

Annex XV report

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

Substance Name(s): Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with \geq 0.1% w/w of 4-nonylphenol, branched and linear (4-NP)¹

EC Number(s): -

CAS Number(s): -

Submitted by: France

Date: March 2019

¹ 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

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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

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

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

EC Number(s): -

CAS number(s): -

- It is proposed to identify the substances 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) according to Article 57(f) of REACH Regulation.

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 proposed to be 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 REACH².

The Member State Committee at its 27th 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 document³ 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 XIV⁴.

Therefore, tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with \geq 0.1%⁵ w/w of 4-nonylphenol, branched and linear (4-NP), are likewise proposed to be 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

² 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>

³ 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>

⁴ 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>

⁵ Ref. to REACH, Article 56(6)a

PART I

Justification

1. Identity of the substance and physical and chemical properties

1.1 Name and other identifiers of the substance

Table 1: Substance identity

EC number:	-
EC name:	-
CAS number (in the EC inventory):	-
CAS number: Deleted CAS numbers:	-
CAS name:	-
IUPAC name:	Tris(4-nonylphenyl, branched and linear) phosphite [with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear]
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	$C_{45}H_{69}O_3P$
Molecular weight range:	689.02
Synonyms:	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.

4-nonylphenol, branched and linear (4-NP) has been identified as a group of SVHC substances according to Article 57(f) REACH⁶.

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.

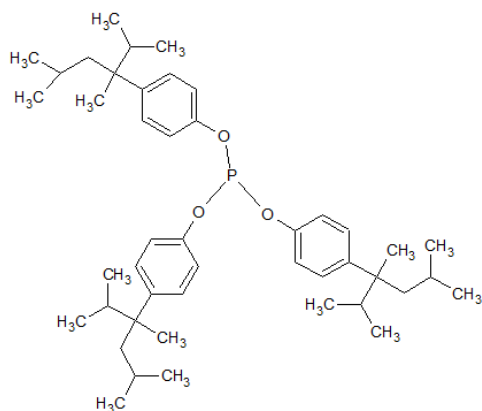
A non-exhaustive list of other TNPP identifiers used includes:

- 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.

⁶ <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: UVCB⁷

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.

⁷ 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*
Physical state at 20°C/101.3 kPa	The substances is a clear liquid.	liquid	Dissemination site
Melting/freezing point	The test was conducted according to ASTM Method D97, as recommended in the OECD 102 guideline.	6°C at 101.3 kPa	Dissemination site
Boiling point	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
Vapour pressure	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
Density	Test equivalent or similar to OECD Guideline 109 (Density of Liquids and Solids)	e.g. 0.98 g/cm ³ at 20 °C	Dissemination site
Water solubility	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
Partition coefficient n-octanol/water (log value)	<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 >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 proposed 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 2012⁸.

4. Human health hazard assessment

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

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 2012⁹.

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

⁹ <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) REACH.

6.2 PBT and vPvB assessment

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

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.

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 proposed to be 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 REACH¹⁰.

The Member State Committee at its 27th 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"¹¹ 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 XIV¹².

¹⁰ 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>

¹¹ 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>

¹² 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>

Therefore, tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq 0.1\%$ ¹³ w/w of 4-nonylphenol, branched and linear (4-NP), are likewise proposed to be identified as substances of very high concern due to their endocrine disrupting properties in the environment.

¹³ Ref. to REACH, Article 56(6)a

Part II

7. Registration and C&L notification status

7.1 Registration status

One of the substances belonging to the group is registered: tris(4-nonylphenyl, branched) phosphite.

Table 4 Registration status of tris(4-nonylphenyl, branched) phosphite

From the ECHA dissemination site ¹⁴	
Registrations	<input checked="" type="checkbox"/> Full registration(s) (Art. 10) <input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)

7.2 CLP notification status

CLP notifications are available for two substances of the group as presented in the table below.

