

**Substance Name: Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with  $\geq 0.1\%$  w/w of 4-nonylphenol, branched and linear (4-NP)**

**EC Number: -**

**CAS Number: -**

**MEMBER STATE COMMITTEE**

**SUPPORT DOCUMENT  
FOR IDENTIFICATION OF**

***TRIS(4-NONYLPHENYL, BRANCHED AND LINEAR)  
PHOSPHITE (TNPP) WITH  $\geq 0.1\%$  W/W OF 4-  
NONYLPHENOL, BRANCHED AND LINEAR (4-NP)<sup>1</sup>***

**AS A SUBSTANCE OF VERY HIGH CONCERN  
BECAUSE OF ITS ENDOCRINE DISRUPTING  
PROPERTIES CAUSING PROBABLE SERIOUS  
EFFECTS TO THE ENVIRONMENT WHICH GIVE RISE  
TO AN EQUIVALENT LEVEL OF CONCERN TO THOSE  
OF CMR<sup>2</sup> AND PBT/vPvB<sup>3</sup> SUBSTANCES  
(ARTICLE 57F)**

**Adopted on 10 June 2019**

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<sup>1</sup> The full name of the entry 4-nonylphenol, branched and linear as it is included in the Candidate List is: 4-nonylphenol, branched and linear - substances with a linear and branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof

<sup>2</sup> CMR means carcinogenic, mutagenic or toxic for reproduction

<sup>3</sup> PBT means persistent, bioaccumulative and toxic; vPvB means very persistent and very bioaccumulative

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## ABBREVIATIONS

4-NP	4-nonylphenol, branched and linear
APERC	Alkylphenols and Ethoxylates Research Council
CLI	Classification and Labelling Inventory
CLP	Classification, Labelling and Packaging regulation (EC) No 1272/2008
CMR	Carcinogenic, Mutagenic, toxic for Reproduction
ERC	Environmental Release category
EUSES	European Union System for Evaluation of Substances
GHS	Globally Harmonised System
HDPE	High density polyethylene
HPLC	High performance liquid chromatography
IC	Industry categories
IPCS	Institute of Peace & Conflict Studies
LLDPE	Polyolefins linear low density polyethylene
LOEC	Lowest observed effect concentration
MC	Main categories
N.e.c.	Not elsewhere classified
OECD	Organisation for Economic Co-operation and Development
PBT/vPvB	Persistent, Bioaccumulative, Toxic / very Persistent, very Bioaccumulative
PVC	Polyvinyl chloride
QSAR	Quantitative Structure Activity Relationship
SID	Substance identification
SPIN	Substances in Preparations in Nordic Countries Database
SVHC	Substance of Very High Concern
TGA	Thermal gravimetric analysis
TGD	Technical Guidance Document (EC, 2003)
TNPP	Tris(4-nonylphenyl, branched and linear) phosphite
UC	Use categories
UVCB	Substances of Unknown or Variable composition, Complex reaction products or Biological materials
WHO	World Health Organisation

## IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57

**Substance Name:** Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with  $\geq$  0.1% w/w of 4-nonylphenol, branched and linear (4-NP)

**EC Number:** -

**CAS number:** -

- The substances are identified, according to Article 57(f) of REACH Regulation, as substances of equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of Regulation (EC) No 1907/2006 (REACH).

### Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Any tris(4-nonylphenyl, branched and linear) phosphite containing  $\geq$  0.1% w/w of 4-nonylphenol, branched and linear are identified as substances of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH). This is because 4-nonylphenol, branched and linear, has been identified as a group of substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 REACH<sup>4</sup>.

The Member State Committee at its 27<sup>th</sup> meeting unanimously agreed that 4-nonylphenol, branched and linear (*substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof*) meet the criteria set out in Article 57(f) of REACH. The reasoning is laid down in the "Member State Committee support document<sup>5</sup> for the identification of 4-nonylphenol, branched and linear (4-NP) as substances of very high concern because of its endocrine disrupting properties which cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR and PBT/vPvB substances", adopted on 13 December 2012. ECHA has included 4-nonylphenol branched and linear in the Candidate List for eventual inclusion in Annex XIV<sup>6</sup>.

Therefore, tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with  $\geq$  0.1%<sup>7</sup> w/w of 4-nonylphenol, branched and linear (4-NP), are likewise identified as substances of very high concern due to their endocrine disrupting properties in the environment.

