Annex XV dossier

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

Substance Name:	**1,2-diethoxyethane**
EC Number:	**211-076-1**
CAS Number:	**629-14-1**

Submitted by:	Slovak Competent Authority (Centre for Chemical Substances and Preparations)
In cooperation with:	Belgian Competent Authority (Belgian Federal Public Service (FPS) Health, Food Chain Safety and Environment, Risk Management Service) and Polish Competent Authority (Bureau for Chemical Substances)
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LIST OF ABBREVIATIONS

2-EEA	2-ethoxyethyl acetate
ATP	Adaptation to Technical Progress
C&L	Classification and Labelling
CAS	Chemical Abstract Service
CLP	Classification, Labeling and Packaging
CMR	Carcinogenic, Mutagenic or Toxic to Reproduction
DEGDME	Bis(2-methoxyethyl)ether
EC	European Community
ECHA	European Chemicals Agency
EEC	European Economic Community
EGDEE	Ethylene glycol diethyl ether
EGDME	Ethylene glycol dimethyl ether
EGEE	Ethylene glycol monoethyl ether
EGME	Ethylene glycol monomethyl ether
EU	European Union
HPVC	High Production Volume Chemicals
HSDB	Hazardous Substances Data Bank
IUPAC	International Union of Pure and Applied Chemistry
OSPA	Oxygenated Solvents Producers Association
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SPIN	Substances in Preparations in the Nordic countries
SVHC	Substance of Very High Concern
TEGDME	Triethylene glycol dimethyl ether
US EPA	U.S. Environmental Protection Agency

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

Substance Name: **1, 2-diethoxyethane**

EC Number: **211-076-1**

CAS Number: **629-14-1**

- The substance is proposed to be identified as substance meeting the criteria of Article 57 (c) of Regulation (EC) 1907/2006 REACH (EU, 2006) owing to its classification as toxic for reproduction category 1B[1, 2] which corresponds to classification as toxic for reproduction category 2; R61[3].

Summary of how the substance meets the criteria as category 1B reproductive toxicant

1,2-diethoxyethane is listed by Index number 603-208-00-5 in the 1st ATP to 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 category 1B (H360D: "May damage the unborn child."). The corresponding classification in Annex VI, part 3, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of the 1st ATP to Regulation (EC) No 1272/2008 is toxic for reproduction category 2, R61 ("May cause harm to the unborn child").

Therefore, this classification of 1,2-diethoxyethane in the 1st ATP to the Regulation (EC) No 1272/2008 (EU, 2009) shows that the substance meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

Registration dossiers submitted for the substance? No.

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[1] Classification in accordance with the 1st ATP to Regulation (EC) No 1272/2008 (Reg. (EC) No 790/2009) Annex VI, part 3, Table 3.1 (list of harmonised classification and labelling of hazardous substances)

[2] There is a mistake in the entry listed in Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.1, indicating the classification as 'Repr. 1**A**, H360Df". The correct classification is Repr. 1**B**, H360Df, which corresponds to Repr. Cat. 2; R61 and Repr. Cat. 3; R62, that are correctly stated in 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. The classification was agreed by the Technical Committee C&L on the Classification and Labelling of Dangerous Substances at its meeting in September 2004. See Summary Record in Annex I.

[3] Classification in accordance with the 1st ATP to the Regulation (EC) No 1272/2008 (Reg. (EC) No 790/2009), Annex VI, part 3, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Council Directive 67/548/EEC)

PART I

JUSTIFICATION

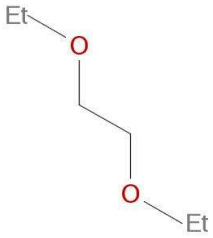
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	211-076-1
EC name:	1,2-diethoxyethane
CAS number (in the EC inventory):	629-14-1
CAS number:	629-14-1
CAS name:	Ethane, 1,2- diethoxy-
IUPAC name:	1,2- diethoxyethane
Molecular formula:	$C_6 H_{14} O_2$
Molecular weight range:	118.18 $gmol^{-1}$
Synonyms:	ethylene glycol diethyl ether, EGDEE, ethyl glyme, diethyl glycol, diethyl cellosolve

Structural formula:



