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-methoxyethyl acetate

EC Number: 203-772-9

CAS Number: 110-49-6

Submitted by: Swedish Chemicals Agency

Date: March 2019

This document has been prepared according to template: TEM-0049.03

CONTENTS

TABLES

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-methoxy ethyl acetate

EC Number: 203-772-9

CAS number: 110-49-6

- 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-methoxyethyl acetate is covered by index number 607-036-00-1 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 (May damage fertility. May damage the unborn child).

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

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

Registration dossiers submitted for the substance? No

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

PART I

Justification

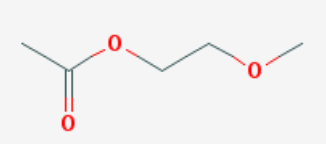
1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	203-772-9
EC name:	2-methoxyethyl acetate
CAS number (in the EC inventory):	110-49-6
CAS number: Deleted CAS numbers:	
CAS name:	
IUPAC name:	2-methoxyethyl acetate; methylglycol acetate,
Index number in Annex VI of the CLP Regulation	607-036-00-1
Molecular formula:	C5H10O3
Molecular weight range:	118.132 g/mol
Synonyms:	Methylglycol acetate 1-Acetoxy-2-methoxyethane Ethylene glycol monomethyl ether acetate Glycol monomethyl ether acetate EGMEA

Structural formula:



1.2 Composition of the substance

Name: 2-methoxyethyl acetate

Description: organic

Substance type: mono-constituent

1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment

2-methoxyethyl acetate is metabolised to form methoxyacetic acid and 2-methoxyethanol. Both these substances have harmonised classifications as Repr. 1B and are included in the Candidate List. These metabolites are assumed to be associated with the reprotoxic effects demonstrated for several glycol ethers with similar structures, including 2-methoxtethyl acetate.

Table 2: Degradation (transformation) product/metabolite methoxyacetic acid

EC number:	210-894-6
EC name:	Methoxyacetic acid
SMILES:	
CAS number (in the EC inventory):	
CAS number:	625-45-6
CAS name:	
IUPAC name:	2-methoxyacetic acid, methoxyessigsäure
Index number in Annex VI of the CLP Regulation	607-312-00-1
Molecular formula:	C3H6O3
Molecular weight range:	
Synonyms:	

Structural formula:

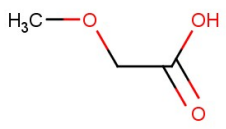
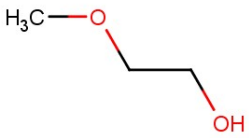


Table 3: Degradation (transformation) product/metabolite 2-methoxyethanol

EC number:	203-713-7
EC name:	2-methoxyethanol
SMILES:	
CAS number (in the EC inventory):	
CAS number:	109-86-4;
CAS name:	
IUPAC name:	2-methoxy-ethanol, 2-methoxyethan-1-ol, 2-methoxyethanol, ethylene glycol monomethyl ether, methylglycol
Index number in Annex VI of the CLP Regulation	603-011-00-4
Molecular formula:	C3H8O2
Molecular weight range:	
Synonyms:	

Structural formula:



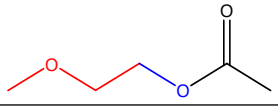
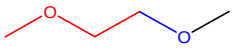
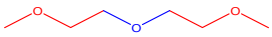
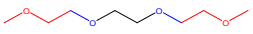
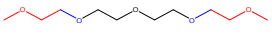
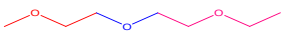
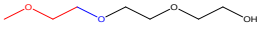
1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)

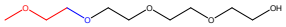
A selection of glycol ethers were sub-grouped based on structural similarity and likely metabolic products. 2-methoxyethyl acetate was included in a group comprising 10 glycol ethers with the generic chemical structure CH3-O-CH2-CH2-O-R. Based on chemical structures, glycol ethers in this group show potential to be metabolised to methoxyacetic acid (MAA) and/or 2-methoxyethanol (EGME) in the body. These two metabolites are thought to be associated with the reprotoxic effect demonstrated for glycol ethers in this group.

Some of the substances in the group are confirmed reproductive toxicants, while others are suspected to cause this effect. Although the chemical structures indicate similarities, all the substances in the group may not necessarily show reprotoxicity, e.g. due to differences in chain lengths and metabolic pathways.

Four members of the group of ten substances are already included in the Candidate list (but not 2-methoxyethyl acetate); seven members have a harmonised classification or are proposed for harmonised classification as Repr. 1B (including 2-methoxyethyl acetate). All members of the group, except 2-methoxyethyl acetate, are registered under REACH. One of the substances in this group, bis(2-methoxyethyl)ether (diglyme) is also included in Annex XIV (see table 4).

Table 4: Structurally related glycol ethers.

