

## SCREENING REPORT

### TO ASSESS WHETHER THE USE OF 1,2-DICHLOROETHANE (EDC) IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH REACH ARTICLE 69(2)

Annex XIV entry	Substance name	Abbreviation	EC	CAS	Latest application date	Sunset date	Intrinsic property
26	1,2-dichloroethane	EDC	203-458-1	107-06-2	22/05/2016	22/11/2017	Carcinogenic (Article 57a)

Source: <https://echa.europa.eu/authorisation-list>

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VERSION NUMBER: 1 (FINAL)

DATE: 29 May 2024

## 1. Conclusions

**Following an assessment of the available evidence, ECHA considers that the use of 1,2-dichloroethane (EDC) for fumigation of freight containers resulting in temporary residues in articles may pose a risk to human health that may not be adequately controlled. ECHA also considers that this risk is addressed by other regulatory actions.**

1,2-Dichloroethane is a carcinogenic substance for which no threshold can be determined below which exposure would be safe.

There is information that indicates that the use or presence of the substance in articles fumigated with 1,2-dichloroethane could lead to human exposure. However, the resulting risk for consumer is addressed by Article 58(2) of the Biocidal Products Regulation (EU No 528/2012), and the Toys Safety Directive (2009/48/EC). In addition, the resulting risks for workers are addressed by the OSH Directive (89/391/EEC) and the Chemical Agents Directive (98/24/EC).

Therefore, under REACH Article 69(2), ECHA's view is that at present there is no need to prepare an Annex XV dossier for restriction.

The assumptions and findings in the draft report were subject to a call for evidence from 2 February to 16 March 2022. The information provided by Member States and industry associations was incorporated in the final report.

## 2. Summary of findings

### 2.1. Identified uses

Based on the information gathered via (i) the SVHC identification process<sup>1</sup>, (ii) the recommendation for inclusion of substances in REACH Annex XIV<sup>2</sup>, (iii) REACH registrations<sup>3</sup>, (iv) applications for authorisation<sup>4</sup>, (v) information from Candidate List substances in articles (SIA) notifications according to REACH Article 7(2)<sup>5</sup> and (v) notifications to the SCIP database<sup>6</sup>, the uses of 1,2-dichloroethane potentially relevant for its presence in articles include:

- manufacturing of vinyl chloride monomer (VCM) for the manufacturing of polyvinyl chloride (PVC) and the production of PVC articles;
- (transported) intermediate under strictly controlled conditions.

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<sup>1</sup> [Proposals to identify Substances of Very High Concern previous consultations - ECHA \(europa.eu\)](#)

<sup>2</sup> [Recommendations for inclusion in the Authorisation List - ECHA \(europa.eu\)](#)

<sup>3</sup> [1,2-dichloroethane 100.003.145 | Overview - ECHA CHEM \(europa.eu\)](#)

<sup>4</sup> [Adopted opinions and previous consultations on applications for authorisation - ECHA \(europa.eu\)](#)

<sup>5</sup> [Information on Candidate List substances in articles - ECHA \(europa.eu\)](#)

<sup>6</sup> In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products): <https://echa.europa.eu/scip>

In addition, 1,2-dichloroethane is reported to be used as a biocide for fumigation of freight containers<sup>7</sup> with the possibility of temporary residues in the fumigated articles<sup>9</sup>.

## 2.2. Hazards, emissions/releases/exposure and risk

### *Information on hazards*

1,2-Dichloroethane is included in REACH Annex XIV based on its carcinogenic properties. Other endpoints are not relevant.

### *Information on emissions/release/exposure*

In the process of vinyl chloride monomer manufacturing, 1,2-dichloroethane is used as intermediate that is recycled and purified. In applications for authorisation residual concentrations of 1,2-dichloroethane in final products were reported usually to be below the Limit of Detection (LoD)/Limit of Quantification (LoQ) of the analytical method used. According to the information from SIA notifications, the SCIP database and information received during the call for evidence for 1,2-dichloroethane, no consumer uses of articles containing 1,2-dichloroethane were identified. In the investigation report on PVC and PVC additives<sup>10</sup>, it is concluded that the available information indicates that the level of residual 1,2-dichloroethane in PVC articles is appropriately controlled.

