

ANNEX B

ENDOSULFAN

B 4 : PROPOSALS FOR CLASSIFICATION AND LABELLING

B.4 Proposals for classification and labelling**B.4.1 Proposals for the classification and labelling of the active substance (IIA, 10)**

The applicant AGREVO has proposed the following classification, with justification.

Proposal

Hazard symbol: T, N

Indication of danger: Toxic.

Dangerous for the environment.

Risk phrases: R24/25; Toxic in contact with skin and if swallowed
R50/53; Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment

Safety phrases: S28; After contact with skin, wash immediately with plenty of water
S36/37; Wear suitable protective clothing and gloves
S45; In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S60; This material and its container must be disposed of as hazardous waste.
S61; Avoid release to the environment.

The applicant CALLIOPE, S.A. has proposed the following classification and labelling of the active substance, without justification:

Proposal

Hazard symbol: T, N

Indication of danger: Toxic.

Dangerous for the environment

Risk phrases: R24/25; Toxic in contact with skin and if swallowed
R36; Irritating to eyes
R50/53; Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment

Safety phrases: S1/2; Keep locked up and out of the reach of children
S28; After contact with skin, wash immediately with plenty of water
S36/37; Wear suitable protective clothing and gloves
S45; In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S60; This material and its container must be disposed of as hazardous waste.
S61; Avoid release to the environment.

The applicant LUXAN, B.V. (excel) has proposed the following classification and labelling of the active substance, without justification:

Proposal

Hazard symbol: T

Indication of danger: Toxic.

Risk phrases: R25. Toxic if swallowed
R 21; Harmful in contact with skin

Safety phrases: S 24/25: Avoid contact with eyes or skin
S 36: Wear protective clothing including respiratory mask, rubber gloves and face shield or goggles.

The proposal of the RAPPORTEUR, is at variance with that of the applicant, as follow;

Proposal

Hazard symbol: T+, N

Indication of danger: Very Toxic.

Risk phrases: Dangerous for the environment
R28: Very toxic if swallowed
R 21: Harmful in contact with skin
R26: Very toxic by inhalation
R50/53; Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment

Safety phrases: S1/2: Keep locked up and out of reach of children
S4; Keep away from living quarters
S13; Keep away from food, drink and animal stuffs
S20; When using do not eat or drink
S27; Take off immediately all contaminated clothing
S28; After contact with skin, wash immediately with plenty of water
S36/37/39; Wear suitable protective clothing and gloves and eye/face protection
S38; In case of insufficient ventilation, wear suitable respiratory equipment.
S45; In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)
S60; This material and its container must be disposed of as hazardous waste.
S61; Avoid release to the environment.

Justification

Hazard Symbol	Test result	Value	Required
E	Non-explosive		No
O	Non-oxidizing		No
F+	Non-flammable		No
F	Non-flammable		No
T+	Rat oral LD ₅₀	48 mg/kg bw (m) 10 mg/kg bw (f)	Yes, R28
	Rat dermal LD ₅₀		No
	Rat inhalation LC ₅₀	0.0345 mg/l (m) 0.0126 mg/l (f)	Yes, R26
	No irreversible damage from single exposure		No
T	Rat oral LD ₅₀		No
	Rat dermal LD ₅₀		No
	Rat inhalation LC ₅₀		No
	No irreversible damage from single exposure		No
	No serious damage from repeated or prolonged exposure		No
Xn	Rat oral LD ₅₀		No
	Rat dermal LD ₅₀	>4000 mg/kg bw (m) 500 mg/kg bw (f)	Yes, R21
	Rat inhalation LC ₅₀		No
	No irreversible damage from single exposure		No
	No serious damage from repeated or prolonged exposure		No
C	No corrosive effects		No
Xi	irritating to rabbit skin	Study required	Study required
	irritation to rabbit eye below 93/21/EEC criteria	Study required	Study required
	No sensitizing to human skin		No
Carcinogenicity	Negative		
Mutagenicity	Negative		Study required
N	Fish LC ₅₀	0.1-46 µg as/L	Yes, R50/53
	Fish NOEC	0.05-0.60 µg as/L	Yes, R50/53
	Daphnia EC ₅₀	62-343 µg as/L	Yes, R50/53
	Daphnia NOEC	63µg as/L	Yes, R50/53
	Algal EC ₅₀	> 560 µ as/L	No

