SUBSTANCE EVALUATION REPORT

Public Name: Trizinc bis(orthophosphate)
EC Number(s): 231-944-3
CAS Number(s): 7779-90-0
Submitting Member State Competent Authority: ROMANIA
Year of evaluation (as given in the CoRAP): 2013

DATE: November 2014

Conclusions of the most recent evaluation step*	Tick relevant box (es)
Concern not clarified; Need to request further information from the Registrant(s) with the draft decision	
Concern clarified; No need of further risk management measures	x
Concern clarified; Need for risk management measures; RMO analysis to be performed	
Other:	

**Include details in the executive summary.*

DISCLAIMER

Executive summary

Grounds for concern

***Initial* concern**

Trizinc bis(ortophosphate) is produced in high tonnage and has a wide, dispersive use and is classified as hazardous for the environment with acute and chronic effect cat.1.

Procedure

Substance evaluation was based on the information presented in the registration dossier in IUCLID, in CSR and in Risk Assessment Report of Zinc phosphate, having regarded certain endpoints which lead to the substance classification and exposure scenarios.

As a natural element, zinc occurs in different forms and compounds.

Our evaluation was based on the basic assumption made in hazard assessment and in CSR (in accordance to the same assumption made in the EU RA process) that the toxicity of zinc and zinc compounds is due to the Zn^{2+}ion. As a consequence, all data was expressed as “zinc”, not as the test compound as such, because ionic zinc is considered to be the causative factor for toxicity.

Trizinc bis(orthophosphate) was originally selected for substance evaluation in order to clarify suspected risks about:

- Wide dispersive use
- Aggregated tonnage.

Concerning tonnage in Europe, according to ECHA 2010 volume is ranking between 10.000 and 100.000 Tn/year.

Conclusions

During the course of evaluation no further information was requested from the Registrant(s).

The information available gives no reasons for concern for adverse effects on human health; therefore there is no reason for classification for human health.

Trizinc bis(ortophosphate) is not classified for physical chemical properties and their health effects.

The water solubility of zinc phosphate exceeds the lowest $L(E)C_{50}$ values for *Daphnia magna*, algae and fish. Therefore trizinc bis(orthophosphate) has an Annex VI entry in CLP (Regulation (EC) No 1272/2008) classified accordingly:

1. CLP, Annex VI Table 3.1

- Aquatic acute cat.1 - H400 (Very toxic to aquatic life)
- Aquatic chronic cat.1 - H410 (Very toxic to aquatic life with long lasting effects).

2. CLP, Annex VI, Table 3.2

- Dangerous for environment - N; R50-53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).

As the worst Risk Characterisation Ratio is less than “1”, the risk for workers and consumers is characterised as acceptable for all types of use of trizinc bis(orthophosphate).

There is no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

CONTENTS

TABLES

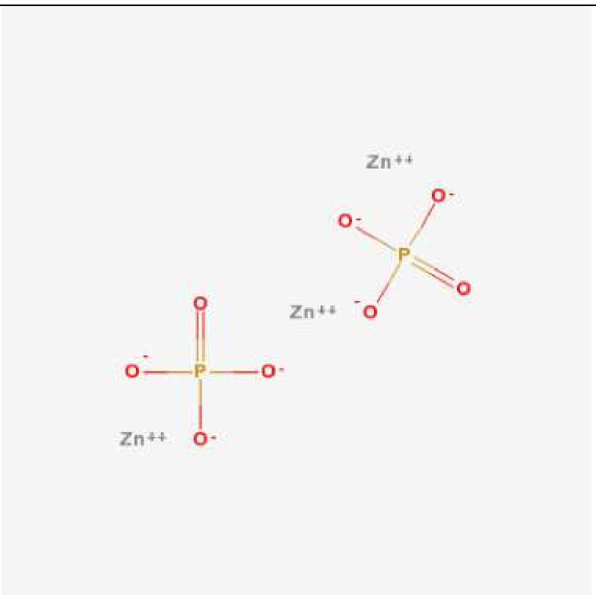
1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	**Trizinc bis(orthophosphate)**
EC number:	231-944-3
EC name:	trizinc bis(orthophosphate)
CAS number (in the EC inventory):	7779-90-0
CAS number:	7779-90-0
CAS name:	Phosphoric acid, zinc salt (2:3)
IUPAC name:	trizinc bis(orthophosphate)
Index number in Annex VI of the CLP Regulation	030-011-00-6
Molecular formula:	H3O4P.3/2Zn
Molecular weight range:	386.113
Synonyms:	Zinc phosphate; trizinc diphosphate

Structural formula:



1.2 Composition of the substance

Name:

A. **trizinc bis(orthophosphate)**
B. **zinc ortho-phosphate**
C. **trizinc bis(orthophosphate)**
D. **trizinc bis(orthophosphate)**
E. **zinc Phosphate**

Description:

A. **–**
B. **Mono constituent substance**
C. **Mono constituent**
D. **–**
E. **Anti-Corrosive**

Degree of purity: *Confidential information*

1.3 Physico-chemical properties

The physico-chemical properties reported in the registration dossiers are summarised in Table 2.

Table 2: Overview of physicochemical properties

Property	Value	Remarks
Physical state at 20°C and 101.3 kPa	The physical state of the substance is **solid** powder, its colour is **white**, it is **odourless**	No guideline followed. Appearance/physical state/color of the substance was determined by visual inspection, odor by smell (organoleptic).
Melting/freezing point	In air, the substance starts melting at **846°C at 1013 hPa**.	EU Method A.1 (Melting / Freezing Temperature)
Boiling point	-	Study scientifically unjustified
Vapour pressure	-	The study does not need to be conducted if the melting point is above 300°C (Column 2 of Annex VII REACH regulation)
Surface tension	The surface tension was 70.40 mN/m which is close to the one of pure water which is 72.75 mN/m.	OECD Guideline 115 (Surface Tension of Aqueous Solutions) The surface tension is close to the value of pure water and **thus the solution of the substance is not surface-active.**
Water solubility	The solubility of Zn in the substance is **2.7 mg/l** at 20 °C **(slightly soluble).**	OECD Guideline 105 (Water Solubility)
Partition coefficient n-octanol/water (log value)	-	Not applicable to metal compounds; The study does not need to be conducted if the substance is inorganic (column 2 of Annex VII of the REACH regulation)
Flash point	-	Not applicable. The study does not need to be conducted if the substance is inorganic (Column 2 of Annex VII of REACH regulation)
Flammability	-	Based on the thermo gravimetric and differential scanning calorimetric measurements and mineral composition the substance has no flammability, explosiveness or auto-inflammability properties.
Explosive properties	-	Based on the thermo gravimetric and differential scanning calorimetric measurements and mineral composition the substance has no flammability, explosiveness or auto-inflammability properties.
Self ignition temperature	-	-
Oxidising properties	The substance has no oxidising properties.	No guideline followed The Pourbaix diagram of the substance was calculated using the EpH module of the HSC 7.0 program.
Granulometry	The $\mathbf{D_{50}}$ of the substance is **<0.02 mm**, the $\mathbf{D_{80}}$ is **<0.02 mm.**	-
Stability in organic solvents and identity of relevant degradation products	-	Stability in organic solvents and identity of relevant degadation products is not an applicable endpoint for inorganic substances according to column 2 of Annex IX of the REACH Regulation.
Dissociation constant	-	The dissociation constant relating to the acidity constant, pKa, as required by the IUCLID database and REACH Guidance document, is not relevant for the substance.
Viscosity	At 20°C, the substance is solid, and viscosity is not applicable. Viscosity of the substance was determined on molten liquid substance. The viscosity decreases with liquid temperature and becomes very high at solid state.	Liquid state viscosity was measured with Thermo Scientific Haake RheoWin Viscotester VT550 rotation viscometer. The measurement technique is based on a rotating sensor and the torque maintaining the preset sensor rotational speed is proportional to the viscosity of the sample.
Auto flammability	Based on the thermogravimetric and differential scanning	-