EC number:	CAS number:	EC name	Structural formula	Regulatory information
203-772-9	110-49-6	2-methoxyethyl acetate		CLH Repr. 1B
203-713-7	109-86-4	2-methoxyethanol		CLH Repr. 1B Candidate list Registered
203-794-9	110-71-4	1,2-dimethoxyethane		CLH Repr. 1B Candidate list Registered
203-924-4	111-96-6	Bis(2-methoxyethyl) ether		CLH Repr. 1B Candidate list Registered Annex XIV (Reach)
203-977-3	112-49-2	1,2-bis(2-methoxyethoxy) ethane		CLH Repr. 1B Candidate list Registered
205-594-7	143-24-8	Bis(2-(2-methoxyethoxy)ethyl) ether		CLH proposal Repr. 1B submitted Registered
213-690-5	1002-67-1	1-ethoxy-2-(2-methoxyethoxy) ethane		Registered
203-906-6	111-77-3	2-(2-methoxyethoxy) ethanol		CLH Repr. 2 CLH intention submitted for Repr. 1B Registered Restricted (entry 54 of Annex XVII)
203-962-1	112-35-6	2-(2-(2-methoxyethoxy)ethoxy ethanol		Registered

245-883-5	23783-42-8	3,6,9,12-tetraoxotridecanol		Registered

1.5 Physicochemical properties

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

2. Harmonised classification and labelling

2-methoxyethyl acetate is covered by Index number 607-036-00-1 in part 3 of Annex VI to the CLP Regulation as follows:

Table 5: 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	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)		
607-036-00-1	2-methoxyethyl acetate methylglycol acetate	203-772-9	110-49-6	Repr. 1B	H360FD	GHS08 GHS07 Dgr	H360FD			

3. Environmental fate properties

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

4. Human health hazard assessment.

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

5. Environmental hazard assessment

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

6. Conclusions on the SVHC Properties

6.1 CMR assessment

2-methoxyethyl acetate is covered by index number 607-036-00-1 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 (May damage fertility. May damage the unborn child).

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

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

Part II

7. Registration and C&L notification status

7.1 Registration status

Table 6 : Registration status

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

No registration submitted.

7.2 CLP notification status

Table 7: CLP notifications

	CLP Notifications[3]
Number of aggregated notifications	7
Total number of notifiers	72

8. Total tonnage of the substance

- The substance is not registered. No information.

Table 8: Tonnage status

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18)	No information/Not registered
Tonnage information from public sources other than registration dossiers (if available)	No information

[2] https://echa.europa.eu/substance-information/-/substanceinfo/100.003.431 (accessed 28 December 2018)
[3] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 28 December 2018)

9. Information on uses of the substance

2-methoxyethyl acetate is not registered under REACH and thus no information on uses is available from any registration. However, the related glycol ethers already included in the Candidate List, are mostly used as process solvents, processing aids and regulators and as intermediates in industrial sites.

According to The Office of Environmental Health Hazard Assessment (OEHHA, California, US) 2-methoxyethyl acetate is used as a solvent for gums, resins, waxes, and oils and in the manufacture of semiconductors, textile printing and photographic films[4].

The substance is included in the SinList because of its harmonised classification as Repr 1B, and according to Chemsec possible uses include e.g.: paints, lacquers, stains, inks, surface coatings, silk-screen printing, photographic and photo lithographic processes, semiconductors, textile, leather, hydraulic fluids, jet fuel, varnishes, paper, acetate adhesives, nitrocellulose, cellulose acetate, gums, resins, waxes, and oils, textile printing and dry-cleaning. Technical functions include solvent, drying retarder, and anti-icing additive, viscosity decreasing agent.[5]

10. Information on structure of the supply chain

No information.

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

2-methoxyethyl acetate is structurally similar to, and form the same metabolite as several other glycol ethers that are already included in the Candidate List. The uses of the substance seem to be similar as for the Candidate listed glycol ethers of this subgroup. Since 2-methoxyethyl acetate may be used as alternative to replace other glycol ethers there is cause for concern. Although not registered under REACH, data from the C&L registrations suggests that the substance is still in use in the EU.

The SVHC Roadmap to 2020 proposes grouping of substances based on inherent toxic properties and uses. According to the Roadmap, there might be cases in which non-registered substances can be considered relevant for identification as SVHC, e.g., when a substance that is currently not produced or used in Europe but might be used as an alternative to another SVHC. Since 2-methoxyethyl acetate might have similar uses as the other glycol ethers, and could be used as substitute for the glycol ethers that are included in the Candidate List, a grouping approach can be used for 2-methoxyethyl acetate with other structurally similar glycol ethers to prevent inappropriate substitution.

Given that the substance is not registered, inclusion of 2-methoxyethyl acetate in Annex XIV based on quantities and wide-dispersive use may not be likely in a near future, as it will be given a low priority score. However, by using a grouping approach based on similarities to other glycol ethers included in the Annex XIV, inclusion may be possible much earlier.

[4] https://oehha.ca.gov/chemicals/ethylene-glycol-monomethyl-ether-acetate
[5] http://sinlist.chemsec.org/search/search?query=110-49-6 (accessed on 28 December 2018)

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.