### Registration dossiers submitted for substances belonging to this group entry:

Yes, for the substance tris(4-nonylphenyl, branched) phosphite

<sup>4</sup> Agreement of the Member State Committee on the identification of 4-nonylphenol branched and linear as a substance of very high concern: <https://echa.europa.eu/documents/10162/baa009d8-5d13-4fcc-bf6a-c68de5aade10>

<sup>5</sup> Member State Committee - Support document for identification of 4-nonylphenol, branched and linear as substances of very high concern because due to their endocrine disrupting properties they cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMRs and PBTs/vPvBs. Adopted on 13 December 2012

<https://echa.europa.eu/documents/10162/3024c102-20c9-4973-8f4e-7fc1dd361e7d>

<sup>6</sup> Decision of the European Chemicals Agency on the Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV. ED/169/2012. <https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153>

<sup>7</sup> Ref. to REACH, Article 56(6)a

## Justification

### 1. Identity of the substance and physical and chemical properties

#### 1.1 Name and other identifiers of the substance

Table 1: Substance identity

<b>EC number:</b>	-
<b>EC name:</b>	-
<b>CAS number (in the EC inventory):</b>	-
<b>CAS number: Deleted CAS numbers:</b>	-
<b>CAS name:</b>	-
<b>IUPAC name:</b>	Tris(4-nonylphenyl, branched and linear) phosphite [with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear]
<b>Index number in Annex VI of the CLP Regulation</b>	-
<b>Molecular formula:</b>	C <sub>45</sub> H <sub>69</sub> O <sub>3</sub> P
<b>Molecular weight range:</b>	689.02
<b>Synonyms:</b>	Phenol, 4-nonyl-, phosphite (3:1) TNPP ADK STAB 1178 DOVERPHOS 4 DOVERPHOS HIPURE 4 Mark CH 55 Mark TNPP Naugard P Naugard PHR Naugard TNPP Naugard TNPP HR Rostabil TNF Rostabil TNF HR tris(nonylphenyl) phosphite Weston 398 Weston 399 Weston TNPP

### Introduction of the group

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.

However, TNPP can also be produced without 4-NP  $\geq$  0.1%.

4-nonylphenol, branched and linear (4-NP) has been identified as a group of SVHC substances according to Article 57(f) REACH<sup>8</sup>.

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

TNPP with the following chemical identifiers: tris(nonylphenyl) phosphite (EC 247-759-6; CAS 26523-78-4) was initially registered as a mono-constituent substance. However, during the substance evaluation process, the identity and composition of TNPP was further clarified. An update of the registration dossier on SID confirmed that the registered substance refers to TNPP with non-linear alkyl chains. ECHA requested the registrants to modify the identifiers of the registered substance to adequately reflect its composition. The registered substance is now defined as a UVCB substance and identified as tris(4-nonylphenol, branched) phosphite, no specific CAS number is given.

It should be noted that a starting material used for manufacturing this substance has been previously identified with the name "nonylphenol". The commercially manufactured "nonylphenols" predominantly consist of C9 alkyl substituents in position 4 (para-) of the phenol ring. Therefore a substance named as "nonylphenol" actually corresponds to the isomer having substituents in para position.

The same reasoning is valid for the use of the name "tris(nonylphenyl) phosphite": given the method of manufacture, a substance named as "tris(nonylphenyl) phosphite" actually corresponds to the isomer having substituents in para position.

Notifications of classification have also been received in the CLI for the identifiers tris(nonylphenyl) phosphite (EC 247-759-6; CAS 26523-78-4), before and after the identity and composition of TNPP were further clarified during the substance evaluation process.

A non-exhaustive list of other TNPP identifiers used includes:

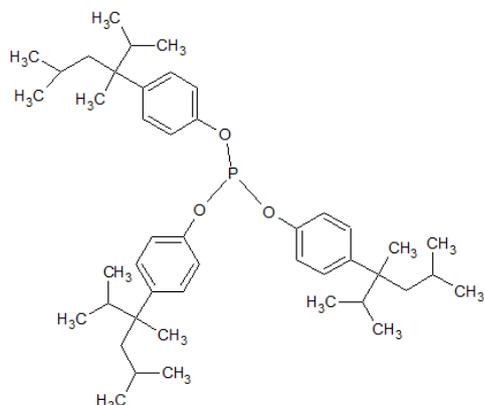
- Phenol, 4-nonyl, phosphite (3:1) with CAS 3050-88-2 and describing a substance with linear alkyl chains. It was used for the pre-registration process;
- Phenol, p-isononyl-, phosphite (3:1) with CAS 31631-13-7 and describing a substance with linear alkyl chains;
- Phenol, p-sec-nonyl-, phosphite with CAS 106599-06-8 and describing a substance with secondary alkyl chains.

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<sup>8</sup> <https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db370>

**Structural formula:**

The structure below display one of the isomers of the registered substance.

**1.2 Composition of the substance**

**Name:** Tris(4-nonylphenyl, branched and linear) phosphite [with  $\geq 0.1\%$  w/w of 4-nonylphenol, branched and linear]

**Description:** group entry

**Substance type:** UVCB<sup>9</sup>

4-nonylphenol, branched and linear (4-NP) are the relevant constituents for this dossier.

