

## Summary of conditions for Rights of Access to the STPP Consortium REACH Registration Dossier and of status of Registration preparation

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### **Consortium status**

The following companies signed in May 2008, following preparatory work launched Spring 2007, a legal Consortium Agreement to cooperate for REACH Registration of STPP (sodium tri poly phosphate):

- BK Giulini GmbH,
- Chemische Fabrik Budenheim,
- FMC Foret S.A.,
- Prayon SA,
- Thermphos International BV.

The President of the Consortium Governing Committee is Maria-José Rodriguez, FMC Foret. The Secretariat is ReachCentrum, Brussels. The technical work of dossier preparation is contracted to Safepharm / Harlan UK.

The objectives defined in the Consortium Agreement are as follows:

*“with a view to fulfilling their regulatory obligations, the Members form by the present a Consortium (see Definitions) in respect of anti-trust and competition legislation, open to any other interested operators subject to the criteria defined hereunder, in order to achieve the Purpose (defined in § II), and in particular to:*

- *share Information, review the available data, identify data gaps, propose additional testing, and, subject to an agreement on a case-by-case basis, perform testing where necessary,*
- *compile and submit a harmonised set of data for Registration and a Registration Dossier,*
- *manage ... Registration and access to this REACH Registration Dossier and to relevant data before and after the Date of Registration, in particular with relation to: other potential REACH Registrants of the Substance, potential REACH Registrants of other substances with potential read-across to/from the Substance, any other party wishing to access or use this dossier for REACH or for any other regulatory purposes,*
- *carry out other joint activities necessary for the REACH Registration of the Substance or relevant to or related to the Purpose.”*

## **Completed Registration Dossier and IUCLID5**

Through this cooperation and agreement, a STPP data search and assessment was completed, existing company-owned and publicly available studies have been listed and Key Studies for each REACH end-point identified, existing studies have been assessed and evaluated, additional studies necessary for REACH Registration of STPP have been identified and these studies have been carried out.

The **complete IUCLID5** file has been finished, including summaries of studies, translations, robust studies and expert assessments where necessary. The STPP reach **Registration Dossier (CSR) has also been completed.**

**Both were ready for Registration submission end 2008.**

This STPP dossier has now been entered into the **ECHA-Cefic REACH Dossier “testing” process** (spring 2009).

**The Dossier will be formally submitted for Joint Registration once this dossier “testing” is completed** and once the ECHA computer (IT) system has been updated to allow Joint Registration.

The summary of the IUCLID5 and CSR Dossier (conclusions for each endpoint and list of studies referenced for each endpoint) are available for verification to all SIEF members after signature of a “commitment and confidentiality” document, defining and committing to confidentiality conditions, and committing to payment of appropriate dossier access costs.

**Proposed Classification and Labelling and Substance Identity** are however included in the present document.

To obtain full Access Rights to the Dossier it is not necessary to become a Consortium Member.

The Consortium Agreement defines precisely the financial and legal conditions under which other companies intending to Register STPP under REACH can obtain Access Rights to the STPP REACH Registration Dossier prepared by the Consortium. This concerns EU manufacturers of STPP, importers, Only Representatives or, in application of REACH, companies importing products such as detergents from which the substance “is intended to be released under normal or reasonably foreseeable conditions of use”.

The Consortium Agreement specifies conditions for cost sharing, administrative costs and for valuation and accounting of existing studies and new information, based on standard prices and cost share principles and on the REACH Guidance Document (data sharing).

Companies purchasing Access Rights to the Dossier will receive a Letter of Access but will not receive copies the IUCLID or CSR files, of the Registration Dossier, or of study reports, summaries or other data. The Access Rights are accorded for use for REACH Registration of STPP only, and for use for no other purposes and for no other substances.

## **Handling of confidential information**

In order to ensure respect of anti-trust obligations, all confidential information (representation of companies, tonnages, impurities, confidential uses, etc) is handled by ReachCentrum, the Consortium’s Secretariat, and is not and will not be circulated to existing Consortium Members nor to other companies requesting Access Rights to the Registration Dossier.

