

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

EC Number: 421-150-7

CAS Number: 143860-04-2

SUPPORT DOCUMENT FOR IDENTIFICATION OF

3-ETHYL-2-METHYL-2-(3-METHYLBUTYL)-1,3-OXAZOLIDINE

AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS CMR¹ PROPERTIES

 $^{1}\ \mathrm{CMR}$ means carcinogenic, mutagenic or toxic for reproduction

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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 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 1B².

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

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 $^{^2}$ 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.

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:	143860-04-2
Deleted CAS numbers:	
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 NO
Molecular weight range:	185.3 g/mol
Synonyms:	Zoldine MS-PLUS

Structural formula:

$$H_3C$$
 CH_3
 CH_3
 CH_3

1.2 Composition of the substance

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

Description: ---

Degree of purity: 90 - 100 %

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Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks	
3-ethyl-2-methyl-2- (3-methylbutyl)-1,3- oxazolidine		90 - 100 %	Information according to the available registration	
421-150-7			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 C	CAS No	Classification			Labelling		Spec.	Notes
				Hazard Class and Categor Y Code(s)	Hazard statement code(s)	Pictogram , Signal Word Code(s	Hazard statement code(s)	Suppl. Hazard statement code(s)	Conc. Limits, M-factors	
613-191-00-6	3-ethyl-2-methyl-2- (3-methylbutyl)-1,3- oxazolidine	421-150-7	143860-04-2	Skin Corr. 1B Aquatic	***	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	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.