

Reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate

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NOTICE : Important information

Please note that this generic exposure scenario is by no means intended to be mandatory, prescriptive or exhaustive. The content of this document is intended for guidance only and whilst the information on uses covered is provided in utmost good faith and has been based on the best information currently available, is to be relied upon at the user's own risk. Ultimately, it is for each company to assess the appropriateness and completeness of the information on a case-by case basis and decide what elements they wish to adopt or to add. In particular, the preparation and content of the e-SDS is the legal responsibility of each company for its own products placed on the market, and the user should verify, complete, correct or adapt this generic document appropriately.

No representations or warranties are made with regards to its completeness or accuracy, in particular regarding the list of uses that are covered, and no liability will be accepted by [the consortium members] for damages of any nature whatsoever resulting from the use of or

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reliance on the information.

The consortium members acknowledge that any activities carried out under REACH have to be carried out in full compliance with EU competition law, in particular but not limited to Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) as well as any applicable national laws.

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier:

Reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate

List Number: 914-172-8

REACH Registration number: [to insert]

Other identifiers: reaction mass of MCP and DCP

1.2 Relevant identified uses of the substance or mixture and uses advised against:

Industrial / professional uses:

- Manufacture of reaction mass of MCP and DCP (exposure scenario 1)
- Formulation of solid and liquid fertilisers (exposure scenario 2)
- Fertiliser use (exposure scenario 3)

Consumer uses:

- Fertiliser use (exposure scenario 3)

No known uses advised against.

1.3 Details of the supplier of the safety data sheet:

[Insert relevant details including contact name, address, phone number, email here]

1.4 Emergency telephone number:

[Insert suitable emergency number and hours of operation]

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SECTION 2. Hazards identification

2.1 Classification of the substance

2.1.1 According to Regulation (EC) No. 1272/2008 (EU CLP):

Eye Damage 1 H318: Causes serious eye damage

2.2 Label elements

2.2.1 According to Regulation (EC) No. 1272/2008 (EU CLP):

Name: reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate

List Number: 914-172-8



Signal word: Danger

Hazard Statements:

H318: Causes serious eye damage

Precautionary Statements:

Prevention:

P280: Wear protective gloves, eye protection and face protection.

Response:

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310: IF IN EYES: Immediately call a POISON CENTER or doctor/physician

NOTE: Information in Section 2.2 MUST be consistent with the information provided on the supplier's labels.

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2.3 Other hazards

The material is not considered to be PBT or vPvB.

SECTION 3. Composition / information on ingredients

3.1 Substance:

Name	EC Number	CAS Number	Typical concentration	Concentration Range
calcium hydrogenorthophosphate	231-826-1	7757-93-9	27% w/w	$>10 \leq 40\%$ w/w
calcium bis(dihydrogenorthophosphate)	231-837-1	7758-23-8	55% w/w	$>40 \leq 75\%$ w/w

Registration Number (if available): 01-2119686864-19-0000

Identification of hazardous impurities (where applicable):

The substance may contain the following impurities derived from the production process and present in the concentrations expressed:

- tricalcium bis(orthophosphate) (EC No. 231 -840 -8): <10%
- orthophosphoric acid (EC No. 231 -633 -2): <5%

Additional impurities present at >1% are other inorganic phosphates or other related inorganic substances, similar to the registered substance, and which do not significantly affect its toxicological and ecotoxicological properties (<10% in total). There are no hazardous impurities present within the substance at levels >1%.

NOTE: The above information on impurities is company specific therefore suppliers to update where necessary and in line with the data that is provided in their joint registration dossier Section 1.2.

SECTION 4. First aid measures

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4.1 Description of first aid measures

Inhalation

In case of exposure by inhalation, remove the casualty to fresh air, rest and seek medical advice.

Ingestion

Rinse mouth out and drink plenty of water (approx. 500 ml). In case of persistent symptoms or discomfort consult a doctor.

Skin Contact

In case of contact with skin, rinse with water for at least 10 to 15 minutes or until the chemical is removed. Remove contaminated clothing.

Eye Contact

Rinse cautiously with water for at least 10 to 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.

4.2 Most important symptoms and effects, both acute and delayed

The reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate causes serious damage to the eyes. No delayed effects are noted.

4.3 Indication of any immediate medical attention and special treatment needed

After eye contact rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.

SECTION 5. Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing media:

The reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate is not flammable. Use fire-fighting measures that suit the environment; CO₂, extinguishing powder or water spray. The first choice is a water spray.

Inappropriate extinguishing media:

Not applicable.