Table 5: CLP notifications

	CLP Notifications ¹⁵	
	Tris(4-nonylphenyl, branched) phosphite	Tris(nonylphenyl) phosphite (EC 247-759-6)
Number of aggregated notifications	3	31
Total number of notifiers	40	1052

8. Total tonnage of the substance

Tonnage is available for the registered substance tris(4-nonylphenyl, branched) phosphite as presented in the table below.

¹⁴ <https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.242.308> (accessed on 26 November 2018)

¹⁵ C&L Inventory database, <http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database> (accessed on 26 November 2018)

Table 6: Tonnage status of tris(4-nonylphenyl, branched) phosphite

Total tonnage band for the registered substance (excluding the volume registered under Art 17 or Art 18) ¹⁶	10,000-100,000 t/pa
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Tonnages of TNPP (as defined by EC no 247-759-6) by uses were also described in the Annex XV transitional report of 2008 and are quoted in section 9 below although this information has not been updated.

9. Information on uses of the substance

The information provided below relates to the registered substance tris(4-nonylphenyl, branched) phosphite.

TNPP is primarily used as an antioxidant to stabilise polymers against degradation by ultraviolet light, in a variety of applications (France, 2008).

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) (ECHA's dissemination site¹⁷).

The chemical safety assessment covers different use scenarios, leading to 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)¹⁸.

¹⁶ <https://echa.europa.eu/fr/substance-information/-/substanceinfo/100.242.308> (accessed on 26 November 2018)

¹⁷ <https://echa.europa.eu/substance-information/-/substanceinfo/100.242.308> (accessed on 18 February 2019)

¹⁸ <https://echa.europa.eu/fr/registration-dossier/-/registered-dossier/14891/3/1/4> (accessed on February 2019)

Table 7: Uses

	Use(s)	Registered use	Use likely to be in the scope of Authorisation
Uses as intermediate		-	-
Formulation or repacking	<ul style="list-style-type: none"> - Stabiliser in polymer - Formulation, packing and distribution - Use of formulated polymer in manufacturing - Manufacture of coating and adhesives 	Yes	Yes
Uses at industrial sites	<ul style="list-style-type: none"> - Stabiliser in polymer - Use of formulated polymer in manufacturing 	Yes	Yes
Uses by professional workers	<ul style="list-style-type: none"> - Professional use of coatings and adhesives 	Yes	Yes
Consumer uses	<ul style="list-style-type: none"> - Consumer use of coatings and adhesives 	Yes	Yes
	<ul style="list-style-type: none"> - Consumer use of food contact polymer articles 	Yes	No
Article service life	<ul style="list-style-type: none"> - Stabiliser in polymer - Consumer use of food contact polymer articles - Use of formulated polymer in manufacturing 	Yes	No

Uses of TNPP (as defined by EC no. 247-759-6) were also described in the Annex XV transitional report of 2008 as follows:

"B.2.1 Manufacture and import of a substance (from the Transitional Report)

TNPP is produced all over the world: Unites States, Europe, India, Korea, Russia, China, etc. (Chemical Information Services, 2002). Three facilities are currently producing TNPP in Europe. On the other hand, the major source of TNPP to Europe is from the United States.

Production capacity (from the Transitional report)

European and North American TNPP producers are organised under the Alkylphenols and Ethoxylates Research Council (APEREC), a not-for-profit trade association, whose members have commercial interest in nonylphenol, octylphenol, and derivatives produced from these compounds. Information on production and imports of TNPP in

Europe were provided by APERC TNPP Consortium. Hardly any individual volume was provided for each producer/importer.

Three facilities are currently producing TNPP in Europe. A fourth facility ceased TNPP production in 2001. Between 1990 and 1997, the production + import volumes were around 5,000 – 10,000 t/year.

Information is available on the combined estimate of TNPP produced within Europe and imported into Europe over the last three years:

- 1999 – approximately 5,565 tonnes
- 2000 – approximately 5,700 tonnes
- 2001 – approximately 6,800 tonnes

As this information is provided by the APERC TNPP Consortium, it cannot be excluded that these volumes do not take into account shipments of product from producers in other parts of the world than Europe and North America. However, according to the APERC TNPP Consortium, the quantity of TNPP from non-TNPP Consortium companies are not expected to be significant.