Property	Value	Remarks
	calorimetric measurements and mineral composition the substance has no flammability, explosiveness or auto-inflammability properties.	
Reactivity towards container material	-	-
Thermal stability	-	-
Relative density	The density of the substance is **3.26 g/cm^3 at 20°C.**	EU Method A.3 (Relative Density)

2 MANUFACTURE AND USES

2.1 Quantities

Between 10.000 and 100.000 Tn/ year.

2.1.1 Manufacturing processes

Not relevant for this evaluation.

2.2 Identified uses

The following uses have been identified by the registrants and are accompanied in the submission by a number of PROC (process category) codes.

Process category (PROC):

PROC 1: Use in closed process, no likelihood of exposure
PROC 2: Use in closed, continuous process with occasional controlled exposure
PROC 3: Use in closed batch process (synthesis or formulation)
PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises
PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)
PROC 6: Calendering operations
PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)
PROC 10: Roller application or brushing
PROC 11: Non industrial spraying
PROC 12: Use of blowing agents in manufacture of foam
PROC 13: Treatment of articles by dipping and pouring
PROC 14: Production of preparations or articles by tabletting, compression, extrusion, pelletisation
PROC 15: Use as laboratory reagent
PROC 19: Hand-mixing with intimate contact and only PPE available.
PROC 21: Low energy manipulation of substances bound in materials and/or articles.
PROC 22: Potentially closed processing operations with minerals/metals at elevated temperature. Industrial setting
PROC 23: Open processing and transfer operations with minerals/metals at elevated temperature
PROC 24: High (mechanical) energy work-up of substances bound in materials and/or articles
PROC 26: Handling of solid inorganic substances at ambient temperature

2.2.1 Uses by workers in industrial settings

The following industrial uses are listed in the registration dossier:

1. Zinc ortho-phosphate production –Wet
2. Component for production of inorganic zinc compounds
3. Electro galvanizing
4. Electroplating
5. Laboratory reagent
6. Zinc production by pyro metallurgy
7. Component for production of organic zinc compounds
8. Component for production of Inorganic pigments
9. Component for production of Coatings / paints, inks, enamels, varnishes
10. Use of $Zn_3(PO_4)_2$-containing paints & coatings
11. Additive for the formulation of nutrition additives

12. Additive for the formulation of animal feedstuffs
13. Additive for the formulation of fertilizers
14. Additive in dentistry products
15. Substrate preparation: sanding of surfaces between application of coatings
16. Component for polymer-matrices, plastics and related preparations

2.2.2 Uses by professional workers

The following professional uses are listed in the registration dossier:

1. Laboratory reagent
2. Use of $Zn_3(PO_4)_2$-containing paints & coatings
3. Use of $Zn_3(PO_4)_2$-containing fertilizer's formulations
4. Substrate preparation: sanding of surfaces between application of coatings

2.2.3 Uses by consumers

The following consumer uses are listed in the registration dossier:

1. Use of $Zn_3(PO_4)_2$-containing paints & coatings
2. Use of $Zn_3(PO_4)_2$-containing fertilizer's formulations

2.3 Uses advised against

Not relevant for this evaluation.

2.3.1 Uses by workers in industrial settings advised against

Not relevant for this evaluation.

2.3.2 Use by professional workers advised against

Not relevant for this evaluation.

2.3.3 Uses by consumers advised against

Not relevant for this evaluation.

3 CLASSIFICATION AND LABELLING

3.1 Harmonised Classification and labelling in Annex VI of the CLP Regulation

Trizinc bis(orthophosphate) is listed in Annex VI of CLP and have a harmonized classification.

Index Number: 030 -011-00-6

EC Number: 231-944-3

Hazard Class, Category Codes and Statements:

Aquatic Acute 1; H400: Very toxic to aquatic life
Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.

Signal word: Warning

Hazard pictogram:

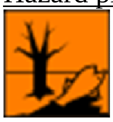
GHS09: environment

3.2 Classification and labelling according to DSD / DPD

3.2.1. Classification and labelling in Annex I of Directive 67/548/EEC

N; R50/53 Dangerous for the environment; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Hazard pictogram:



3.3 Self-classification

Some of the notifications in the CLP inventory include in addition an either acute or chronic M factor = 1.

4 ENVIRONMENTAL FATE PROPERTIES

4.1 Degradation

4.1.1 Abiotic degradation

4.1.1.1 Hydrolysis

Not relevant for this evaluation.

4.1.1.2 Phototransformation/photolysis

Not relevant for this evaluation.

4.1.1.2.1 Phototransformation in air

Not relevant for this evaluation.

4.1.1.2.2 Phototransformation in water

Not relevant for this evaluation.

4.1.1.2.3 Phototransformation in soil

Not relevant for this evaluation.

4.1.2 Biodegradation

4.1.2.1 Biodegradation in water

Not relevant for this evaluation.

4.1.2.1.1 Estimated data

Not relevant for this evaluation.

4.1.2.1.2 Screening tests

Not relevant for this evaluation.

4.1.2.1.3 Simulation tests (water and sediments)

Not relevant for this evaluation.

4.1.2.1.4 Summary and discussion of biodegradation in water and sediment

Not relevant for this evaluation.

4.1.2.2 Biodegradation in soil

Not relevant for this evaluation.

4.1.3 Summary and discussion on degradation

Not relevant for this evaluation.

4.2 Environmental distribution

4.2.1 Adsorption/desorption

Not relevant for this evaluation.

4.2.2 Volatilisation

Not relevant for this evaluation.

4.2.3 Distribution modelling

Not relevant for this evaluation.

4.2.4 Summary and discussion of environmental distribution

Not relevant for this evaluation.

4.3 Bioaccumulation

4.3.1 Aquatic bioaccumulation

Not relevant for this evaluation.

4.3.2 Terrestrial bioaccumulation

Not relevant for this evaluation.

4.3.3 Summary and discussion of bioaccumulation

Not relevant for this evaluation.

4.4 Secondary poisoning

Not relevant for this evaluation.

5 HUMAN HEALTH HAZARD ASSESSMENT

5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1 Non-human information

Not relevant for this evaluation.

5.1.2 Human information

Not relevant for this evaluation.

5.1.3 Summary and discussion on toxicokinetics

Not relevant for this evaluation.