ECHA considered the potential presence of 1,2-dichloroethane in imported articles as an impurity from the production process of the articles. However, due to the high volatility of the substance with a vapour pressure of 10 247 Pa at 25°C and since the production process of PVC articles usually includes several processing steps (including heating), ECHA considers unlikely the emissions of 1,2-dichloroethane from PVC articles resulting from impurity from the production process.

However, emission of 1,2-dichloroethane has been detected from imported articles (irrespective of their material) such as 'polyresin' and Santa Clause figures<sup>11</sup>, sex toys and squishy products for children<sup>12</sup>, children's shoes, cotton socks and doll playhouses<sup>13</sup>, and 'holiday decorations'<sup>14</sup> that have the potential to lead to human exposure (consumers and workers). The evidence indicates that the presence of the substance in articles and emitted

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<sup>7</sup> [Health risks and prevention practices during handling of fumigated containers in ports - Publications Office of the EU \(europa.eu\)](#);

<sup>8</sup> BAUR, X., POSCHADEL, B. & BUDNIK, L. T. 2010. High frequency of fumigants and other toxic gases in imported freight containers—an underestimated occupational and community health risk. *Occupational and environmental medicine*, 67, 207-212

<sup>9</sup> BUDNIK, L. T., AUSTEL, N., GADAU, S., KLOTH, S., SCHUBERT, J., JUNGNICHEL, H. & LUCH, A. 2017. Experimental outgassing of toxic chemicals to simulate the characteristics of hazards tainting globally shipped products. *PLoS one*, 12, e0177363

<sup>10</sup> [98134bd2-f26e-fa4f-8ae1-004d2a3a29b6 \(europa.eu\)](#)

<sup>11</sup> [RIVM rapport 609021033 The release of pesticides from container goods](#)

<sup>12</sup> [Undersøgelse og risikovurdering af parfume og andre organiske forbindelser i squishy legetøj \(mst.dk\)](#)

<sup>13</sup> BUDNIK, L. T., AUSTEL, N., GADAU, S., KLOTH, S., SCHUBERT, J., JUNGNICHEL, H. & LUCH, A. 2017. Experimental outgassing of toxic chemicals to simulate the characteristics of hazards tainting globally shipped products. *PLoS one*, 12, e0177363

<sup>14</sup> DOUCETTE, W. J., HALL, A. & GORDER, K. 2010. Emissions of 1, 2-dichloroethane from holiday decorations as a source of indoor air contamination. *Groundwater Monitoring & Remediation*, 30, 67-73

from the articles seems to originate mainly from the use of 1,2-dichloroethane as biocide for fumigation of freight containers<sup>15</sup>.

In the course of preparing this report, it was also identified that workers opening freight containers and handling articles from such containers could be exposed to 1,2-dichloroethane and other hazardous substances (such as phosphine, methylbromide, chloropicrin, ethylene oxide, benzene, formaldehyde, toluene) at concentrations several orders of magnitude above national or EU occupational limit values<sup>161718</sup>.

#### *Characterisation of risk*

RAC derived the dose-response curve for the lifetime cancer risk of 1,2-dichloroethane<sup>19</sup>. Based on the information presented above, it is expected that there is no risk from 1,2-dichloroethane in PVC articles, because its presence in articles is negligible. This assumption was not contradicted during the call for evidence.

ECHA did not evaluate the potential risk for consumers and workers from articles fumigated with 1,2-dichloroethane. However, taking into account that for this carcinogenic substance no safe threshold can be identified, any exposure should be minimised.

Furthermore, 1,2-dichloroethane is a biocidal active substance not approved in the EU. According to Article 58(2) of the Biocidal Products Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, only articles treated with biocidal products for which all active substances have been approved for the relevant product-type and use are allowed to be placed on the EU market, unless the exemption of article 58(1) applies. This exemption specifies that in case the sole treatment undertaken was the fumigation or disinfection of a container, no residues are expected to remain from such treatment. To ensure that from fumigation with 1,2-dichloroethane no residues are expected in articles to be placed on the market, the enforcement bodies of the Biocidal Regulation would need to be informed. This issue was communicated to the ECHA Forum for Enforcement for further considerations.