European production plants have also reported their production volumes for the year 2001. Imported volume for the same year is also available. [...]

B.2.2 Uses (from the Transitional report)

TNPP is used as a stabiliser in the processing of various plastic and rubber products. They are used with hindered phenolic antioxidants in plastic food packaging. In the stabilisation process, TNPP is gradually oxidised and nonylphenol is released (Building Research Establishment Ltd., 2001).

TNPP is also used as a secondary antioxidant in polymer formulations (Ullmann, 1985).

About 25 to 35 facilities are processing TNPP in Europe. Their consumption ranges from a few tonnes to over 400 tonnes/year.

An estimate of the breakdown of TNPP uses was developed based on an informal survey of North American and European manufacturers. Quantitative breakdown of TNPP uses are given in Table B.0.2.1. The information pertains to sales of TNPP in 1999. [...] Corresponding volumes are calculated using the total tonnage of 8,000 t.

Table B.0.2.1: Typical quantitative breakdown of TNPP Uses

	Percentage of tonnage	Volume (tonnes)	Industrial Category / Use Category
Polyvinylchloride (PVC) film	35%	2,800	IC 11 / UC 49
Polyolefins linear low density polyethylene (LLDPE)	15%	1,200	IC 11 / UC 49
High density polyethylene (HDPE)	10%	800	IC 11 / UC 49
Rubber	37%	2,960	IC 11 / UC 49
Other/Unknown	3%	240	IC 55 / UC 0

	Percentage of tonnage	Volume (tonnes)	Industrial Category / Use Category
TOTAL	100%	8,000	

In the SPIN Database (Substances in Preparations in Nordic Countries), the following industrial uses are described:

Table B.0.1.2: Industrial uses of TNPP in the Nordic Countries (in Tonnes)

	1999¹	2000²	2001³
Manufacture of chemicals and chemical products	156	27	< 0.1
Manufacture of rubber and plastic products	38	105	n. i.
Manufacture of furniture; manufacturing n.e.c.	n. i.	0.4	0.1
Manufacture of fabricated metal products, except machinery and equipment	n. i.	0.2	0.1
Construction	n. i.	0.2	0.1
Manufacture of wood and products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials	< 0.1	< 0.1	0.1
Total	194	132.8	0.4

n. i.: not indicated

¹: Information was available for Sweden only

²: Information was available for Sweden, Denmark and Norway

³: Information was available for Denmark and Norway.

TNPP is also mentioned in the following industrial categories: publishing, printing and reproduction of recorded media / sale, maintenance and repair of motor vehicles and motorcycles; retail sale of automotive fuel / manufacture of other transport equipment n.e.c. However, the volumes used in such industries could be considered as negligible (> 0.1 t/y in each country).

Besides, the following use pattern is described in the SPIN database:

Table B.0.2.3: Use pattern of TNPP in the Nordic Countries (in Tonnes)

	1999¹	2000²	2001³
Stabilizers	118	120	n.i.
Intermediates	-	1	n. i.
Others	1	1	n. i.
Adhesives, binding agents	n. i.	0.5	< 0.1
Paints, lacquers and varnishes	< 0.1	0.3	< 0.1
Fillers	< 0.1	> 0.1	0.2
Total	119	122.8	0.2

n.i.: not indicated

¹: Information was available for Sweden only

²: Information was available for Sweden, Denmark and Norway

³: Information was available for Denmark and Norway.

TNPP is also mentioned in the following use categories: lubricants and additives / reprographic agents. However, the volumes used in such applications could be considered as negligible (> 0.1 t/y in each country).

From these tables, it could be stated that TNPP is mainly used as a stabiliser for the manufacture of rubbers and plastic products.

