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RÉPUBLIQUE FRANÇAISE

Ministère
de l'Écologie,
du Développement
durable
et de l'Énergie

RISK MANAGEMENT OPTIONS ANALYSIS

CONCLUSION DOCUMENT

for

"DTPA" salts

Na5DTPA

EC No 205-391-3

CAS No 140-01-2

DTPA Acid
EC No 200-652-8
CAS No 67-43-6

Member State(s): France

October 2015

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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.

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].

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 other Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern

1. OVERVIEW OF OTHER REGULATORY PROCESSES / EU LEGISLATION

Two DTPA salts are analysed in a risk management option analysis dossier by France, published on December 2014.

Directive 2010/75/EU of 24 November 2010 on industrial emissions (integratedpollution prevention and control)

The Directive 2010/75/EU of 24 November 2010 on industrial emissions (integratedpollutionprevention and control) strengthens the application of Best Available Techniques (BAT),making BAT conclusions the reference point in the permitting process. In order to determine best available techniques and to limit imbalances in the Union asregards the level of emissions from industrial activities, reference documents for bestavailable techniques (BREF) are drawn up, reviewed and, where necessary, updated throughan exchange of information with stakeholders.

The following BREF referencing DTPA have been identified:

BREF Production of Pulp, Paper and Board, Final Draft July 2013

Emissions from the use of chelating agents in peroxide-based bleaching technologies:The presence of heavy metal ions promotes the decomposition of peroxide resulting in lowerbrightness and higher peroxide consumption. Therefore, sodium silicate (waterglass,Na_2SiO_3) and chelating agents (e.g. EDTA, DTPA) are added both during bleaching and beforebleaching to form complexes with heavy metals (Fe, Mn, Cu, Cr), which prevents the pulpfrom discolouring and the peroxide from decomposing.Once in the environment, EDTA/DTPA have the ability to remobilise heavy metals (lead,mercury, cadmium) from natural water sediments, may accumulate in water bodies or reachthe drinking water supply via waste water input.

BREF for the Textiles Industry, European Commission, July 2003

Considerable amounts of surfactants are used in pretreatment as detergents, wetting agents,etc. Pollutants of concern may be found in water effluent from pretreatment activities, suchas poorly bio-eliminable complexing agents used as hydrogen peroxide stabilisers (e.g. EDTA,DTPA, phosphonates), etc.

PARCOM Recommendation 94/5 concerning Best Available Techniques and Best Environmental Practice for Wet Processes in the Textile Processing Industry

OSPAR Convention for the protection of the marine environment of the North-East AtlanticMeeting of the Hazardous Substances Committee (HSC) - WISMAR: 19 - 23 April 2004. This commission recommends the substitution of such chemicals, giving preference in theselection of auxiliaries and chemicals to products with a high degree of biodegradability, lowhuman and ecological toxicology, low volatility and low smell intensity. The avoidance ofEDTA, DTPA and NTA is cited.

Regulation 2003/2003 EC of 13 October 2003 relating to fertilisers

DTPA is part of the List of authorised organic chelating and complexing agents for micronutrients.The chelating agents are to be identified and quantified by European Standard EN13368 part 1 and part 2.

Fertilisers must display certain technical characteristics laid down by mandatory provisions.These provisions concern more particularly the composition. This regulation states that it is"necessary to authorise tolerances on the declared nutrient contents. In the interest of theagricultural user, it is advisable to keep these tolerances within narrow limits." For instance,for iron chelate the minimum content of nutrients (percentage by weight) is 5 % of watersoluble iron, of which the chelated fraction is at least 80 %.

No limit concentration of chelatants present in the fertilizers has been identified.

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 *[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]*	✓
Harmonised classification and labelling	✓
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	
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

DTPA has a high production volume (10,000 – 100,000 tonnes) and is wide-dispersive(numerous consumer uses). DTPA is potentially used in a wide number of industries includingpulp and paper industries (main use), laundry detergents, cleaners, soaps, and textiles. Thissubstance may be present in final products (< 2% in consumer cleaning products and <0.1% in personal care products). Important uses (according to their tonnage) are regulatedby specific EU legislation that provide a similar level of pressure for substitution asauthorisation (e.g for pulp and paper industry, see section "2.3 Regulatory context").However, many other uses, including consumer products, are not covered.
The members of the *amino carboxylic acid-based chelants category (including Na5DTPA)*possess hazard properties for human health (skin and eye irritation, repeated-dose toxicityand reproductive/developmental toxicity). These effects are associated with the chelation ofmetals and the subsequent toxicological effects related to metal deficiency.Furthermore, the *amino carboxylic acid-based chelants category (including Na5DTPA)*members possess properties indicating a hazard to the environment.
Finally, the RAR performed by Germany have identified a need for limiting the risks toEnvironment for EDTA, another aminocarboxylic acid-based chelantwith similar uses.