A non-exhaustive list of relevant numerical identifiers for the Candidate List entry "4-Nonylphenol, branched and linear" is available on the ECHA's website <https://echa.europa.eu/documents/10162/19c11ec2-7e7e-4a82-935e-36c1fa13ce8d> as a support document to the corresponding entry in the candidate list.

**1.3 Identity and composition of degradation products/metabolites relevant for the SVHC assessment**

Not applicable.

**1.4 Identity and composition of structurally related substances (used in a grouping or read-across approach)**

Not applicable.

**1.5 Physicochemical properties**

For the registered substance tris(4-nonylphenol, branched) phosphite, which is covered by the group entry, physicochemical properties are given in Table 2 below.

<sup>9</sup> Substances of Unknown or Variable composition, Complex reaction products or Biological materials

Table 2: Overview of physicochemical properties

Property	Description of key information	Value	Reference/source of information*
<b>Physical state at 20°C/101.3 kPa</b>	The substances is a clear liquid.	liquid	Dissemination site
<b>Melting/freezing point</b>	The test was conducted according to ASTM Method D97, as recommended in the OECD 102 guideline.	6°C at 101.3 kPa	Dissemination site
<b>Boiling point</b>	Test performed according to OECD Guideline 103. Substance starts to decompose before boiling. Thermal Gravimetric Analysis (TGA) was used to determine onset of degradation.	303°C at 101.3 kPa	Dissemination site
<b>Vapour pressure</b>	Extrapolated from results obtained by isoteniscope (method ASTM D2879) at temperatures ranging from 125 to 350 °C. Extrapolation was recalculated from data in dissemination site because it was not linear. A more reliable linear relation is obtained with $\ln(P_{vap})=f(\ln T)$ .	$8.5 \cdot 10^{-4}$ Pa at 25 °C	Recalculated from dissemination site
<b>Density</b>	Test equivalent or similar to OECD Guideline 109 (Density of Liquids and Solids)	e.g. 0.98 g/cm <sup>3</sup> at 20 °C	Dissemination site
<b>Water solubility</b>	The flask method based on OECD Guideline 105 was used. TNPP was not detected in the saturated aqueous test solution. Therefore, it is concluded that the water solubility of TNPP is below the detection limit of the substance, estimated to be 0.6 mg/l at 24 °C in this test.	<0.6 mg/l at 24 °C	Re-evaluated from dissemination site
<b>Partition coefficient n-octanol/water (log value)</b>	<p>All of the available information on TNPP, indicated that it will have a very high octanol-water partition coefficient, with log Kow estimates ranging from 6 to &gt;20. This range takes into account both the highest result obtained using QSAR models and the fact that this substance was expected to have a high log Kow based on its structure.</p> <p>Considering the high hydrophobic potential of TNPP which contains 27 aliphatic and 18 aromatic carbons, this would be expected for this compound. The draft EU Risk Assessment Report (EU RAR October 2007) considered this endpoint in detail in a sensitivity analysis that was provided in Annex 1 of that assesment. The assesment concluded that a log Kow of 14 is appropriate for TNPP.</p> <p>A study concluded that it was not appropriate to conduct the partition coefficient measurement because the solubility of TNPP in water was too low and the reaction of TNPP with octanol does not allow the measurement of adequate TNPP concentrations in octanol. Another study determined that a more appropriate approach at estimating the Kow was an HPLC method based on OECD guidelines 117. The analysis of TNPP was conducted with gradient HPLC. Butyl benzene, diethylhexyl phthalate, diisononylphthalate and diisodecylphthalate were used as standards with known Kow's to develop a calibration curve. Based on this approach, TNPP was estimated with a log Kow of 14 or greater. A standard could not be found that had a Kow of 14 to test the calibration.</p>	Log Kow : 14	Dissemination site

\* <https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/14891>. Dissemination site was accessed on 12.11.2018

## 2. Harmonised classification and labelling

The registered substance tris(nonylphenyl) phosphite (EC no.247-759-6), is covered by Index number 015-202-00-4 in part 3 of Annex VI to the CLP Regulation as follows:

**Table 3: Classification according to Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008**

Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
015-202-00-4	tris(nonylphenyl) phosphite	247-759-6	26523-78-4	Skin Sens. 1	H317	GHS09 GHS07, Warning	H317			
				Aquatic Acute 1	H400					
				Aquatic Chronic 1	H410		H410			

## 3. Environmental fate properties

The identification of TNPP with  $\geq 0.1\%$  w/w 4-nonylphenol, branched and linear as substances of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) is based on the identification of 4-nonylphenol, branched and linear as a group of substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 REACH.

The group of 4-NP is already included in the candidate list. A detailed assessment of their environmental fate properties is available in the "Member state committee support document for identification of 4-nonylphenol, branched and linear as a substance of very high concern because of its endocrine disrupting properties which cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR and PBT/vPvB substances", adopted on 13 December 2012<sup>10</sup>.