5.2 Special hazards arising from the substance or mixture

The release of phosphoric acid.

5.3 Advice for fire-fighters

Wear appropriate skin and eye protection. See Section 8.2.

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bis(dihydrogenorthophosphate) and calcium
hydrogenorthophosphate****SECTION 6. Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Avoid contact with eyes; always use personal protection equipment. Avoid causing dust. Ventilate if in enclosed area. Prevent public access prior to cleaning.

6.2 Environmental precautions

Do not allow concentrated solutions to enter drainage system, surface or ground water.

6.3 Methods and material for containment and cleaning up

Collect product mechanically. Dispose of contaminated material according to the waste disposal recommendations. Clean with water. Avoid sweeping to reduce dust.

6.4 Reference to other sections

Refer to Section 8 for suitable PPE.
Refer to Section 13 for disposal considerations.

SECTION 7. Handling and storage**7.1 Precautions for safe handling**

Technical measures: sufficient ventilation and local suction is required in accordance with the details in the annex to the SDS. Do not eat, smoke or drink. Do not handle damaged sacks. Clean work areas well to avoid dust. Clean clothes and equipment with a vacuum.

7.2 Conditions for safe storage, including any incompatibilities

The reaction mass does not require specific storage measures. No incompatible materials identified.

7.3 Specific end use(s)

See annex for details of end uses covered in the exposure scenarios and CSR. The exposure scenarios detailed in the annex represent a worst case for exposure to humans and the environment.

SECTION 8. Exposure controls / personal protection**8.1 Control parameters**

Workplace exposure limits:
General dust exposure limit, German TRGS 900 (2006) 20 mg/m³.

[please check occupational limits for the country you supply to and insert limit here if available]

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DNELS (worker):

Exposure route	Exposure pattern	DNEL (workers)
Inhalation	Acute systemic effects	As no acute toxicity hazard has identified, there is no requirement to derive acute DNELs. Therefore only long term DNELs have been derived.
	Long term systemic	4.07 mg/m ³
Dermal	Acute systemic effects	As no acute toxicity hazard has identified, there is no requirement to derive acute DNELs. Therefore only long term DNELs have been derived.
	Long term systemic	As the substance to be registered is an inorganic solid, absorption through the skin is not an appropriate route of exposure. Dermal exposure will not result in systemic toxicity and therefore it is not considered to be appropriate to calculate a dermal DNEL.

No DNELs can be derived for local effects as no dose-response relationship can be identified in any of the studies available.

DNELs (general population):

Exposure route	Exposure pattern	DNEL (general population)
Inhalation	Acute systemic effects	As no acute toxicity hazard has identified, there is no requirement to derive acute DNELs. Therefore only long term DNELs have been derived.
	Long term systemic	3.04 mg/m ³
Oral	Acute systemic effects	As no acute toxicity hazard has identified, there is no requirement to derive acute DNELs. Therefore only long term DNELs have been derived.
	Long term systemic	Consumer uses of inorganic phosphates (with Na ⁺ , K ⁺ , Ca ²⁺ , Mg ²⁺ and Al ³⁺ cations), besides food and water, do not contribute noticeably to the oral intake of phosphates. Oral intake is predominately via food and water in the form of food additives or similar or from natural sources. It is therefore considered appropriate to use the Maximum tolerable daily intake (MTDI) value of 70 mg/kg bw /day of phosphorus as calculated by the Joint FAO/WHO Expert Committee on Food Additives (JEFCA) as any toxicity effects noted via the oral route are not attributable to the cation but are as a result of high doses of phosphates

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Dermal	Acute systemic effects	As no acute toxicity hazard has identified, there is no requirement to derive acute DNELs. Therefore only long term DNELs have been derived.
	Long term systemic	As the substance to be registered is an inorganic solid, absorption through the skin is not an appropriate route of exposure. Dermal exposure will not result in systemic toxicity and therefore it is not considered to be appropriate to calculate a dermal DNEL.

No DNEL can be derived for local effects as no dose-response relationship can be identified in any of the studies available.

