

# Summary of STPP Chemical Safety Report

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## **Risk Management Measures**

Sodium tripolyphosphate (STPP) is not classified according to Directive 67/584/EEC or Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006.

The use of STPP can indirectly contribute to the risk of eutrophication in circumstances where phosphates are not removed in sewage treatment. The eutrophication risk related to STPP use is addressed below in detail, concluding that:

- eutrophication is very site and situation specific, and should be addressed by local measures.
- where eutrophication risk reduction measures are necessary, these should address all sources of phosphates, and in particular include phosphate removal from municipal sewage.

## **Declaration and communication of risk management measures**

Not required, consequently: no declaration of measures, no declaration of communication

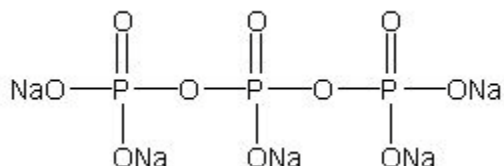
## **Substance identity**

Sodium tripolyphosphate (STPP) is a solid inorganic compound used in detergents and in a large variety of household cleaning products, mainly as a builder, but also in human foodstuffs, animal feeds, industrial cleaning processes and ceramics manufacture.

STPP is widely used in regular and compact laundry detergents (powder, liquid, gel, tablets), automatic dishwashing detergents (powder, liquid, gel, tablets), toilet cleaners, surface cleaners, and a wide range of specialist industrial detergents and cleaning products, and provides a number of functions including sequestration of "water hardness" enabling surfactants to function effectively, pH buffering, dirt emulsification and prevention of deposition, hydrolysis of grease, and dissolving-dispersing dirt particles.

EC number:	231-838-7 237-004-9
EC name:	Pentasodium triphosphate Triphosphoric acid, sodium salt
CAS number (EC inventory):	7758-29-4 13573-18-7 15091-98-2
CAS number:	7758-29-4 13573-18-7 15091-98-2
CAS name:	Sodium tri polyphosphate Sodium tri polyphosphate hexahydrate
IUPAC name:	Pentasodium triphosphate
Annex I index number	
Molecular formula:	$\text{Na}_5\text{P}_3\text{O}_{10}$ $\text{H}_{5-x}\text{P}_3\text{O}_{10}\text{Na}_x$ (where x is approximately 5) $6\text{H}_2\text{O}\cdot\text{Na}_5\text{P}_3\text{O}_{10}$
Molecular weight range:	367.862 – 475.8

## **Structural formula:**



## **Composition of the substance**

This section is considered confidential business information and will be provided individually by the individual Registrants.

## **Physicochemical properties**

<b>Property</b>	<b>Value</b>
Physical state at 20°C and 101.3 kPa	White powder
MELTING/FREEZING POINT	622°C
Boiling point	Not determined
Relative density	2.55
Vapour pressure	Not required
Surface tension	Testing not justified
Water solubility	148000 mg/L at 20 °C
Partition coefficient n-octanol/water (log value)	Not required
Flash point	Not required
Flammability	Not flammable
Explosive properties	Not explosive
Self-ignition temperature	Not applicable
Oxidising properties	Not oxidising
Granulometry	company specific information on particle size is included in the IUCLID dossier
Stability in organic solvents and identity of relevant degradation products	Not required
Dissociation constant	pKa = 9.52-9.55 at 25°C
Viscosity	Testing not justified
Auto flammability	Not required
Reactivity towards container material	Not applicable
Thermal stability	Stable up to 622°C

## **Identified uses**

For ECHA codes, see:

[http://guidance.echa.europa.eu/docs/guidance\\_document/information\\_requirements\\_r12\\_en.pdf](http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf)

