Regulatory Management Option Analysis Conclusion Document

Substance Name: Prop-2-yn-1-ol
EC Number: 203-471-2
CAS Number: 107-19-7

Authority: The Netherlands (NL-CA)
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Foreword

The purpose of Regulatory Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The main reason for this RMOA of prop-2-yn-1-ol, is the fact that some evidence for carcinogenicity was found in the 2008 NTP 2-year inhalation study (on prop-2-yn-1-ol with 0.17% formaldehyde), as in both mice and male rats, the formation of nasal respiratory epithelial adenoma was found at the highest test concentrations (64 ppm). The carcinogenic activity may or may not be contributed to the presence of formaldehyde (0.17%). It should be noted that the target organs and the type of tumors are similar to the ones induced by formaldehyde, which favors the idea that the tumors are due this impurity. Repeating the study with pure substance (without impurities) could provide insight but is considered to be disproportionate. In addition, studies on the Mode of Action or Adverse Outcome Pathways can be useful in the evaluation of the carcinogenic properties of the pure substance versus formaldehyde.

Although no carcinomas were found, the increased incidences of nasal respiratory epithelial adenoma and mononuclear cell leukaemia can warrant the assignment a C&L classification 2 for carcinogenicity (Carc. 2) of prop-2-yn-1-ol. A self-classification for the composition with an impurity of ≤0.5% formaldehyde already states Carc. 1B, which is in line with the guidance on CLP (applying the CLP-rules the presence of an impurity classified with Carc. 1B above 0.1% should be considered comparable to mixtures, leading to a classification with Carc. 1B).

Risk for the general public of being exposed to prop-2-yn-1-ol is not expected, as the substance is only used in industrial processes and in professional uses. However, workers on industrial sites and those that professionally use (mixtures with) prop-2-yn-1-ol may be exposed. The regulatory management options, should therefore focus on reducing exposure of workers and preventing exposure of the general public by strictly controlling emission to the environment and consumer uses.

A substance evaluation of formaldehyde was performed by France and the Netherlands (co-evaluating Member state) because of concerns for CMR characteristics, exposure of workers, the high aggregated tonnage and its wide dispersive use. In addition, a restriction dossier has been drafted for formaldehyde releasing substances, mixtures and articles for consumers by ECHA.[2]

Relevant EU-legislation

The use of prop-2-yn-1-ol as a solvent is subject to the VOC Solvent Emissions Directive (1999/13/EC), implemented as an instrument for reduction of industrial emissions of VOCs, and the Paints Directive (2004/42/EC), implemented to limit the emissions of VOCs due to the use of organic solvent in paints, varnishes and vehicle refinishing products. Prop-2-yn-1-ol has a vapour pressure ≥0.01 kPa (at 293,15K), making it a volatile organic compound by definition of the Directive.

The Chemical Agents Directive (98/24/EC) lays down minimum requirements for the protection of workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents. The use of prop-2-yn-1-ol falls into this category.

The group to which prop-2-yn-1-ol belongs (alkyne alcohols, their esters, ethers and salts) is present as nr. 16 in Annex II (list of substances prohibited in cosmetic products) in Regulation (EC) No 1223/2009, because they may cause skin irritation. For this entry in the Cosmetic Directive, no scientific opinion has ever been published.

European occupational exposure limits (based on average 8h exposure per day), source: https://limitvalue.ifa.dguv.de

[2] https://echa.europa.eu/nl/registry-of-restriction-intentions/-/dislist/details/0b0236e182439477

OEL-value (mg/m^3)	**Country**
0.5	The Netherlands
4.7	Germany, Austria, Switzerland,
2.5	Denmark, Norway
2.3	Finland, UK, Belgium, Spain
2.0	France, Ireland
1.0	Latvia
3.0	Poland

2. CONCLUSION OF RMOA

The highest risks of prop-2-yn-1-ol are associated with industrial and professional uses. Enforcement of RMMs, phase out of high exposure uses, and/or incentives for substitions through existing legislation (VOC Solvent Emissions Directive; Paints Directive; Chemical Agents Directive) are the most viable RMOs. Enforcement authorities could take this up in their routine inspections, without considerable additional costs.

Preparation of a CLP dossier for Harmonised classification of carcinogenicity of prop-2-yn-1-ol could be considered, mainly as input for potential unforeseen future uses. However, Carc. 2 classification would not lead to further regulatory management measure than already available based on acute and long term effects for workers. It should be noted that based on the guidance on CLP (applying the CLP-rules) the presence of an impurity classified with Carc. 1B above 0.1% should be considered comparable to mixtures, leading to a classification with Carc. 1B.

