

RISK MANAGEMENT OPTIONS ANALYSIS

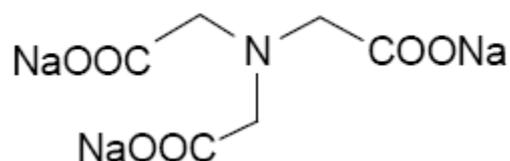
CONCLUSION DOCUMENT

for

Trisodium nitrilotriacetate (NTA)

EC No 225-768-6

CAS No 5064-31-3



Member State: Denmark

Dated: August 2014, Final version

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

The RMO and the underlying surveys are a part of the review of the substances on the Danish List of undesirable substances (LOUS-review).

The Danish EPA has conducted a survey of all substances listed on the Danish "List of Undesirable Substances" (LOUS). Access to the surveys carried out so far can be found at the following link: http://www.mst.dk/English/Chemicals/assessment_of_chemicals/LOUS_2012_2015/.

The survey carried out for Trisodium nitrilotriacetate provides an overview of the use and the environmental and human health aspects of the substance. The results of the survey have been used as the main background information for this RMO. We have not included the evaluation of the risk for workers of physical/chemical properties in the evaluation. It should be noted that Trisodium nitrilotriacetate (in this report abbreviated as Na₃NTA) is the most commonly used salt of the Nitrilotriacetic acid (NTA). From the data available, it is not always clear, if NTA and Na₃NTA addresses NTA, Na₃NTA or both. In terms of toxicology and ecotoxicology it is NTA (CAS No. 139-13-9) that determines the hazard of the substance.

When dissolved in water, Na₃NTA dissociates. The carboxylic acid, NTA, forms salts with various available cat-ions. NTA in its fully ionized form has four functional groups. Three carboxylates and one amine groups are available for complexing with an appropriate metal ion. This phenomenon where more than one of the NTA functional groups is involved in binding with a central metal ion is known as chelation. Complexes are formed in water between metal ions and NTA.

The current status of Na₃NTA and NTA pertaining to relevant EU legislation and a Danish Executive Order are summarised in Table 1 below.

TABLE 1
RELEVANT LEGISLATION PERTAINING TO THE MANUFACTURE AND USE OF TRISODIUM NITRILOTRIACETATE (Na₃NTA) AND NITRILOTRIACETIC ACID (NTA)

Legal instrument	EU/national	Status of Na ₃ NTA and NTA
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REACH Regulation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	Registration of production and use in tonnage band for Na ₃ NTA: 10,000-100,000 tonnes per year.
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures	<p>EU harmonised classification is available for Na₃NTA addressing health.</p> <p>There is a specific concentration limit for Na₃NTA of > 5 w% when introduced in mixtures. If the substance is included in mixtures in a concentration exceeding this limit the mixture must also be classified.</p> <p>There is no EU harmonised classification for NTA, but a notified classification is available from the ECHA CLP inventory.</p>
Directive on Chemicals Agents at Work	Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work	<p>No recommendation regarding indicative Occupational Exposure Limit (OEL) values is available</p> <p>No SCOEL (Scientific Committee on Occupational Exposure Limits) has been made.</p>
Carcinogens Directive	Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work	On the protection of workers from the risks related to exposure to carcinogens or mutagens at work.
Danish Executive Order on the Performance of Work	Danish Executive Order No. 559 of 17 June 2004	Section 16. Any unnecessary effect of substances and materials shall be avoided. Therefore, the effect of substances and materials during work shall be reduced to the lowest level reasonably practicable taking account of technical progress, and any limit values fixed shall be complied with.
Waste Framework Directive	Directive 2008/98/EC the European Parliament and of the Council of 19 November 2008 on waste	<p>Na₃NTA is as a consequence of its classification as Carc. 2 included in Annex III: Properties of waste which render it hazardous.</p> <p>Na₃NTA is as a consequence of its classification as Carc. 2 included in Annex 4: Properties and weight % which classifies waste as hazardous.</p>

Water Framework Directive	Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy	No environmental quality standards (EQS values) has been established for Na ₃ NTA and NTA. NTA or its sodium salts are not on the amended list of priority substances. NTA is however as a consequence of its classification as Carc. 2 included in the ANNEX VIII Indicative list of the main pollutants.
Cosmetics Directive	Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC) Article 4b.	The use in cosmetic products of substances classified as carcinogenic, mutagenic or toxic for reproduction, of category 2, under Annex I to directive 67/548/EEC shall be prohibited unless safe use is concluded in an evaluation performed by the Scientific Committees on Consumer Safety (SCCS).
Biocide Regulation	Regulation (EU) No 528/2012 of the European Parliament and the Council of 22 May 2012 concerning the making available on the market and use of biocidal products	NTA is included in Annex I: "List of active substances identified as existing" of the Commission Regulation 1451/2007 on biocides, referring to the work programme under the previous Biocidal Products Directive (Directive 98/8/EC). Na ₃ NTA and NTA are not included in Annex II: "On active substances to be examined under the review programme" of this Directive. Note: NTA itself does not have biocidal properties, but it is known that complexing agents can increase the effects of biocides.
Basel Convention	Basel Convention on the control of transboundary movements of hazardous wastes and their disposal	Basel Convention regulates wastes classified as hazardous (Annex III): Substances or wastes which, if they are inhaled or ingested or if they penetrate the skin, may involve delayed or chronic effects, including carcinogenicity.

2. CONCLUSION OF RMOA

Conclusions	Tick box
Need for follow up regulatory action at EU level <i>[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]</i>	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	

Restrictions	
Other EU-wide measures	
No need for regulatory follow-up action	X

Na₃NTA has an EU harmonised classification as Carc. 2 according to the CLP Regulation. Directive 2004/37/EC gives general rules on how to control the exposure and risk for workers using carcinogens, with the aim of reducing worker exposure to as low a level as possible. In Denmark, a classification of a substance as a category 2 carcinogen has already elicited a demand for substituting the substance for less hazardous substances.

Since the substance is used in both cleaning agents for household and industrial use, there is a potential for direct exposures of both consumers and workers. However, it seems as there has been a steep decline of Na₃NTA in Denmark and the EU in recent years due to regulatory and industry initiatives. Accordingly, minimal risk of the substance is expected in the future.

Based on the Risk Assessment report of Na₃NTA finalised in 2008, a Risk Reduction Strategy was formulated. The strategy focused on the possible risk to workers and recommended an EU harmonised classification of Na₃NTA and establishment of an OEL at Community level. An EU harmonised classification, including Carc. 2, is now in place, but no OEL has been established at Community level so it is still a measure. However, it may seem that setting an OEL will only marginally further reduce worker exposure.

Based on the existing regulation and the current trends in substance use, we conclude that there are no appropriate risk management options for Na₃NTA that needs to be taken at the moment.