

**Risk Management Option Analysis Conclusion Document**

**Substance Names: Vinyl acetate [1]; Vinyl propionate [2]**

**EC Numbers: 203-545-4 [1]; 203-293-5 [2]**

**CAS numbers: 108-05-4 [1]; 105-38-4 [2]**

**Authority: Swedish Chemicals Agency (KemI)**

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# Foreword

The purpose of Risk 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]](#footnote-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.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

In 2011, the RAC has adopted the Opinion for harmonised classification[[2]](#footnote-2) of vinyl acetate (VA) as Carc. 2 (H351), Acute Tox. 4 (H332), STOT SE 3 (H335), Flam. Liq. 2 (H225).

Vinyl propionate (VP) has no harmonised classification. The registrant has self-classified it as Carc. 2 (H351) using read-across of data from the studies available on VA in order to fill the data gaps for *in vivo* mutagenicity and carcinogenicity.

In 2015, VA was subject to manual screening due to an initial concern for endocrine disruption and CMR properties. The outcome of the manual screening performed by the Finnish CA was “Candidate for substance evaluation - CoRAP” based on potential concerns for endocrine disruption, toxicity to reproduction and sensitization. The outcome of the SEV[[3]](#footnote-3) was published in November 2020. Based on the information available in the registration dossier, the eMSCA (Latvia) did not identify any potential or inadequately controlled risk for any of the endpoints of concern, thus concluding that there was no need for regulatory follow-up at EU level.

In 2019, both vinyl esters were subject to manual screening (performed by SE CA) as part of the vinyl esters group due to an initial concern for carcinogenicity and mutagenicity effects, with vinyl acetate as a group seed. Based on the read-across justification document provided in the registration dossier, the Swedish CA was of the opinion that the read-across of data from VA performed for covering the data gaps in the registration dossier of VP is acceptable. Therefore, the self-classification of VP as Carc. 2 based upon read-across of data from VA is considered appropriate. The outcome of the manual screening was to further assess the possibility of proposing CLH for Carc. 1B and Muta 2. for both VA and VP, supported by read-across from acetaldehyde, the common metabolite of the two vinyl esters. Acetaldehyde is carcinogenic and mutagenic, with a harmonised classification[[4]](#footnote-4) as Carc. 1B and Muta. 2.

The present RMOA was conducted to assess in detail the need for risk management measures for these two vinyl esters.

### CONCLUSION OF RMOA

The carcinogenic mechanism of action for VA and VP has been suggested to depend on the *in vivo* accumulation of the metabolite acetaldehyde, which is formed by both VA and VP. As also detailed in the RAC Opinion on vinyl acetate (2011), a threshold mechanism of action is thought to be active for the carcinogenicity of VA and VP, as the accumulation of acetaldehyde is dependent on the activities of the enzymes involved, i.e. acetaldehyde could accumulate if ALDH (aldehyde dehydrogenase) is saturated. Based on the information provided in the registration, the limited amount of acetaldehyde formed from the metabolism of VA and VP is not considered to be sufficient for the saturation of ALDH. Furthermore, as stated in the Guidance document on the application of the CLP Criteria (2017) and in the RAC Opinion on vinyl acetate (2011), the existence of a secondary mechanism of action with the implication of a practical threshold above a certain dose level may lead to a classification in Category 2 rather than Category 1.

Therefore, based on the in-depth evaluation performed in the present RMOA, the Swedish CA sees no need to update the classifications for VA and VP, as initially suggested after the manual screening performed in 2019.

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| **Conclusions** | **Tick box** |
| Need for follow-up regulatory action at EU level: |  |
| *Harmonised classification and labelling* |  |
| *Identification as SVHC (authorisation)* |  |
| *Restriction under REACH* |  |
| *Other EU-wide regulatory measures* |  |
| Need for action other than EU regulatory action |  |
| No action needed at this time | x |

### No action needed at this time

Based upon the available data, no risks were identified for uses of either vinyl ester. Moreover, it is considered that the current RMMs (harmonised classification and self-classification) are sufficiently protective for the workers handling the monomers.

However, it has to be noted that at the time the RMOA was initiated, VP had a high number of C&L notifiers (n=44) without proper self-classification as Carc. 2. The Swedish CA has contacted the C&L Inventory notifiers of VP (but also the lead-registrant) to remind them of their obligation under Art. 41 of the CLP Regulation, in order to ensure consistent self-classification. This has resulted in 1/44 notifiers self-classifying VP as Carc. 2.

There is still quite a large number of C&L notifiers (n=43) without proper self-classification as Carc. 2, and RRM in the form of CLH may therefore be warranted. The Swedish CA therefore encourages the other notifying companies to update their C&L Inventory notifications in order to ensure appropriate RRM for the safety of the workers handling VP.

However, based on the low tonnage, that the only registered uses are industrial, and uncertainty regarding whether notifications are made for the monomer or (co)polymers, the Swedish CA leans towards that the self-classification by the lead registrant is sufficient as RRM. No further action is thus considered necessary at this point in time.

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> [↑](#footnote-ref-1)
2. [Vinyl acetate - Registry of CLH intentions until outcome - ECHA (europa.eu)](https://www.echa.europa.eu/en/web/guest/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180a1283a) (accessed on the 11th of December 2020) [↑](#footnote-ref-2)
3. [Vinyl acetate - Substance evaluation - CoRAP - ECHA (europa.eu)](https://www.echa.europa.eu/en/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180b93351) (accessed on the 8th of December 2020) [↑](#footnote-ref-3)
4. [Acetaldehyde - Registry of CLH intentions until outcome - ECHA (europa.eu)](https://www.echa.europa.eu/en/web/guest/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1806d8424) (accessed on the 11th of December 2020) [↑](#footnote-ref-4)