PNECs:

Compartment	Remarks
PNEC aqua (freshwater)	In order to fulfil the requirements of Regulation (EC) No. 1907/2006 (REACH) PNEC values have been calculated (see Registration dossier). These values are not considered to be scientifically meaningful as calcium, magnesium, and phosphate are essential nutrients present as dissolved ions in the natural environment (please refer to data on hydrolysis) in quantities greater than the derived PNEC (Concentrations are expected to vary according to location). The available aquatic toxicity studies have demonstrated that these ions are not toxic to aquatic organisms at the limit concentrations suitable for these tests. Therefore there is sufficient weight of evidence for the absence of dangerous properties of the substance. Further testing for determination of aquatic toxicity parameters is not scientifically justified and therefore, in accordance with Annex 11 (1.2) and Annex 11 (3.3.2) of Regulation No. 1907/2006, derivation of a PNEC is not appropriate. As such the calculations are only intended to be illustrative of the hypothetical worst case, and are not representative of the realistic risks to the environment, and as such should not be used in a risk characterisation under REACH. In addition, as prescribed by the guidance on information requirements and chemical safety assessment, Chapter R.10: characterisation of dose[concentration]-response for the environment, appropriate assessment factors are required to calculate the PNECs; these factors are considered to further distort the final value, thus making the PNEC considerably lower than the observed levels in the natural environment (meaning that the predicted no effect level is less than a level which occurs naturally without detrimental effect).
PNEC aqua (marine water)	
PNEC aqua (intermittent releases)	
PNEC STP	50 mg/L The PNEC is based on the NOEC from the ASRI study. The assessment factor used takes the use of read-across data into account and uses the assessment factor appropriate for use of a NOEC value. (AF for use of NOEC = 10, AF for use of data on an analogue material = 2. Overall AF = 20)
PNEC sediment	No data is available for freshwater sediments. Na ⁺ , K ⁺ , Mg ²⁺ , Ca ²⁺ and

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(freshwater)	PO ₄ ³⁻ ions are ubiquitous in the environment and are found naturally in soil, water and sediment. All are assimilated by species residing in the sediment, water or soil and are essential for maintaining a good chemical balance. It is therefore unlikely that inorganic phosphates of this nature would be toxic to sediment organisms and hence toxicity studies are scientifically unjustified.
PNEC sediment (marine water)	No data is available for marine sediments. Na ⁺ , K ⁺ , Mg ²⁺ , Ca ²⁺ and PO ₄ ³⁻ ions are ubiquitous in the environment and are found naturally in soil, water and sediment. All are assimilated by species residing in the sediment, water or soil and are essential for maintaining a good chemical balance. It is therefore unlikely that inorganic phosphates of this nature would be toxic to sediment organisms and hence toxicity studies are scientifically unjustified.
PNEC soil	No data is available for soil macroorganisms. Na ⁺ , K ⁺ , Mg ²⁺ , Ca ²⁺ and PO ₄ ³⁻ ions are ubiquitous in the environment and are found naturally in soil, water and sediment. All are assimilated by species residing in the sediment, water or soil and are essential for maintaining a good chemical balance. Furthermore inorganic phosphate fertilizers (containing Na ⁺ , K ⁺ , Mg ²⁺ , Ca ²⁺ and PO ₄ ³⁻ ions) are often added to soils to improve soil quality. Given the extensive use of inorganic phosphates as soil fertilizers and the natural occurrence of the ions in the environment it is unlikely that inorganic phosphates of this nature would have a detrimental effect on soil macroorganisms and plants and hence toxicity studies are scientifically unjustified.
PNEC oral	Inorganic phosphates are not considered to pose a risk of secondary poisoning as they are unlikely to bioaccumulate due to the fact that they are not lipophilic and will therefore not accumulate in fatty tissues. It is not considered necessary to derive a PNEC to take into account the risk of secondary poisoning and no further testing is considered necessary.

8.2 Exposure controls

Appropriate engineering controls: Ensure work area is well ventilated or exhausted (where appropriate and in line with the exposure scenarios). Provide eye wash station.

Respiratory protection: See annex for details of processes requiring respiratory protection. In case of insufficient ventilation, wear suitable respiratory device such as EN141 or EN405, Type A or Dust mask according to DIN EN 140 or 149 (FFP1 or FFP2).

Skin protection: Laboratory coat or overalls and plastic or rubber boots. Store protective clothing separately.

Eye protection: Tightly sealed chemical safety goggles (compliant with EN 166:2001)

Hand protection: In case of spray contact at least protection index 2 recommended, according to more than 30 min. penetration time (EN 374).

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Layer thickness of gloves at least: 0.4 mm.

In case of prolonged and intensive contact protection index 6 recommended, according to more than 480 min. penetration time (EN 374).

Layer thickness of gloves at least: 0.7 mm

Material of gloves:

- Butyl rubber, BR
- Fluorocarbon rubber (Viton)
- Nitrile rubber, NBR
- Natural rubber, NR
- Chloroprene rubber, CR
- Neoprene gloves.

