Annex XV report

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance Name: 2-methylimidazole

EC Number: 211-765-7

CAS Number: 693-98-1

Submitted by: Sweden

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PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

Substance name: 2-methylimidazole

EC number: 211-765-7

CAS number: 693-98-1

- The substance is proposed to be identified as a substance meeting the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1B[1].

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

2-methylimidazole is covered by index number 613-330-00-0 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (360Df: "May damage the unborn child. Suspected of damaging fertility").

Therefore, the classification of the substance in Regulation (EC) No 1272/2008 shows that it fulfils the criteria for classification in the hazard class:

- Toxic for reproduction category 1B in accordance with Article 57 (c) of the REACH Regulation.

Registration dossiers submitted for the substance? Yes

[1] Classification in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008.

PART I

Justification

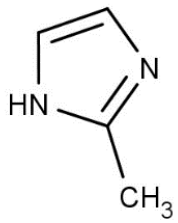
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	211-765-7
EC name:	2-methylimidazole
CAS number (in the EC inventory):	693-98-1
CAS name:	1*H*-Imidazole, 2-methyl-
IUPAC name:	2-methyl-1*H*-imidazole
Index number in Annex VI of the CLP Regulation	613-330-00-0
Molecular formula:	C4H6N2
Molecular weight range:	82.1 g/mol
Synonyms:	2-methylglyoxaline

Structural formula:



1.2 Composition of the substance

Name: 2-methylimidazole

Description: organic

Substance type: mono-constituent

1.3 Physicochemical properties

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

2. Harmonised classification and labelling

2-methylimidazole is covered by index number 613-330-00-0 in part 3 of Annex VI to the CLP Regulation as follows:

Table 2: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No	Chemical name	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)		
613-330-00-0	2-methylimidazole	211-765-7	693-98-1	Repr. 1B	H360Df	GHS08 Dgr	H360Df	-	-	-

3. Environmental fate properties

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

4. Human health hazard assessment

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

5. Environmental hazard assessment

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

6. Conclusions on the SVHC Properties

6.1 CMR assessment

2-methylimidazole is covered by index number 613-330-00-0 of Regulation (EC) No 1272/2008 in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) and it is classified in the hazard class toxic for reproduction category 1B (hazard statement 360Df: "May damage the unborn child. Suspected of damaging fertility").

Therefore, the classification of the substance in Regulation (EC) No 1272/2008 shows that it fulfils the criteria for classification in the hazard class:

- toxic for reproduction category 1B in accordance with Article 57 (c) of the REACH Regulation.

6.2 PBT and vPvB assessment

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

6.3 Assessment under Article 57(f)

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

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 3 Registration status

From the ECHA dissemination site[2]	
Registrations	☒ Full registration(s) (Art. 10) ☒ Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

Table 4: CLP notifications

	CLP Notifications[3]
Number of aggregated notifications	26
Total number of notifiers	707

8. Total tonnage of the substance

Table 5: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)[4]	10+ t/pa
Tonnage information from public sources other than registration dossiers (if available)	No information

9. Information on uses of the substance

According to the registration dossier, 2-methylimidazole is used in industrial settings[5]. Registered uses are specified in Table 6. Uses of 2-methylimidazole reported in the literature include as a catalyst, starting material, chemical intermediate or component in the manufacture of pharmaceuticals, photographic and photothermographic chemicals,

[2] ECHA dissemination site (accessed 2020-02-17)
[3] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 17 Feb 2020)
[4] https://www.echa.europa.eu/sv/web/guest/registration-dossier/-/registered-dossier/5866 (accessed 2020-02-17)
[5] ECHA dissemination site (accessed 18 February 2020)

dyes and pigments, agricultural chemicals and rubber. In addition, uses of 2-methylimidazole have been reported as a polymerisation crosslinking accelerator and hardener for epoxy resin systems for semiconductor potting compounds and soldering mask as well as a component of numerous polymers including epoxy resin pastes, acrylic rubber-fluororubber laminates, films, adhesives, textile finishes and epoxy silane coatings. It has also been described as a dyeing auxiliary for acrylic fibers and plastic foams[6].

According to registers from the Nordic database SPIN[7], Denmark, Finland, Norway and Sweden report uses of 2-methylimidazole with amounts up to 1.9 tons per country and year (latest year reported is 2017). 2-methylimidazole is mainly used in the manufacturing of fabricated metal products, machinery and equipment, transport equipment, and chemicals and chemical products. The products are mainly paints, lacquers and varnishes. Industrial (Denmark, Finland, Norway and Sweden) and consumer uses (Norway) are reported.

No downstream user (DU)-reports have been found for 2-methylimidazole.

Table 6: Uses

	Use(s)	Registered use	Use possibly in the scope of Authorisation
Uses as intermediate		Yes	No
Formulation or repacking	Formulation of mixtures Charging and discharging of substances and mixtures	Yes	Yes
Uses at industrial sites	Use in industrial chemicals processes Use in polymerisation reactions (catalyst) Use in laboratories	Yes	Yes
Uses by professional workers		No	No
Consumer uses		No	No
Article service life		No	No

10. Information on structure of the supply chain

No information available.

[6] https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr516.pdf
[7] http://spin2000.net/ (accessed 17 Feb 2020, last update 2017)

References

EU(2006). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. Official Journal of the European Union, L396: 1-849.

EU (2008). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packing of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union, L353: 1-1355.

References have been inserted as footnotes in the text of the document.