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-dichloroethane**
EC Number:	**203-458-1**
CAS Number:	**107-06-2**

Submitted by:	Slovak Competent Authority (Centre for Chemical Substances and Preparations)
Version:	August 2011

PUBLIC VERSION: This report does not include confidential annexes referred to in Parts I and II.

CONTENTS

TABLES

LIST OF ABBREVIATIONS

CMR	Carcinogenic, Mutagenic or toxic to Reproduction
DCE	Dichloroethane
EDC	Ethylene dichloride
ESIS	European chemical Substances Information System
IUCLID	International Uniform Chemical Information Database
MAC	Maximaal Aanvaarde Concentraties
MEL	Maximum Exposure Limit
OEL	Occupational Exposure Limit
PBT	Persistent, Bioaccumulative and Toxic
PPE	Personal Protection Equipment
PVC	Polyvinyl chloride
RIVM	National Institute for Public Health and the Environment
SER	Social and Economic Council of the Netherlands
SPIN	Substances in Preparations in the Nordic countries
SVHC	Substance of Very High Concern
TGG	Time Weighted Average
TLV	Threshold Limit Value
TRK	Technische Richtkonzentrationen
VCM	Vinyl chloride monomer
vPvB	very Persistent and very Bioaccumulative

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

EC Number: **203-458-1**

CAS Number: **107-06-2**

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

Summary of how the substance(s) meet(s) the CMR (1A or 1B) criteria

1,2-dichloroethane is listed by Index number 602-012-00-7 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 carcinogen, Carc. 1B (H350: "May cause cancer.") The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is carcinogen category 2 (R45: "May cause cancer.")

Therefore, this classification of 1,2-dichloroethane in Regulation (EC) No 1272/2008 (EU, 2008) shows that the substance meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

Registrations 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.

[2] Classification in accordance with Regulation (EC) No 1272/2008, 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:	203-458-1
EC name:	1,2-dichloroethane
CAS number (in the EC inventory):	107-06-2
CAS number:	107-06-2
CAS name	Ethane, 1,2-dichloro-
IUPAC name:	1,2-dichloroethane
Index number in Annex VI of the CLP Regulation	602-012-00-7
Molecular formula:	$C_2 H_4 Cl_2$
Molecular weight range:	98.96 $gmol^{-1}$
Synonyms:	Ethylene dichloride, dichloroethylene, 1,2-DCE, 1,2-EDC

Structural formula:

1.2 Composition of the substance

Name: 1,2-dichloroethane

Description: ---

Degree of purity: 96 – 100 % (w/w)

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
1,2-dichloroethane EC number: 203-458-1	≥ 98.4 % (w/w)	96 – 100 % (w/w)	Based on the registration dossier

Table 3: Impurities

Confidential (see confidential Annex I)

Table 4: Additives

Confidential (see confidential Annex I)

1.3 Physico-chemical properties

Table 5: Overview of physicochemical properties[3]

Property	Value	Remarks
Physical state at 20 °C and 101.3 kPa	liquid	
Melting/freezing point	-36 °C at 101,3 kPa	CRC Handbook and secondary literature data
Boiling point	83.6 °C at 760 mm Hg	Mumford, S.A.; Philips, J.W.C., 1950
Density	1.2455 g/cm^3 at 20 °C	Garcia-Gimenez, 2008
Viscosity	0.829 cP (centi-poises = mPa s) at 20 °C	Mumford, S.A.; Philips, J.W.C., 1950
Vapour pressure	10247 Pa at 25 °C	Nath, 1994
Water solubility	7.9 g/l at 25 °C	Banerjee, 1980
Partition coefficient n-octanol/water (log value)	Log Pow 1.45 at 20 °C	Veith, 1980 Experimental, flask-shake method
Surface tension	32.45 dynes/cm at 20 °C	Mumford, S.A.; Philips, J.W.C., 1950
Flash point	13 °C	Bartholome, 1975
Autoignition temperature	440 °C at 101,3 kPa	Bartholome, 1975
Oxidizing properties	No oxidizing properties	Due to structural reasons
Explosive properties	No explosive properties	Due to structural reasons

[3] The data included in the Table 5 are based on registration dossier.