3.1.1 Harmonised classification and labelling

For Human Health, based on the ability of the body to compensate for changes in zinc status and the minimal amount of zinc that could be affected by DTPA, it is unlikely that exposure to DTPA in the workplace will affect an individual's zinc status leading to adverse effects. The physicochemical properties of the substance (low vapour pressure, poor dermal absorption) and the results of the chemical safety assessment of Na5DTPA are consistent with this assumption.

Using a conservative approach, the use of consumer products give low RCR values according to the Lead registrant of Na5DTPA. The RCR values for the combined routes (oral, inhalation and skin contact) are low.
However, DTPA serves as chelating agent in a wide variety of consumer products and is considered persistent in the environment. The cumulative exposure (including drinking water, food, etc.) of the general population has not been calculated.
Even though Na5DTPA and DTPA Acid are not expected to cause direct ecotoxicological effects at the levels typically found in natural waters, but rather exert their influence by affecting mineral (metal ion) balance in aqueous or biological systems, their widespread use has raised concern about their ultimate fate in the environment. Their complex formation properties depending on environmental conditions - as pH, water hardness, metal concentrations - may affect the distribution and mobilization of heavy metals. Additionally, due to their persistency or slow transformation in the environment and their implication in eutrophication of natural water systems, chelants are a cause of concern and several research works on their replacement by chelating agents with improved biodegradability are currently under investigation.
Na5DTPA and DTPA Acid are widely used as chelating agents by industrials, professionals and consumers. As presented by the registrant in the CSR, the environmental risk assessment for DTPA Acid lead to acceptable risks for all emissions scenarios. For Na5DTPA, even if acceptable, the levels of environmental risk associated to the production, to the formulation, to the industrial uses of DTPA in pulp bleaching and washing, and to the use as a process chemical and as an intermediate are closed to the acceptability threshold of 1, particularly for the aquatic compartment. Several risk management measures, enhancing the biodegradation rate for example, have been used in the exposure scenarios but without any data or any description of their onsite technologies allowing such a reduction of emissions.
Consequently, and as it was previously applied for EDTA, there is a need for limiting the emissions considering the tonnage of Na5DTPA and DTPA Acid, their wide dispersive uses and their high persistency in the environment.

Finally, toxicological data seems sufficient to support a classification Repr. 1B (H360D - May damage the unborn child) according to CLP Regulation No1272/2008/EC: this would lead to better information of pregnant women and a reduction of the concentration of DTPA in consumer products.

Such harmonized classification (Repr. 1B) has a direct impact in different regulations:

- ✓ On the health protection of workers from the risks related to exposure to CMR categories 1A and 1B, at least in France (the directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work does not consider reprotoxicity, on the contrary of the French worker legislation). Substitution and, if not technically feasible, collective protection measures are preferred to avoid/reduce occupational exposure. The Member States shall also establish arrangements for carrying out relevant health surveillance of workers.

- ✓ On the health protection of consumers: reduction of the concentration of DTPA in consumer products (generic concentration limit of 0.3 % according to CLP Regulation).

- ✓ Other restrictions in specific regulations, such as the Toy Safety Directive (2009/48/EC): CMR substances are no longer allowed in accessible parts of toys. This classification could also lead to identify this substance as a substance of very high concern (SVHC), with a possibility to include it in Annex XIV according to Art. 57(c) of REACH Regulation.

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

The projected regulatory action for DTPA is harmonised classification according to CLP RegulationNo1272/2008/EC as Repr. 1B H360D. Thus, this classification could also lead to identify this substance as a substance of very high concern (SVHC), with a possibility to include it in Annex XIV according to Art. 57(c) of REACH Regulation. The identification of DTPA as SVHC is not envisaged at this stage.