<b>Identified use</b>	<b>Process category (PROC)</b>	<b>Preparation Category (PC)</b>	<b>Sector of Use (SU)</b>	<b>Article category (AC)</b>
Detergent ingredient	Mixing.	washing and cleaning products (including solvent based products)	C20.4 - manufacturing: manufacture of soap and detergents, cleaning and polishing preparations, perfumes and	

			toilet preparations
Use in construction materials	Manufacture of construction and technical materials	building and construction preparations not covered elsewhere	F - construction
Metal and surface treatment	Industrial uses: uses of substances as such or in preparation at industrial sites	metal surface treatment products, including galvanic and electroplating products	C25 - manufacturing: manufacture of fabricated metal products, except machinery and equipment
Leather processing	Leather processing	leather tanning, dye, finishing, impregnation and care products	C15 - manufacturing: manufacture of leather and related products
Textiles processing industries	Textile processing	textile dyes, finishing and impregnating products	C13 - manufacturing: manufacture of textiles
Manufacture of paints, varnishes, coatings, printing inks	Industrial uses: uses of substances as such or in preparation at industrial sites	coatings and paints, fillers, putties, thinners	C20.3 - manufacturing: manufacture of paints, varnishes and similar coatings, printing ink and mastics
Use in water treatment	Addition	water softeners	E39 - water supply; sewerage, waste management and remediation activities: remediation activities and other waste management services
		floculant	E39 - water supply; sewerage, waste management and remediation activities: remediation activities and other waste management services
Drilling fluids	Use in oil well and other drilling fluid applications/liquefying and conditioning	inorganic/organic substances and preparations used as ph-regulators,	B - mining and quarrying

	earths, muds and clays	flocculants, precipitants, neutralization agents and comparable unspecific uses	
		adhesives, sealants	B - mining and quarrying
Use in cosmetics	Blending	stabiliser	C20.4 - manufacturing: manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations
Use in human foods, animal feeds, medical and pharmaceutical products.	Mixing	food and fodder additive	C 10 - manufacturing: manufacture of food products
Manufacture of paper	Manufacture of pulp, paper and paper products	paper and board dye, finishing and impregnation products	C17 - manufacturing: manufacture of paper and paper products
Laboratory reagent	Laboratory chemicals	laboratory chemicals	P - education M72 - professional, scientific and technical activities: scientific research and development

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Identified use	Sector of Use (SoU)	Product Category (PC)	Process category (PROC)	Article category (AC)
STPP Production	SU3 SU8 SU9	NA	PROC2 PROC8b PROC9 PROC26	NA
Detergent manufacturing and uses	SU3 SU10 SU21 SU22	<del>PC6</del> PC35 PC36	PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8b PROC 9 PROC 10 PROC 11 PROC 13 PROC 14 PROC 15 PROC19 PROC26	NA
Manufacture of construction and technical materials (cements, mortars, ceramics)	SU3 SU10 SU13 SU19 SU22	NA	PROC 4 PROC 5 PROC8a PROC 8b PROC9 PROC10 PROC 19 PROC26 PROC Xyz (elevated temperature in furnaces)	NA
Metal processing and surface treatment	SU3 SU10 SU14 SU15 SU22	PC14 PC25	PROC 4 PROC 7 PROC8b PROC 10 PROC 13 PROC19	NA
Leather processing (tannery)	SU3 SU5 SU19	PC23	PROC3 PROC4 PROC5 PROC8b PROC9 PROC13 PROC19 PROC26	NA
Textiles processing industries	SU3 SU5 SU19	PC34	PROC 2 PROC3 PROC4 PROC5 PROC6 PROC8a PROC 8b PROC 9 PROC 13	NA
Manufacture and use of paints, varnishes, coatings, printing inks, mastics, etc. Includes exposure during application (industrial, professional and consumer application) and the life of the coating in the home/environment/workplace ...	SU3 SU10 SU11 SU12 SU14 SU15 SU16 SU17 SU19 SU21 SU22	PC1 PC5 PC9 PC9a PC9b PC18 PC23 PC24 PC26 PC30	PROC1 PROC2 PROC3 PROC4 PROC5 PROC7 PROC8a PROC8b PROC9 PROC10 PROC11 PROC13 PROC14	NA