5.2 Acute toxicity

Not relevant for this evaluation.

5.2.1 Non-human information

5.2.1.1 Acute toxicity: oral

Not relevant for this evaluation.

5.2.1.2 Acute toxicity: inhalation

Not relevant for this evaluation.

5.2.1.3 Acute toxicity: dermal

Not relevant for this evaluation.

5.2.1.4 Acute toxicity: other routes

Not relevant for this evaluation.

5.2.2 Human information

Not relevant for this evaluation.

5.2.3 Summary and discussion of acute toxicity

Not relevant for this evaluation.

5.3 Irritation

5.3.1 Skin

5.3.1.1. Non-human information

Not relevant for this evaluation.

5.3.1.2. Human information

Not relevant for this evaluation.

5.3.2 Eye

5.3.2.1. Non-human information

Not relevant for this evaluation.

5.3.2.2. Human information

Not relevant for this evaluation.

5.3.3 Respiratory tract

5.3.3.1. Non-human information

Not relevant for this evaluation.

5.3.3.2. Human information

Not relevant for this evaluation.

5.3.4 Summary and discussion of irritation

Not relevant for this evaluation.

5.4 Corrosivity

5.4.1 5.4.1. Non-human information

Not relevant for this evaluation.

5.4.2 Human information

Not relevant for this evaluation.

5.4.3. Summary and discussion of corrosion

Not relevant for this evaluation.

5.5 Sensitisation

Not relevant for this evaluation.

5.5.1 Skin

5.5.1.1 Non-human information

Not relevant for this evaluation.

5.5.1.2 Human information

Not relevant for this evaluation.

5.5.2 Respiratory system

5.5.2.1 Non-human information

Not relevant for this evaluation.

5.5.2.2 Human information

Not relevant for this evaluation.

5.5.3 Summary and discussion on sensitisation

5.6 Repeated dose toxicity

5.6.1 Non-human information

5.6.1.1 Repeated dose toxicity: oral

Three studies with reliability “2” have been performed on mice, rats Wistar and rats Sprague Dawley for the repetead dose toxicity after oral administration of the zinc sulphate or zinc monoglycerolate.
Based on the results of studies, the lowest NOAEL value of 13 mg Zn/kg bw/day with zinc monoglycerolate test (Edwards K. and Buckley P, 1995) and the NOAEL value of 104 mg Zn/kg bw/day and 53.5 mg Zn/kg bw/day (Maita K, Hirano M, Mitsumori K, Takashi K and Shirasu Y, 1981) with zinc sulphate tests were determined.

5.6.1.2 Repeated dose toxicity: inhalation

Studies with reliability “2” have been performed on Guinea pigs Hartley for the inhalation exposure of the zinc oxide.
Based on the results of studies, the NOAEL value of 2.7 mg ZnO/m^3 (Lam HF, Chen LC, Ainsworth D, Peoples S and Amdur MO, 1988) and the marginal LOAEL value of 2.3 mg ZnO/m^3 (Conner et al., 1988) for the inhalatory exposure were determined.
These endpoints are considered not relevant for classification.

5.6.1.3 Repeated dose toxicity: dermal

In a study performed with zinc oxide, zinc omadine, zinc sulphate and zinc undecylenate (131 µCi/mole of ^{65}Zn), topically applied to shaved skin on the back of rabbits (application consisted of 2.5 mg zinc compound containing 5 µCi ^{65}Zn) was emphasized that chemical differences in the compounds do not play a very important role in the skin uptake of ^{65}Zn. High concentrations of ^{65}Zn were observed in the cortical and cutical zones of the hair shaft, being the highest in the keratogenous zone. No data were given on systemic absorption (Kapur *et al.*, 1974).

In another study, application of ZnO dressings (containing 250 µg Zn/cm^2) to rats for 48 hours with full-thickness skin excision, it was observed a 12% delivery of zinc ions from the dressing to each wound, while application of $ZnSO_4$ dressings (containing 66 µg Zn/cm^2) resulted in a 65% delivery of ions to each wound. The data suggest that the application of ZnO resulted in sustained delivery of zinc cations causing constant wound-tissue zinc cation levels due to its slow dissociation rate, while the more water soluble $ZnSO_4$ delivers zinc ions more rapidly to the wound fluid with subsequent rapid transferral into the blood (Agren *et al.*, 1991a).

A study with reliability “2” has been performed on rat for acute dermal toxicity of the zinc sulphate (Van Huygevoort AHMBM, 1999a). Based on the results of study, the LD_{50} value > 2,000 mg/kg bw for the dermal exposure was determined.

This endpoint is considered not to be of concern, due to the low level of dermal absorption of zinc compounds and the lack of acute dermal effects.

5.6.1.4 Repeated dose toxicity: other routes

Not relevant for this evaluation.

5.6.2 Human information

Studies performed on humans who were supplemented with zinc (as zinc gluconate) have shown that women are more sensitive to the effects of high zinc intake and that a dose of 50 mg Zn/day is the human NOAEL. This equals a daily exposure of 0.83 mg/kg bw.
The endpoint is not expected to be of concern for zinc compounds on oral repeated dose toxicity.

5.6.3 Summary and discussion of repeated dose toxicity

Non-human information

The marginal LOAEL value of 2.3 mg ZnO/m^3 for the inhalatory exposure is considered not relevant for classification.

The LD_{50} value > 2,000 mg/kg bw for acute dermal toxicity is considered not to be of concern.

Human information

Studies performed on humans who were supplemented with zinc have shown that women are more sensitive to the effects of high zinc intake and that a dose of 50 mg Zn/day is the human NOAEL.
A classification for repeated dose toxicity is not needed, according to Annex I of Directive 67/548/EEC and Annex VI of Regulation (EC) No 1272/2008.

5.7 Mutagenicity

5.7.1 Non-human information

5.7.1.1 In vitro data

Not relevant for this evaluation.

5.7.1.2 In vivo data

Not relevant for this evaluation.

5.7.2 Human information

Not relevant for this evaluation.

5.7.3 Summary and discussion of mutagenicity

Not relevant for this evaluation.

5.8 Carcinogenicity

5.8.1 Non-human information

5.8.1.1 Carcinogenicity: oral

Not relevant for this evaluation.

5.8.1.2 Carcinogenicity: inhalation

Not relevant for this evaluation.

5.8.1.3 Carcinogenicity: dermal

Not relevant for this evaluation.

5.8.2 Human information

Not relevant for this evaluation.

5.8.3 Summary and discussion of carcinogenicity

Not relevant for this evaluation.

5.9 Toxicity for reproduction

5.9.1 Effects on fertility

5.9.1.1 Non-human information

Not relevant for this evaluation.

5.9.1.2 Human information

Not relevant for this evaluation.

5.9.2 Developmental toxicity

5.9.2.1 Non-human information

Not relevant for this evaluation.

5.9.2.2 Human information

Not relevant for this evaluation.

5.9.3 Summary and discussion of reproductive toxicity

Not relevant for this evaluation.

5.10 Endocrine disrupting properties

Not relevant for this evaluation.

5.11 Other effects

5.11.1 Non-human information

5.11.1.1 Neurotoxicity

Not relevant for this evaluation.

