

SCREENING REPORT

TO ASSESS WHETHER THE USE OF BIS(2-METHOXYETHYL) ETHER (DIGLYME) 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
25	Bis(2- methoxyeth yl) ether	Diglyme	203-924-4	111-96-6	22/02/2016	22/08/2017	Toxic for reproduction (Article 57c)

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

CONTACT DETAILS:

EUROPEAN CHEMICALS AGENCY P.O. BOX 400, FI-00121 HELSINKI, FINLAND ECHA.EUROPA.EU

VERSION: 1 Final

DATE: 21 February 2024

1. Conclusions

Following an assessment of the available evidence, ECHA considers that there is currently no use of diglyme in articles (domestic or imported) which may pose a risk to human health that is not adequately controlled.

Diglyme is covered by entry 25 of REACH Annex XIV. It is a Toxic for reproduction (Article 57c) substance for which ECHA's Committee for Risk Assessment¹ has established dermal and inhalation DNELs². However, there is no information that indicates that the use or presence of the substance in articles would lead to human exposure. This conclusion is based on the following two elements:

- 1. the current information on identified uses and exposure of diglyme in articles;
- 2. the assumption that diglyme is not used in batteries produced nor placed on the market at present in Europe.

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. If diglyme's use in batteries is commercialised in the future, any potential risk would be addressed by the recently adopted EU Batteries Regulation³.

The above conclusions as well as the assumptions and findings in the draft report were subject to a Call for Evidence that took place from 11 October to 22 November 2023. Two organisations – one national authority and one industry association provided information that has been incorporated into the report. The additional information received during the Call for Evidence did not impact the conclusions.

2. Summary of findings

2.1. Identified uses

The combined evidence from the EU regulatory documents⁴, ECHA databases^{5,6}, and online⁷ searches indicates that diglyme can be used in the production of articles, for example in the production of plastic and rubber parts for vehicles, electronic components and batteries. Given its technical function, diglyme is typically used as a **solvent** or **processing aid** in production processes, and it is not likely to be present in the articles placed on the market unless it is used as an electrolyte in batteries.

Information on uses in articles

Diglyme has been registered by six companies in the total tonnage band of 100 - 1000 tonnes per year. Four of the registrations were active in January 2024. The registrations

³ REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning batteries and waste

⁷ <u>SciFinder</u>[№]

¹ <u>Committee for Risk Assessment</u>

² Application for Authorisation: DNEL Setting for Reprotoxic Properties of Diglyme <u>RAC/33/2015/08</u>

batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC ⁴ Annex XV Dossier - Diglyme

⁵ In accordance with the <u>Waste Framework Directive (</u>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 <u>SCIP database</u>, i.e., Substances of Concern In articles as such or in complex objects (Products):

⁶ ECHA's Dissemination site diglyme and <u>SCIP database</u>

list uses as a solvent or process chemical at industrial sites. Consumer uses of diglyme are advised against.

Active REACH registrations⁸ report potential uses in articles for vehicles, in plastics, and electronic components. SCIP notifications also list these uses but no information is available in any sources that would explain any technical function or why diglyme would be present in such articles as finished products. In addition, the presence of diglyme is also reported in batteries through SCIP notifications.

Since the sunset date for diglyme was passed in August 2017, its use in the EEA⁹ has been limited to those uses within the scope of authorisation¹⁰ and those exempted¹¹. In January 2024, there were twelve authorised uses¹² as a solvent or process chemical. None of these uses leads to diglyme being present in articles. Exempted uses do not either include any uses in articles. In addition, it is worth noting that no substances in articles (SiA)¹³ notifications on diglyme have been submitted to ECHA.

Automotive

The 2012 SVHC identification Annex XV Background document¹⁴ indicates that diglyme has been used in car care products. However, such a use is not relevant for this report as it is about a mixture used on cars but not incorporating the substance into an article. No other automotive related uses were found during data base searches. In addition, it is worth noting that automotive companies commonly have supplier requirements (e.g. Scania¹⁵) that do not allow Candidate List¹⁶ substances in their products.

Plastic products

A review of a list of over 400 of the most commonly used functional additives and pigments in plastics that ECHA has developed jointly with industry – PLASI Initiative¹⁷ – did not indicate that diglyme would be used as an additive that would remain in articles made of plastics. During the database searches, no information was found about any potential use of diglyme in the production of plastic or rubber. Danish Authorities contributed to the Call for Evidence by providing their 2016/2017 report on 3D Printers and 3D Printed Products. In that study, they identified in migration tests diglyme in some 3D printing materials in low concentrations (<0.05 mg/L)¹⁸. They did not report any diglyme in printers. **Electronic components**

The uses of diglyme in electronics notified to the SCIP database mentions components and liquid crystal display (LCD) screens but do not provide any further details. Japan automotive parts association indicated during the Call for Evidence that diglyme can be

⁸ ECHA Brief Profile: Bis(2-methoxyethyl) ether

⁹ For further information on the uses of the substance and regulatory actions, please consult ECHA's website: <u>https://echa.europa.eu/</u>

¹⁰ Adopted opinions for authorisation

¹¹ See <u>ECHA Questions and Answers:</u> Authorisation scope

¹² ECHA dissemination site - <u>Diglyme</u>

¹³ Notifying substances in articles

¹⁴ Background document for bis(2-methoxyethyl)ether (<u>Diglyme, DEGDME</u>) 2012

