Analysis of the most appropriate risk management option (RMOA)

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

EC/List Number: 701-028-2

CAS Number: -

Authority: FR

Date: 12 December 2018

Public version.

Cover Note

FR-MSCA intends to initiate a SVHC dossier for TNPP, as one of the concerns discussed in this RMOA is related to the presence of 4-NP branched as an impurity of very high concern that may be above the threshold of 0.1% in TNPP.

In the meantime, substance evaluation is on-going for TNPP (testing material with the highest purity) to address if TNPP is degradated into 4-NP under environmental conditions and to evaluate its PBT/vPvB properties. A the end of the evaluation and depending of the results, a second SVHC dossier may be initiate by FR-MSCA in order to cover the different grades of the substance.

These parallel processes are justified considering the timelines of the substance evaluation procedure and the widespread uses / high tonnage band of this hazardous substance on the European market.

Comments and additional relevant information are invited on this RMOA by 12 January 2019.

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1 IDENTITY OF THE SUBSTANCE

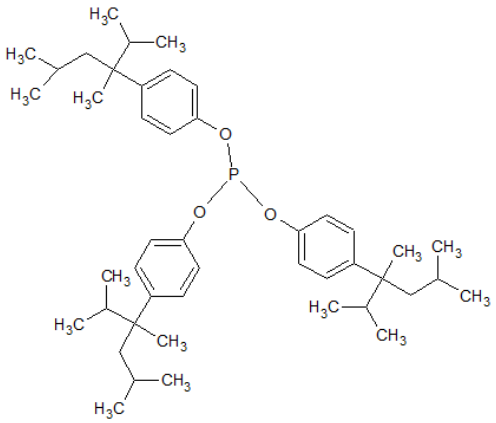
1.1 Other identifiers of the substance

Table 1: Other Substance identifiers

EC/List name (public):	Tris (4-nonylphenol,branched)phosphite
IUPAC name (public):	-
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	C45H69O3P
Molecular weight or molecular weight range:	689.02
Synonyms:	TNPP

Type of substance ☐ Mono-constituent ☐ Multi-constituent ☒ UVCB

Structural formula:



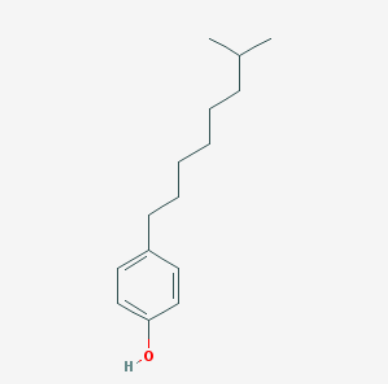
Other relevant information about substance composition

Confidential

Table: Impurity

EC number:	284-325-5
EC name (public):	Phenol, 4-nonyl-, branched
CAS number:	84852-15-3
CAS name (public):	4-nonylphenol, branched
IUPAC name (public):	4-(4,6-dimethylheptan-2-yl)phenol; 4-(5,6-dimethylheptan-2-yl)phenol; 4-(5,6-dimethylheptyl)phenol; 4-(7-methyloctyl)phenol
Index number in Annex VI of the CLP Regulation:	601-053-00-8
Molecular formula:	C15H24O
Molecular weight or molecular weight range:	
Synonyms:	*Nonylphenol* *4-NP*

Structural formula:



1.2 Similar substances/grouping possibilities

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 able to degrade into 4-NP. Indeed, 4-NP linear is also of interest as a substance of very high concern (SVHC).

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 2: 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[1]
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

[1] Please specify the relevant entry.

Other processes/ EU legislation	☐ Other (provide further details below)

TNPP (tris(nonylphenyl) phosphite) 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.

TNPP 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: Phenol, 4-nonyl-, branched (list number 701-028-2)**.

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 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The tris(nonylphenol) phosphite (with the identifiers: EC number 247-759-6, CAS number 26523-78-4, Index No 015-202-00-4) had the following harmonized classification:

- Skin Sens H317

- Aquatic Acute 1 H400

- Aquatic Chronic 1 H410

There was not enough valid data to conclude on M-factor regarding the environmental classification.

However, as a consequence of the change in the substance identity, the old EC number is not used anymore and has been replaced by a List number. It seems therefore that the **harmonized classification is not directly applicable to the new profile**, but would probably need a new an Annex XV CLH dossier to ensure that the data used for building the classification report are still usable for the substance (List) and that classification applies also to the newer profile (still to be confirmed by ECHA CLH team).

3.1.2 Self classification

The notified classification and labelling according to CLP criteria are the following:

- Skin Sens H317

- Aquatic Acute 1 H400

- Aquatic Chronic 1 H410

- Aquatic Chronic 4 H413

- Aquatic Tox. 4 H302

- Skin Corr. 1B H314

- Repr. 2 H361fd

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

No proposal identified but could be considered if the old classification does not apply anymore.