## 4. Human health hazard assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (f) of REACH Regulation.

## 5. Environmental hazard assessment

A detailed assessment of the environmental hazard of the group of 4-NP is available in the "Member state committee support document for identification of 4-nonylphenol, branched and linear as a substance of very high concern because of its endocrine disrupting properties which cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR and PBT/vPvB substances", adopted on 13 December 2012<sup>11</sup>.

<sup>10</sup> <https://echa.europa.eu/documents/10162/3024c102-20c9-4973-8f4e-7fc1dd361e7d>

<sup>11</sup> <https://echa.europa.eu/documents/10162/3024c102-20c9-4973-8f4e-7fc1dd361e7d>

## 6. Conclusions on the SVHC Properties

### 6.1 CMR assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (f) of REACH Regulation.

### 6.2 PBT and vPvB assessment

Not relevant for the identification of the substance as SVHC in accordance with Article 57 (f) of REACH Regulation.

### 6.3 Assessment under Article 57(f)

Tris(4-nonylphenyl, branched and linear) phosphite with  $\geq$ 0.1% w/w 4-nonylphenol, branched and linear are identified as substances of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH) where they contain any constituent or group of constituents (including impurities) of the group "4-nonylphenol, branched and linear"  $\geq$ 0.1% in total owing to its endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of REACH Regulation.

#### 6.3.1 Conclusion on the hazard properties and equivalent level of concern assessment

Any tris(4-nonylphenyl, branched and linear) phosphite containing  $\geq$  0.1% w/w of 4-nonylphenol, branched and linear are identified as substances of very high concern in accordance with Article 57(f) of Regulation (EC) 1907/2006 (REACH). This is because 4-nonylphenol, branched and linear, has been identified as a group of substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 REACH<sup>12</sup>.

The Member State Committee at its 27<sup>th</sup> meeting unanimously agreed that 4-Nonylphenol, branched and linear (*substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof*) meet the criteria set out in Article 57(f) of REACH. The reasoning is laid down in the "Member State Committee support document<sup>13</sup> for identification of 4-nonylphenol, branched and linear (4-NP) as substances of very high concern because of its endocrine disrupting properties which cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR and PBT/vPvB substances", adopted on 13 December 2012. ECHA has included 4-nonylphenol branched and linear in the Candidate List for eventual inclusion in Annex XIV<sup>14</sup>.

<sup>12</sup> Agreement of the Member State Committee on the identification of 4-nonylphenol branched and linear as a substance of very high concern: <https://echa.europa.eu/documents/10162/baa009d8-5d13-4fcc-bf6a-c68de5aade10>

<sup>13</sup> Member State Committee - Support document for identification of 4-nonylphenol, branched and linear as substances of very high concern because due to their endocrine disrupting properties they cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMRs and PBTs/vPvBs. Adopted on 13 December 2012  
<https://echa.europa.eu/documents/10162/3024c102-20c9-4973-8f4e-7fc1dd361e7d>

<sup>14</sup> Decision of the European Chemicals Agency on the Inclusion of substances of very high concern in the Candidate

Therefore, tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with  $\geq 0.1\%$ <sup>15</sup> w/w of 4-nonylphenol, branched and linear (4-NP), are likewise identified as substances of very high concern due to their endocrine disrupting properties in the environment.

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List for eventual inclusion in Annex XIV. ED/169/2012. <https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153>

<sup>15</sup> Ref. to REACH, Article 56(6)a

## References

- ECHA (2012a). Agreement of the Member State on the identification of 4-nonylphenol branched and linear as a substance of very high concern: <https://echa.europa.eu/documents/10162/baa009d8-5d13-4fcc-bf6a-c68de5aade10>
- ECHA (2012b). Member State Committee - Support document for identification of 4-nonylphenol, branched and linear as substances of very high concern because due to their endocrine disrupting properties they cause probable serious effects to the environment which give rise to an equivalent level of concern to those of CMRs and PBTs/vPvBs. Adopted on 13 December 2012 <https://echa.europa.eu/documents/10162/3024c102-20c9-4973-8f4e-7fc1dd361e7d>
- ECHA (2012c). Decision of the European Chemicals Agency on the Inclusion of substances of very high concern in the Candidate List for eventual inclusion in Annex XIV. ED/169/2012. <https://echa.europa.eu/documents/10162/dea74d46-dc8e-4b10-947b-51a19d890153>
- EU RAR (2007). European Union Risk Assessment Report. Tris(nonylphenyl) phosphite. CAS no: 26523-78-4. EINECS no: 247-759-6. Risk assessment. Environment version: August 2007 - Human Health version: February 2006. <https://echa.europa.eu/documents/10162/522e8584-1797-4a11-960b-3c813b37495f>