 $^{^{15}\ \}underline{\text{STD4321}}$ Scania Requirements for Suppliers of Bodywork

 $^{^{16}\,\}underline{\text{Candidate List}}$ of substances of very high concern for Authorisation

¹⁷ https://echa.europa.eu/mapping-exercise-plastic-additives-initiative

¹⁸ <u>Risk Assessment of 3D Printers and 3D Printed Products</u>, Ministry of Environment and Food of Denmark, Survey of chemical substances in consumer products No. 161, May 2017

contained in the spacer of LCDs as an impurity of the main solvent that is used for ensuring a uniform space between the two glass substrates holding the liquid crystal material. The diglyme concentration in the spacer was indicated to be 0.02%. This is below the 0.1% threshold for substances in articles.

Other sources¹⁹ note that diglyme has been used in etching fluids in the electronics sector. However, no information could be found that would indicate that such a use would lead to diglyme's presence in finished electronic components or products. In addition, according to information collected during public consultations²⁰ in the SVHC identification process on diglyme, the producers of the substance (Association of Oxygenated Solvent Producers) indicated that their Charter on Glycolethers requires suppliers to request declarations from customers that diglyme is not used for products placed on the market for general public. Additionally, a recent review paper²¹ on solvents for semiconductor industry, which lists chemicals used in the sector, does not include diglyme as one of the solvents for the wet process of microelectronics or optoelectronics. The paper covers cleaning and drying of precision electronic components of chips, liquid crystals, magnetic heads and circuit boards.

Batteries

The use of diglyme in batteries, though identified in a few databases, does not seem to be currently relevant at EU level.

If diglyme would be used as an electrolyte, it would be present as an integral part (substance/in mixture²²) of batteries, and the placing on the market or the use of an article (here batteries) which contains an Annex XIV substance would not be subject to the authorisation requirement²³. However, if the production of such batteries, requiring incorporation of diglyme as an electrolyte, would take place in the EU, this use of diglyme would require an authorisation.

No application for authorisation has been submitted for the use of diglyme in the production of batteries in Europe.

The use of diglyme as an electrolyte is only listed in REACH registrations that are no longer active. As the use of diglyme as an electrolyte has not yet been commercialised, the few entries reported in the SCIP database may not be reliable or may indicate that batteries with diglyme are imported into Europe. The call for evidence did not provide any evidence that there are batteries with diglyme as an electrolyte being imported into the EU.

Recent market research on internet indicates that diglyme's global market is expected to expand from 2023 to 2028 and that electrochemistry is one of the main market segments for the substance. Unfortunately, no volume trends for this segment are publicly available. However, numerous online articles and database information indicate an active development work on diglyme as an electrolyte for sodium-ion and lithium-ion batteries (see e.g.^{14, 24, 25}). This may lead to use of diglyme in batteries in the future. If this use is

¹⁹ Diglyme Analysis of alternatives

²⁰ Background document for bis(2-methoxyethyl)ether (Diglyme, DEGDME) 2012

²¹ Chemical use in the semiconductor manufacturing industry

²² <u>ECHA 2017</u> Guidance on requirements for substances in articles

²³ ECHA Q&A 564: Does the authorisation requirement apply to the use of substances in articles?

²⁴ <u>ACS Publications</u>: Stable and Unstable Diglyme-Based Electrolytes for Batteries with Sodium or Graphite as Electrode

²⁵ Royal Society of Chemistry: Glyme-based electrolytes: suitable solutions for next-generation lithium batteries

commercialised in the EU, any potential risk would be addressed by the recently adopted Batteries Regulation²⁶. Informal contacts with the European battery industry during the screening assessment indicate that diglyme is not known to be used in batteries that are currently placed on the EU market.

2.2. Emissions/releases/exposure and risk

Information on emissions/release/exposure

Automotive and plastic products & electronic components: Based on the SCIP database submissions, diglyme is indicated to be potentially present in vehicle parts, and electrical equipment. However, given the technical function of the substance as a solvent and process chemical, it is expected that the substance is not likely to be present in such articles in the EEA.

Batteries: There is no information available that would currently indicate the presence of diglyme containing batteries on the market at European level. However, extensive research and development work is ongoing globally in this field. If the use of diglyme as an electrolyte in batteries is commercialised in Europe, it is not possible to exclude at that stage a potential exposure of workers producing, servicing or recycling/dismantling diglyme containing batteries as well as consumers who would have such batteries in complex objects they use.

Characterisation of risk

Automotive and plastic products & electronic components: Based on the information presented above, it is expected that there is no risk from diglyme because the presence of diglyme in these articles is unlikely.

Batteries: The screening did not identify any risk at present. If in future risks will arise from the use in batteries, regulatory measures should be reconsidered. Potential future risks (if any) would be addressed under the Battery Regulation if the use of diglyme as an electrolyte in batteries becomes relevant in the EU.

²⁶ REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning <u>batteries and waste</u> <u>batteries</u>, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC

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 REACH²⁷. 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 uses²⁸:

- 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).

²⁷ Q&A ID: 0564: <u>https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0564</u> 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.

²⁸ <u>https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c</u>