5.11.1.2 Immunotoxicity

Not relevant for this evaluation.

5.11.1.3 Specific investigations: other studies

Not relevant for this evaluation.

5.11.2 Human information

Not relevant for this evaluation.

5.11.3 Summary and discussion of specific investigations

Not relevant for this evaluation.

5.12 Derivation of DNEL(s) / DMEL(s)

5.12.1 Overview of typical dose descriptors for all endpoints

For the derivation of the derived no effect levels (DNEL(s)), the occupational exposure limits have been established for soluble (i.e., represented by zinc chloride) as well as slightly soluble/insoluble zinc compounds (i.e., represented by zinc oxide) to manage workers risk in operations where zinc exposure might occur. The human health endpoints that have been identified to be of importance for the various zinc compounds were:

- Acute oral and inhalation toxicity

- Skin and eye irritation
- Repeat dose toxicity humans (i.e., effect at LOAEL: reduced ESOD activity) and animals (i.e., effect at LOAEL: pancreatic damage)

The summarised DNELs have been calculated for worker and consumer exposure to soluble and slightly soluble/insoluble zinc compounds according to the ECHA guidance methodology.

5.12.2 Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptor for critical health effects

The DNEL's for workers and consumers following oral or dermal exposure to soluble and slightly soluble/insoluble compounds are as follows:

- **Oral**

DNELoral sol Zn = 50 mg Zn/day (i.e., 0.83 mg Zn/kg bw/day);
DNELoral insol Zn = 50 mg Zn/day (i.e., 0.83 mg Zn/kg bw/day);

- **Dermal**

DNELdermal sol Zn = 500 mg Zn/day (i.e., 8.3 mg Zn/kg bw/day);
DNELdermal insol Zn = 5000 mg Zn/day (i.e., 83 mg Zn/kg bw/day);

A detailed scientific justification for the OELs is not available, the existing values OELs have ensured workers safety for decades which correlates with the DNELs derived from the human volunteer studies.
Considering a conservative approach it is proposed that for inhalation exposure to soluble and slightly soluble/ insoluble zinc compounds, the existing OEL values are used as the respective DNEL against which to judge the adequacy of workplace risk management measures (RMM) to control airborne exposure to zinc compounds:
Two approaches were used in establishing the critical DNELs for inhalatory exposure of workers or consumers to zinc compounds:

1. Based on existing oral human dietary supplement studies
2. Worker exposure using existing OELs.

Detailed scientific studies for the OELs are not available. However, the values below which correlates with the DNELs derived from the human volunteer studies have ensured workers safety in the meanwhile.

- Inhalation - Worker

DNELinhal soluble Zn (worker) = 1 mg Zn/m^3;
DNELinhal insoluble Zn (worker) = 5 mg Zn/m^3;

- Inhalation - Consumer

DNELinhal soluble Zn (consumer) = 1.3 mg Zn/m^3;
DNELinhal insoluble Zn (consumer) = 2.5 mg Zn/m^3;

The above values are considered adequate within RMMs part.

5.13 Conclusions of the human health hazard assessment and related classification and labelling

No reason for classification.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO CHEMICAL PROPERTIES

Not relevant for this evaluation.

7 ENVIRONMENTAL HAZARD ASSESSMENT

7.1 Aquatic compartment (including sediment)

7.1.1 Toxicity data

The **short-term acute aquatic** toxicity database for zinc includes 10 species (1 algae, 4 invertebrates and 5 fish species) and a significant number of data are presented at both low and neutral/high pH.

As a rule, algae are not tested under standardised conditions at low pH. Chronic algae *Selenastrum capricornutum* data (72 hrs NOECs) revealed that the sensitivity of algae is much lower at lower pH. Fish toxicity at low pH is also not critical in this respect. The values for the daphnids are representative for the sensitivity of organisms to zinc at low pH, therefore the lowest value observed for *Ceriodaphnia dubia* was used for the classification at low pH.

At neutral/high pH, the value obtained on the algae *Selenastrum capricornutum* was the lowest of the dataset and was taken as reference value for classification at this pH.

The reference values for the Zn^{2+}ion that were used for the acute aquatic toxicity hazard assessment of Zn^{2+} were:

- for low pH: 0.413 mg Zn/l (based on single lowest value for *Ceriodaphnia dubia*)
- for the neutral/high pH: 0.136 mg Zn/l (based on single lowest value for *Selenastrum capricornutum* (=*Pseudokircherniella subcapitata*).

Aquatic chronic toxicity: freshwater

The 23 distinct chronic species ecotoxicity values have been used for the statistics on the species sensitivity distribution (SSD) for deriving the 5th percentile values. The "species mean" NOEC values used for PNEC derivation (freshwater $PNEC_{add, aquatic}$) range from 19 to 530 µg /l.

Given the multitude of relevant high quality data, statistical extrapolation was used to determine the freshwater PNEC. Additional to the RAR, 6 species were added, including a taxonomic group. The following results were obtained:
- for algae, the NOEC of the BLM (Biotic Ligand Model) - species *Pseudokircherniella subcapitata* was the lowest of the SSD at pH 8 (19 µg /l) - to a water of pH 8.0, hardness 24 mg $CaCO_3$ and DOC 2.0 mg/l. With the BLM, a corresponding species NOEC of 142 µg/l was calculated for this species at pH 6 (other water conditions same).
- for invertebrates, the BLM - species *Daphnia magna* gives a species mean at pH 8 of 98 µg/l, corresponding to a water of pH 8, hardness 24 mg $CaCO_3$/l and DOC 1,2 mg/l. The *Daphnia magna* - BLM predicts at pH 6 (other water conditions same) a species NOEC of 82 µg/l.
- for *Oncorhynchus mykiss*, the species mean at pH 8 is 146 µg /l (hardness 45 mg/l, DOC 2 mg/l). Using the corresponding species BLM gives a species NOEC of 146 µg /l at pH 6 (other conditions same).

Using these data, the following reference values for chronic zinc aquatic toxicity were derived:
-at pH 8.0: 19 µg Zn/l (*Pseudokircherniella subcapitata*)
-at pH 6.0: 82µg Zn/l (*Daphnia magna*).

The above values support environmental classification such as chronically effect cat.1.

Aquatic chronic toxicity: marine waters

Statistical extrapolation was used to derive the marine PNEC. The 39 species mean NOECs values from 9 taxonomic groups (tests with reliability "1" and "2"-most) were used. The 5th percentile value of the SSD results in a value of 6.09 µg Zn_{added}/l.
The NOAEC resulting from a marine mesocosm study was 12 µg Zn/l.

7.1.1.1 Fish

7.1.1.1.1 Short-term toxicity to fish

Five key studies with reliability “2” were provided for species: *Thymallus arcticus, Oncorhynchus kisutch, Cottus bairdii, Oncorhynchus mykiss* and *Pimephales promelas.* Tests were done according to standard protocol or equivalent.

Data were grouped per species according to pH and hardness: low/medium (<100mg $CaCO_3$/l) and medium/high (>100 mg $CaCO_3$/l).
Fish are generally less sensitive than invertebrates and algae.