B.4.2a Proposals for the classification and labelling of preparations (IIIA, 12.3 and 12.4)

Applicant: Hoechst Schering AgrEvo GmbH – Makhteshim Agan International Co-ordination Centre (Task force)

Manufacturer: Hoechst Schering AgrEvo GmbH

Tradenames: Thiodan 35 EC, Cyclodan, Thionex, Endofan, Thyonex, FAN 35

The applicant has proposed the following classification and labelling of the plant protection product, with justification:

Proposal

Hazard symbol: T

Indication of danger: Toxic.

Risk phrases: R10; Flammable
R24/R25; Toxic in contact with skin and if swallowed
R 38; Irritating to skin
R41; Risk of serious damage to eyes.

Safety phrases: S1/2; Keep locked up and out of reach of children
S 13; Keep away from food, drink and animal feeding stuffs
S20/21; When using do not eat, drink or smoke
S26; In caso of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S36/37/39; Wear suitable protective clothing, gloves and eye/face protection
S45; In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

Use should be made of the safety advice (S-phrases) associated with the R-phrases and of the more detailed specification reflecting more closely the specific conditions during use of plant protection products. Following this procedure the following specific instructions for operator protection have been established.

- **Wear protective gloves when handling the undiluted product.**
- **Wear protective garment and sturdy footwear (e.g. rubber boots) when handling the undiluted product.**
- **Wear a rubber apron when handling the undiluted product**
- **Wear tight goggles when handling the undiluted product.**

The proposal of the RAPPORTEUR, is at variance with that of the applicant, as follow;

Proposal

Hazard symbol: F, T+, Xi

Indication of danger: Very Toxic.

Irritant

Risk phrases: R10; Flammable

R28; Very toxic if swallowed

R 24; Toxic in contact with skin

R26; Very toxic by inhalation

R38; Irritating to skin

R41; Risk of serious damage to eyes

Safety phrases: S1/2; Keep locked up and out of reach of children

S4; Keep away from living quarters

S13; Keep away from food, drink and animal stuffs

S20; When using do not eat or drink

S27; Take off immediately all contaminated clothing

S28; After contact with skin, wash immediately with plenty of water

S36/37/39; Wear suitable protective clothing and gloves and eye/face protection

S38; In case of insufficient ventilation, wear suitable respiratory equipment.

S45; In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

Justification

Hazard Symbol	Test result	Value	Required
E	Non-explosive		No
O	Non-oxidizing		No
F+	Non-flammable		No
F	Flammable	Flash point closed: 316 ± 2 K (43 ± 2 °C) Flash point open: 330 ± 8 K (57 ± 8 °C)	Yes, R10
T+	Rat oral LD ₅₀	67 mg/kg bw (m) 17 mg/kg bw (f)	Yes, R28
	Rat inhalation LC ₅₀	0.263 mg/l (m) 0.0594 mg/l (f)	Yes, R26
	No irreversible damage from single exposure		No
T	Rat dermal LD ₅₀	412 mg/kg (m) 266 mg/kg (f)	Yes, R24
	No serious damage from repeated or prolonged exposure		
Xi	irritating to rabbit skin		Yes, R38
	irritation to rabbit eye below 93/21/EEC criteria		Yes, R41
	No sensitizing to human skin		No
Carcinogenicity	Negative		
Mutagenicity	Negative		

B.4.2b Proposals for the classification and labelling of preparations (IIIA, 12.3 and 12.4)

Applicant: Calliope, S.A.

Manufacturer: Calliope, S.A.

Tradenames: Callistar

The applicant has proposed the following classification and labelling of the plant protection product, without justification:

Proposal

Hazard symbol: T, C

Indication of danger: Toxic.

Corrosive

Risk phrases: R10; Flammable

R25; Toxic if swallowed

R21; Harmful in contact with skin

R 34; Causes burns

R 36; irritating to eyes

R 41; Risk of serious damage to eyes.