2 HARMONISED CLASSIFICATION AND LABELLING

1,2-dichloroethane is listed by Index number 602-012-00-7 in 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)		
602-012-00-7	1,2,-dichloroethane	Flam. Liq. 2 Carc. 1B Acute Tox. 4 * Eye Irrit. 2 STOT SE 3 Skin. Irrit. 2	H225 H350 H302 H319 H335 H315	GHS02 GHS08 GHS07 Dgr	H225 H350 H302 H319 H335 H315			

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
602-012-00-7	1,2,-dichloroethane	F; R11 Carc. Cat. 2; R45 Xn; R22 Xi; R36/37/38	F; T R: 45-11-22-36/37/38 S: 53-45		E

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-dichloroethane is listed by Index number 602-012-00-7 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 carcinogen, Carc. 1B (H350: “May cause cancer.”). The corresponding classification in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 is carcinogen category 2 (R45: “May cause cancer.”).

Therefore, this classification of 1,2-dichloroethane in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as carcinogen in accordance with Article 57 (a) 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 AND RELEASES FROM MANUFACTURE

1.1 Manufacture, import, export and use quantities

Data for determining manufacturing sites currently producing 1,2-DCE is obtained from the European chemical Substances Information System (ESIS, at ex-ECB website). The list of 34 producers/importers (not specified) of 1,2-DCE in Europe is published on the ESIS. It is likely that this information is not topical.

Table 8: List of producers/ importers according to ESIS system

Company	Country
AKZO NOBEL CHEMICALS B.V.	NETHERLANDS
ATOCHEM	FRANCE
BASF AG	GERMANY
BASF ANTWERPEN N. V.	BELGIUM
BAYER AG	GERMANY
CELANESE GMBH	GERMANY
CHEMIE GMBH BITTERFELD-WOLFEN	GERMANY
DEGUSSA AG	GERMANY
DEGUSSA-H&#65533;LS AG	GERMANY
DOW DEUTSCHLAND INC., WERK STADE	GERMANY
ENICHEM S.P.A.	ITALY
ETHYL PETROLEUM ADDITIVES INTERNATIONAL	UK
EUROBROM B.V.	NETHERLANDS
EVC (DEUTSCHLAND) GMBH	GERMANY
EVC (ITALIA) SPA	ITALY
EVC (UK) LIMITED	UK
HOECHST AG	GERMANY
HUELS AG	GERMANY
HYDRO PLAST AB	SWEDEN
ICI CHEMICALS & POLYMERS LIMITED	UK

ICI CHEMICALS & POLYMERS LIMITED	UK
LIMBURGSE VINYL MAATSCHAPPIJ	BELGIUM
OCCIDENTAL CHEMICAL CORPORATION	USA
PETRASOL B.V.	NETHERLANDS
SHELL	FRANCE
SHELL CHIMIE	FRANCE
SOLVAY ALKALI GMBH	GERMANY
SOLVAY S.A.	BELGIUM
VINICLOR S.A.	SPAIN
VINNOLIT MONOMER GMBH	GERMANY
VINTRON GMBH	GERMANY
WACKER - CHEMIE GMBH	GERMANY
WYETH LEDERLE	ITALY
ý®®Êð×ÝÌ ÊýËÐý®Ì×Ì	GREECE

Over 95% of ethylene dichloride in 2009 was consumed in the production of vinyl chloride monomer for polyvinyl chloride production. Other very small uses for EDC include chlorinated solvents, ethyleneamines and vinylidene chloride (SRI, 2009).

Global consumption of EDC grew by about 4.5% per year from 2004 to 2007, but fell significantly in late 2008 as a result of the economic crisis. Consumption in 2008 was about the same as that in 2005 (SRI, 2009).

Based on data reported by the European Chemical Industry submitted in IUCLID Dataset, quantity of ethylene dichloride was more than 1 000 000 tones (not specified).

The total annual volume of 1 , 2 -DCE currently manufactured in the EU is estimated in the range above 1 000 000 tons. The substance is mainly used in the synthesis of vinyl chloride monomer. Manufacture of the substance and use as an intermediate on site represents more than 95 %, use as an (transported) intermediate for VCM synthesis represents more than 4 % of the total amount of the substance. However, the substance is also used as an intermediate in fine chemical synthesis and as a solvent in chemical and pharmaceutical industries. This use represents around 0.2 % of the total used amounts. More detailed information is provided in confidential Annex II.

The SPIN database[4] was searched for information on 1 , 2-DCE in products on the national markets of Norway, Sweden, Finland and Denmark (2005-2009).