3.1.4 CLP Notification Status

Table 4: CLP Notifications

	CLP Notifications[2]
Number of aggregated notifications	3
Total number of notifiers	40

[2] C&L Inventory database, http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database (accessed 2 July 2018).

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[3]

4.1 Tonnage and registration status

Table 5: Tonnage and registration status

From ECHA dissemination site	
Registrations	☒ Full registration(s) (Art. 10) ☐ Intermediate registration(s) (Art. 17 and/or 18)
Total tonnage band for substance (excluding volume registered under Art 17 or Art 18, or directly exported)	10,000-100,000 tpa

4.2 Overview of uses

TNPP's primary use is as an **antioxidant to stabilise polymers** against degradation by ultraviolet light, in a variety of applications.

Release to the environment of this substance is likely to occur from: indoor use, outdoor use resulting in inclusion into or onto a materials (e.g. binding agent in paints and coatings or adhesives) and indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment).

The chemical safety assessment covers different use scenarios, including professional and consumer exposure. TNPP may be present in a variety of applications with a potential of exposure from articles, polymers, mixtures (e.g. paints, adhesives…).

Moreover, there are several wide dispersive uses e.g.:

- ✓ Use of Formulated Polymer in Manufacturing (ERC 10a/11a);
- ✓ Professional Use of Coatings and Adhesives (ERC 8c/8f);
- ✓ Consumer Use of Food Contact Polymer Articles (ERC 11a);
- ✓ Consumer Use of Coatings and Adhesives (ERC 8c/8f).

[3] *Dissemination site was accessed on 2 July 2018.*

4.3 Additional information

The substance '4-nonylphenol branched' is on the Candidate List (Decision ED/169/2012 of 18 December 2012) due to its endocrine disrupting properties for the Environment. It is considered also as a "priority hazardous substance" under under the Water Framework Directive 2000/60/EC (WFD) for which, at the community level, nonylphenol discharge/emission/loss **must cease or be phased out by 2026**. Moreover, since 2009, nonylphenol has been subject to marketing and use restrictions under Regulation (EC) No 1907/2006.

Naiades is the French national interface for accessing data from rivers and lakes. It allows users to access data collected by water agencies and laboratories on physical parameters, chemical concentrations, species inventories and hydromorphology in one single point in standardized formats. It offers access to raw or aggregated data (indicators, indices). With the code corresponding to 4,NP branched, data provided report samples with a maximum concentration of 0.9 µg/L of 4,NP in water (based on around 9,600 measures in the past 2 years, with a mediane concentration of 0.03 µg/L),and very high concentrations up to 9110 µg/kg in sediments (based on around 400 measures in the past 2 years, with a mediane concentration of 40 µg/kg).

Those data show that environmental exposure to 4, NP still occur (in 2016-2017).

Regarding REACH activities on the nonylphenol group:

- 4,NP (branched and linear) has been put on the candidate list the 19th December of 2012 and then has been added to the annex XIV (entry 43). Its use and presence in the environment should therefore decrease unless other substances that contain it are still releasing it.
- Nonylphenol, branched, ethoxylated (NPEO) was selected for substance evaluation by UK. Substance evaluation conclusion has been published in February 2018 on ECHA website. UK noted that NPEO is already listed on the Candidate List and Annex XIV because it can transform to relevant amounts of an endocrine disrputing substance in the environment.

5 JUSTIFICATION FOR THE RISK MANAGEMENT OPTION

5.1 Need for (further) risk management

TNPP presents several wide dispersive uses, its primary use is as an antioxidant to stabilise polymers, but it is also used in adhesives, coatings and other articles.

Uncertainties remains unsolved about the release of 4-Nonylphenol by the degradation of TNPP. The ongoing substance evaluation aims to clarify this concern.

The grade of TNPP (i.e. pure or commercial) associated with the different exposure scenarios is not described in the chemical safety assessment. As a consequence, considering the widespread uses and the presence of a SVHC superior to 0.1% in the 'commercial' grade of the substance, eMSCA considers necessary to initiate a SVHC dossier before the end of substance evaluation for the commercial grade.

Indeed, the status of impurities of very high concern have been discussed many times with the RiME experts. A proposal of the Best Risk Management Option for these impurities has been presented in CARACAL-20 (Doc. CACS/20/2016) following a discussion in RiME-2/2016.

This proposal lists (de-)prioritisation criteria that aim at defining which substances with impurity of very high concern should be considered as priority and proportionnate for possible further regulatory risk management measures.

(de-)prioritisation criterion A: Proportion of registration dossiers of the parent substance containing the impurity of concern. In past screening exercises, a minimum proportion of 30% of registration dossiers for a given parent substance was required (among other criteria) for the parent substance with the impurity of concern to be short-listed; this proportion could be raised, or lowered.

For TNPP, the repartition of the 2 grades is not known. Therefore it is not possible to assess this criteria. A value of 50% could be set by default.