The following information was taken into account for acute fish toxicity for the derivation of PNEC**:**
-for *Oncorrhynchus mykiss*: LC_{50} =0.169 mg Zn/l (single value) at neutral/high pH and low hardness;
-for *Pimephales promelas* (single values): LC_{50} =0.780 mg Zn/l at low pH (high hardness) and 0.330 mg Zn/l at neutral/high pH, high hardness;
-for *Pimephales promelas*: LC_{50}=0.780 mg Zn/l (at low pH); 0.33mg Zn/l at neutral/high pH.

The above values support environmental classification such as chronically effect cat.1.

7.1.1.1.2 Long-term toxicity to fish

Nine key studies with reliability “1” and “2” were provided for freshwater fish species, part of 4 families: Cyprinodontidae (*Jordanella*), Cyprinidae (*Phoxinus*, *Pimephales*), Salmonidae (*Oncorrhynchus*, *Salvelinus*, *Salmo trutta*) and Cottidae (*Cottus*). Tests were done according to OECD Guideline or equivalent.

Two key studies with reliability “2” were provided for saltwater species comes from the family Clupeidae (*Clupea harengus*). The fish species NOEC is combined with the other marine chronic data in the SSD to give the HC5 from which the PNEC saltwater is derived.

The following information was taken into account for long-term fish toxicity for the derivation of PNEC:
- Freshwater: NOECs range between 0.044 and 0.530 mg Zn/l (dissolved concentrations)
- Marine: NOEC = 0.025 mg Zn/l (dissolved concentrations)

7.1.1.2 Aquatic invertebrates

7.1.1.2.1 Short-term toxicity to aquatic invertebrates

Nineteen key studies with reliability “1” and “2” were provided for seven species: *Daphnia magna*, *Daphnia pulex, Daphnia carinata*, *Ceriodaphnia dubia*, *Ceriodaphnia reticulate*, *Tetrahymena thermophila* and *Thamnocephalus platyurus.* Tests were done according to OECD Guideline or equivalent.
Ceriodaphnia dubia was for all test conditions the most sensitive species.

Data were grouped per species according to:
- pH: low (6 -7) - neutral/high (7 - 8.5)
- hardness: low/medium (<100mg $CaCO_3$/l) and medium/high (>100 mg $CaCO_3$/l).

The following information was taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC (lowest LC_{50}):

-for *Ceriodapnia dubia*: 0.413 mg Zn/l (single value) at low pH and low hardness;
-for *Ceriodapnia dubia*: >0.53 mg Zn/l (single value) at low pH and high hardness;
-for *Ceriodapnia dubia*: 0.147 mg Zn/l (geomean value) at neutral/high pH and low hardness;
-for *Ceriodapnia dubia*: 0.228 mg Zn/l (geomean value) at neutral/high pH and high hardness.

7.1.1.2.2 Long-term toxicity to aquatic invertebrates

Fifty-six key studies with reliability "1" and "2" were provided for 13 different freshwater invertebrate species and 26 marine invertebrate species. Tests were done according to OECD Guideline or equivalent.

The freshwater species are part of several different taxonomic groups: poriferans (4 species), molluscs (2 species), crustaceans (4 species), rotifers (2 species) and insects (1 species). The sensitivity of these species is equally distributed over the species sensitivity distribution.

The marine species are part of several different taxonomic groups: annelids (4 species), cniderians (1 species), crustaceans (6 species), echinoderms (5 species), molluscs (9 species) and nematods (1 species). The sensitivity of these species is equally distributed over the species sensitivity distribution.

The invertebrate species NOECs are combined with the other freshwater and marine chronic data in the SSD to give the HC5 from which the respective PNECs are derived.

The following information was taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC:

- Freshwater: species NOECs range between 0.037 and 0.400 mg Zn/l (dissolved concentrations);
- Marine: species NOECs range between 0.0056 and 0.9 mg Zn/l (dissolved concentrations).

7.1.1.3 Algae and aquatic plants

Twenty-two key studies with reliability "1" and "2" were provided. Tests were performed according to OECD Guideline or equivalent.
<u>Acute freshwater toxicity</u> - information is on 1 species which is in both the acute and chronic aquatic database on zinc the most sensitive. The lowest IC50 value is taken as reference value for classification for acute effect at neutral/high pH.
<u>Chronic freshwater toxicity</u> - data on 2 species, one of which is the most sensitive of all freshwater organisms, second species is less sensitive.
<u>Chronic seawater toxicity</u> – data on 12 species, for which 3 species are in low part of the species sensitivity distribution; one species of macro-algae is the second most sensitive of all seawater organisms.

The following information was taken into account for effects on algae/cyanobacteria for the derivation of PNEC:

- acute toxicity to freshwater algae: lowest IC50 0.136 mg Zn/l (*Selenastrum capricornutum*; single value) (neutral/high pH);
- chronic toxictiy to freshwater algae: lowest NOEC 0.019 mg Zn/l (*Pseudokircherniella subcapitata =Selenastrum capricornutum*; geomean of 27 data);
- chronic toxicity to marine algae: species NOECs range between 0.0078 and 0.67 mg/l (dissolved concentrations).

The above values justify trizinc bis(ortophosphate) chronic category 1 classification according to CLP.

7.1.1.4 Sediment organisms

Nine key studies with reliability "1" were provided for 7 freshwater sediment species. Tests were performed according to standard protocol or equivalent. Two long-term field colonization studies are available for freshwater sediments.

Two key studies with reliability "1" and "2" were provided for 2 marine sediment species. Tests were performed according to standard protocol or equivalent. No field studies were found for marine sediments.

The following information was taken into account for sediment toxicity for the derivation of PNEC:

- freshwater: species mean NOECs used for PNEC derivation range from 201 to 1135 mg/kg dw. The species mean NOEC added range between 146 to 1101 mg/kg dw (after correction for background);
- freshwater sediments (field studies): overall NOECecosystem of 725 mg/kg dw added zinc (Liber et al., 1996; Burton et al., 2005) have observed minor effects on species richness and macroinvertebrate density at concentration of 119 mg/kg dw added zinc;
- marine water: NOEC reproduction of 730 mg/kg dw (amphipod *Melita plumulosa)* and NOEC emergence of 250 mg/kg dw (mangrove *Avicennia marina)*. After background correction, the NOEC values have become 490 mg/kg dw and 207.1 mg/kg dw for *M. plumulosa* and *A. marina*, respectively.

7.1.1.5 Other aquatic organisms

The EU risk assessment on zinc (ECB 2008) used one chronic NOEC on *Cladophora glomerata* in the PNEC database. Additional information on long term experiments on 4 higher aquatic plant species was used as supportive evidence, demonstrating the low sensitivity of this taxonomic group.

The following information was taken into account for effects on aquatic plants other than algae for the derivation of PNEC:

- chronic NOEC for one multicellular algae species available (0.06mg Zn/l);
- chronic NOEC >650µg Zn/l on all 4 higher aquatic plant species tested.

NOEC for one multicellular algae species available demonstrated the chronic effect cat.1

7.1.2 Calculation of Predicted No Effect Concentration (PNEC)

7.1.2.1 PNEC water

All PNECs were expressed as "added" concentration to the background.