Environmental controls: Refer to Sections 6, 7, 12 and 13 of the SDS.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Property	Value	Method
Appearance; including colour and physical state	Solid, cream granules	Observed
Odour	Odourless	Observed
Odour threshold	Not available	
pH	pH 3.5	As measured in the water solubility study (EU Method A.6)
Melting point/freezing point	>450°C	EU Method A.1
Initial boiling point and boiling range	Not determined	According to Regulation No. 1907/2006, a study for boiling point is not required for solids which melt above 300°C
Flash point	Not determined	According to Regulation No. 1907/2006, the flash point does not need to be assessed for inorganic chemicals.
Evaporation rate	Not available	
Flammability (Solid, gas)	Not flammable	Based on prediction and use based observations
Upper/lower flammability or explosive limits	Not applicable	
Vapour pressure	Not determined	According to Regulation No.

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		1907/2006, a study for the vapour pressure need not be conducted if the melting point is above 300°C.
Vapour density (Air = 1)	Not applicable	
Relative density	2.27 at 20 ± 0.5°C	EU Method A.3
Solubility(ies)	Water: 40.4 g/L at 20 ± 0.5°C (very soluble)	EU Method A.6 Result is expressed as dissolved orthophosphate at a nominal loading rate of 100 g/L
Partition coefficient: N-octanol/water	Not determined	According to Regulation No. 1907/2006, the partition coefficient n-octanol/water does not need to be assessed for inorganic chemicals.
Auto-ignition temperature	No auto-ignition anticipated	Based on prediction
Decomposition temperature	Not applicable	
Viscosity	Not determined	Testing not technically possible: According to the relevant OECD guideline (OECD 114) a study cannot be conducted on a substance that is a solid at room temperature.
Explosive properties	Not considered to be explosive	Prediction – in accordance with EU Method A14
Oxidising properties	No oxidising properties	Prediction – in accordance with EU Method A17

9.2 Other information

Testing has been performed on the reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate, in accordance with Annex X of REACH.

SECTION 10. Stability and reactivity

10.1 Reactivity

Non-reactive under recommended storage and handling conditions.

10.2 Chemical stability

Stable under recommended storage and handling conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions are considered unlikely.

10.4 Conditions to avoid

None identified.

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10.5 Incompatible materials

None identified.

10.6 Hazardous decomposition products

None.

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Toxicological endpoint	Value (including relevance to CLP criteria)	Method
Acute toxicity		
Oral	Oral; LD ₅₀ (rat) = >2000 mg/kg bw/day. Not classified.	Rat, OECD 420. Klimisch reliability 1.
Dermal	LD ₅₀ = 2000 mg/kg bw/day	Weight of evidence approach using available studies on analogous calcium and magnesium orthophosphates.
Inhalation	Not determined	Reaction mass not considered to present an inhalation risk
Skin corrosion/irritation	Not irritating to the skin.	Reconstituted human epidermis model, OECD 431. Klimisch reliability 1
Serious eye/damage/irritation	Serious eye damage – category 1.	Rabbit, OECD 405. Klimisch reliability 1
Respiratory or skin sensitisation	Non- sensitiser	Mouse, OECD 429, EU Method B.42. Klimisch reliability 2 – read across from analogous substance. No data to suggest substance is a respiratory sensitiser.
Germ cell mutagenicity	Not considered to be mutagenic.	The reaction mass is not expected to produce germ cell genotoxic damage.
Carcinogenicity	Not considered to be a carcinogen.	Not required for REACH. No data to suggest likelihood of carcinogenicity.
Reproductive toxicity	Not considered to be a reproductive toxicant	No evidence of reproductive toxicity based on expert assessment of all available relevant data.
STOT-single exposure – all routes	No STOT SE observed via the	Not applicable.

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	oral, dermal or inhalation routes.	
STOT-Repeated exposure - all routes	Not considered to induce specific organ toxicity after repeated exposure via oral route.	Rats and dogs, Variety of sub-acute, sub-chronic data available on calcium bis(dihydrogenorthophosphate) and analogous materials. Key study conducted on sodium aluminium phosphate. The only indication of systemic toxicity observed in the tests performed on sodium aluminium phosphate was nephrocalcinosis observed in the renal tubes. Rats generally and particularly female rats are known to be susceptible to nephrocalcinosis when administered high doses of phosphates (typically starting at about 0.5 – 1.0 % in the diet). The effects are only seen in high dose animals (well above the recommended classification limits for STOT RE as defined in the Guidance on the Application of Regulation (EC) No 1272/2008) and therefore classification for STOT RE is not justified and no classification is proposed.
Aspiration hazard	No aspiration hazard identified	Not applicable.