(de-)prioritisation criterion B: Share of the tonnage of the parent substance containing the impurity of concern in the total registered tonnage of the parent substance. This criterion has not been used so far; a minimum proportion of 20% could initially be set, and then adapted based on experience.

For TNPP, the tonnage band is given for the whole substance. Once again, it is not possible to assess this criteria without information on the repartition of the 2 indicated grades.

(de-)prioritisation criterion C: Total volume/tonnage of the impurity of concern registered in the parent substance. This criterion has not been used so far; a value of 1 tpa in the parent substance could be set.

Considering the high tonnage band of TNPP (10,000-100,000 tpa) and the concentration of impurity of concern, the criteria is considered as fulfilled.

(de-)prioritisation criterion D: Wide-dispersiveness of the uses of the parent substance containing the impurity of concern only.

As indicated in paragraph 4.2, TNPP has several wide dispersive uses.

(de-)prioritisation criterion E: Difference between the concentration of the impurity of concern in the parent substance and the specific/generic concentration limit (S/GCL) for classification (when relevant).

This criterion is not appropriate in TNPP case as the impurity of concern relates to ED properties (not covered by the CLP).

(de-)prioritisation criterion F: Number of different uses of the parent substance containing the impurity of concern. If exposure can be expected from multiple sources, it will in general be more difficult to control this exposure and a higher priority could be given to prioritising these.

TNPP is used in very different mixtures and articles: paints, coatings or adhesives, long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment…).

Overall, in a conservative approach, eMSCA considers that TNPP fulfills the 6 criteria in a prioritizing way and should be considered as priority for possible further regulatory risk management measures. Considering the ED properties of the impurity of concern, the SVHC route is considered as the most appropriate.

Table 6: SVHC Roadmap 2020 criteria

	Yes	No
a) Art 57 criteria fulfilled?	(x)	
b) Registrations in accordance with Article 10?	x	
c) Registrations include uses within scope of authorisation?	x	
d) Known uses not already regulated by specific EU legislation that provides a pressure for substitution?	x	

To date, article 57 criteria is fulfilled only for a certain grade of TNPP.

The ongoing evaluation aims to clarify in a first step if the degradation of TNPP could result in the release of 4-Nonylphenol under environmental conditions.

5.2 Identification and assessment of risk management options

TNPP can be considered as a source of 4-nonylphenol in the environnement, due to the presence of this substance as impurity. Due to its environmental endocrine disruptor properties, 4 nonylphenol is on the REACH Candidate List and is already subject to specific restrictions on its marketing and use under REACH (Annex XVII). The substance is also on the Annex X that lists priority substances (Decision 2455/2001/EC) under the Water Framework Directive 2000/60/EC (WFD). The presence of 4-nonylphenol in the monitoring data from France and other EU Member States indicates that the substance continues to be widely emitted from industrial and domestic sources and arrives subsequently to the rivers. Some water bodies in France are non-compliant with the Environmental Quality Standard (EQS) regarding to 4 nonylphenol.

In addition, the WFD requires the cessation or phasing-out of discharges, emissions and losses of priority hazardous substances by 2026. This means that there is political agreement that 4-NP is a high priority for ongoing aquatic emission reduction at EU level. However, aside from setting an EQS, the WFD legislation itself does not prescribe the means to achieve cessation of emissions. Member States are responsible for putting measures in place to achieve cessation of emissions. Member States may therefore fail to meet the WFD objectives if further risk management measures are not put in place.

It’s worth noting that the TNPP case has been discussed in two ECHA bodies: PBT Expert group and the RiME+.

For the overall PBT assessment, FR got advice from the PBT EG.

As a consequence of that discussion, and considering the timelines of the substance evaluation procedure and the long history of eMSCA with that substance, **the following strategy is currently carried on**:

- Require data in the frame of the substance evaluation to clarify remaining concerns.
- In parallel, identify the grade, where 4-nonylphenol branched may be above the threshold of 0.1% of the composition of TNPP, as SVHC with an Annex XV dossier. This dossier will therefore be prepared for February 2019 with the following entry: Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% w/w of 4-nonylphenol, branched and linear (4-NP).

That proposal of initiating an RMOA process, at the same time as substance evaluation process, was welcomed by the RiME+ following a presentation of the case in RiME+2/2018 (Sofia, 14-45 May 2018).

5.3 Conclusions on the most appropriate (combination of) risk management options

FR-MSCA has initiated a SVHC dossier in order to address the 'commercial' grade, for the reasons developed in section 5.1. 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). Therefore, 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 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.

5.4 References

Annex XV transitionnal report for TNPP. Prepared by France, 20.11.2008.

Chemical safety report, TNPP - New EC Number. Dated 07.09.2017.

European Union Risk Assessment Report for TNPP (Environment - Version August 2007, Human Health - Version February 2006).

Strategy For Limiting Risks (Workers) of TNPP. Prepared by France. Draft of 13th February 2008