The preferable regulatory management option is to our point of view to identify formaldehyde as SVHC, based on the classification Carc. 1B. The contamination of prop-2-yn-1-ol with >0.1% formaldehyde in certain compositions would cover the obligation for notification of SVHC substances above 0.1% and 1 tonne per year. It is probably more efficient to identify formaldehyde as SVHC than to start the restriction or authorization process for formaldehyde contaminated prop-2-yn-1-ol. In such a way the concern arising from other formaldehyde containing substances (above 0.1%) is also covered with this regulatory option. We would like to discuss in RiME+ how other member states and ECHA see this and if SVHC identification is needed or beneficial in general.

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Harmonised classification and labelling

The substance already has a Harmonised Classification in Annex VI of the CLP:
Flam. Liq. 3 (H226), Acute Tox. 3 (H301, H311, H331), Skin Corr. 1B (H314) and Aquatic Chronic 2 (H411).

Additional to the harmonised classification, the self-classification include the hazard statements:

- Acute tox. 2 – fatal in contact with skin (H310),
- Acute tox. 2 – fatal if inhaled (H330),
- Eye dam. 1 – causes serious eye damage (H318), and

- STOT RE 2 – may cause damage to organs through prolonged or repeated (including dermal and via inhalation) exposure (H373; affected organs: liver, kidney).

For prop-2-yn-1-ol containing impurities with formaldehyde (≤0.5% and 0.1%) self-classification includes hazard statements:
- Skin sens. 1A – may cause an allergic skin reaction (H317), and
- Carc. 1B – may cause cancer (H350).

Regarding carcinogenicity, it can be concluded that there is a difference in the interpretation of the study results in the NTP report and the REACH registration dossier. The carcinogenic activity may or may not be contributed to the presence of formaldehyde (0.17%). It should be noted that the target organs and the type of tumors are similar to the ones induced by formaldehyde, which favors the idea that the tumors are due this impurity. Repeating the study with pure substance (without impurities) could provide insight but is considered to be disproportionate. In addition, studies on the Mode of Action or Adverse Outcome Pathways can be useful in the evaluation of the carcinogenic properties of the pure substance versus formaldehyde.

The impurity formaldehyde (CAS number 50-00-0) does have a harmonised classification for a CMR category (Carc. 1B). For prop-2-yn-1-ol with this impurity in a concentration ≥0.1% (w/w) a classification for Carc. 1B is needed. Formaldehyde is one of the precursors of the most common production processes of prop-2-yn-1-ol.

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

It could be discussed if STOT RE 2 is sufficient justification for SVHC identification (based on 57f (ELoC)). Currently, this seems not an appropriate option. If SVHC identification would be feasible this would result in the advantage is the substance self is regulated regardless the presence of formaldehyde as impurity. The SVHC listing of prop-2-yl-1-ol is possible in case of a CMR Cat. 1A of 1B classification, which seems not to be feasible on the currently available data and is therefore not possible.

Thusfar, only formaldehyde, oligomeric reaction products with aniline have been identified as SVHC. The SVHC listing of formaldehyde would also address other substances with formaldehyde as impurity above 0.1%. The contamination of prop-2-yn-1-ol with >0.1% formaldehyde in certain compositions would cover the obligation for notification of SVHC substances above 0.1% and 1 tonne per year.

3.3 Restriction under REACH

It is probably more efficient to identify formaldehyde as SVHC than to start the restriction or authorization process for formaldehyde contaminated prop-2-yn-1-ol. In such a way the concern arising from other formaldehyde containing substances (above 0.1%) is also covered with this regulatory option. We would like to discuss in RiME+ how other member states and ECHA see this and if SVHC identification is needed or beneficial in general.

4. References

NRC, 2013. Acute Exposure Guideline Levels for Selected Airborne Chemicals, Volume 14. Committee on Acute Exposure Guideline Levels; Committee on Toxicology; Board on Environmental Studies and Toxicology; Division on Earth and Life Studies; National Research Council. National Academies Press, Washington (DC), USA.

National Institute of Health, 2008. NTP Technical Report on the toxicology and carcinogenesis studies of propargyl alcohol (CAS NO 107-19-7) in F344/N rats and B6C3F1 mice (Inhalation studies), National Toxicology Program, NTP 552. NIH Publication No. 08-5893, National Institutes of Health, Public Health Service, U.S. Department of Health and Human Services, September 2008.

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

An indicate a preliminary timetable for the risk management measures discussed above are indicated in the table below.

Follow-up action	Date for intention	Actor
Identification of formaldehyde as SVHC		