The substance has been assessed with regards to the data requirements of Annex X of REACH.

SECTION 12. Ecological information

12.1 Toxicity

Toxicological endpoint	Value (including relevance to CLP criteria)	Species, Method
Acute fish toxicity	96 hr LC ₅₀ = > 100 mg/L 96 hr NOEC = 100 mg/L	Rainbow trout, OECD 203, EU Method C.1. Conducted on analogous substance, reliability 2.
Acute <i>Daphnia</i> toxicity	48 hr EC ₅₀ = > 100	<i>Daphnia magna</i> , OECD 202, EU

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	mg/L 48 hr NOEC = >100 mg/L	Method C.2. Conducted on analogous substance, reliability 2.
Algal growth inhibition	72 hr EC ₅₀ = > 100 mg/L 72 hr NOEC = >100 mg/L Basis for effect: growth rate	<i>Desmodesmus subspicatus</i> (algae), OECD 201, EU Method C.3. Conducted on analogous substance, reliability 2.
Activated Sludge Respiration	3 hr EC ₅₀ = > 1000 mg/L 3 hr NOEC = 1000 mg/L	Activated sludge of a predominantly domestic sewage, OECD 209, EU Method C.11, EPA OPPTS 850.6800. Conducted on analogous substance, reliability 2.

The substance has been assessed with regards to the data requirements of Annex X of REACH

12.2 Persistence and degradability

The reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate is an inorganic phosphate, biodegradation studies are not applicable. No further testing is deemed to be necessary.

12.3 Bioaccumulative potential

The reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate is hydrolysed to orthophosphate and calcium ions in aqueous and biological systems. The degradation products of calcium bis(dihydrogenorthophosphate) are essential nutrients (food elements) for plants, and stimulate the growth of water plants (macrophytes) and/or algae (phytoplankton) and are ubiquitous in the environment. The potential for bioaccumulation is therefore considered to be minimal.

12.4 Mobility in soil

No data available:

A batch equilibrium study according to OECD Guideline 106 was deemed to be not applicable to the reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate for the following reasons:

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Firstly, analysis of the test material may not be possible due to interference from the soil extracts that may leach into the aqueous media during the test. This would prevent quantification of the test material.

In addition, the mobility of the test item would be dependent on the anion exchange capacity of the soils as the main component of the test material is an anion. This absorption relationship would not be anticipated to correlate with the organic carbon content of the soils and is considered to be beyond the scope of the OECD 106 method.

12.5 Results of PBT and vPvB assessment

According to the Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT Assessment, the PBT and vPvB criteria of Annex XIII to the regulation do not apply to inorganic substances. Therefore the reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate is not considered to require any further assessment of PBT properties.

12.6 Other adverse effects

No sediment or terrestrial toxicity data exists. Substance is not considered to be hazardous to sediment dwelling or terrestrial organisms. According to the criteria of the European classification and labelling system, the substance does not require classification as hazardous for the environment

SECTION 13. Disposal considerations**13.1 Waste treatment methods**

Disposal recommendations are made based on the material as supplied. Disposal must be in accordance with current applicable laws and regulations.

Disposal of substance: Dispose of in accordance with national and local regulations for special waste via an appropriately licensed waste contractor. Do not discharge to drains or STP.

Disposal of packaging: Empty containers and clean out appropriately before reuse or disposal. Packaging may be recycled if thoroughly cleaned. Packaging that cannot be cleaned should be disposed of according to national and local regulations for special waste via an appropriately licensed waste contractor.

Regulatory disposal information:

European waste codes: Waste producers need to assess the process used when generating the waste and its contaminants in order to assign the most appropriate waste disposal code(s).

Recommended code: European waste catalogue 16 03 03 inorganic wastes containing dangerous substances

SECTION 14. Transport information

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Transport classifications (ADR/RID/IMDG/IATA) are not defined in the REACH Registration Dossier for the substance. The information provided here is therefore not derived from this Dossier and is based on other information available to the Consortium Members. The Transport classifications (ADR/RID/IMDG/IATA) provided here are indicative and based on the data in the REACH dossier for the pure substance only and may not be applicable for solutions or other preparations. Please seek advice from your Dangerous Good Safety Advisor.

According to information available: UN transport classification: Not Classified (for pure substance as solid and solution in water)

14.1 UN number			
	LAND (ADR/RID)	SEA (IMDG)	AIR (IATA)
14.2 UN proper shipping name			
14.3 Transport hazard class(es)			
Labels			
14.4 Packing group			
14.5 Environmental hazards			
14.6 Special precautions for user			
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code			

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SECTION 15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

[COMPANY TO INCLUDE ANY INFORMATION RELEVANT TO THE COUNTRY OF PRODUCT AND/OR SUPPLY]

This safety data sheet is compliant with Regulation (EC) No 1907/2006 (REACH) (including the amendment, Regulation (EU) No 453/2010 and Regulation (EC) No. 1272/2008 (EU CLP).