In addition, Directive 2009/48/EC on the safety of toys specifies that substances classified as carcinogenic 1B are prohibited in toys in concentrations equal to or above 0.1 %, unless a safety assessment has been carried out showing it is safe.

To minimise risks for workers opening freight containers and handling articles from such containers fumigated with 1,2-dichloroethane and other hazardous substances adequate guidance and preventive (e.g. active ventilation of the container prior to opening) or protective measures (e.g. personal protective equipment) are required. Handling of fumigated containers at the port and at the end-user is already regulated by the OSH

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<sup>15</sup> BUDNIK, L. T., AUSTEL, N., GADAU, S., KLOTH, S., SCHUBERT, J., JUNGNIKEL, H. & LUCH, A. 2017. Experimental outgassing of toxic chemicals to simulate the characteristics of hazards tainting globally shipped products. *PLoS one*, 12, e0177363

<sup>16</sup> [Health risks and prevention practices during handling of fumigated containers in ports - Publications Office of the EU \(europa.eu\)](#)

<sup>17</sup> [99-SHEcan - Summary report PRINTING ALLOWED \(1\).pdf](#)

<sup>18</sup> BAUR, X., POSCHADEL, B. & BUDNIK, L. T. 2010. High frequency of fumigants and other toxic gases in imported freight containers—an underestimated occupational and community health risk. *Occupational and environmental medicine*, 67, 207-212

<sup>19</sup> [RAC EDC 15June15B \(europa.eu\)](#)

Directive (89/391/EEC) and Chemical Agents Directive (98/24/EC), which stipulate that a risk assessment must be carried out by the employer and, depending on the results that appropriate measures must be taken before work starts. If applicable, this risk assessment has to include the safe entering of sea containers and safe handling of goods from such containers. However, the European Agency for Safety and Health at Work<sup>20</sup> reported that many freight containers are not or not sufficiently labelled making enforcement more difficult and that compliance with present regulations has been reported to be low, partly because of companies' failure to adequately translate the regulations into operational management. ECHA has also communicated this issue to the ECHA Forum for Enforcement for further considerations.

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<sup>20</sup> EU OSHA (2018) Health risks and prevention practices during handling of fumigated containers in ports - Literature Review, 2018. Available at <https://osha.europa.eu/en/publications/handling-fumigated-containers-ports-health-risks-and-prevention-practices>

## Background and scope of Article 69(2) screening

Screening reports are prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006. The article requires that ECHA, after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), considers if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepares an Annex XV restriction dossier.

Thus, REACH Article 69(2) screening reports are targeted at the potential release or exposure to the Annex XIV substance(s) from an article throughout its lifecycle (including the waste stage) and whether such use(s) should be restricted. Screening reports are focused on the human health and/or environmental hazards due to which the substance is placed on the Annex XIV. Other hazards are not required to be taken into account for the purpose of the screening. Similarly, in the event ECHA proposes that an Annex XV dossier for restrictions is prepared, the scope of the work will be restricted to the risks arising from the Annex XIV intrinsic properties only unless the scope is expanded on request by the European Commission to include other endpoints. It is to be noted that REACH restrictions do not apply in certain cases. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to human health of the use of the substance in cosmetic products, and when a substance is used as an on-site isolated intermediate.

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of the screening reports. Incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH<sup>21</sup>. The incorporation process carried out in third countries is outside the scope of EU legislation (and REACH Authorisation). However, it should be noted that articles, if imported to the EU, are within the scope of these investigations. The incorporation is regarded to cover two types of uses<sup>22</sup>:

- a) The substance is incorporated into an article during its production, or
- b) The substance, alone or in a mixture, is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g. coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

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<sup>21</sup> Q&A ID: 0564: <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564> Note that ECHA will investigate for this report whether applications for authorisation/authorisation decisions cover the incorporation of the substance into an article and possible cumulative effects of the substance due to authorisations.

<sup>22</sup> [https://echa.europa.eu/documents/10162/23036412/articles\\_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c](https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c)