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(s):	**1,3-propanesultone**
EC Number:	**214-317-9**
CAS Number:	**1120-71-4**

Submitted by: ECHA at the request of the European Commission

Date: 03 August 2015

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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(s): **1,3-propanesultone**

EC Number: **214-317-9**

CAS Number: **1120-71-4**

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

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

1,3-propanesultone is covered by index number 016-032-00-3 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 carcinogenicity category 1B (hazard statement H350: "May cause cancer").

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

- Carcinogenicity category 1B in accordance with Article 57 (a) of REACH.

Registration dossiers submitted for the substance? Yes

[1] Classification in accordance with section 3 of Annex I to Regulation (EC) No 1272/2008.

PART I

Justification

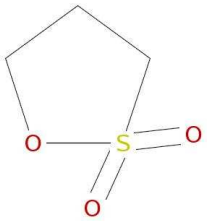
1. Identity of the substance and physical and chemical properties

1.1. Name and other identifiers of the substance

Table 1: Substance identity

EC number:	214-317-9
EC name:	1,3-propanesultone
CAS number (in the EC inventory):	1120-71-4
CAS name:	1,2-oxathiolane, 2,2-dioxide
IUPAC name:	1,2-oxathiolane 2,2-dioxide
Index number in Annex VI of the CLP Regulation	016-032-00-3
Molecular formula:	$C_3H_6O_3S$
Molecular weight range:	122.14
Synonyms:	1,2-oxathiolane-2,2-dioxide; 1,2-oxathiolane-2,2-dione

Structural formula:



1.2. Composition of the substance

Name: 1,3-propanesultone

Description: Solid

Substance type: mono-constituent

Table 2: Constituents

Constituents	Typical concentration	Concentration range	Remarks
1,3-propanesultone (EC No. 214-317-9)	≥ 80 % w/w	-	-

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

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

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

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

1.5. Physicochemical properties

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

2. Harmonised classification and labelling

1,3-propanesultone is covered by Index number 016-032-00-3 in part 3 of Annex VI to the CLP Regulation as follows:

Table 3: 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)		
016-032-00-3	1,3-propanesultone; 1,2-oxathiolane 2,2-dioxide	214-317-9	1120-71-4	Carc. 1B Acute Tox. 4 * Acute Tox. 4 *	H350 H312 H302	GHS08 GHS07 Dgr	H350 H312 H302		Carc. 1B; H350: C ≥ 0,01 %	-

** For certain hazard classes, including acute toxicity and STOT repeated exposure, the classification according to the criteria in Directive 67/548/EEC does not correspond directly to the classification in a hazard class and category under Regulation (EC) No 1272/2008. In these cases, the classification shall be considered as a minimum classification. Please see Annex VI of Regulation (EC) No 1272/2008, Section 1.2.1 on minimum classification for further details.*

See Section 7.3 for information on CLP notification status.

3. Environmental fate properties

Not relevant for the identification of the substance as SVHC in accordance with Article 57 points (a) to (e) REACH.

4. Human health hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 points (a) to (e) REACH.

5. Environmental hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 points (a) to (e) REACH.

6. Conclusions on the SVHC Properties

6.1. CMR assessment

1,3-propanesultone is covered by index number 016-032-00-3 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 carcinogenicity category 1B (hazard statement H350: "May cause cancer").

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

- carcinogenicity category 1B in accordance with Article 57 (a) of REACH.

6.2. PBT and vPvB assessment

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

6.3. Equivalent level of concern assessment

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

Part II

7. Registration and C&L notification status

7.1. Tonnage and registration status

Table 4: Tonnage and registration status

From the ECHA dissemination site[2,3]	
Registrations	☒ Full registration(s) (Art. 10) ☒ Intermediate registration(s) (Art. 17 and/or 18)
Total tonnage band for the substance (excluding the volume registered under Art 17 or Art 18, or directly exported)	0 - 10 t/pa

7.2. Imports and exports of the substance into and from the EU

Information removed due to confidentiality.

7.3 CLP notification status

Table 5: CLP notifications

	CLP Notifications[4]
Number of aggregated notifications	9
Total number of notifiers	159

[2] http://apps.echa.europa.eu/registered/data/dossiers/DISS-a133d47a-d54b-1c04-e044-00144f67d031/DISS-a133d47a-d54b-1c04-e044-00144f67d031_DISS-a133d47a-d54b-1c04-e044-00144f67d031.html
[3] http://apps.echa.europa.eu/registered/data/dossiers/DISS-ba7d7f6b-c1e8-71ab-e044-00144f67d031/DISS-ba7d7f6b-c1e8-71ab-e044-00144f67d031_DISS-ba7d7f6b-c1e8-71ab-e044-00144f67d031.html
[4] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 25 June 2015)

8. Information on uses of the substance

The substance is used as an intermediate in the manufacture of fine and bulk chemicals. As a transported isolated intermediate 1,3-propansultone is used as a pre-product to manufacture aqueous polyurethane dispersions as well as pre-product for the manufacture of light-sensitive dyes for photographic and radiographic films. As an on-site isolated intermediate 1,3-propansultone is used to manufacture sulfopropylated substances by complete conversion with amines, mercaptanes, alcoholates and carboxylates. It is also used as a laboratory reagent. These uses are out of the scope of authorisation.

Uses which appear to be in the scope of authorisation include formulation and use in the electrolyte fluid in the production of lithium ion batteries at industrial sites. While the use of these batteries (which are regarded as articles) does not fall in the scope of the authorisation requirement, the potential releases of 1,3-propansultone from the use and waste stage of batteries will be taken into account during the prioritisation of the substance to Annex XIV. However, based on the available information, releases from batteries during their service-life and during the waste stage appear to be negligible.

Table 6: Uses

	Use(s)	**Use in the scope of Authorisation**
Uses as intermediate	In the manufacture of fine and bulk chemicals	No
Formulation	Formulation of mixtures (including electrolytes)	Yes
Uses at industrial sites	Laboratory reagent Use in the electrolyte fluid of lithium ion batteries	No Yes
Uses by professional workers	Professional use of lithium-ion batteries	No
Consumer Uses	Consumer use of lithium-ion batteries	No
Article service life	Use in lithium ion batteries	No

9. Information on structure of the supply chain

The supply chain for 1,3-propanesultone does not appear to be complex. It appears to involve a limited number of stages (manufacture/import of the substance, formulation and incorporation into articles).

REFERENCES

References for Part I

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.

ECHA (2015): 1,3-propanesultone. Information on registered substances, published on ECHA's website http://apps.echa.europa.eu/registered/registered-sub.aspx#search (accessed on 10 June 2015).

References for Part II

ECHA (2015). 1,3-propanesultone. Information on registered substances, published on ECHA's website http://apps.echa.europa.eu/registered/registered-sub.aspx#search (accessed on 10 June 2015).

ECHA RMOA (2015). Analysis of the most appropriate risk management option for 1,3-propanesultone. PACT – RMOA and hazard assessment activities: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact/-/substance-rev/1966/del/50/col/staticField_-105/type/asc/pre/3/view

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 (2007). Corrigendum to 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, L136: 3-280.

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.