The registrant calculated the freshwater and marine PNECs by means of statistical extrapolation, using available chronic NOEC values as input. The database was sufficiently large and answers the basic requirements to use an SSD.

The freshwater PNEC was set at the level of the HC5 resulting in a PNECadd value of 20.6 µg (dissolved) zinc/l. Evidence does not support assessment factor >1.

The marine PNEC was set at the level of the HC5 resulting in a PNECadd value of 6.1 µg (dissolved) zinc/l. Evidence does not support assessment factor >1.

7.1.2.2 PNEC sediment

The registrant calculated the freshwater $PNEC_{add}$, sediment for zinc by means of statistical extrapolation, using available chronic benthic NOEC values as input. The database was sufficiently large and answers the basic requirements to use an SSD.

The PNEC sediment (freshwater) was set at the level of the HC5 resulting in a PNECadd value of 117.8 mg/kg sediment dw. Evidence does not support assessment factor >1.

The PNEC sediment (marine water) was calculated using partition coefficient method resulting a PNECadd value of 56.5 mg/kg sediment dw. Evidence does not support assessment factor >1.

7.2 Terrestrial compartment

7.2.1 Toxicity test results

7.2.1.1 Toxicity to soil macro organisms

Not relevant for this evaluation.

7.2.1.2 Toxicity to terrestrial plants

Not relevant for this evaluation.

7.2.1.3 Toxicity to soil micro-organisms

Not relevant for this evaluation.

7.2.1.4 Toxicity to other terrestrial organisms

Not relevant for this evaluation.

7.2.2 Calculation of Predicted No Effect Concentration (PNEC soil)

Not relevant for this evaluation.

7.3 Atmospheric compartment

Not relevant for this evaluation.

7.4 Endocrine disrupting properties

Not relevant for this evaluation.

7.5 Microbiological activity in sewage treatment systems

7.5.1 Toxicity to aquatic micro-organisms

Not relevant for this evaluation.

7.5.2 PNEC for sewage treatment plant

Not relevant for this evaluation.

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

7.6.1 Toxicity to birds

Not relevant for this evaluation.

7.6.2 Toxicity to mammals

Not relevant for this evaluation.

7.6.3 Calculation of PNECoral (secondary poisoning)

Not relevant for this evaluation.

7.7 Conclusion on the environmental hazard assessment and on classification and labelling

7.7.1. Classification under Annex I dangerous substances directive 67/548/EEC

Trizinc bis(orthophosphate) was classified N; R50-53 (Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment) according to Directive 67/548/EEC (ECB 2008).

7.7.2. Classification under 2nd Adaptation to Technical Progress (ATP) to the CLP Regulation (2nd ATP CLP)

Taking into consideration ecotoxicological data for algae, invertebrates and fish the harmonised classification as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410), according to CLP Regulation is confirmed.

Short-term toxicity data:
- low pH: EC50=0.413 mg Zn/l (based on single lowest value for *Ceriodaphnia dubia*)
- the neutral/high pH: EC50=0.136 mg Zn/l (based on single lowest value for *Selenastrum capricornutum* (=*Pseudokircherniella subcapitata*)
- the molecular weight ratio of trizinc bis(orthophosphate) versus the Zn^{2+}ion (136 x MW $(Zn_3(PO_4)_2$ / MW (Zn) =136 x 385/65 = 806µg substance /l at pH 8 as worst case).

The M-Factor for the acute aquatic effect of trizinc bis(orthophosphate) is 1.

Long-term toxicity data:
- pH 8.0: NOEC=19 µg Zn/l (*Pseudokircherniella subcapitata*)
- pH 6.0: NOEC=82µg Zn/l (*Daphnia magna*).

No M-factors are specified for trizinc bis(orthophosphate) in the current harmonised classification (Annex VI entry of CLP). However, based on the data presented above, the evaluating MSCA is of the opinion that the M-factor for chronic aquatic effect of trizinc bis(orthophosphate) should be M=10, referring to the lowest chronic aquatic ecotoxicity value (NOEC) observed for the algae Pseudokircherniella subcapitata (19µg Zn/l) at neutral pH

8 PBT AND VPVB ASSESSMENT

8.1 Assessment of PBT/vPvB properties – Comparison with the criteria of Annex XIII

8.1.1 Persistence assessment

Not relevant for this evaluation.

8.1.2 Bioaccumulation assessment

Not relevant for this evaluation.

8.1.3 Toxicity assessment

Not relevant for this evaluation.

8.1.4 Summary and overall conclusions on PBT and vPvB Properties

Not relevant for this evaluation.

9 EXPOSURE ASSESSMENT

Approach of exposure assessment

It was assumed that the individual zinc compounds are all transformed into ionic species. Another assumption was that all emissions are diffuse.
For the exposure assessment at local scale, data reported in the EU Risk Assessment (ECB RAR, 2008), were used and, where appropriate, they were completed with data reported by the companies and other updates.
Several generic exposure scenarios (GES) were developed for each use, based on similarity of processes. In general, measured data were used for exposure assessment. For the scenarios where no measured data were available, exposure models were used.
For the assessment of occupational exposure related to the places/processes where workers are involved in, exposure assessment was done using the worst case approach (full shift exposure with highest potential at the workplace).
Environmental exposure at local level is integrating the total emissions of a given site, considering it as a whole.
Consumer exposure assessment was done following the EU risk assessment (ECB RAR, 2008), combining the exposures from the use of different zinc containing articles. Due to the integrated approach, the consumer scenario is relevant for all zinc substances.
The regional exposure assessment included the industrial and diffuse emissions of all zinc compounds (overall assessment, according to the EU risk assessment). However, the exposure assessment was extended from EU-15 to EU-27 and updated. The regional assessment is relevant to all zinc substances. The calculated regional PECadd values to which the natural background concentrations have been added were compared to monitoring data for regional zinc concentrations.

The generic exposure scenarios (GES) developed by Registrant(s) for trizinc bis(orthophosphate) are summarised in table below:

