

**Risk Management Option Analysis Conclusion Document**

**Substance Name: Nitrilotriacetic acid**

**EC Number: 205-355-7**

**CAS Number: 139-13-9**

**Authority: Health and Safety Authority**

**Date: May, 2022**

**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

|  |  |  |
| --- | --- | --- |
| RMOA |  | Risk Management Option Analysis (RMOA) - Ireland, May 2022 |
| REACH Processes | Evaluation | Compliance check[[2]](#footnote-2), Final decision |
| Testing proposal |
| CoRAP and Substance Evaluation |
| Authorisation | Candidate List |
| Annex XIV |
| Restri-ction | Annex XVII |
| Harmonised C&L |  | Annex VI (CLP) (see section 3.1) |
| Processes under other EU legislation |  | Plant Protection Products Regulation  Regulation (EC) No 1107/2009 |
|  | Biocidal Product Regulation  Regulation (EU) 528/2012 and amendments |
| Previous legislation |  | Dangerous substances Directive  Directive 67/548/EEC (NONS) |
|  | Existing Substances Regulation[[3]](#footnote-3)  Regulation 793/93/EEC (RAR/RRS) |
| (UNEP) Stockholm convention (POPs Protocol) |  | Assessment |
|  | In relevant Annex |
| Other processes/ EU legislation |  | Other (provide further details below)[[4]](#footnote-4), [[5]](#footnote-5) |

### 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

Nitrilotriacetic acid does not have a harmonised classification under Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation). It is self-classified as Carcinogenicity Category 2 H351 by 352 of 514 notifiers to the C&L Inventory.

Trisodium nitrilotriacetate is the most commonly used salt of nitrilotriacetic acid. In terms of toxicology and ecotoxicology, it is expected that Na3NTA would dissociate into NTA and Na+ and therefore the hazardous properties of Na3NTA are expected to be driven by NTA. Trisodium nitrilotriacetate has a harmonised classification as Carcinogenicity Category 2 H351 under CLP.

Based on current available information including read-across justification to Trisodium Nitrilotriacetate and CLP notifications, we consider the data included in the RMOA supports the need for further risk management in the preparation of an Annex VI CLH dossier for harmonised classification for Carcinogenicity Category 2.

Since Nitrilotriacetic acid has industrial, professional and consumer uses, and since not all notifiers to the C&L database have self-classified as Carc. 2, we conclude that the most appropriate risk management measure is to prepare an Annex VI CLH dossier for harmonised classification.

### 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** |
| Proposed Annex VI CLH dossier for Nitrilotriacetic Acid for harmonised classification | 2023-2024 | CA Ireland |

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. Compliance check opened and closed (2016) without issuing a compliance check final decision [↑](#footnote-ref-2)
3. European Union Risk Assessment Report Trisodium Nitrilotriacetate [↑](#footnote-ref-3)
4. Detergent Regulations (EC) No. 648/2004 [↑](#footnote-ref-4)
5. COMMISSION DECISION (EU) 2017/1218 of 23 June 2017 establishing the EU Ecolabel criteria for laundry detergents [↑](#footnote-ref-5)