Risk Management Option Analysis Conclusion Document

Substance Name: tris(4-nonylphenyl, branched and linear) phosphite

EC Number: -

CAS Number: -

Authority: France

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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].

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.

[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

1. IDENTITY OF THE SUBSTANCE

TNPP can exist with linear and/or branched alkyl chains. 4-NP can be present in TNPP as an impurity and the characteristics of the alkyl chains of 4-NP is expected to reflect the characteristics of the alkyl chains of the corresponding TNPP.

4-nonylphenol, branched and linear (4-NP) has been identified as a group of SVHC substances according to Article 57(f) REACH.

Therefore, all forms of TNPP, with branched and/or linear alkyl chains, are included in the present group, if they contain ≥ 0.1% of 4-NP, branched or linear.

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA) other than this RMOA	
REACH Processes	Evaluation	☐ Compliance check, 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 Regulation 793/93/EEC (RAR/RRS)	

(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes/ EU legislation	☐ Other (provide further details below)

TNPP (tris(nonylphenyl) phosphite) (CAS No 26523-78-4) has been assessed under the Existing Substances Regulation (ESR, Council Regulation (EEC) No. 793/93). The risk assessment report prepared by France has been published in 2008. Regarding human health, it has been concluded that there is a concern due to skin sensitisation upon dermal contact during manufacture of the substance, manufacture of products containing TNPP and use of preparations containing TNPP.

A Risk Reduction Strategy with respect to workers has been developed and agreed in April 2008. Classification of TNPP as a sensitizer was finalised in the Commission working group on the Classification and Labelling of Dangerous Substances in November 2005. As a result of its classification as hazardous substance, TNPP is subject to general regulations concerning its supply and handling and to the legislation for workers' protection currently in force at Community level. These regulations are generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply. Therefore, no further risk reduction measures are recommended. No risk was observed for consumers.

The environmental risk assessment was incomplete when the ESR work ceased. The RAR concluded to a need of further testing. The requirements reported in the Regulation EC n° 466/2008/EC (on certain priority "existing" substances) included:

- Information on structure of TNPP;
- Information on water solubility;
- Log Kow determination;
- Hydrolysis test;
- Toxicity test with daphnia magna chronic test provided for the classification.

The tris(nonylphenyl)phosphite (CAS n°26523-78-4) has an harmonised classification and labelling (ATP03) approved by the European Union. The substance is classified as: very toxic to aquatic life, very toxic to aquatic life with long lasting effects and may cause an allergic skin reaction. The harmonised classification and labelling of the substance was discussed by the Risk assessment Committee (RAC). No new environmental fate/hazard data on TNPP have been provided since the RAC opinion published in 2010 (available at: https://echa.europa.eu/documents/10162/73eb5208-662c-48d0-b878-62ee714d1dc0).

Most of the information requested in the Regulation EC n° 466/2008/EC was not provided and the initials concerns e.g. regarding impurities (nonylphenol), PBT/vPvB properties remain unsolved. Thereafter, the substance was included in the Community

rolling plan (CoRAP) for substance evaluation in 2013 for the initial grounds of concern relating to Environment/Suspected PBT; Exposure/wide dispersive use; consumer use; Exposure to sensitive populations; high RCR; aggregated tonnage and with the following identifiers:

Public Name	Tris(nonylphenyl)phosphite
EC number	247-759-6
EC name	Tris(nonylphenyl)phosphite
CAS number (in the EC inventory)	26523-78-4
CAS number	26523-78-4
CAS name	Phenol, nonyl-, 1,1',1''-phosphite
IUPAC name	Phenol, nonyl-, phosphite (3:1)
Index number in Annex VI of the CLP Regulation	015-202-00-4 ; New entry in 3rd ATP to CLP
Molecular formula	C45H69O3P

TNPP was initially registered as a mono-constituant. However, during the substance evaluation process, ECHA has considered that the substance identity needed to be adapted first for appropriately reflecting the identity and composition of the registered substance. Therefore, a decision was addressed to registrants requesting information to clarify the identity and composition of TNPP. After an update of the registration dossier on SID which confirmed that the substance refers to tris(4-nonylphenol, branched)phosphite, ECHA requested the registrants to modify the identifiers in line with the composition of the substance.

The List number 701-028-2 is now associated to the registered substance TNPP (the substance identity was changed in March 2016). Registration dossiers have been updated accordingly and substance evaluation is still on-going with regard to that new identity. In this RMOA, TNPP stands for the following name: tris(4-nonylphenol, branched)phosphite with the List number 701-028-2 and no specific CAS number.

Indeed, since 2014, TNPP is registered as an UVCB substance only (previously it was also registered as a mono-constituent substance). Information on the branching of nonylphenol was provided by the registrant.

3. 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:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	X
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

4. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

FR-MSCA has initiated a SVHC dossier in order to address the 'commercial' grade of registered TNPP (List n°701-028-2). As one of the concerns discussed in this RMOA is related to the presence of 4-NP branched as an impurity, there may be an interest to look at similar substances. According to ECHA, similar phosphites having at least one "nonylphenyl" substituent have been pre-registered. ECHA intends to perform a preliminary search in its database, to identify other relevant substances containing 4-NP (branched or linear) as an impurity or potential defradation product. Indeed, 4-NP linear is also of interest as a substance of very high concern (SVHC).

TNPP can exist with linear and/or branched alkyl chains. 4-NP can be present in TNPP as an impurity and the characteristics of the alkyl chains of 4-NP is expected to reflect the characteristics of the alkyl chains of the corresponding TNPP. 4-nonylphenol, branched and linear (4-NP) has been identified as a group of SVHC substances according to Article 57(f) REACH. Therefore, all forms of TNPP, with branched and/or linear alkyl chains, are included for SVHC identification, if they contain ≥ 0.1% of 4-NP, branched or linear. The identification of TNPP with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP) is a first dossier that might serve other dossiers build on the same concern.

In parallel, substance evaluation is on-going for TNPP (List n°701-028-2) to address the remaining concerns. A the end of the evaluation and depending of the results, a second SVHC dossier may be initiated by FR-MSCA in order to cover all the grades of the substance.

5. 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.

Follow-up action	**Date for follow-up**	**Actor**
Annex XV dossier for SVHC	February 2019	France