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Identified use	Sector of Use (SoU)	Product Category (PC)	Process category (PROC)	Article category (AC)
		PC31 PC32 PC34 PC35 PC36 PC39	PROC15 PROC19	
Chemical industry	SU3 SU8 SU9 SU12 SU10	NA	PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 7 PROC8a PROC 8b PROC 9 PROC14 PROC15 PROC19 PROC26	NA
Addition to drinking water (mains supply, localised treatment ...)	SU3 SU22	PC20 PC36 PC37	PROC1 PROC2 PROC8a PROC 8b PROC 9 PROC19	NA
Oil well and other drilling fluid applications, liquefying and conditioning earths, muds, clays	SU2a SU2b SU3	PC20	PROC 3 PROC4 PROC 5 PROC 8b PROC 9 PROC26	NA
Treatment of waste water (flocculation)	SU3 SU22	PC20 PC36 PC37	PROC1 PROC2 PROC8a PROC 8b PROC 9 PROC19	NA
addition to closed process water circuits (for example domestic or institutional boiler/heating circuits, cooling waters, industrial process waters ...)	SU3 SU22	PC20 PC30 PC36 PC37	PROC1 PROC2 PROC8a PROC 8b PROC 9 PROC19 PROC Xyz (elevated temperature in furnaces, boilers)	NA
Stabiliser for toothpastes <sup>1</sup>	SU10 SU21	PC20 PC28 PC39	PROC 3 PROC 5 PROC8a PROC 8b PROC 9 PROC10 PROC11 PROC14	NA
Stabiliser in other cosmetics uses <sup>1</sup>	SU10 SU21	PC20 PC28 PC39	PROC 3 PROC 5 PROC8a PROC 8b PROC 9 PROC10 PROC11 PROC 14	NA

Identified use	Sector of Use (SoU)	Product Category (PC)	Process category (PROC)	Article category (AC)
Uses in human foods, animal feeds, medical and pharmaceutical products <sup>2</sup>	SU3 SU4 (exempted) SU10 SU20 SU21 SU22	PC29	PROC 3 PROC4 PROC 5 PROC7 PROC8a PROC 8b PROC 9 PROC13 PROC19	NA

<sup>1</sup> these uses are excluded from Title IV of REACH only (supply chain information) because covered by the Cosmetics Directive 76/768/EC.

<sup>2</sup> excluded from REACH implementation by REACH (Art. 2).

## Uses advised against

None identified

## Classification and labelling

### Classification in Annex I of Directive 67/548/EEC

Sodium tripolyphosphate is not classified:

- for physical - chemical properties
- for health effects
- for the environment

### Labelling in Annex I of Directive 67/548/EEC

Not required

## Self classification(s) and labelling

Endpoints	Classification	Reason for no classification
Explosiveness	Not classified	data lacking
Oxidising properties	Not classified	data lacking
Flammability	Not classified	data lacking
Thermal stability	Not classified	data lacking
Acute toxicity	Not classified	conclusive but not sufficient for classification
Acute toxicity- irreversible damage after single exposure	Not classified	conclusive but not sufficient for classification
Repeated dose toxicity	Not classified	conclusive but not sufficient for classification
Irritation / Corrosion	Not classified	conclusive but not sufficient for classification
Sensitisation	Not classified	conclusive but not sufficient for classification
Carcinogenicity	Not classified	conclusive but not sufficient for classification

Mutagenicity - Genetic Toxicity	Not classified	conclusive but not sufficient for classification
Toxicity to reproduction- fertility	Not classified	conclusive but not sufficient for classification
Toxicity to reproduction- development	Not classified	conclusive but not sufficient for classification
Toxicity to reproduction - breastfed babies	Not classified	data lacking
Environment	Not classified	conclusive but not sufficient for classification