1.2 Composition of the substance

Name: 1,2-diethoxyethane

Description: ---

Degree of purity: 99 – 100 % (w/w)

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
1,2-diethoxyethane EC number: 211-076-1	≥ 99 % (w/w)	99 – 100 % (w/w)	Based on C&L notification

Table 3: Impurities

Impurities	Typical concentration	Concentration range	Remarks
			No information available

Table 4: Additives

Additives	Typical concentration	Concentration range	Remarks
			No information available

1.3 Physico-chemical properties

Table 5: Overview of physicochemical properties

Property	Value	Remarks
Physical state at 20 °C and 101.3 kPa	liquid	
Melting point	-74 °C at 101,3 kPa	Hazardous Substances Data Bank, USA (HSDB, 2007)
Boiling point	121.4 °C at 1013 hPa	Hazardous Substances Data Bank, USA (HSDB, 2007)
Density	0.8484 g/cm^3 at 20 °C	Hazardous Substances Data Bank, USA (HSDB, 2007)
Vapour pressure	3.37 mm Hg at 25 °C	Hazardous Substances Data Bank, USA (HSDB, 2007)
Water solubility	83.7 g/l at 25 °C	Hazardous Substances Data Bank, USA (HSDB, 2007)
Partition coefficient n-octanol/water (log value)	Log Pow 0.66 (measured)	Hazardous Substances Data Bank, USA (HSDB, 2007)
Surface tension	0.026 N/m at 20 °C	Hazardous Substances Data Bank, USA (HSDB, 2007)
Flash point	35 °C (open cup)	Hazardous Substances Data Bank, USA (HSDB, 2007)
Auto-ignition temperature	208 °C	Hazardous Substances Data Bank, USA (HSDB, 2007)
Explosive properties	Forms explosive mixture with air	Hazardous Substances Data Bank, USA (HSDB, 2007)

2 HARMONISED CLASSIFICATION AND LABELLING

1, 2-diethoxyethane is listed by Index number 603-208-00-5 in 1st ATP to the Regulation (EC) No 1272/2008 and classified in Annex VI as provided in tables 6 and 7.

Table 6: 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	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)		
603-208-00-5	1,2,-diethoxyethane	Flam. Liq. 2 Repr. 1B Eye Irrit. 2	H225 H360Df H319	GHS02 GHS08 GHS07 Dgr	H225 H360Df H319	EUH019		

Table 7: 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	Classification	Labelling	Concentration Limits	Notes
603-208-00-5	1,2,-diethoxyethane	F; R11 R19 Repr. Cat. 2; R61 Repr. Cat. 3; R62 Xi; R36	F; T R: 61-11-19-36-62 S: 53-45		

3 ENVIRONMENTAL FATE PROPERTIES

Not relevant.

4 HUMAN HEALTH HAZARD ASSESSMENT

Not relevant.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant.

6 CONCLUSIONS ON THE SVHC PROPERTIES

6.1 PBT, vPvB assessment

Not relevant.

6.2 CMR assessment

1, 2-diethoxyethane is listed by Index number 603-208-00-5 in the 1st ATP to the 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 category 1B (H360D: “May damage the unborn child.”). The corresponding classification in Annex VI, part 3, Table 3.2 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of the 1st ATP to the Regulation (EC) No 1272/2008 is as toxic for reproduction category 2, R61 (“May cause harm to the unborn child”).

Therefore, this classification of 1,2-diethoxyethane in the 1st ATP to the Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

6.3 Substances of equivalent level of concern assessment

Not relevant.

PART II

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

1 INFORMATION ON MANUFACTURE, IMPORT/EXPORT, USES AND RELEASES FROM MANUFACTURE

1.1 Manufacture, import/export and uses

1,2-diethoxyethane has not been registered yet. The envisaged registration deadline was November 30th 2010. Nevertheless the substance has been pre-registered by 59 companies.

This substance is not reported by EU Industry as an HPVC or LPVC and is not listed in a priority list (as foreseen under Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances).