[4] Please note: The total amount of a substance included in the SPIN database is the added quantity of the substance in all products without the amount of substances exported. Therefore, if a substance is registered first as the imported raw material and then again as part of the final preparation the quantity will be counted twice. Substances which are imported and then used for the formulation of chemical products, which is very often the case in the Nordic countries, will thus, be accounted for with up to double the actual amount. Therefore, the tonnages might be considered as overestimations.

It is important to note that the use accounted for in SPIN is the use of substances in chemical products and preparations. Non-chemical products are not included. Thus the substance can very well be used and present in other kinds of products. Total quantities and the total number of products have not been reported to SPIN if the substance is contained in less than 4 products and is registered by less than 3 companies.

Table 9: 1,2-DCE in products according to SPIN for 2005 – 2006

Country	2005		2006	
	Nr of preparations	tonnage	Nr of preparations	tonnage
Norway	4	360544.1	5	418407.1
Sweden	7	11.0	8	4548
Finland	confidential		confidential	
Denmark	confidential		confidential	
Total:		**360555.1**		**422955.1**

Table 10: 1,2-DCE in products according to SPIN for 2007– 2008

Country	2007		2008	
	Nr of preparations	tonnage	Nr of preparations	tonnage
Norway	confidential		confidential	
Sweden	7	2576.0	4	4307.0
Finland	confidential		confidential	
Denmark	confidential		5	0.0*
Total:		**2576.0**		**4307.0**

Table 11: 1,2-DCE in products according to SPIN for 2009

Country	2009	
	Nr of preparations	tonnage
Norway	confidential	
Sweden	6	3834.0
Finland	confidential	
Denmark	6	0.0
Total:		**3834.0**

*"0.0 tons" means that the notified volumes were smaller than 0.1 tons.

Information on the use, production, and emissions of 1,2-DCE was requested from Member States Competent Authorities (questionnaire sent on May 9, 2011). The information provided is summarized bellow. More details are provided in confidential Annex II.

According to German pollutant release and transfer register the emissions of 1,2-DCE to air are estimated on 76.8 t and emissions to waste water on 0.1 t in Germany for the year 2009. No up to date information on manufactured/imported quantities beyond the information in the registration dossiers are available.

Currently the substance is not manufactured in Bulgaria; the substance was imported to the country in the period of 2008 – 2010.

The substance is not manufactured in Cyprus and not used by industry in any considerable amounts.

There are no registrations of 1,2-DCE by Estonian chemical companies. According to Estonian customer database the substance was imported from Russia during the period of 2006 – 2009.

According to information from Lithuania only one company is dealing with the substance as a wholesaler.

The information from Ireland indicates that there is no import of the substance. Substance is used by downstream user solely as a solvent/reagent in the pharmaceutical industry.

In The UK the substance was included in some of the preliminary scoping work for HSE´s carcinogens programme and according to their results was viewed as a low priority for further work.

In Poland the substance is manufactured and used for the production of VCM by one company in high production volumes.

In Sweden all companies that manufacture or import chemical products over 100 kg a year have to report this to Products Register. According to this database the quantity of the substance (manufactured and imported) for year 2009 was in high tonnage volumes; most of this quantity was exported. The substance was used as a raw material.

In the Netherlands 1,2-dichloroethane is produced and is used for the production of vinyl chloride, chlorinated solvents and flavourings and is used during the production of pharmaceuticals, rubber, degreasing solvents and adhesives.
1,2-DCE can be emitted to all compartments and almost all emissions originate from chemical industry. Exposure can take place mainly via inhalation in chemical industry but also in construction industry, sewage treatment, water companies and during consumer use. Total emissions are stable since 2001, however, due to new policies to reduce emissions the emission of 1,2-dichloroethane might have exceeded the limits in 2010. During 2000-2005 concentrations in the Dutch surface waters were below detection limits and during 2003-2005 concentrations in the air were also below limits. An 8 hours TGG limit value for workers of 7 mg/m^3 could be derived. This limit value was based on an advice of the Social and Economic Council of the Netherlands. The highest exposure of workers to 1,2-dichloroethane occurs during maintenance procedures, the limit of 7 mg/m^3 was exceeded during these procedures. When appropriate precautions were taken, exposures were below the limit of 20 mg/m^3. More recent data on exposures of workers were not found.
Exposures might also take place from imported shipping containers. 1,2-Dichloroethane is used to control vermin during transport and storage and emissions to air can take place when opening the container, resulting in human exposure via inhalation and environmental exposure. A report from the RIVM (2007) shows that the percentage of containers treated with 1,2-dichloroethane has increased over the last years and that the concentrations found are more often above the corresponding MAC value.