### Classification according to Regulation (EC) No 1272/2008

Endpoints	Classification	Reason for no classification
Explosives	Not classified	data lacking
Flammable gases	Not classified	data lacking
Flammable aerosols	Not classified	data lacking
Oxidizing gases	Not classified	data lacking
Gases under pressure	Not classified	data lacking
Flammable liquids	Not classified	data lacking
Flammable solids	Not classified	data lacking
Self-reactive substances and mixtures	Not classified	data lacking
Pyrophoric liquids	Not classified	data lacking
Pyrophoric solids	Not classified	data lacking
Self heating substances and mixtures	Not classified	data lacking
Substances and mixtures which in contact with water emits flammable gases	Not classified	data lacking
Oxidising liquids	Not classified	data lacking
Oxidising solids	Not classified	data lacking
Organic peroxides	Not classified	data lacking
Substance and mixtures corrosive to metals	Not classified	data lacking
Acute toxicity - oral	Not classified	conclusive but not sufficient for classification
Acute toxicity - dermal	Not classified	conclusive but not sufficient for classification
Acute toxicity - inhalation	Not classified	conclusive but not sufficient for classification

Skin corrosion/irritation	Not classified	conclusive but not sufficient for classification
Serious damage/ eye irritation	Not classified	conclusive but not sufficient for classification
Respiratory sensitization	Not classified	data lacking
Skin sensitization	Not classified	conclusive but not sufficient for classification
Aspiration hazard	Not classified	data lacking
Germ cell mutagenicity	Not classified	conclusive but not sufficient for classification
Carcinogenicity	Not classified	conclusive but not sufficient for classification
Reproductive toxicity	Not classified	conclusive but not sufficient for classification
Effects on or via lactation	Not classified	data lacking
Hazardous to the aquatic environment	Not classified	conclusive but not sufficient for classification

## Self-Labeling

Not required

## Specific concentration limits:

Not required

## **Environmental fate properties**

### **Degradation - Hydrolysis**

Hydrolysis is faster in the presence of biological material, organisms and biological enzymes

From the cited literature data and calculations, hydrolysis of STPP:

In pure water: half life approx 70 hours at 25°C, 200 hours at 12°C

In sewage: half life approx 7 hours at 15°C and 3 hours at 20°C.

In sea water: half life approx 7 days.

In sediment: half life approx 2 days.

In laundry washing machine: approx 20-30% hydrolysis during wash cycle.

Hydrolysis of a calcium – STPP complex in sediment: half life approx 3 days

### **Photodegradation**

Not applicable.

### **Biodegradation**

Not applicable.

### **Environmental distribution**

No available data concerning concentrations of STPP in the aquatic environment.

Some data showing no STPP in outflow of sewage works.

Atmospheric exposure is not anticipated.

### **Adsorption/desorption**

The Freundlich adsorption coefficient (Kf) = 2.85

Log Koc = 2.15

### **Volatilisation**

STPP is not predicted to be volatile.

### **Bioaccumulation**

STPP is hydrolysed to orthophosphate in aqueous and biological systems. The degradation products of sodium tripolyphosphate are essential nutrients (food element) for plants, and stimulate the growth of water plants (macrophytes) and/or algae (phytoplankton).

The potential for bioaccumulation is therefore considered to be minimal.

### **Secondary poisoning**

Not applicable.

## **Human health hazard assessment**

### **Toxicokinetics (absorption, metabolism, distribution and elimination)**

Polyphosphates are not absorbed as such in the intestinal tract, but they can be hydrolysed in vivo by enzymes with the formation of monophosphates, mainly orthophosphate and possibly pyrophosphate, which are then absorbed. This is further supported by the fact that systemic effects of polyphosphates are very similar to those of orthophosphates. It was estimated that approximately two-thirds of ingested phosphates is absorbed from the gastro-intestinal tract.

No data have been identified with regard to dermal absorption properties. It is generally considered that the percutaneous absorption of salts or ionic substances is limited

#### **Acute toxicity: oral**

Three reliable acute oral toxicity tests are available in which no mortalities were observed at 2 000 – 4 000 mg/kg (rat, Sprague Dawley m/f). Several supporting studies are in agreement with these results.

#### **Acute toxicity: inhalation**

Key study shows no signs of toxicity after 4 hours at the maximum attainable concentration of 0.39 mg/L air (rat, Wistar m/f).