15.2 Chemical Safety Assessment.

A Chemical Safety Assessment is available for the reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate.

SECTION 16. Other information

This SDS supersedes the SDS dated [TO BE COMPLETED BY COMPANY SUPPLYING SDS]

The following amendments have been made:

- SDS has been fully revised and re-written in accordance with Regulation (EU) No 453/2010 and Regulation (EC) No. 1272/2008 (EU CLP).
- Any further amendments to be detailed by supplier of SDS
- Section 2.1: Classification according to Council Directive 67/548/EEC removed in accordance with Regulation (EU) No. 453/2010

Sources of Key data used:

- Registration dossier submitted to ECHA in accordance with Regulation (EC) No. 1907/2006 and therefore a full reference list can be found in the corresponding CSR.

Abbreviations and acronyms used:

AF = Assessment factor
DNEL = Derived no effect level
EC50 = Median effect concentration
LC50 = Median lethal concentration
LD50 = Median lethal dose
LEV = Local Exhaust Ventilation
NOAEL = No observed adverse effect level

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NOEC = No observed effect concentration
PBT = Persistent bioaccumulative toxic
PEC = Predicted effect level
PNEC = Predicted no effect level
PRE = Personal Respiratory Equipment
OEL = Occupational Exposure Limit
SDS = Safety data sheet
STOT-SE = Specific target organ toxicity – single exposure
STOT-RE = Specific target organ toxicity – repeated exposure
STP = Sewage treatment plant
vPvB = Very persistent very bioaccumulative



**Reaction mass of calcium
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hydrogenorthophosphate****Annex: summary of relevant exposure scenarios**

ES1: Industrial manufacture of the reaction mass of MCP and DCP	19
ES2: Formulation of solid and liquid fertilisers	22
ES3: Professional and private fertiliser use	30

**ES1: Industrial manufacture of the reaction mass of
MCP and DCP**

The manufacturing processes are described by the ECHA use descriptor system in the following way: SU 8, 9; PC 0; PROC 1,2,3AC not applicable; ERC 1

1.1 Process and activities

The substance is manufactured in an industrial closed, continuous process at indoor facilities. The reaction mass of MCP and DCP is obtained by reaction of a calcium source (lime) with purified phosphoric acid. The reaction is performed in a reactor granulator under precise conditions. All processes are automated. Such processes may be operated on 365 days a year for 24 hours a day divided into three working shifts. Samples of the manufactured product have to be taken regularly and are analysed for quality assurance in an on-site laboratory. The granular product is milled and screened in order to obtain a suitable particle size and is dried in a gas drier to obtain a product moisture content of 2-3%. The final product is automatically transferred to storage tanks by passing through the screener.

In case of defects with the processes, such as a leakage of pipes or equipment breakage, repair and maintenance work is done after the affected part of the system has been separated from the process, completely emptied and flushed with water where appropriate. Cleaning tasks such as wiping the floors or manufacturing and packaging equipment are performed regularly.

1.2 Operational conditions

No information about frequency and duration of the various tasks is available. In the first-tier assessment of exposure a frequency of once a day and an exposure duration of 8 hours will be considered. No information about the concentration of the substance in the final product is available. In the first-tier assessment the concentration of MCP/DCP reaction mass of 100% w/w was used to assess exposure to the solid substance.

1.3 Risk management measures

Workers wear appropriate personal protection equipment, such as gloves, dust masks and safety glasses when breaching the system or handling the pure substance. Safety showers and eye washes are installed to be available in the case of accidental contact. Local exhaust ventilation may be present when solids are handled to reduce the likelihood of inhalation exposure to dusts.

1.4 Waste related measures

Emissions of particles into the air of workplaces or the atmosphere can be significantly reduced by the use of cyclones, gas scrubbers or bag filters. The efficiency of the process is

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maximised in such a way that minimal emission of phosphates into the wastewater will occur. In addition, phosphate can be precipitated from the wastewater by addition of metal ions. Solid and liquid waste has to be incinerated or appropriately disposed of as chemical waste.

1.5 Exposure estimation

No measured workplace concentrations or personal exposure concentrations are available. The occupational exposure to MCP/DCP reaction mass was modelled with the ECETOC TRA tool (ECETOC 2010). The modelled exposure concentrations are given in Table 35. Two grades of solid MCP/DCP reaction mass with fine and medium particle sizes were considered.