In Slovakia, the substance is registered as transported isolated intermediate in high tonnage range and is used in production of VCM.

1.2 Releases from manufacture

Workplace exposure can occur either in an EDC manufacturing facility or in the various industrial or manufacturing facilities that use EDC. It is produced, distributed, stored and consumed in closed systems. Those working with EDC in manufacturing operations could be exposed during maintenance, sampling, testing or other procedures. Each manufacturing facility should have a thorough training program for employees, appropriate work processes and safety equipment in place to limit unnecessary EDC exposure (Dow, 2007).

The SPIN database was also searched for information on 1,2-DCE concerning the environmental/worker/consumer exposure in Norway, Sweden, Finland and Denmark (2008-2009).

Table 12: Exposure information based on SPIN data for 2008 - 2009

Country	Year	Use Index						Range of Use
		Surface water	Air	Soil	Waste water	Consumer	Worker	
DK	2009	-	x	-	xx	-	Under development	**
NO	2009	-	-	-	x	-	Under development	*
SE	2009	-	x	-	x	x	Under development	**
DK	2008	-	x	-	xx	-	Under development	*
NO	2008	x	-	-	x	-	Under development	*
SE	2008	-	x	-	x	-	Under development	*

Parameter	Symbol	Value	Explanation
Use Index	x	3	One or several uses indicate a potential exposure
	xx	4	One or several uses indicate a probable exposure
	-	0-2	The registered use do not indicate direct exposure*
Range of Use	*	1-3	Very narrow range of applications
	**	4-10	Narrow range of applications

* Note that registered Use Categories do not include all potential uses of the chemical and possibility for direct exposure can therefore not be excluded.

Further information obtained from registration documentation including the summary of risk management measures implemented during manufacture of 1,2-DCE is provided in confidential Annex II.

1.2.1 Occupational exposure and releases from manufacture

Current occupational exposure to 1,2-dichloroethane occurs predominantly during the manufacture of chemicals, such as vinyl chloride, where 1,2-dichloroethane is used as an intermediate. Since the substance is produced in closed systems, stored and filled in tanks via pipeline no direct worker exposure does result. In occupational settings, however, exposure to 1,2-dichloroethane might occur during sampling processes for analytical purposes (i.e. quality control). Exposure measurements performed in the course of working place surveillance during the years 1995 through 1999 yielded 1,2-dichloroethane concentrations ranging from 0.5 to 15.3 mg/m^3 (0.122 to 3.72 ppm) with an average value of 4.59 ± 3.83 mg/m^3 (1.12 ± 0.93 ppm). The exposures were mainly caused by sampling procedures with open systems. During filling processes in tanks no worker exposure results since all steps are conducted via pipelines. In addition, for filling of the material into containers closed systems are applied. Another important exposure occurs during maintenance procedures, i.e. high pressure cleaning of facilities and filter exchanges. Exposure measurements have been undertaken during these processes, too, with values determined being in the range of 2 to 151 mg/m^3 (0.49 to 36.7 ppm). It should be stressed that using PPE equipment (including respiratory protection) was mandatory for the workers of the maintenance crew during these operations for about 3 – 5 days/year (OECD, 2002).

Mean concentrations of 1,2-dichloroethane at three production plants in the United Kingdom in 1990 were 2.8, 3.2 and 6.8 mg/m^3; 95% of samples contained less than 20 mg/m^3, while maximum values at the plants were 18, 80 and 160 mg/m^3 (IPCS, 1995).

For 1,2-dichloroethane working place limit values have been established in various European countries (OECD, 2002).

According to Slovak legislation, technical guidance value for 1,2- dichloroethane is established to be 5 ppm/20 mg/m^3.

More detailed data regarding the occupational exposure to 1,2- dichloroethane, including risk management measures applied obtained from registration documentation, are provided in confidential Annex II.

1.2.2 Environmental emissions from manufactures

The majority of 1,2-dichloroethane released into the environment enters the atmosphere from its production and use as a chemical intermediate and solvent. It has been detected at low levels in ambient and urban air, groundwater and drinking-water samples (HSDB, 2000).