At present regulatory measures for the use of the substance are generally covered by entry 30 of Annex XVII of REACH regulation, which is related to substances which appear in Part 3 of Annex VI of Regulation (EC) No 1272/2008 classified as toxic to reproduction category 1A or 1B (Table 3.1) or toxic to reproduction category 1 or 2 (Table 3.2). The substances of entry 28 – 30 shall not be placed on the market or used for supply to the general public as substance or constituent of other substances, or in mixtures when the individual concentration in the substance or mixture is equal to or greater to the concentration limit specified in Part 3 of Annex VI of Regulation (EC) No 1272/2008 or the relevant concentration specified in directive 1999/45/EC. The packaging of such substances and mixtures must be marked legibly and indelibly as follows: “Restricted to professional users”.

The substance is listed in ECHA C&L Inventory database, (ECHA, 2012), as provided in Table 8:

Table 8: Summary of Classification and Labelling (updated 07/03/2012)

EC Number	CAS Number	IUPAC Name
211-076-1	629-14-1	1,,2 Diethoxyethane

Classification		Labelling			Specific Concentration limits, M-Factors	Notes	Number of Notifiers
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	Pictograms Signal Word Code(s)			
Flam. Liq. 2	H225	H225	EUH019	GHS07 GHS02 GHS08			200
Eye Irrit. 2	H319	H319					

Repr. 1A	H360	H360		Dgr			
Flam. Liq. 2	H225	H225		GHS07 GHS02 GHS08 Dgr			23
Eye Irrit. 2	H319	H319					
Repr. 1A	H360	H360					
Flam. Liq. 3	H226	H226		GHS07 GHS02 GHS08 Dgr			3
Eye Irrit. 2	H319	H319	EUH019				
Repr. 1B	H360	H360					
Flam. Liq. 2	H225	H225		GHS02 GHS08 Dgr			1
Eye Irrit. 2	H319	H319	EUH019				
Repr. 1A	H360	H360					
Flam. Liq. 2	H225	H225		GHS08 Dgr			1
Eye Irrit. 2	H319	H319					
Repr. 1B	H360	H360					

Number of Aggregated Notifications: 5

The substance is listed in the “Chemical Book” database and, according to it, is offered for sale by 10 European suppliers, by 33 suppliers from China, 4 suppliers from Japan and 15 suppliers from USA (Chemical Book, 2012).

The US production volume of the substance in 1994 was according to data obtained from US EPA Non-confidential Inventory Update Reporting in the range of 10 000 – 500 000 pounds (corresponding to 4.54 – 227 tons) (US EPA, 2012).

The SPIN database (Substances in Preparations in the Nordic Countries) was searched for information on 1 , 2-diethoxyethane in products on the national markets of Norway, Sweden, Finland and Denmark. There is only one entry in the database; the substance was present in consumer preparations in Sweden during the years 1999-2001. No more information is given due to confidential reasons (SPIN, 2012).

Over half of all glycol ether consumption (including E-series and P-series depending on whether they are made from ethylene or propylene) is for use as a solvent in various formulations, such as paints, inks and cleaning fluids. Nonsolvent uses for glycol ethers include hydraulic and brake fluids, anti-icing agents and chemical intermediates. The United States is the largest producer, consumer and exporter of E-series glycol ethers in the world. In 2009, the United States accounted for about 25% of the world consumption of E-series glycol ethers; Western Europe and China accounted for 22% and 21%, respectively. Growth in E-series glycol ether consumption will be greatest in China, with an average annual growth rate of 11% during 2009 – 2014, followed by Canada, the Middle East and Mexico with growth rates of 4.9%, 4.7% and 4.6% during this period, respectively. Overall, E-series glycol ether consumption will grow at an average rate of 5% per year through 2014 (IHS, 2010).

1,2-diethoxyethane belongs to the glyme family of chemicals, of which monoglyme, diglyme and triglyme have been already identified as SVHC. In chemical terms, glymes are end-capped polyols comprised of ethylene and propylene glycols. The end-capping of the glycol chain can be done with methyl, ethyl, butyl or, in general, alkyl groups (Clariant, 2012).

The available information on uses of the substance is quite limited. More detailed information on uses of glymes (polyglycol ethers) in general was obtained from product brochure of the NOVOLYTE (the former Fine Chemicals Division of Ferro Corp).