The TRA tool predicts 8-hour TWA airborne workplace concentrations for handling of solid MCP/DCP reaction mass with medium dustiness of up to 1 mg/m³ for closed processes and of 0.5 mg/m³ for closed processes with controlled exposure. The 8-hour TWA airborne workplace concentrations for handling of solid MCP/DCP reaction mass with high dustiness are up to 0.01 mg/m³ for the closed processes, up to 1.0 mg/m³ at dedicated facilities. Local exhaust ventilation with efficiencies between 90% and 95% are necessary for processes leading to elevated exposure levels in order to keep the airborne workplace concentrations at acceptable levels.

Workers have to wear appropriate safety glasses to avoid eye contact with MCP/DCP reaction mass. It is recommended that workers wear appropriate dermal protection to reduce their dermal exposure to the substance.

Occupational exposure to MCP resulting from manufacturing activities

Process Category	Activity Type	LEV	Duration (hours)	PRE	Weight fraction (%)	Skin surface area (cm ²)	Airborne conc. (mg/m ³)	Dermal dose (mg/kg bw/day)
Solid, medium dustiness								
1 - Use in closed process, no likelihood of exposure	Industrial	No	4 to 8	No	100	240	0.010	0.343
2 - Use in closed, continuous process with occasional controlled exposure	Industrial	No	4 to 8	No	100	480	0.500	1.371
3 - Use in closed batch process (synthesis or formulation)	Industrial	No	4 to 8	No	100	240	1.000	0.343
Solid, high dustiness								

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1 - Use in closed process, no likelihood of exposure	Industrial	No	4 to 8	No	100	240	0.010	0.343
2 - Use in closed, continuous process with occasional controlled exposure	Industrial	No	4 to 8	No	100	480	1.00	1.37
3 - Use in closed batch process (synthesis or formulation)	Industrial	No	4 to 8	No	100	240	1.00	0.343

1.6 Consumer exposure to MCP/DCP reaction mass due to manufacture

No consumer exposure resulting from the manufacture of the substance is expected. Thus, no assessment of consumer exposure to MCP/DCP reaction mass is performed.

1.7 Indirect exposure to MCP/DCP reaction mass via the environment due to manufacture

No indirect exposure of humans via the environment is expected for MCP/DCP reaction mass, as the substances can be effectively removed from the wastewater and will be rapidly hydrolysed or metabolised to soluble inorganic orthophosphates in the environment. Thus, no assessment of indirect exposure of humans via the environment is performed.

1.8 Environmental exposure to MCP/DCP reaction mass due to manufacture

Pyrophosphates are hydrolysed to soluble inorganic orthophosphate (PO_4^{3-}) in wastewater, sewerage systems and natural waters. In addition, organisms can break down pyrophosphates to orthophosphates by the help of phosphatases. No direct acute or long-term adverse effects on aqueous or terrestrial organisms are anticipated with orthophosphates in the environment. Because phosphates are a key nutrient for plants, elevated phosphate concentrations in water can lead to excessive growth of algae and other water plants (eutrophication) if they represent the growth-limiting factor. Although in some cases nutrient enrichment will be absorbed and might not have an apparent effect, in other circumstances, it can lead to negative effects. These can range from ecosystem modifications, through algal blooms, to in extreme cases (through decomposition of plant biomass) oxygen depletion and collapse of the biocenosis in a surface water. To avoid such undesirable effects, phosphate emissions to surface water via industrial wastewater are regulated in the Council Directive 96/61/EC concerning integrated pollution prevention and control. It states that phosphates have to be taken into account for fixing emission limit values for industrial wastewater. In order to meet the requirements it may be necessary to add a treatment step for phosphate removal from industrial wastewaters before these are released to the aqueous environment.

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Reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate**ES2: Formulation of solid and liquid fertilisers**

The manufacturing processes are described by the ECHA use descriptor system in the following way: SU 1,8, 9 10; PROC 2, 3, 5, 8b, 9; AC not applicable; ERC 1, 2

2.1 Process and Activities

The raw material MCP/DCP reaction mass is delivered to formulators of fertilisers in appropriate transport containers or bags in liquid or solid form. The substance is unloaded at dedicated facilities, stored at the formulation sites and on demand automatically transferred to the formulation process. Samples may be taken from the delivered material and analysed in on-site laboratories for quality assurance. The formulation of solid or liquid fertilisers or the addition of micronutrients and additives to solid or liquid fertilisers is performed in closed, continuous or batch processes. Formulation involves an extensive mixing or blending step that may run continuously for 24 hours a day. Workers have to control the formulation process, do regular inspection rounds and perform cleaning and maintenance tasks. The final solid fertiliser products are weighed, filled into small containers, packed and made ready for shipment at dedicated filling lines. The solid fertiliser product is used as such or dissolved by workers or professional downstream users and diluted (at the formulation sites or further down the supply chain) in closed or open batch processes to get liquid and soluble fertilisers. The final liquid fertilisers are weighed, filled into small containers, packed and made ready for shipment at dedicated filling lines. The solid and liquid fertilisers are sold to professional and private users.

