Analysis of the most appropriate risk management option (RMOA)

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

EC Number: **203-444-5**

CAS Number: **106-93-4**

Authority: ECHA at the request of the European Commission

Dated: 16 July 2015

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1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Other substance identifiers

EC name (public):	1,2-dibromoethane
IUPAC name (public):	1,2-dibromoethane
Index number in Annex VI of the CLP Regulation	602-010-00-6
Molecular formula:	C2H4Br2
Molecular weight or molecular weight range:	187.8612 g.mol^{-1}
Synonyms: [1]	Ethylene dibromide (EDB)

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:

[1] Please note this is a non-exhaustive list.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 2: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII
Harmonised C&L	☒ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation - Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation - Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation - Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes/ EU legislation	☒ Other (provide further details below)	

EU legislation that applies to classified CMRs category 1A/1B applies to this substance including occupational health and safety legislation, and restrictions for CMRs in entry 28 of REACH Annex XVII and in the Toys Safety Directive.

This substance is banned under the Cosmetic Products Regulation (Annex II, entry 651). It is banned as a pesticide in the EU and it is listed under the Prior Informed Consent procedure of the Rotterdam Convention (identified by name for its use as a pesticide). There is a SCOEL Recommendation on occupational exposure limits for this substance (SCOEL, 2011). It is also to be noted that the substance is listed as a potential new ozone depleting substance, but no legal action has yet been taken to include it in the Montreal Protocol or, at the EU level, in the Ozone Depleting Substances Regulation.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table 3: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
602-010-00-6	1,2-dibromoethane	203-444-5	106-93-4	Carc. 1B Acute Tox. 3 * Acute Tox. 3 * Acute Tox. 3 * Eye Irrit. 2 STOT SE 3 Skin Irrit. 2 Aquatic Chronic 2	H350 H331 H311 H301 H319 H335 H315 H411	*	-

3.1.2 Self classification

- In the registrations:

  STOT SE 1, H335

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

  Carc. 1A, H350
  Carc. 2, H351

3.1.3 CLP Notification Status

Table 4: CLP Notifications

	CLP Notifications[2]
Number of aggregated notifications	13
Total number of notifiers	130

3.2 Additional hazard information

The substance (1,2-dibromoethane) meets the criteria of Article 57 (a) of Regulation (EC) 1907/2006 (REACH) owing to its classification as carcinogen 1 B[3].

[2] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 2 September 2014)

[3] 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.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[4]

4.1 Tonnage and registration status

Table 5: Tonnage and registration status

From ECHA dissemination site	
Registrations	☒ Full registration(s) (Art. 10) ☐ Intermediate registration(s) (Art. 17 and/or 18)
Total tonnage band for substance (excluding volume registered under Art 17 or Art 18, or directly exported)	1000-10,000 tpa

4.2 Overview of uses and exposure information

This substance is used as an intermediate in the manufacture of fine chemicals and pharmaceuticals and it is used as a laboratory reagent. Some of the tonnage indicated for the manufacture of fine chemicals/pharmaceuticals may be non-intermediate (use as a processing aid). However, the information available in the registrations does not allow a conclusion to be drawn on the tonnage for this potential non-intermediate use.

SCOEL note the use of the substance as a chemical intermediate in synthesis and as a non-flammable solvent for resins, gums and waxes (SCOEL, 2011). The main substance manufactured from1,2-dibromoethane is vinyl bromide. The potential solvent use is not explicitly identified in the registrations.

1,2-dibromoethane is also used as an anti-knock additive in leaded aviation gasoline (Avgas) used by piston engines which represent around 50 000 aircraft. This use falls under the scope of authorisation.

In accordance with information provided by the Commission, "*Avgas represents less than 1% of the aviation fuel used in aviation (although exact data are not known) the rest being jet fuel. Unleaded aviation gasoline is currently not appropriate for piston engines* which require high octane gasoline. *Such piston engines represent approximately 70% of the aviation gasoline used. Nevertheless, some of these piston engines are compatible with existing unleaded aviation gasoline".*

[4] Information obtained from ECHA's dissemination website, http://echa.europa.eu/information-on-chemicals/registered-substances (accessed 02 September 2014)

Table 6: Uses

	Use(s)
Uses as intermediate	- Intermediate in manufacture of fine chemicals and pharmaceuticals
Formulation	- Non-intermediate use as an anti-knock additive in refineries in production of aviation fuel[5]
Uses at industrial sites	- Laboratory reagent - Potential non-intermediate use in fine chemical/pharmaceutical manufacture as a processing aid
Uses by professional workers	
Consumer Uses	
Article service life	

4.3 Additional information

Based on information provided in the registrations, it appears that there is potential for exposure to workers and the environment from the uses of this substance, which the registrants recommend to address through specified conditions of use including various risk management measures.

