

**Risk Management Option Analysis Conclusion Document**

**Substance Name:** Trisodium 2-[[4-[[4-[(4-amino-6-chloro-1,3,5-triazin-2-yl)amino]-5-sulphonatonaphthyl]azo]-2,5-dimethylphenyl]azo]benzene-1,4-disulphonate; C.I. Reactive Orange 35

**EC Number:** 274-410-5

**CAS Number:** 70210-13-8

**Authority:** Swedish Chemicals Agency

**Date:** 18 June 2021

**DISCLAIMER**

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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

*Please provide a brief overview of completed/ongoing processes (including RMOA) and EU legislation relevant for the substance.*

### CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

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

### Need for follow-up regulatory action at EU level

### Harmonised classification and labelling

Currently, C.I. Reactive Orange 35 is self-classified as Skin Sens. 1A (H317) and STOT RE 2; H373 (blood, oral) by the lead registrant. The SE CA agrees with the lead registrant that C.I. Reactive Orange 35 fulfils the criteria for classification as Skin Sens. 1A; H317. Among the notified self-classifications in the C&L Inventory, the hazard category for skin sensitisation is diverging. The incorrect self-classification by several notifiers (i.e., Skin Sens. 1, Skin Sens. 1B or no classification for skin sensitisation) justifies the need for harmonised classification and labelling at Community level. The self-classification for STOT RE 2; H373 (blood, oral) is based on read-across from C.I. Reactive Black 39 lithium sodium salt. Depending on the outcome of the CCH, the need for further RRM such as CLH should be revisited.

Harmonisation of the classification of a substance could significantly contribute to reducing the risk to professionals, as mandatory labelling of products and mixtures containing the substance at a concentration at or above the classification limit would help raise the awareness of companies and workers to the hazards.

For consumers, the correct sub-categorisation and concentration limit is also important to trigger the relevant labelling. In case C.I. Reactive Orange 35 will have a harmonised classification as Skin Sens. 1/1A/1B, it would also fall under the ongoing restriction on sensitisers in textile if the restriction will be adopted according to the current proposal[[2]](#footnote-2).  Overall, this could have an important impact on consumer safety.

Due to the lack of data on other endpoints (genotoxicity, repeated dose toxicity and reproductive toxicity), a possible further need for harmonised classification could be envisaged based on the outcome of the compliance check. This RMOA should therefore be revisited once such data has become available.

### Need for action other than EU regulatory action

### Compliance check (CCH)

Based on the available information, the SE CA conclusion is that the read-across justification does not fulfil the requirements of Annex XI of REACH. Hence, compliance check to evaluate the read-across applied by the registrants for acute dermal toxicity, repeated dose toxicity, mutagenicity in mammalian cells, reproductive toxicity, hydrolysis and adsorption is warranted.

### TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

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| **Follow-up action** | **Date for follow-up** | **Actor** |
| CLP Annex VI dossier | June / 2022 | Sweden |
| Compliance check |  | ECHA |

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. [Skin sensitising, irritative and/or corrosive... - Registry of restriction intentions until outcome - ECHA (europa.eu)](https://echa.europa.eu/sv/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136) [↑](#footnote-ref-2)