Local exposure scenarios

$GES_{Zn3(PO4)2}$ 0	**Industrial use of primary or secondary zinc bearing material in the manufacture of $Zn_3(PO4)_2$ in several process steps, collection of the substance produced and packaging** (Sector: Production Use: Manufacture of substance)	**environmental exposure**
		worker exposure
$GES_{Zn3(PO4)2}$ 1	**Industrial use of $Zn_3(PO4)_2$ in the formulation of preparations by mixing thoroughly, dry or in a solvent, the starting materials with potentially pressing, pelletising, sintering, possibly followed by packing .** (Sector: Formulation Use: Formulation)	**environmental exposure**
		worker exposure
$GES_{Zn3(PO4)2}$ 2	**Industrial use of $Zn_3(PO4)_2$ or $Zn_3(PO4)_2$-formulations in the manufacturing of other inorganic or organic zinc substances through different process routes, with potentially drying, calcining and packaging.** (Sector: 1st tier application Use: manufacture of other zinc compounds)	**environmental exposure**
		worker exposure
$GES_{Zn3(PO4)2}$ 3	**Industrial and professional use of $Zn_3(PO4)_2$ as active laboratory reagent in aqeous or organic media, for analysis or synthesis.** (Sector: 1st tier application Use: Laboratory reagent)	**environmental exposure**
		worker exposure
$GES_{Zn3(PO4)2}$ 4	**Industrial use of $Zn_3(PO4)_2$ or $Zn_3(PO4)_2$ -formulations as component for the manufacture of solid blends and matrices for further downstream use.** (Sector: 1st tier application Use: Component for solid blends and matrices)	**environmental exposure**
		worker exposure
$GES_{Zn3(PO4)2}$ 5	**Industrial use of $Zn_3(PO4)_2$ or $Zn_3(PO4)_2$-formulations as component for the manufacture of dispersions, pastes or other viscous or polymerized matrices.** (Sector: 1st tier application Use: Component for production of dispersions, pastes and other viscous matrices)	**environmental exposure**
		worker exposure
$GES_{Zn3(PO4)2}$ 6	**Industrial and professional use of solid substrates containing less than 25%w/w of $Zn_3(PO_4)_2$.**	**environmental exposure**

	(Sector: 2nd tier application Use: downstream use containing solid preparations)	**worker exposure**
$GES_{Zn3(PO4)2}$ 7	**Industrial and professional use of dispersions, pastes and polymerised substrates containing less than 25%w/w of $Zn_3(PO_4)_2$** (Sector: 2nd tier application Use: downstream use containing liquid and pasty preparations)	**environmental exposure**
		worker exposure

9.1. Human Health

9.1.1. Exposure assessment for worker

According to EU risk assessment, no occupational limit values for zinc phosphate have been established.
As presented in the RA for $Zn_3(PO_4)_2$, the main uses of the zinc phosphate are:
- Production of zinc phosphate,
- Production of paint,
- Use of paint.

However, the registrant has provided assessment of occupational exposure to zinc phosphate to more uses, providing relevant data and also recent data on specific exposure (measured and modelled).

9.1.1.1. Overview of uses and exposure scenarios

Each exposure scenario developed for zinc phosphate and presented above has addressed the worker exposure contributing scenario.

Assumptions, calculations and estimations of the exposure scenarios done by the Registrant (s) are appropriate.

Based on the data from the risk assessment and additional recent measured data for GES 0, GES 1, GES 2, GES 4 and GES 5, there is no risk predicted for workers for these scenarios if the risk management measures as described in the scenarios are applied.

For GES 3, based on modelling of exposure with MEASE model, no risk is predicted for workers in the laboratory using $Zn_3(PO_4)_2$ and other zinc compounds, following the risk management measures as described.

Based on modelling of exposure, no risk is predicted indoor for workers/professional users, for the majority of the PROC codes (4, 5, 6, 8a, 8b, 9, 10, 13, 14, 21, 22, 24) of this scenario, following the risk management measures indicated. For the PROCs 7, 11, 19, 26 however, respiratory protection (e.g. with P1 mask) can be considered for given time periods.
Outdoors, no risk is predicted for the PROCs 4, 5, 6, 8a, 8b, 9, 10, 13, 14, 19, 21, 22, 24. For PROCs 11 and 26, respiratory protection is recommended when exposure exceeds 1 hr.

Based on modelling of exposure, no risk is predicted for workers/professional users indoor for most of the PROC codes of this scenario (4, 5, 8a, 8b, 9, 10, 13, 19), following the risk management measures indicated. For PROCs 7,11 some form of respiratory protection may be considered as exposure is predicted to be somewhat higher (yet no risk situation predicted).
Outdoors, no risk is predicted for the PROCs 4, 5, 8a, 8b, 9, 10, 13, 19. For PROC 11, respiratory protection is needed when exposure time exceeds 1 hr.

9.1.1.2. Scope and type of exposure

It is assumed that oral exposure is prevented by the hygienic measures. Thus, risk characterisation for workers is limited to dermal and inhalation routes of exposure.
Furthermore, it is assumed that zinc cation is the determining factor for systemic toxicity.
Also, it is assumed that all zinc compounds (including metallic zinc) are changed into the ionic species and all toxicity data were used and expressed as the zinc cation.

Hazard assessment section	Target group	Route of exposure	Type of effect	Potential effect
Human Health	Worker	Inhalation	Acute and chronic, local and systemic	no
		Dermal		no
		Eyes		no

9.1.1.2.1. Monitoring data

In scenarios **$GES_{Zn3(PO4)2}$ 0, $GES_{Zn3(PO4)2}$ 1, $GES_{Zn3(PO4)2}$ 2, $GES_{Zn3(PO4)2}$ 4 and $GES_{Zn3(PO4)2}$ 5** worker exposure was assessed using measured data.

9.1.1.2.2. Modelled data

In scenarios **$GES_{Zn3\ (PO4)2}$ 3, $GES_{Zn3\ (PO4)2}$ 6 and $GES_{Zn3\ (PO4)2}$ 7** worker exposure was assessed using the MEASE model.

9.1.1.2.3. Comparison of monitoring and modelled data

Not relevant for this evaluation.

9.1.2. Exposure assessment for consumer

9.1.2.1. Overview of uses and exposure scenarios

$Zn_3\ (PO_4)_2$ can be used in several consumer products: in paint (also anti-corrosive paints), lacquers and varnishes, corrosion inhibitors, fillers, and surface treatment. In these products the percentage of zinc phosphate is maximum 20%.

In the CSR, the registrant has presented the consumer exposure analysis of RA (ECB 2008), with possible uses and exposure assumptions for the consumer (paint, cosmetics, drugstore products).

9.1.2.2. Scope and type of exposure

The Registrant (s) has taken into account to the risk characterisation the specific exposure estimates of the different zinc compounds. The cumulative uptake resulted to be 1.6 mg Zn^{2+}/d and this value was also taken across to the risk characterisation.

9.1.2.2.1. Monitoring data

Not relevant for this evaluation.

9.1.2.2.2. Modelled data

Not relevant for this evaluation.

9.1.2.2.3. Comparison of monitoring and modelled data

Not relevant for this evaluation.

9.2. Environmental exposure assessment

The local environmental exposure assessment of zinc phosphate, as presented in CSR, is based on the industrial releases of zinc during the following life cycle stages:

1. Production of zinc phosphate
2. Formulation and processing of zinc phosphate in paints

The Registrant(s) presents the exposure estimations based on RA (ECB 2008) and on more recent data which were also included. PEC for water, sediment and soil was calculated for each scenario.

Assessments for GES are done for the site as a whole.

Thus, two scenarios were considered to be analysed by the registrant in environmental exposure assessment:

i. Local exposure

- For the assessment at local scale, several generic exposure scenarios (GES) were developed, relevant for the different identified uses.
- Environmental emissions (especially to water) are usually integrating all emissions from a given site and cannot be distinguished for each process; assessments in GES are done for the site as a whole.