Glymes are widely used as reaction media for processes involving alkali metal hydroxides, sodium hydride and alkali metals due to high stability and solvency. Glymes are also useful as solubilizing agents, extractants and selective solvents.
Glymes have applications in fabric cleaning compounds, such as a dry powder carpet cleaner, in all purpose liquid detergent compositions, in noncaustic alkaline, waterbased oven cleaners, and in bathroom mildew removers.
Glymes are useful in liquid stain removers for contact lenses, in compositions for wall paper removal, in cleaners for rubber based marking on tire sidewalls, and in cleansers for removal of biological materials from laboratory diagnostic equipment. Semi permeable membranes used in water purification are regenerated by washing with glymes. Fouled anion exchange resins are cleaned using glymes.
Glymes are useful as priming agents for removal of surface water from parts and in compositions for removal of rust-inhibiting oil coatings. Glymes are also useful in compositions used in cleaning felts for papermaking.
Glymes are useful in a variety of ink formulations. Glymes are useful in correction fluids and re-touching liquids for toner images, in photosensitive coating solutions in diazo processes, in alkaline processing solutions in diffusion transfer photography, and for desensitizing compositions for pressure sensitive copying paper.
Glymes are useful as the solvent in design of sorption heat pumps and in absorption refrigeration units. Refrigeration absorption fluids using glymes as solvent in various compositions are well known. Glymes are useful in working fluids for solar absorption refrigeration units.
Glymes are powerful solvents for many polymer systems and find a role in many coating applications, including one- and two-part polyurethanes and epoxies.
Glymes are useful in formulating adhesives for cigarette filter fibers and the covering tape.
Glymes are used in various applications in electronic industry (NOVOLYTE, 2008).

According to the HSDB, major uses of the substance 1 , 2-diethoxyethane are as follows: inert reaction medium, solvent for ester gum, shellac and some resins and oils, organic synthesis (reaction medium), solvent and diluents for detergents, dye solvents in non-grain raising stains (HSDB, 2007).

Glymes are amongst the strongest aprotic and polar solvents known in chemical synthesis. The lack of reactive functional groups makes them inert in chemical synthesis applications and thus superior to other aprotic and polar solvents (Clariant, 2012).
Based on information obtained from Clariant website and various product brochures, Clariant has been identified as a supplier of a range of glycol ethers. Nevertheless 1 , 2-diethoxyethane is not among the Clariant products.

1.2 Releases from manufacture

1.2.1 Occupational exposure and releases from manufacture

Occupational exposure to ethylene glycol diethyl ether may occur through inhalation and dermal contact with this compound at workplaces where ethylene glycol diethyl ether is produced or used. Monitoring and use data indicate that the general population may be exposed to ethylene glycol diethyl ether via inhalation of ambient air, ingestion of food and drinking water, and dermal contact with this compound and other products containing ethylene glycol diethyl ether (HSDB, 2007).

Clariant restricts the sale of glymes that have shown the potential for reproductive toxicity to industrial and professional applications in which any potential exposure to workers is minimized. Residues in final products must be below regulatory limits. After use, glymes must be either recycled or disposed of properly. Clariant glymes customers must sign an end-use declaration before delivery to ensure that appropriate Product Stewardship practices are followed (Clariant, 2012).

1.2.2 Environmental emissions from manufactures

Ethylene glycol diethyl ether's production and use as a solvent for ester gum, shellac, some resins and oils, in organic synthesis, as a solvent and diluents for detergents may result in its release to the environment through various waste streams (HSDB, 2007).

2 CURRENT KNOWLEDGE ON ALTERNATIVES

OSPA members pay particular attention to promoting alternatives to glycol ethers classified as toxic for reproduction. In Europe the use of glycol ethers classified as toxic for reproduction from category 2 has continually fallen and has now reached very marginal volumes (less than 1% of European glycol ethers market). These substances can be used only in an industrial environment where exposure levels and risks must be controlled and where there is no technical alternative in terms of substitute. The customer must ensure that Occupational Exposure/Emissions are within the legal constraints and there is no remaining residue of these glycol ethers left in the end product (EGEPA, 2012).