## Cost of STPP Dossier Access and financial rules

The cost of full Access to the STPP Registration Dossier is approximately as follows:

- Advantage Compensation Payment: corresponds to the goodwill, experience, know-how and cooperation between the Initial Members which have enabled successful completion of the Registration Dossier  
= 20 000 €
- Dossier Contribution Cost: corresponds to an equal sharing of the total Dossier costs through to submission of Registration : preparation work, purchase of access to existing studies (including end points of eutrophication, long-term effects), cost of additional studies necessary to achieve all REACH end-points, dossier writing including producing summaries of a number of studies not to date included for the IUCLID file, producing Robust IUCLID Summaries and expert assessments for specific endpoints where recent studies are not available and cannot be carried out (mammal testing), consortium management ...  
= approximately as estimated to date 310 000 €\*\*

DIVIDED by  $(N+1)^* = (5 + 1) = 6$

= approximately 52 000 €\*\*

▪ **TOTAL (per company)**

**= approximately 72 000 €\*\* \*\*\***

NOTES:

\* the Dossier Contribution Cost depends on the number of Members of the Consortium (N), at present = 5

\*\* the total Dossier costs are currently estimated and may be modified as a function of the cost of Access to existing long-term studies deemed to be required for Registration, final costs of IUCLID summaries and expert evaluations of studies currently under finalisation, and as a result of any other unforeseen costs necessary for Registration

\*\*\* some studies may not be required for Registration for volumes in different tonnage bands < 1,000 tonnes / year, in which case the costs to companies registering for such lower volumes may consequently be lower.

If companies wish to become a Member of the Consortium, an additional Entry Fee of 20 000 € is asked, to cover existing Members' time and Consortium Administration costs (modifying Consortium Agreement, adjusting budget and accounting system, etc) and to compensate possible financial benefit through cost sharing if further companies purchase Dossier Access. This is NOT necessary to obtain full access to the Registration Dossier, for which the cost is that indicated above under total per company.

**In all cases, the following general financial rules apply:**

"In all cases, the payments indicated cover access, as specified, to the Registration Dossier and/or Information as these stand only, and with no guarantee of their validity or acceptance by the Agency. In particular, if after the Date of Registration, the Agency requests further testing of the Substance or for other reasons it becomes necessary to develop or supply further Information to support the Registration of the Substance, then the Members are not obliged to bear these costs and are not obliged to carry out the required work, unless they decides to do so through the Consortium or otherwise. Such further work and costs may be shared between all parties who choose to continue to support the Registration or the work organised in other ways to be defined."

"In all cases, the payments indicated are due per company manufacturing, importing or representing the Substance: one company's payment will cover its Affiliates (*note: that is any legal entity controlling, controlled by, or under common control with a Member*), payment by an Only Representative of more than one company will be calculated per company according to the number of companies represented."

## **Further information and next steps:**

**If your company is potentially interested in purchasing Access Rights to the full STPP REACH Registration Dossier** or to part of it and/or in becoming a Consortium Member,

**OR**

**If your company or organisation owns information or studies concerning STPP:**

→ you should

- Verify your agreement with the proposed Substance Identification, Classification & Labelling and Sectors of use, Preparation, Process and Article categories to be covered by the STPP Registration, see end of the present document
- request the STPP Consortium REACH Registration information pack by sending an email to [stpp@reachcentrum.eu](mailto:stpp@reachcentrum.eu) **indicating your name and company.**
- You will then receive:
  - the full STPP Consortium Agreement text, including in particular confidentiality and financial conditions
  - the list of all existing relevant studies in the Consortium's possession (those owned by Consortium members, publicly published studies)
  - a "Commitment and confidentiality form" to be completed, signed and returned by SIEF members wishing to obtain access to the Joint STPP Registration

→ you should then:

- send to the Secretariat a list of any other existing studies in your possession, not on the Consortium list
- sign and return the "commitment and confidentiality form" and STPP Joint Registration questionnaire, in particular noting the commitment to the confidentiality conditions and financial conditions defined in the Consortium Agreement text

On receipt of this signed form, the Secretariat will send to you, under the confidentiality conditions agreed on this form, summary of the IUCLID5 and CSR Registration Dossier and invoices for payment of Dossier Access Costs.

On receipt of payment of invoices, you will receive a formal Letter of Access to the Registration Dossier and instructions for inclusion of your company in the Registration process.

## **SIEF communications:**

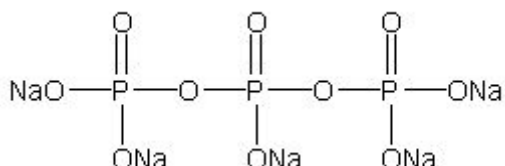
Consortium Secretariat: Secretariat: ReachCentrum, 6 avenue E. van Nieuwenhuysse, B1160 Bruxelles, Belgium.

Please note that the Consortium Secretariat and the member companies do NOT have the resources necessary to communicate directly and individually with the over one thousand members of the SIEF for STPP, and therefore, in that our REACH and anti-trust obligations are fulfilled by the information process indicated above, the Consortium Secretariat and the Consortium member companies will generally NOT RESPOND TO ANY emails or contacts except as where necessary to finalise formal agreements and exchange information with companies having already signed the "commitment and confidentiality" form requested from [stpp@reachcentrum.eu](mailto:stpp@reachcentrum.eu) or to take into account NEW information (additional to that in the list of existing studies already identified by the Consortium, see above).