Safety phrases: S1/2; Keep locked up and out of reach of children

S 13; Keep away from food, drink and animal feeding stuffs

S44; Risk of explosion if heated under confinement.

The proposal of the RAPPORTEUR, is at variance with that of the applicant, as follow;

Proposal

Hazard symbol: C, T, Xi

Indication of danger: Corrosive

Toxic.

Irritant

Risk phrases: R25; Toxic if swallowed

R34; Causes burns

R38; Irritating to skin

R41; Risk of serious damage to eyes

Safety phrases: S1/2; Keep locked up and out of reach of children

S4; Keep away from living quarters

S13; Keep away from food, drink and animal stuffs

S20; When using do not eat or drink

S27; Take off immediately all contaminated clothing

S28; After contact with skin, wash immediately with plenty of water

S36/37/39; Wear suitable protective clothing and gloves and eye/face protection

S38; In case of insufficient ventilation, wear suitable respiratory equipment.

S45; In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

Justification

Hazard Symbol	Test result	Value	Required
E	Non-explosive		No
O	Non-oxidizing		No
F+	Non-flammable		No
F		Test required	Test required
T	Rat oral LD ₅₀	50 mg/kg	Yes, R25
	Rat dermal LD ₅₀	2000 mg/kg	No
	Rat inhalation LC ₅₀	Test required	No
	No irreversible damage from single exposure		No
	No serious damage from repeated or prolonged exposure		No
C	C corrosive effects		Yes, R34
Xi	irritating to rabbit skin		Yes, R38
	irritation to rabbit eye below 93/21/EEC criteria		Yes, R41
	No sensitizing to human skin		No
Carcinogenicity	Negative		No
Mutagenicity	Negative		No

B.4.2c Proposals for the classification and labelling of preparations (IIIA, 12.3 and 12.4)

Applicant: Luxan

Manufacturer: Excel Industries Ltd.

Tradenames: Endosulfan 35% EC

The applicant has proposed the following classification and labelling of the plant protection product, without justification:

Proposal

Hazard symbol: T

Indication of danger: Toxic.

Risk phrases: R10; Flammable
R25; Toxic if swallowed
R21; Harmful in contact with skin

Safety phrases: S24/25; Avoid contact with eyes or skin
S23, Do not breathe vapour or spray mist
S36; Wear protective clothing including respiratory mask, rubber gloves, and face shields or goggles

The proposal of the RAPPORTEUR, is at variance with that of the applicant, as follow;

Proposal

Hazard symbol: C, T, Xi

Indication of danger: Corrosive
Toxic.
Irritant

Risk phrases: R25; Toxic if swallowed
R21; Harmful in contact with skin
R34; Causes burns
R38; Irritating to skin
R41; Risk of serious damage to eyes

Safety phrases: S1/2: Keep locked up and out of reach of children
S4; Keep away from living quarters
S13; Keep away from food, drink and animal stuffs
S20; When using do not eat or drink
S27; Take off immediately all contaminated clothing
S28; After contact with skin, wash immediately with plenty of water
S36/37/39; Wear suitable protective clothing and gloves and eye/face protection
S38; In case of insufficient ventilation, wear suitable respiratory equipment.

S45; In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

Justification

Hazard Symbol	Test result	Value	Required
E	Non-explosive		No
O	Non-oxidizing		No
F+	Non-flammable		No
F		Flash point closed: 46.5 °C	Yes, R10
T	Rat oral LD ₅₀	28 mg/kg	Yes, R25
	Rat dermal LD ₅₀	1006 mg/kg	No
	Rat inhalation LC ₅₀	Test required	No
	No irreversible damage from single exposure		No
	No serious damage from repeated or prolonged exposure		No
Xn	Rat dermal LD ₅₀	1006 mg/kg	Yes, R21
C	C corrosive effects		Yes, R34
Xi	irritating to rabbit skin		Yes, R38
	irritation to rabbit eye below 93/21/EEC criteria	Test required	Yes, R41
	No sensitizing to human skin		No
Carcinogenicity	Negative		No
Mutagenicity	Negative		No

B.4.3 References relied on

The applicant has not submitted any reference concerning this point.

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