

**RISK MANAGEMENT OPTIONS ANALYSIS
CONCLUSION DOCUMENT**

for

Nitric acid

EC No 231-714-2

CAS No 7697-37-2

Member State: Germany

Dated: 29 August 2014

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

Overview of completed/ongoing regulatory processes

• **Harmonised classification and labelling**

- RAC-24 opinion: classification proposal for acute inhalation toxicity adopted: Acute Tox. 1; H330 (Fatal if inhaled) with the supplemental hazard information EUH071 (Corrosive to the respiratory tract) (ECHA/NA/13/22-2013).
- 13th Meeting of CARACAL (26-28 November 2013): publication of the final RAC-24 opinion with the 7th ATP draft to CLP
- Industry proposed different classification for acute inhalation toxicity of nitric acid (February 2014): classification for two types distinguished by concentration ranges: pure fuming nitric acid and nitric acid below 70 %
- Follow-up 13th CARACAL: aMSCA proposed postponement of the inclusion of the adopted new classification in the 7th ATP to CLP (February 2014)
- 14th Meeting of CARACAL (2-3 April 2014): aMSCA explained the postponement of the entry for acute inhalation toxicity in Table 3.1 Annex VI, CLP
- Industry meeting with aMSCA (April 2014): Result: Submission of a guideline conform study for acute inhalation toxicity to define the toxicity of concentrated nitric acid (70 % at the azeotrop point) by industry until June 2015
- aMSCA will await the outcome of testing for acute inhalation toxicity by industry before conclusions will be drawn for a classification and labelling of nitric acid solutions below 70 %

• **Regulation (EU) No. 98/2013 on the marketing and use of explosive precursors**

Pursuant to Article 4(3c) of the Regulation (EU) No. 98/2013 on the marketing and use of explosive precursors which will come into force in September 2014, nitric acid shall not be made available to the general public as the substance on its own, or in mixtures or substances including it, except if the concentration is equal to or lower than 3 % w/w (limit value set out in Annex I), but no higher than 10 % w/w in case a well-established registration system has been established.

• **RMOA**

The RMOA has been developed due to the observed intoxications that occurred by using nitric acid-containing cleaning agents, e.g. POR-ÇÖZ imported from Turkey. Cleaning agent POR-ÇÖZ containing 20 % or more nitric acid was sold in DE and BE.

The RMOA was shared with MSCAs, ECHA and COM for commenting in October 2013.

- Comments received

It was agreed that it is important to prevent consumers from using products containing high concentrations of nitric acid, if these are found on the market. The Regulation (EU) No 98/2013 on the marketing and use of explosive precursors was considered sufficient to manage the risk; additionally it was suggested to assess the effectiveness of this regulation and initiate a restriction, if Regulation (EU) No. 98/2013 seems to be not sufficient.

2. 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.

Conclusions	Tick box
Need for follow up regulatory action at EU level	X
Harmonised classification and labelling	X
Identification as SVHC (authorisation)	
Restrictions	(X)
Other EU-wide measures	X
No need for regulatory follow-up action	

3. FOLLOW-UP OF REGULATORY RISK MANAGEMENT ACTION AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

Nitric acid is a high production volume chemical. The substance is produced/imported at high tonnage (> 1000 t/a). Due to its hazard properties exposure must be avoided.

In the EU the substance is widely used by workers and is registered for consumer uses, too. However, currently no consumer exposure assessment which indicates concentrations above traceable levels is provided. Therefore the use of higher concentrations of nitric acid in consumer products would not be covered for the registrations above 100 t/a.

3.1.1 Harmonised classification and labelling

Nitric acid is legally classified and labelled for its corrosive reactions to skin, eyes and mucosa with category 1A, H314 according to CLP. The evaluation of the data of nitric acid regarding acute inhalation toxicity has verified the concern that the supplement of the current classification for acute inhalation toxicity is required. RAC-24 agreed with the proposal of the aMSCA to classify nitric acid with Acute Tox. 1; H330 (Fatal if inhaled) with the supplemental hazard information EUH071 (Corrosive to the respiratory tract).

The current classification of nitric acid by adding classification for acute inhalation toxicity is needed in order to ensure precautions for safe handling, use and disposal, e.g. international trade of nitric acid. Also the classification and labelling is a prerequisite for appropriate risk management on legislative and company level and may trigger substitution in some markets.

In February 2014 industry provided explanations to the aMSCA that two entries on the classification for acute inhalation toxicity of nitric acid are proposed. The classification should distinguish between pure fuming nitric acid (with concentrations > 70 %) and nitric acid below 70 %.

While fuming nitric acid is characterised by the release of NO_x (nitrous fumes) the data submitted by industry suggest that diluted nitric acid up to concentrations of about 70 % has a comparably low vapour pressure and does not release nitrous fumes by itself (only

in contact with metals). As a consequence, inhalation studies with diluted nitric acid are carried out with the aerosol and only minute levels of vapour can be expected to be present in their test atmosphere. The toxicity of the aerosol/vapour atmosphere (at nitric acid concentration < 70 %) needs further examination.

Due to these circumstances the aMSCA has proposed to postpone the inclusion of the entry for acute inhalation toxicity into Annex VI to CLP with the 7th ATP.

As the result of an industry meeting with the aMSCA (April 2014) the registrant agreed to perform a guideline conform study on acute inhalation toxicity to define the toxicity of concentrated nitric acid (ca. 70 % at the azeotropic composition) for an appropriate classification of nitric acid until June 2015.

The aMSCA will await the outcome of this testing before conclusions will be drawn for a classification and labelling of nitric acid solutions below 70 %.

3.1.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

3.1.3 Restriction

The aMSCA has concluded that the effectiveness of the Regulation (EU) No 98/2013 on the marketing and use of explosive precursors should be assessed before a restriction is initiated.

The aMSCA will closely monitor the impact of this restriction on reported cases of poisoning by nitric acid and consider further measures under REACH if appropriate, regardless of the result of the classification harmonisation process.

3.1.4 Other Union-wide regulatory risk management measures

Regulation (EU) No 98/2013 on the marketing and use of explosive precursors

The Regulation (EU) No 98/2013 on the marketing and use of explosive precursors, which will come into force in September 2014, is directed to prevent access to certain substances and mixtures known as explosive precursors to the general public. Nitric acid is identified as a substance that can be misused for the illicit manufacture of explosives. With this regulation the several national laws, regulations and administrative provisions, which are divergent and liable to cause barriers to trade within the EU, were harmonised in order to improve the free movement of chemical substances and mixtures within the internal market and, to the extent possible, to remove distortions of competition, while ensuring a high level of protection of the safety of the general public.

Due to the derogations from the prohibition defined in this regulation a complete restriction on the sale to consumers of any product containing 10 % or more of nitric acid and a conditional restriction on mixtures containing > 3 % and < 10 % is imposed. The conditional restrictions are fairly onerous and require all transactions to be recorded; the recipient must have valid ID with them at the time of purchase; they must physically sign for the product; and state what they are using it for. Additionally shops need to maintain hard copy records of transactions for a period of 5 years from the date of the transaction (according to Article 8).

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

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

Follow-up action	Date for intention	Actor
Submission of a guideline conform acute inhalation toxicity study	June 2015	industry
Evaluation of inhal. tox study, Revised CLH-Proposal	End of 2015	aMSCA
Monitor cases of poisoning by nitric acid	continually	aMSCA