## Proposed STPP substance identity

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

### Structural formula:



## **Proposed STPP Classification & Labelling (67/548/EEC)**

### **Classification according to Directive 67/548/EEC criteria**

#### **Classification**

Sodium tripolyphosphate is not classified:

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

#### **Labelling**

Not required

#### **Self classification(s) and labelling**

Explosiveness	Not classified
Oxidising properties	Not classified
Flammability	Not classified
Thermal stability	Not classified
Acute toxicity	Not classified
Acute toxicity- irreversible damage after single exposure	Not classified
Repeated dose toxicity	Not classified
Irritation / Corrosion	Not classified
Sensitisation	Not classified
Carcinogenicity	Not classified
Mutagenicity - Genetic Toxicity	Not classified
Toxicity to reproduction- fertility	Not classified
Toxicity to reproduction- development	Not classified
Toxicity to reproduction – breastfed babies	Not classified
Environment	Not classified

#### **Specific concentration limits:**

Not required

## **Proposed STPP Classification & Labelling (1272/2008 = GHS)**

### **Classification according to Regulation (EC) 1272/2008 criteria**

<b>Endpoints</b>	<b>Classification</b>
Explosives	Not classified
Flammable gases	Not classified
Flammable aerosols	Not classified
Oxidizing gases	Not classified
Gases under pressure	Not classified
Flammable liquids	Not classified
Flammable solids	Not classified
Self-reactive substances and mixtures	Not classified
Pyrophoric liquids	Not classified
Pyrophoric solids	Not classified
Self heating substances and mixtures	Not classified
Substances and mixtures which in contact with water emits flammable gases	Not classified
Oxidising liquids	Not classified
Oxidising solids	Not classified
Organic peroxides	Not classified
Substance and mixtures corrosive to metals	Not classified
Acute toxicity	Not classified
Skin corrosion/irritation	Not classified
Serious damage/ eye irritation	Not classified
Respiratory sensitization	Not classified
Skin sensitization	Not classified
Aspiration hazard	Not classified
Germ cell mutagenicity	Not classified
Reproductive toxicity	Not classified
Hazardous to the aquatic environment	Not classified

## Proposed STPP description of 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)

Non-confidential applications to be covered by the STPP Consortium Registration Dossier:

Identified use	Sector of Use (SoU)	Preparation Category (PC)	Process category (PROC)	Article category (AC)
STPP Production	NA	NA	PROC2 PROC9	NA
detergent uses	SU10 SU21 SU22	PC6 PC35	PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 8 PROC 9 PROC 10 PROC 11 PROC 13 PROC 14 PROC 15	NA
construction materials	SU13	PC10	PROC 4 PROC 5 PROC 8 PROC 19	NA
ceramics manufacture	SU13	PC10	PROC 4 PROC 5 PROC 8 PROC Xyz (elevated temperature in furnaces)	NA
metal and surface treatment	SU14	PC14 PC25	PROC 4 PROC 7 PROC 10 PROC 13	NA
leather manufacture (tannery)	SU5	PC23	PROC4	NA
textiles processing industries	SU5	PC34	PROC 2 PROC 9 PROC 13	NA
manufacture of paints, varnishes, coatings, printing inks, mastics, etc	SU10 SU19	PC9	PROC3 PROC4 PROC5	NA
chemical industry	SU8 SU12 SU10	PC19 PC20 PC32	PROC 1 PROC 2 PROC 3 PROC 4 PROC 5 PROC 7 PROC 8 PROC 9 PROC14	NA
addition to drinking water (mains supply, localised treatment ...)	SU22	PC37 PC20	PROC 8 PROC 9	NA
oil well and other drilling fluid applications, liquefying earths, muds, clays	SU2	PC20	PROC 3 PROC 5	NA

Identified use	Sector of Use (SoU)	Preparation Category (PC)	Process category (PROC)	Article category (AC)
treatment of waste water (flocculation)	SU3	PC20	PROC 8 PROC 9	NA
addition to closed process water circuits (for example domestic or institutional boiler/heating circuits, cooling waters, industrial process waters ...)	SU3	PC37 PC30 PC36	PROC 8 PROC 9 PROC Xyz (elevated temperature in furnaces, boilers)	NA
stabiliser for toothpastes <sup>1</sup>	SU10 SU21	PC39	PROC 3 PROC 5 PROC 8 PROC 9	NA
stabiliser in other cosmetics uses <sup>1</sup>	SU10 SU21	PC28 PC39	PROC 3 PROC 5 PROC 8 PROC 9 PROC 14	NA
uses in human foods, animal feeds, medical and pharmaceutical products <sup>2</sup>	SU4 (exempted) SU10 SU21	PC29	PROC 3 PROC 5 PROC 8 PROC 9	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).