#### **Acute toxicity: dermal**

Key study shows LD<sub>50</sub> >4640 mg/kg (24 hours) (rabbit, New Zealand White).

### **Summary and discussion of acute toxicity**

STPP is not classified for acute toxicity

#### **Irritation : skin**

7 studies including one performed to OECD guidelines and GLP showing no irritation, negligible or slight irritation, on rabbits, guinea pigs, humans. STPP is not classified for skin irritation

#### **Irritation: eye**

4 studies including one performed to OECD guidelines and GLP showing no irritation, slight or mild irritation (rabbit).

STPP is not classified for eye irritation

#### **Irritation: Respiratory tract**

No data. Supporting evidence consistent with STPP being an irritable dust.

#### **Corrosivity**

STPP is not corrosive

#### **Sensitisation : skin**

One OECD guideline and GLP Local Lymph Node Assay study: STPP is not a skin sensitizer

#### **Sensitisation : Respiratory system**

No data

## Repeated dose toxicity: oral

STPP was evaluated for chronic toxicity in a 2-year study in rats as well as 28 day studies in rats and dogs. The no-observed adverse effect level in the 2-year study is 0.5% in the diet or 225 mg/kg/day.

## Repeated dose toxicity: inhalation

The consortia are aware of a Klimisch 3 28-day inhalation toxicity study on three mammalian species. A repeated dose (90-day) inhalation toxicity study in the rat has been proposed.

## Repeated dose toxicity: dermal

No data

## Mutagenicity: In vitro data

4 negative references  
STPP is not mutagenic *in vitro*.

## Mutagenicity: In vivo data

3 negative references  
STPP is not mutagenic *in vivo*

## Summary and discussion of mutagenicity

Although limited documentation was generally available on the assays reported, the negative results support the lack of evidence for genetic toxicity for STPP *in vitro* and *in vivo*

## Carcinogenicity

One 2-year study in rats: no apparent increase in the incidence of any specific tumour type in rats surviving to terminal sacrifice

Two additional studies on similar compounds are presented for weight of evidence:

In a chronic toxicity/carcinogenicity study on sodium hexametaphosphate (SHMP), no treatment-related increase in tumour incidence was observed at any dose in rats.

In a chronic toxicity/carcinogenicity study on sodium trimetaphosphate (STMP), no treatment-related increase in tumour incidence was observed at any dose in rats.

STPP is not classified as a mutagen and the basic structure has no structural alerts for carcinogenicity. Inorganic phosphate is a naturally-occurring nutrient essential for mammalian survival.

## Toxicity for reproduction: fertility

One 2-year study in rats: no effect on fertility or litter size, nor on growth or survival of offspring. Organ weights of third generation animals sacrificed at one month were unaffected or not statistically significant. The results provided support the assumption that there is no concern with regard to effects of STPP on reproduction.

Two additional studies on similar compounds are presented for weight of evidence:

Three generation reproduction studies have been conducted on SHMP and STMP. Both these sodium phosphates showed no effects on reproductive performance

## Developmental toxicity

4 studies in rat, rabbit, mouse, hamster: STPP was not found to be a teratogen at any of the dose levels tested and did not exhibit maternal toxicity.

## Summary and discussion of reproductive toxicity

In addition to the above, STPP has a long history of use as a food additive and is considered to be “generally recognised as safe” (GRAS) by the US food and drugs agency. (US authorisation number: FDA n° 182-6810 –EU authorisation number E452I). Throughout its use as a food additive there have been no indications of toxicity to fertility or teratogenic effects.

## **Derivation of DNEL(s) /DMELs**

Route to route extrapolation is used for dermal exposure. An additional assessment factor of 2 is applied. For workers, inhalation exposure is applicable and therefore route to route extrapolation is applied. Assuming the absorption for oral and inhalation is 100% (worst case)  
The corrected inhalatory NOAEC = 396.7 mg/kg bw/day

### **Application of assessment factors: Oral exposure**

The total assessment factor applied is 300

### **Application of assessment factors: Dermal exposure**

The total assessment factor applied is therefore 600

### **Application of assessment factors: Inhalation exposure**

The total assessment factor applied is therefore 600.

