

**Risk Management Option Analysis Conclusion Document**

**Substance Name:** Tetra(sodium/potassium)-7-[(E)-{2-acetamido-4-[(E)-(4-{[4-chlor-6-({2-[(4-fluor-6-{[4-(vinylsulfonyl)phenyl]amino}-1,3,5-triazin-2-yl)amino]propyl}amino)-1,3,5-triazin-2-yl]amino}-5-sulfonato-1-naphthyl)diazenyl]-5-methoxyphenyl}diazenyl]-1,3,6-naphthalintrisulfonate; C.I. Reactive Brown 51

**EC Number:** 466-490-7

**CAS Number: -**

**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

There are no ongoing processes for this substance except for this RMOA.

### 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 |  |
| No action needed at this time |  |

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

### Harmonised classification and labelling

Currently, C.I. Reactive Brown 51 is self-classified as Skin Sens. 1; H317: May cause an allergic skin reaction, and Repr. 2; H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child[[2]](#footnote-2). The SE CA consider that C.I. Reactive Brown 51 fulfils the criteria for harmonised classification as Repr. 1B; H360F and Skin Sens. 1A; H317.

If the proposal for CLH is adopted, C.I. Reactive Brown 51 would be covered by entry 30 of REACH Annex XVII, which means that the substance would be restricted for supply to the general public when the individual concentration of the substance as such or in a mixture is ≥0.3% (assuming that classification as Repr. 1B with a general concentration limit would be adopted). Moreover, it would fall under the scope of the proposed restriction on skin sensitisers in textile[[3]](#footnote-3). Overall, this could have an important impact on consumer safety.

Depending on the outcome of the CLH proposal, the need for further regulatory risk management such as SVHC identification could be considered.

### 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 |

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. C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed 16 November 2020). [↑](#footnote-ref-2)
3. [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-3)