Industrial use

Formulation and processing steps are necessary to manufacture plastic and rubber products. Formulation could be defined as the stage where TNPP is combined in a process of blending and mixing into a polymer or into another material while during the processing step, the TNPP containing material is formed. It is not known to what extent formulation and processing may occur at the same site.

Production of Polyvinylchloride (PVC) film

PVC containing TNPP may be used in many products like shower curtains, floorings and wall coverings.

Production of Polyolefins linear low density polyethylene (LLDPE)

LLDPE films containing TNPP are used for the manufacture of bags and food packaging. Many national regulations are covering the use of TNPP in food contact materials (Table B.2.2.2) **Error! Reference source not found.**

Table B.2.2.2: Global food contact regulations specific to TNPP

Country	Regulation
USA	Food and Drug Administration (FDA) – 21 CFR Part 178.2010
Japan	Self-restrictive Requirements on Food-Contact Articles Japan, Hygienic Olefin and Styrene Plastics Association (JHOSPA) (March 1996), Section A4-2, maximum 1.2%
European Union	Plastics Directive 2002/72/EC, pm/ref. No. 74400, specific migration limit 30 mg/kg
Germany	BfR Recommendation VI, maximum 2.0% total of all stabilisers BGA: maximum 6% in plastics
Netherlands	Food Packaging and Utensils Decree of 01.10.1979 as amended Chapter 1
France	Brochure 1227 (Avril 1990) maximum 1.0%
Italy	Min. Decree of 21.03.1973 maximum 0.3% Min. Decree of 0.04.1985
Spain	Royal Decree 125/1982 of 30.04.1982 Resolution of 4.11.1982

Belgium	Royal Decree of 11.05.1992, specific migration limit 30 mg/kg
United Kingdom	BIBRA/BBF Code of Practice (1991) Rec. No. C.159, maximum 1.0%

Production of High density polyethylene (HDPE)

HDPE containing TNPP is used in the manufacture of many products like blow-molded plastic drums or outer wrapping (film) of cigarette boxes or tea boxes.

Production of rubber

Rubber containing TNPP are used for example in tires and shoes soles.

Other applications (from the Transitional report)

TNPP is used in other applications than plastic and rubber productions. Using the information provided in the SPIN database, it could be supposed that these other applications include the use of TNPP in publishing, printing and reproduction activities, in the manufacture of products of wood, of fabricated metal products, of furniture and in the construction activities. However, no more specific information is available.

Use of end-products

Shower curtains, flooring and wall coverings, bags and food packaging, blow-molded plastic drums, outer wrapping films, tires and shoes soles are examples of plastic and rubber end-products containing TNPP. For all these products, both private and professional end-uses may happen. However, it could be expected that TNPP or NP releases due to the use of end-products are negligible.

Recovery and disposal

No information on recovery has been submitted. In view of the end-products containing TNPP that are manufactured, it could be assumed that products containing TNPP may be either recycled into new products, disposed in landfill or incinerated.

TRENDS

Releases of TNPP and or NP (nonylphenol) to the environment occur during production, transport, storage, formulation and processing of plastic and rubber products. In addition, releases may also take place through the uses of the end-products. Finally, waste disposal of the end-products may also release TNPP or NP into the environment.

The different industry categories (IC), use categories (UC) and main categories (MC) used in the EUSES calculations are described in Table B.2.0.4.

Table B.2.0.4: Industrial Categories (IC), Use Categories (UC) and Main categories (MC) used in EUSES calculations

Life cycle stages		IC	UC	MC	A-Table	B-Table
Production		11	49	I b	A 1.1	B 1.4
PVC films (2,800 t)	Formulation	11	49	III	A 2.1	B 2.3