## **Corrected dose descriptor(s)**

Corrected dose descriptor(s) per endpoint and endpoint-specific DNEL(s)/DMEL(s) for the relevant exposure pattern.

Endpoint	Route	Most relevant quantitative dose descriptor (mg/kg bw/day)	Corrected dose descriptor (mg/kg bw/day)	Overall AF applied	Endpoint-specific DNEL/DMEL (mg/kg bw/day)
		Local	Systemic		Systemic
Repeated dose toxicity sub-acute/ sub-chronic/ chronic	oral	225		300	0.750
	dermal	225		600	0.375
	inhalation	225	396.7	600	0.661

## **Human health hazard assessment of physicochemical properties**

### **Explosivity**

Phosphates are not explosive.

### **Flammability**

Phosphates are not flammable.

### **Oxidising potential**

STPP is not predicted to have oxidising potential due to its chemical structure and from experience of applications.

## **Environmental hazard assessment**

### **Short-term toxicity to fish**

<i>Danio rerio</i>	LC <sub>0</sub>	LC <sub>50</sub>	LC <sub>100</sub>
Key study: 24h	1600	>1850	2000

### **Long-term toxicity to fish**

<i>Danio rerio</i>	
Key study : 96h	LOEC = 5 mg/l

### **Short-term toxicity to aquatic invertebrates**

*Daphnia magna*  
Several studies, EC<sub>50</sub> (48-h) > 100 mg/l

### **Long-term toxicity to aquatic invertebrates**

No data

### **Algae and aquatic plants**

*Scenedesmus subspicatus*  
E<sub>r</sub>C<sub>50</sub> (90-h) = 160 mg/L  
*Skeletonema costatum*  
NOEC (6-d) >900 mg/L

### **Sediment organisms**

No data

### **Other aquatic organisms**

Effects on shellfish observed in several studies are discussed. The results from these tests are uncertain when used for assessment of aquatic toxicity.

## **Other effects: Eutrophication:**

After use, STPP will hydrolyse by chemical and biological mechanisms in washing machines, water, sewage and sewage treatment works, sediments and sludges to orthophosphates PO<sub>4</sub><sup>-</sup> (see section on hydrolysis above). European Eutrophication Risk Assessment of detergent phosphates is discussed, concluding “ that at an EU level, the estimated difference between the eutrophication risk (as a %) with and without P-based household detergents is typically around the range 2.5 – 10 % based for Mediterranean ecosystem types and around the range 0.5 – 3 % based on the Atlantic & Central European shallow lake effect assessment.” The eutrophication risks, and also the additional eutrophication risks related to detergent phosphates, are very variable in different regional situations as a result of the characteristics of hydrology, population density and agricultural intensity, among other factors. The most effective Risk Reduction Management Strategies are the reduction of agricultural phosphate discharges and the removal of phosphates in sewage works. The implementation of the latter will in any case address detergent phosphates contribution to eutrophication.

## **Predicted No Effect Concentrations (PNEC)**

### **PNEC water**

	Value	Assessment factor
PNEC aqua – freshwater (mg/l)	0.005	1000
PNEC aqua - marine water (mg/l)	0.005	1000

### **PNEC sediment**

No toxicity data for sediment compartment. PNEC's are calculated. Calculated PNEC sediment (mg/kg d.w.): 0.19

### **PNEC soil**

No toxicity data for soil compartment. Calculated PNEC soil (mg/kg d.w.): 0.14

### **Atmospheric compartment**

Atmospheric exposure is not anticipated.

### **PNEC sewage treatment systems**

Not required

### **Non compartment specific effects relevant for the food chain (secondary poisoning)**

Secondary poisoning is not anticipated for this substance

## **Conclusion on environmental classification and labelling**

Sodium tripolyphosphate is not classified for the environment.

### **PBT and VPvB assessment**

STPP is not PBT or vPvB and does not meet the criteria for classification as dangerous and therefore the exposure assessment and risk characterisation sections of the chemical safety report are not required.