The PECadds that are taken across to the risk characterization (from RA):

- surface water maximum local zinc concentrations (PECadds): 1.23 µg/l and 175 µg/l (total zinc)
- maximum atmospheric zinc concentrations (PECadds): 0.285 µg/m3 and 2.51 µg/m^3.

ii. Regional exposure

- According to RA, regional assessment of environmental exposure as a result of use of zinc containing products was made
- It is assumed that all emissions related to the use of different substances combine in the environment; thus, no substance-specific assessment was made, but overall assessment, combining all emissions from zinc containing products at the same time
- The basis of the analysis were the environmental release factors for different zinc articles discussed in RA
- The registrant extended the assessment from EU-15 to EU-27
- Also, updates of emissions and monitoring data were made.

9.2.1. Aquatic compartment (incl. sediment)

9.2.1.1. Overview of uses and exposure scenarios

Local exposure scenarios

Assumptions, calculations and estimations of the exposure scenarios done by the Registrant(s) are appropriate.

Based on the data from the risk assessment and additional recent data for GES 0, GES 1, GES 2, GES 3, GES 4 and GES 5, there is no risk for water and sediment, if risk management measures are applied.

GES 6 and GES 7 indicate no risk for water and sediments at quantities up to 100 T/y. For more than 100 T/y, a refined assessment should be done and risk management measures should be applied to ensure safe use.

9.2.1.2. Scope and type of exposure

Hazard assessment section	Route of exposure or environmental compartment	Type of effect	Potential effect
Environment	Water (freshwater, marine)	Acute and chronic	yes
	Water sediments (freshwater, marine)	Acute and chronic	yes
	Sewage treatment	Acute and chronic	yes

9.2.1.2.1. Monitoring data

In scenarios **$GES_{Zn3(PO4)2}$ 0, $GES_{Zn3(PO4)2}$ 1, $GES_{Zn3(PO4)2}$ 2, $GES_{Zn3(PO4)2}$ 4** and **$GES_{Zn3(PO4)2}$ 5** water and sediment exposures were assessed using measured data.

9.2.1.2.2. Modelled data

In scenarios **GES$_{Zn3(PO4)2}$ 1, GES$_{Zn3(PO4)2}$ 3, GES$_{Zn3(PO4)2}$ 4, GES$_{Zn3(PO4)2}$ 5, GES$_{Zn3(PO4)2}$ 6** and **GES$_{Zn3(PO4)2}$ 7** water and sediment exposures were assessed using modelling.

9.2.1.2.3. Comparison of monitoring and modelled data

The registrant presents a comparison between measured and calculated regional zinc concentrations, taking into account the natural background concentration added to the calculated values.
For surface water (freshwater and marine water), analysis concludes that modelled data underestimate the measured data. Thus, for risk characterisation, measured data is to be used.
For sediments (freshwater and marine), analysis of the comparison concludes that preference should be given to measured data as well.

9.2.2. Terrestrial compartment

9.2.2.1. Overview of uses and exposure scenarios

Not relevant for this evaluation.

9.2.2.2. Scope and type of exposure

Not relevant for this evaluation.

9.2.2.2.1. Monitoring data

Not relevant for this evaluation.

9.2.2.2.2. Modelled data

Not relevant for this evaluation.

9.2.2.2.3. Comparison of monitoring and modelled data

Not relevant for this evaluation.

9.2.3. Atmospheric compartment

9.2.3.1. Overview of uses and exposure scenarios

Not relevant for this evaluation.

9.2.3.2. Scope and type of exposure

Not relevant for this evaluation.

9.2.3.2.1. Monitoring data

Not relevant for this evaluation.

9.2.3.2.2. Modelled data

Not relevant for this evaluation.

9.2.3.2.3. Comparison of monitoring and modelled data

Not relevant for this evaluation.

9.3. Combined exposure assessment

Not relevant for this evaluation.

10 RISK CHARACTERISATION

10.1. Human Health

10.1.1. Workers

Risk characterisation for workers is limited to dermal and inhalation routes of exposure.

The eMSCA concludes that since for all GESs the Risk Characterisation Ratio is less than “1” (for some of them lower than “0.05”), the risk for workers is characterised as acceptable for all types of use of trizinc bis(orthophosphate).

10.1.2. Consumers

No separate assessment for consumer exposure by each local exposure scenario was made, but indirect exposures were combined in an integrated scenario.

The eMSCA concludes that the risk characterisation ratios are below 0.5 and that there is no concern for consumers, neither for zinc phosphate nor for regularly used zinc compounds taken together.

10.1.3. Indirect exposure of humans via the environment

Not relevant for this evaluation.

10.2. Environment

10.2.1. Risk characterisation for PBT

Not relevant for this evaluation.

10.2.2. Aquatic compartment (incl. sediment)

Not relevant for this evaluation.

10.2.3. Terrestrial compartment

Not relevant for this evaluation.

10.2.4. Atmospheric compartment

Not relevant for this evaluation.

10.2.5. Microbiological activity in sewage treatment systems

Not relevant for this evaluation.

10.3. Overall risk characterisation

10.3.1. Human health (combined for all exposure routes)

Not relevant for this evaluation.

10.3.2. Environment (combined for all exposure routes)

Not relevant for this evaluation.

11. OTHER INFORMATION

Not applicable.

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ABBREVIATIONS

BAF	Bioaccumulation factors
BCF	Bioconcentration factors
BLM	Biotic ligand model
DNA	Deoxyribonucleic acid
DNEL	Derived no effect levels
DNELoral sol Zn	Derived no effect levels - oral for soluble zinc compounds
DNELoral insol	Derived no effect levels - oral for insoluble zinc compounds
DNELdermal sol Zn	Derived no effect levels - dermal for soluble zinc compounds
DNELdermal insol Zn	Derived no effect levels - dermal for insoluble zinc compounds
DNELinhal soluble Zn	Derived no effect levels - inhalation for soluble zinc compounds
DNELinhal insoluble Zn	Derived no effect levels - inhalation for insoluble zinc compounds
DOC	Dissolved Organic Carbon
EASE	Estimation and assessment of substance exposure
EDTA	Ethylenediaminetetraacetic acid
ESOD	Erythrocyte superoxide dismutase
EUSES 2.0	European Union System for the Evaluation of Substances 2.0
GSD	Geometric Standard Deviation
HC5	The 5^{th} percentile value
Kp	Partition coefficient for the distribution between different fractions
Kpsusp	Kp for solid particulate matter and water
Kp_{sed}	Kp for the distribution between sediment and water
LOAEL	Lowest-observed-adverse-effect level
LC_{50}	Lethal Concentration
LD_{50}	Lethal Dose, 50% or median lethal dose
M	Factor for acute / chronic aquatic effect o
MMAD	Mass Median Aerodynamic Diameter
NOAEL	No observed adverse effect level
OEL	Occupational exposure limit
PEC_{add}	Added Predicted Environmental Concentrations
$PNEC_{add}$	Added Predicted No Effect Concentrations
PNEC-STP	Predicted No-Effect Concentrations for micro organisms in sewage treatment plants
RAR (ECB 2008).	EU risk assessment on zinc
RMMs	Risk Management Measures
SCE	sister chromatide exchange
SSD	sensitivity distribution
TGD.	Technical Guidance Document

ANNEX: CONFIDENTIAL INFORMATION