

Annex XV dossier

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, vPvB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name: 3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine

EC Number: 421-150-7

CAS Number: 143860-04-2

Submitted by: European Chemicals Agency at the request of the European Commission

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PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR 1A OR 1B, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance Name: 3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine

EC Number: 421-150-7

CAS number: 143860-04-2

The substance is proposed to be identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH) owing to its classification as toxic for reproduction category 1B¹.

Summary of how the substance meets the criteria set out in Article 57 (c) of REACH (Repr. 1B).

3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine is covered by Index number 613-191-00-6 in Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360F ***: "May damage fertility"). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction, Repr. Cat. 2, R60 ("May impair fertility").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Registration dossier(s) submitted for the substance? Yes

¹ Classification in accordance with Regulation (EC) No 1272/2008 Annex VI, part 3, Table 3.1 List of harmonised classification and labelling of hazardous substances.

PART I

JUSTIFICATION

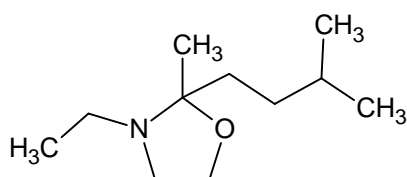
1 Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	421-150-7
EC name:	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine
CAS number (in the EC inventory):	143860-04-2
CAS number: Deleted CAS numbers:	143860-04-2
CAS name:	Oxazolidine, 3-ethyl-2-methyl-2-(3-methylbutyl)-
IUPAC name:	3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine
Index number in Annex VI of the CLP Regulation	613-191-00-6
Molecular formula:	C ₁₁ H ₂₃ N O
Molecular weight range:	185.3 g/mol
Synonyms:	Zoldine MS-PLUS

Structural formula:



1.2 Composition of the substance

Name: 3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine

Description: ---

Degree of purity: 90 - 100 %

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
3-Ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine 421-150-7		90 - 100 %	Information according to the available registration dossiers

2 Harmonised classification and labelling

3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine is covered by Index number 613-191-00-6 in Annex VI, part 3 of Regulation (EC) No 1272/2008 as follows:

Table 3: Classification according to part 3 of Annex VI, Table 3.1 ((list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
613-191-00-6	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	421-150-7	143860-04-2	Repr. 1B Skin Corr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360F *** H314 H400 H410	GHS08 GHS05 GHS09 Dgr	H360F *** H314 H410			

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Table 4: Classification according to part 3 of Annex VI, Table 3.2 (list of harmonized classification and labelling of hazardous substances from Annex I of Council Directive 67/548/EEC) of Regulation (EC) No 1272/2008

Index No	International Chemical Identification	EC No	CAS No	Classification	Labelling	Concentration Limits	Notes
613-191-00-6	3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	421-150-7	143860-04-2	Repr. Cat. 2; R60 C; R34 N; R50-53	T; N R: 60-34- 50/53 S: 53-45-60- 61		

3 Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57c.

4 Human health hazard assessment

See section 2 on harmonised classification and labelling.

5 Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57c.

6 Conclusions on the SVHC Properties

6.1 CMR assessment

3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine is covered by Index number 613-191-00-6 in Regulation (EC) No 1272/2008 and classified in Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances) as toxic for reproduction, Repr. 1B (H360F ***: "May damage fertility"). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised and classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is toxic for reproduction, Repr. Cat. 2, R60 ("May impair fertility").

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that it meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

PART II

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

The available use and exposure information is provided in the registration dossiers (authorities with access rights only) or on ECHA's dissemination website²:

<http://echa.europa.eu/information-on-chemicals>

ECHA has not carried out further analysis of this information.

² Information published by ECHA on the substance can be searched at this site (field "Search for Chemicals" at upper right) by EC number, CAS number or substance name.