Information on alternatives and socio-economic consequences has not been gathered for this RMOA.

[5] Based on available information the concentration of 1,2-dibromoethane in aviation fuel is <0.1%

5 JUSTIFICATION FOR THE RISK MANAGEMENT OPTION

5.1 Need for (further) risk management

The substance is considered to be of potential relevance under the SVHC Roadmap to 2020 (Table 7).

Table 7: SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled?	✓	
b) Registrations in accordance with Article 10?	✓	
c) Registrations include uses within scope of authorisation?	✓	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	✓	

5.2 Identification and assessment of risk management options

REACH Candidate List and Authorisation

This substance is registered for uses within the scope of authorisation (i.e. formulation of anti-knock additive into aviation fuels and possibly some non-intermediate use in fine chemical/pharmaceutical manufacture). The substance meets the relevancy criteria in the Roadmap (Table 7), and therefore the inclusion of the substance in the Candidate List for eventual inclusion in Annex XIV could be considered.

While motor fuels are exempt from the authorisation requirement in REACH (Art 56(4)c) with reference to the Fuel Quality Directive (98/70/EC), aircrafts are not covered by that Directive. Aircraft fuel standards are defined by international organisations such as ASTM. The ASTM D910-13 specifies the requirements for leaded aviation gasoline and identifies 1,2-dibromoethane as one of the additives. It should be noted that tetraethyllead, which is also used as a fuel additive in leaded aviation gasoline, was included in the Candidate List in December 2012 at the request of the Commission.

Further information on potential regulatory management options for this substance as provided by the Commission

"To address the health and environmental concerns in Europe from the use of leaded aviation gasoline a support for transition to unleaded gasoline should be considered in the European regulatory framework. At present the fuel quality directive concerns automotive fuel. An option could be to consider its extension to aviation fuel. However, aviation fuels are addressed in international standards, such as ASTM, and a European fuel quality directive does not seem to be the most appropriate instrument. Currently, the ASTM D910-13 specifies the

requirements for leaded aviation gasoline (Avgas), other ASTM unleaded avgas standards exist but they are not sufficient to meet the high octane requirement which is needed for around 70% of the aviation gasoline used. New ASTM standards for high octane unleaded aviation gasoline are being progressed, however due to differences between American and European environmental fuel requirements, fuels developed under these standards would not meet all European environmental requirements notably in terms of aromatic content.

Taking regulatory measures (e.g. under the fuel quality directive or under a separate new directive) at this stage would result in preventing certain general aviation (GA) operations in Europe since there would be no feasible alternative to the current fuel that can be used.

Before imposing a transition to unleaded aviation gasoline, there is first the need to develop a high octane with low aromatic content unleaded substitute to the existing leaded gasoline for aviation, then propose the development of a new international fuel standard for this unleaded gasoline, get the fuel approved by the engine and aircraft manufacturers, ensure availability of the unleaded fuels at the airports and airfields in Europe and finally consider the best regulatory option to transition to unleaded aviation gasoline in Europe."

5.3 Conclusions on the most appropriate (combination of) risk management options

This substance is classified as carcinogenic Category 1B and therefore it fulfils the REACH Article 57 criteria. The substance is registered for uses within the scope of authorisation (i.e. formulation of anti-knock additive into aviation fuels and potentially some non-intermediate use in fine chemicals/pharmaceutical manufacture). The substance could be proposed to be identified as a Substance of Very High Concern to be included in the Candidate List for potential prioritisation to Annex XIV.

However, the European Commission considers that it is more appropriate to address the main non-intermediate use of the substance, i.e. additive in leaded aviation gasoline, at international level and/or under other EU legislation than REACH. The Commission further stresses the need to develop an alternative to leaded aviation gasoline with high octane grade and low aromatics content.

Substances, such as 1,2-dibromoethane, for which the conclusion is that there is no current need for action under the Roadmap, will be revisited in the relevant re-screening activity to consider any new information. This will include consideration of progress on the particular aspects highlighted above. In the re-screening activities any reassessment of the conclusions now drawn should take into consideration that a five years period may be needed to allow evaluation of progress on these aspects.

5.4 References

SCOEL, 2011. Recommendation from the Scientific Committee on Occupation Exposure Limits for 1,2-dibromoethane (ethylene dibromide). SCOEL/SUM/166. March 2011.