Life cycle stages		IC	UC	MC	A-Table	B-Table
	Processing	11	49	II	A 3.11	B 3.9
LLDPE films (1,200 t)	Formulation	11	49	III	A 2.1	B 2.3
	Processing	11	49	II	A 3.11	B 3.9
HDPE films (800 t)	Formulation	11	49	III	A 2.1	B 2.3
	Processing	11	49	II	A 3.11	B 3.9
Rubber (2,960 t)	Formulation	11	49	III	A 2.1	B 2.3
	Processing	11	49	II	A 3.11	B 3.9
Others (200 t)	Formulation	15	55	III	A 2.1	B 2.3
	Processing	15	55	II	A 3.16	B 3.14

A default fraction of TNPP in formulation is suggested in TGD (E.C., 2003) Emission Scenario Document for rubber Industry: up to 1.5 % (wt) for processing aids used as stabilisers. However, TNPP manufacturers have submitted better approximations of this value, for different formulated products (Personal communication from TNPP consortium, 1st April 2004):

- *PVC film* 0.8-1.5 %
- *Polyolefins* 0.1-0.2 %
- *Rubber* 0.4-1.0 %”

This information from 2008 may not reflect the current situation. The public consultation will provide an opportunity to collect useful comments to update this information that is not directly relevant for SVHC identification but is relevant at later stages (prioritisation).

10. Information on structure of the supply chain

The Annex XV transitional report (2008) on TNPP (EC no 247-759-6) reports that three facilities were producing TNPP in Europe and about 25 to 35 facilities were processing TNPP in Europe (see section 9 above).

This information from 2008 may not reflect the current situation. The public consultation will provide an opportunity to collect useful comments to update this information that is not directly relevant for SVHC identification but is relevant at later stages (prioritisation).

The substance tris(4-nonylphenyl, branched) phosphite is currently registered by 8 registrants and includes an exposure scenario for manufacture, indicating that the substance is still manufactured within the EU (ECHA's dissemination site¹⁹).

No further information is available on the structure of the supply chain.

¹⁹ Accessed on 5 December 2018
<https://echa.europa.eu/registration-dossier/-/registered-dossier/14891>

11. Additional information

11.1 Substances with similar hazard and use profiles on the Candidate List

No relevant information for TNPP.

4-nonylphenol, branched and linear (4-NP) has already 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 REACH14 and included in the Candidate List.

Furthermore, the similar substances 4-heptylphenol, branched and linear, 4-*tert*-octylphenol and 4-*tert*-pentylphenol are already included in the candidate list due to their endocrine disrupting properties for the environment (Art. 57(f)).

11.2 Alternatives

Alternative stabilisers are available and in use. Their suitability to substitute TNPP depends on the properties needed for specific applications.

11.3 Existing EU legislation

No relevant information for TNPP.

The substance '4-nonylphenol, branched and linear' is on the Candidate List (Decision ED/169/2012 of 18 December 2012) due to its endocrine disrupting properties for the environment.

4-NP is considered also as a "priority hazardous substance" 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. This means that there is political agreement that 4-NP is a high priority for ongoing aquatic emission reduction at EU level. Nevertheless, the WFD does not provide any practical means of ensuring that emissions will in fact cease, so Member States may fail to meet the WFD objective without further risk management measures. In addition, authorisation will not address other sources of the registered substance. Monitoring data (from the UK, as example) indicates that 4-NP continues to be widely emitted from industrial and domestic sources to waste water treatment plants (WWTP) and consequently to rivers in the UK and other EU member states. Some waterbodies in the UK are at risk of non-compliance with the Environmental Quality Standard (EQS) for the registered substance. Current and planned risk management measures under REACH are therefore likely to be insufficient to control the risks and to meet the requirements of the WFD. In this regard, since 2009, nonylphenol has been subject to marketing and use restrictions under Regulation (EC) No 1907/2006 but efforts to reduce its release to the environment need to be continued.

11.4 Previous assessments by other authorities

TNPP identified as tris(nonylphenyl) phosphite (EC 247-759-6; CAS 26523-78-4) was prioritised and evaluated under the Existing Substance Regulation (ESR) (Regulation (EEC) No 793/93) and an Annex XV transitional report for this substance was submitted by France in 2008 (France, 2008).

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