

European Commission



**Draft Assessment Report prepared according to the Commission
Regulation (EU) N° 1107/2009**

XDE-729 Methyl (Halauxifen-methyl) Volume 3 – B.4

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Co-Rapporteur Member State: France**

Version History

When	What
2013-12-19	Initial DAR

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B.4 PROPOSALS FOR CLASSIFICATION AND LABELLING**B.4.1 Active substance: XDE-729 Methyl (Halauxifen-methyl)****Physical and chemical properties**

None

Classification of the active substance on the basis of toxicological properties**Classification proposal according to Directive 67/548/EEC**

Hazard symbol: None

Indication of danger: None

Risk phrases: None

Safety phrases: None

Justification: The active substance does not meet the criteria for classification on the basis of its toxicological properties under Directive 67/548/EEC.

Classification proposal according to Regulation 1272/2008

Pictogram: None

Signal word: None

Hazard class: None

Hazard statements: None

Justification: The active substance does not meet the criteria for classification on the basis of its toxicological properties under Directive 67/548/EEC.

Classification of the active substance for environmental effects**Provisional classification of the active substance for environmental effects according to 67/548/EEC**

XDE-729 methyl (67/548/EEC)		
Hazard symbol:		Dangerous for the environment
Risk phrases:	R 50/53	Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment
Safety phrases:	S60	This material and its container must be disposed of as hazardous waste
	S61	Avoid release to the environment. Refer to special instructions/safety data sheets
	S59	Refer to manufacturer/supplier for information on recovery/recycling
<u>Justification for the proposals:</u>		
Risk phrases:	R 50	<i>Myriophyllum spicatum</i> 14 d E _r C ₅₀ 0.000393 mg a.s./L (< 1 mg/L)
	R53	Not readily biodegradable
Safety phrases:	S60/61	Recommended for substances that may cause effects in the environment
	S59	Recommended for all dangerous substances recommended for recovery/recycling but <u>obligatory</u> for substances classified as dangerous for the ozone layer (R59)

Provisional hazard classification of the active substance for environmental effects according to Regulation (EC) 1272/2008

Pictogram	GHS09
Signal word	Warning
Hazard statements	H400/H410: Very toxic to aquatic life/Very toxic to aquatic life with long lasting effects (acute/chronic category 1).
M-factor	1000 acute; 1000 chronic
Precautionary statements	P273 Avoid release to the environment P391 Collect spillage P501 Dispose of contents/ container to ... (in accordance with local/ regional/ national/ international regulation (to be specified))

Justification for classification according to Regulation (EC) 1272/2008

H410	Required as XDE-729 methyl is an 'acute category 1' and 'chronic category 1' substance, as defined by: i) <i>Myriophyllum spicatum</i> 14 d E_rC_{50} 0.000393 mg a.s./L ii) <i>Myriophyllum spicatum</i> 14 d NOEC <0.0000617 mg a.s./L iii) substance not 'rapidly biodegradable' (cross ref fate section 8.4.3)
M-factor	i) <i>Myriophyllum spicatum</i> 14 d E_rC_{50} 0.000393 mg a.s./L (> 0.0001 to $\leq$ 0.001 mg/L) ii) <i>Myriophyllum spicatum</i> 14 d NOEC <0.0000617 mg a.s./L (> 0.00001 to $\leq$ 0.0001 mg/L, not rapidly biodegradable)
GHS09 Pictogram	Required for 'acute category 1' and 'chronic category 1' substance
Signal word 'Warning'	Required for 'acute category 1' and 'chronic category 1' substance
P273, P 391, P 501	Required for 'acute category 1' and 'chronic category 1' substance

B.4.2 Plant Protection Product: 'GF-2573'**Physical and chemical properties**

None

Classification of the preparation on the basis of toxicological properties**Classification proposal according to Directive 1999/45/EEC**

Hazard symbol:	X _i
Indication of danger:	Irritant
Risk phrases:	R38 Irritating to skin , R43 May cause sensitisation by skin contact)
Safety phrases:	S24/25 Avoid contact with skin and eye S37 Where suitable gloves

Justification for classification: R38 is required on the basis on the observations (mean score of 2 for erythema or oedema observed in at least two of the three animals tested), in a standard skin irritation study in rabbits. R43 is required on the basis of a positive result ($SI \geq 3$) in a local lymph node assay.

Classification proposal according to Regulation 1272/2008

Pictogram:	GHS07
Signal word:	Warning
Hazard class:	Skin Sensitisation Category 1B
Hazard statements:	H317 May cause an allergic skin reaction

Justification: Skin Sensitisation Category 1B is justified on the basis of the results ($SI \geq 3$, $EC_{3\%} \geq 2\%$) of a local lymph node assay.

The personal protective equipment (PPE) requirements arising from the classification of 'GF-2573' (Xi Irritant, R38 'Irritating to skin', R43 'May cause sensitisation by skin contact' and H317 'May cause allergic skin reaction') are as follows.

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

Classification of the preparation for environmental effects**Provisional hazard Classification/Labelling of plant protection products according to 1999/45/EEC**

‘GF-2573’ (1999/45/EEC)		
Hazard symbol:		Dangerous for the environment
Risk phrases:	R 50/53	Very toxic to aquatic organisms, may cause long term adverse effects in the aquatic environment
Safety phrases:	S35	This material and its container must be disposed of in a safe way.
	S57	Use appropriate containment to avoid environmental contamination.
	S59	Refer to manufacturer/supplier for information on recovery/recycling
<u>Justification for the proposals:</u>		
Risk phrases:	R 50	<i>Myriophyllum spicatum</i> 14 g ErC50 = 0.0844 mg formulation/L (< 1 mg/L)
	R53	Active substance not readily biodegradable
Safety phrases:	S35/57	Recommended for products that may cause effects in the environment
	S59	Recommended for all dangerous substances recommended for recovery/recycling but obligatory for substances classified as dangerous for the ozone layer (R59)

The product labels should carry the wording from Article 10, section 1.2 of Directive 1999/45/EC:

‘To avoid risks to man and the environment, comply with instructions for use’

and the Annex V of Directive 91/414/EEC ‘General provisions’ phrase, SP1:

‘Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).’

Provisional Hazard Classification/Labelling of plant protection products according to Regulation (EC) 1272/2008

Pictogram	GHS09
Signal word	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects (acute/chronic category 1).
Precautionary statements	P391 Collect spillage P501 Dispose of contents/ container to ... (in accordance with local/ regional/ national/ international regulation (to be specified))

Justification for product ('mixture') classification according to Regulation (EC) 1272/2008:

H 410	Required as 'GF-2573' is an 'acute category 1' and 'chronic category 1' formulation, as defined by: i) <i>Myriophyllum spicatum</i> 14 d E_rC_{50} = 0.0844 mg/L ii) <i>Myriophyllum spicatum</i> 14 d NOEC _r = 0.00732 mg/L iii) Active substance not 'rapidly biodegradable'
GHS09 Pictogram	Required for 'chronic category 1' mixture
No signal word	Required for 'chronic category 1' mixture
P 391, P 501	Required for 'chronic category 1' mixture. 'P273' not required since mixture (product) is intended for use in the environment.

B.4.3 References relied on

Refer to B.6.2 and B.6.11 of the Toxicology section and B.9.2.1 of the Ecotoxicology section.