of "worst-case" applications are summarised in Table 5.14d

**Table 5.14d:** Estimated operator exposure from a representative sample of use conditions

Crop	Product Name	Application equipment	Total systemic exposure (mg/kg bw/day)			
			UK POEM		GERMAN	
			No PPE	PPE	No PPE	PPE
Field	Endocel 35 EC	Hand held sprayers	0.731	0.289	---	---
		Tractor mounted boom	1.464	0.051	0.178	0.006
Field	Callistar	Tractor mounted boom	0.437	0.032	0.155	0.005
		Tractor mounted boom wiht rotary disc	0.447	0.032	0.155	0.005
Field	Thiodan EC 35	Tractor mounted boom	2.14	0.07	0.267	0.009
High	Thiodan EC 35	Airblast spraying whit tractor mounted equipment	2.179	0.245	0.336	0.027



The AOEL for endosulfan has been proposed by the rapporteur at 0.004 mg/kg bw/day

		UK POEM		German model	
		Total systemic exposure (mg/kg bw/day)	% AOEL	Total systemic exposure (mg/kg bw/day)	% AOEL
Endocel 35 EC Field crop-Hand held sprayers	No PPE	0.731	18275	---	---
	PPE	0.289	7225	---	---
Endocel 35 EC Field crop-Tractor mounted boom	No PPE	1.464	36600	0.178	4450
	PPE	0.051	1275	0.006	150
Callistar Field crop-Tractor mounted boom	No PPE	0.437	10925	0.155	3875
	PPE	0.032	800	0.005	125
Callistar Field crop-Tractor mounted boom with rotary disc	No PPE	0.447	11175	0.155	3875
	PPE	0.032	800	0.005	125
Thiodan EC 35 Field crop-Tractor mounted boom	No PPE	2.14	53500	0.267	6675
	PPE	0.07	1750	0.009	225
Thiodan EC 35 High crop_Airblast spraying	No PPE	2.179	54475	0.336	8400
	PPE	0.245	6125	0.027	675

**In conclusion, based on estimates by the German and the UK operator exposure models, all uses of Endosulfan result in exposed over than the AOEL proposed .**

**B.6.15 References relied on**

Annex IIA or Annex IIIA point	Author(s) Year Title Reference	GLP GEP Y / N	Published Y / N	Owner	Data Protection
IIA/5.2.4	██████████ 1997 <sup>a</sup> Primary Dermal Irritation in the rabbit Doc. No. A58442	YES	NO	AgrEvo	YES
IIA/5.2.5	██████████ 1997b Primary Eye Irritation in the rabbit Doc. No. A58443	YES	NO	AgrEvo	YES
IIA/5.2.6	██████████ 1996 Contac Hypersensitivity in albino guinea pigs. Maximization Test. Doc. No. A58132	YES	NO	AgrEvo	YES
IIA/5.3.2.1/2	██████████ <i>et al</i> 1985 13 week Toxicity study in rats followed by 4- week withdrawal period. Doc. No. A30700	YES	NO	AgrEvo	YES
IIA/5.3.2.3/3	██████████ 1989 1-year feeding study to Beagle dogs Doc. No. A40441	YES	NO	AgrEvo	YES
IIA/5.3.3.1/1	██████████ 1985 <sup>a</sup> Subchronic dermal Toxicity in Wistar rats Doc. No. A30750	YES	NO	AgrEvo	YES
IIA/5.4	████████████████████ 1983 Mouse micronucleus test following oral administration. Report No. 83.0458	YES	NO	AgrEvo	NO
IIA/5.4	██████████ 2000 Chromosome aberration assay in bone marrow cells of the rat with Endosulfan Report No. 644101	YES	NO	AgrEvo	NO
IIA/5.4	████████████████████ 1995 Endosulfan-induced biochemical changes in the testis of rats. Published in Vet. Human Toxicol., 37: 547-549.		YES		NO

Annex IIA or Annex IIIA point	Author(s) Year Title Reference	GLP GEP Y / N	Published Y / N	Owner	Data Protection
IIA/5.4	██████████ 1996 Ameliorating effect of vitamin C on murine sperm toxicity induced by three pesticides (endosulfan, phosphamidon and mancozeb) Published in Mutagenesis, 11: 33-36		YES		NO
IIA/5.4	██████████. 1997 Effect of endosulfan on the testis of growing rats. Published in Bull. Environ. Contam. Toxicol., 58: 79-86		YES		NO
IIA/5.4	██████████ 1989 Chromosomal aberrations in peripheral lymphocytes of cotton field workers exposed to pesticides Published in Environmental Research, 49: 1-6		YES		NO
IIA/5.4	██████████ 1991b Clastogenic effect of pesticides in peripheral lymphocytes of cotton-field workers Published in Mutation Research, 261: 177-180		YES		NO
IIA/5.4	██████████, R. 1990 Toxicological evaluation of the insecticide endosulfan Report No. A67384	NO	NO	AgrEvo	NO
IIIA/7.1/A39426	██████████, E. 1988 Endosulfan water dispersible powder (50%) subchronic dermal toxicity (21 treatments in 30 days) in the Wistar rat Report No. 87.0664	YES	NO	AgrEvo	YES
IIIA/7.1/A39279	██████████, H.J., ██████████ Ch. 1988 Endosulfan emulsifiable concentrate subchronic (4-week) repeated dose dermal toxicity study in rats Report No. 88.1735	YES	NO	AgrEvo	YES