The use of glycol ethers has changed significantly over the past 30 years. Low molecular weight E-series have been phased-out and progressively replaced by low molecular weight P-series whenever possible. There is a trend to shift from E-series to P-series and an obvious willingness to substitute where alternative solutions exist or as a consequence of strengthening regulation and voluntary measures to reduce exposure in the workplace (Kettenis, P., 2005).

3 RISK-RELATED INFORMATION

Currently there is no registration for 1 , 2-diethoxyethane, however the substance has been pre-registered and CLP notifications have been submitted as well. This would indicate that the substance is used in EU in non significant amounts. Available information on uses of the substance and the related exposure and risks is very limited.

The substance belongs to the group of glycol ethers; several of them have been identified as SVHC and have been included in the candidate list (EGEE, EGME, 2-EEA, EGDME, DEGDME and TEGDME). With regard to above mentioned facts, identification of 1 , 2-diethoxyethane as SVHC seems to be relevant to preclude possible substitution of the identified SVHCs with an unidentified substance of equal level of concern.

4 REFERENCES

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Annex 1: SUMMARY RECORD: Meeting of the Technical Committee C&L on the Classification and Labelling of Dangerous Substances. Arona, 21-24 September 2004

EXTRACT from :

ECBI/139/04 REV. 2

Ispra, 28 October 2005

SUMMARY RECORD

Meeting of the Technical Committee C&L on the

Classification and Labelling of Dangerous Substances

Arona, 21-24 September 2004

1,2-Diethoxyethane (F036)

(CAS No: 629-14-1, EC No: 211-076-1)

Classification proposal: R11 – [R19]– Repr. Cat. 2; 61 – Repr. Cat. 3; 62 – Xi; R36

ECBI/15/03 FR, Proposal for classification of 1,2-dioxyethane for CMR 05/03.

ECBI/15/03 Add. 2: DE, confirmation of flammability R11.

ECBI/15/03 ADD. 3: FR, TOXICITY OF 1,2-DIOXYETHANE (EGDEE) FOR FERTILITY, CLARIFICATIONS ON THE FRENCH

POSITION FOR CLASSIFICATION.

ECBI/15/03 Add. 4: Th. Schendler, DE, Classification of 1,2-diethoxyethane with R19

In November 2003 the Group agreed to classify 1,2-Diethoxyethane with R11 and Repr. Cat. 2; R61, and they would continue the discussion on irritation, effects on eye and fertility at the next meeting. During the follow up period of the meeting D sent in a document (ECBI/15/03 Add. 2 to confirm classification with R11. FR submitted a document further explaining the background to their proposal to classify with Repr. Cat. 2; R60.

In May 2004 the Group agreed to classify with Repr. Cat. 3; R62 and Xi; R36.

Conclusion:

The Group agreed to classify 1,2-Diethoxyethane with Xi; R36 and Repr. Cat. 3; R62

The following classification proposal has been agreed:

F; R11 – Repr. Cat. 2; R61 – Repr. Cat. 3; R62 – Xi; R36

Labelling: **Symbol: T, F**

R Phrases: 61-11-36-62

S Phrases: 53-45

Follow up: DE found out that also R19 should be discussed for this substance because in the C&L proposal it was mentioned that the substance may form organic peroxides.

ECB will consult the Phys. Chem. Experts on this, who will make a proposal for classification, concerning this endpoint.

Application of R19 will be discussed at the next meeting.

The phys chem. experts were consulted in a written procedure on the application of R19 and agreed that this substance should be classified with R19. In document ECBI/15/03 Add. 4 a non standardised test is used, but based on experience this is a valid test showing that R19 should be applied.

The TC C&L agreed to add R19.

Thomas Schendler, the chair of the phys chem. group, remarked that there is also a classification with R11. To the S-phrases S16 should be added 'Keep away from sources of ignition – No smoking'. That was agreed by the Group.

Conclusion:

The Group agreed to classify 1,2-Diethoxyethane with R19 and to add S16.

The following classification proposal has been agreed:

F; R11 – R19 - Repr. Cat. 2; R61 – Repr. Cat. 3; R62 – Xi; R36

Labelling: **Symbol: T, F**

R Phrases: 61-11-19-36-62

S Phrases: 16-53-45

This classification will be sent to DG ENV for inclusion into the 30th ATP.