3.1.3 Restriction

A restriction of DTPA and its salts, as permitted by REACH Regulation, could:
- restrict all uses of these substances;
- restrict only specific uses (e.g. leading to the most emissions into Environment).

The proportionality of these options has not been assessed in this RMOA. A restriction of alluses would however lead to high economic consequences due to the number of activitysectors concerned.

3.1.4 Other Union-wide regulatory risk management measures

Do nothing in the framework of REACH

Directive 2008/1/EC concerning integrated pollution prevention and control (IED)

The BREF "Production of Pulp, Paper and Board, Final Draft July 2013" gives informationregarding permitting and monitoring of DTPA in this activity sector: in particular somenational regulations and regional competent authorities ask pulp mills within the area of theirresponsibility to reduce emissions of EDTA or DTPA to the receiving waters (e.g. in Austria orGermany), assessing the availability of substitutes case by case. If recipient rivers or lakesare used to provide drinking water, environmental officials set increasingly strict limits onpermissible EDTA and DTPA concentrations.

The BREF for the "Textiles Industry, European Commission, July 2003" stated thatcomplexing agents can often be avoided. Nevertheless, when they need to be used,compounds are available as an alternative: readily biodegradable or at least bioeliminableand that do not contain N or P in their molecule (e.g. polycarbonates, polyacrylates,gluconates, citrates and some sugar-acrylic acid copolymers). Costs are comparable,although higher quantities may be necessary in some cases.
OSPAR Convention for the protection of the marine environment of the North-East Atlanticrecommends also that the waste water at the sites of occurrence must not contain EDTA,DTPA and phosphonates[12].

Regulation 1980/2000/EC on a revised Community eco-label award scheme

The objective of the Community eco-label award scheme is to promote products which havethe potential to reduce negative environmental impacts.
EDTA and its salts shall not be included in the product, either as part of the formulation or aspart of any mixture included in the formulation, according to criterion 3 of EU Ecolabeldescribed in Commission Decision of 28 June 2011 on establishing the ecological criteria forthe award of the EU Ecolabel to all-purpose cleaners and sanitary

cleaners.**DTPA and its salts could be included in the criteria of the Ecolabel considering a similar hazard profile for the environment.**

Directive 2000/60/EC establishing a framework for Community action in the fieldof water policy Water Framework Directive

With regard to pollution prevention and control, Community water policy should bebased ona combined approach using control of pollution at source through the setting of emission limitvalues and of environmental quality standards.

EQS (Environmental Quality Standard) have been developed for EDTA (INERIS, 2012):
- EQS surface water = 40 ìg/L (maximum value = 78 ìg/L);
- EQS marine water = 7.4 ìg/L (maximum value = 7.8 ìg/L).

In the same line, an EQS for DTPA with specific data on this substance could also beproposed as an EU threshold values to control the aquatic emissions of DTPA.

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

In the meantime, Industry has proposed classification annex XV dossiers for both DTPA substances (CAS 140-01-2, EC 205-391-3 and CAS 67-43-6, EC 200-652-8), dossiers submitted in April and June 2015.

The classification proposed for pentasodium DTPA (CAS 140-01-2) is: Acute tox. 4, H332, STOT RE 2, H373, Repr. 2, H361d (for the development); and for DTPA acid (CAS 67-43-6): Acute tox. 4, H332, Eye irrit.2, H319, Repr.2, H361d (SCL ≥ 3% for the development), and STOT RE 2, H373.

Currently, France is expecting with particular attention the public consultation of both classification dossiers and will follow attentively the instruction of these dossiers by ECHA.

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for intention	Actor
Annex XV dossier for classification	Pentasodium DTPA, EC 205-391-3, CAS 140-01-2, submitted intention date : 16/04/2015, Classification proposed: Acute tox 4, H332 ; STOT RE2, H373 ; Repr 2, H361d DTPA acid, EC 200-652-8, CAS 67-43-6, submitted intention date: 09/06/2015,	Industry

	Classification proposed : Acute tox 4, H332 ; Eye irrit 2, H319 ; Repr 2, H361d ; STOT RE 2, H373 ; with SCL>= 3% for Repr 2, H361d.	
French comments on both CLH dossiers	2015/2016	Anses
Re-assessment of the RMOA according to the RAC opinion on the harmonised classification	2016/2017?	Anses