Rural or background atmospheric concentrations in Western Europe and North America are approximately 0.2 µg/m^3. Average levels in cities vary from 0.4 µg/m^3 to 1.0 µg/m^3, increasing to 6.l µg/m^3 near petrol stations, parking garages and production facilities (WHO, 2000).

According to UK Environment Agency, normal levels found in the environment are unlikely to be of concern. (EA UK, 2011).

More details about environmental emissions and releases from manufacture are provided in confidential Annex II.

2 USES OF THE SUBSTANCE

2.1 Overview of uses

2.1.1 Historical use

1,2-Dichloroethane has been replaced as a solvent and degreaser by less toxic compounds. It once served as a solvent for processing pharmaceutical products; for fats, oils, waxes, gums, resins, and particularly for rubber; and in paint, varnish, and finish removers (HSDB, 2000).

The substance was also used as an insect fumigant for stored grains and in mushroom houses, a soil fumigant in peach and apple orchards, a cleaner for upholstery and carpets, a solvent in textile cleaning and metal degreasing, a lead scavenger in antiknock gasoline, a starting material for chlorinated solvents such as vinylidene chloride, a dispersant for plastics and elastomers such as synthetic rubber, an ore flotation compound, and as an extractant in certain food processes (NTP, 2005; IARC, 1979).

According to Annex XVII of REACH (EU, 2006), at present the substance shall not be used as substance or in mixtures for the supply to the general public when individual concentration is equal or greater than the relevant specific concentration limit specified in part 3 of Annex VI of Regulation (EC) No 1272/2008 or relevant concentration specified in Directive 1999/45/EC.

2.1.2 Current use

Over 95% of EDC in 2009 was consumed in the production of vinyl chloride monomer for polyvinyl chloride production. Other very small uses for EDC include chlorinated extraction and cleaning solvents, manufacture of ethyleneamines and vinylidene chloride (SRI, 2009).

According to information from registration documentation the prevailing use of the substance is as an intermediate in the synthesis of vinyl chloride monomer. However, the substance is also used as an intermediate in fine chemical synthesis and as a solvent in chemical and pharmaceutical industries. Even though this use (probably partly wide dispersive) represents small percentage of the total used amounts it would already bring the substance in the high tonnage band.

More detailed information about uses of the substance obtained from registration documentations is included in the confidential Annex II.

2.2 Alternatives

On the basis of the information from the industry there are no relevant alternatives to EDC for production of VCM which is the prevailing use of EDC.
According to information from pharmaceutical industry using the substance as solvent/reagent in the manufacture of an active pharmaceutical ingredient, currently it is not feasible to substitute 1,2-DCE with a less hazardous alternative for both technical and economic reasons. Substitution of the substance with a less hazardous solvent/reagent would involve development of an alternative chemical synthetic route. Pharmaceutical industry is already subject to a very high degree of regulation, which provides a high level of protection for workers, the environment and patients.

3 RISK-RELATED INFORMATION

3.1 Human Health Risk Assessment

Working place limit values for 1,2-dichloroethane (see Table 13) have been established in various countries including the region of the U.S. and Japan (OECD, 2002).

Table 13: Working place limit values for 1,2-dichloroethane

Country	Type of limit value	Value (ppm)
Denmark	OEL (skin notation)	1
France	OEL	10
Germany	TRK (technical standard value)	5
Japan	TLV	10
Netherlands	MAC (OEL)	1.5
UK	MEL	5
US	TLV	10

Note: TRK values in Germany have been ceased some years ago. In Netherlands working exposure limits values are not longer expressed as MAC but as OEL.

According to Slovak legislation technical guidance value for 1,2-dichloroethane is established to be 5 ppm / 20 $mg.m^{-3}$.

For workers, the requirements of the Carcinogens and Mutagens Directive 2004/37/EC (EU, 2004) shall be complied with. This requires compliance with objectives to prevent exposure, substitution of dangerous chemicals by less dangerous chemicals and, where this is not technically possible, by minimization of exposure.

More details about risk related information are provided in confidential Annex II.

4 REFERENCES

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ANNEX I

CONFIDENTIAL INFORMATION TO PART I OF THE ANNEX XV DOSSIER

ANNEX II

CONFIDENTIAL INFORMATION TO PART II OF THE ANNEX XV DOSSIER