2.2 Operational conditions

No information about frequency and duration of the various tasks in the formulation of fertilisers is available. In the first-tier assessment of exposure a frequency of once a day and an exposure duration of 8 hours will be considered. No information about the concentration of the substance in solutions or solid products is available. In the first-tier assessment of exposure the concentration of MCP/DCP reaction mass in concentrated solutions will be set to >25% w/w. A concentration of 100% w/w will be used to assess exposure to the solid substance. The concentration in the solid or liquid fertiliser products will be set to 10% w/w.

2.3 Risk management measures

The processes are fully contained to avoid accidental exposure. Workers wear appropriate personal protection equipment, such as gloves, dust masks and safety glasses when coming into contact with the substance. Safety showers and eye washes are installed to be available in the case of accidental contact. Local exhaust ventilation may be present to reduce the likelihood of inhalation exposure to dusts.

2.4 Waste related measures

Emissions of particles into the air of workplaces or the atmosphere can be significantly reduced by the use of cyclones, gas scrubbers or bag filters. The efficiency of the process is maximised in such a way that minimal emission of phosphates into the wastewater will occur. In addition, phosphate can be precipitated from the wastewater by addition of metal ions. Solid and liquid waste has to be incinerated or appropriately disposed of as chemical waste. The solid waste product if not contaminated may also be used as a product (re-used).

Reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate**2.5 Exposure estimation****Worker exposure to MCP/DCP reaction mass****Industrial setting**

The handling of MCP/DCP reaction mass in the form of powdery or granular solid materials may generate airborne dusts that can be inhaled. No information about measured workplace concentrations of MCP/DCP reaction mass -containing dusts occurring during the handling of the solid substance are available. Workers handling MCP/DCP reaction mass may also experience dermal exposure to the substance. The inhalation and dermal exposure of workers to solid MCP/DCP reaction mass was modelled with the TRA tool. The modelled inhalation and dermal exposure concentrations are given in Table 36 and 37 together with the conditions of exposure.

Industrial workers may be exposed to elevated concentrations of MCP/DCP reaction mass as a result of the handling of solid substance or mixtures. In formulation processes, workers may be exposed to the pure MCP/DCP reaction mass during transfer activities at dedicated facilities (PROC 8b). Professional workers performing transfer and loading tasks at dedicated facilities may be exposed to airborne concentrations of the pure, powdery MCP/DCP reaction mass of 25 mg/m³ in the absence of RMMs and 1.25 mg/m³ in the presence of LEV with a 95% efficiency during a working shift of 8 hours. The use of LEV with an efficiency of at least 90% is required at all professional sites where the powdery material is used in order to keep the dust concentrations at a reasonably low level.

The modelled airborne concentrations of formulated powdery mixtures containing 10% MCP/DCP reaction mass is 1 mg/m³ for the closed processes, 25 mg/m³ without LEV and 1.25 mg/m³ with LEV for filling at dedicated lines. The airborne concentrations of pure, powdery MCP/DCP reaction mass during the activities performed without LEV are thus 0.1 mg/m³ for closed processes, 2.5 mg/m³ for mixing and blending and 2.5 mg/m³ for filling tasks. The modelled airborne concentration for liquid formulations (>25% MCP/DCP reaction mass) is 1.54 mg/m³. The modelled dermal doses of liquid or solid materials (pure MCP/DCP reaction mass for transfer activities and formulated mixture for all other tasks) are 1.37 to 34.3 mg/kg/day (closed processes), 1.371 mg/kg/day (mixing and blending) and 0.686 mg/kg/day (transfer, loading, filling) if no skin protection is taken into account.

Professional setting

The handling of MCP/DCP reaction mass in form of powdery or granular solid materials may generate airborne dusts that can be inhaled. No information about measured workplace concentrations of MCP/DCP reaction mass -containing dusts occurring during the handling of the solid substance are available. Workers handling MCP/DCP reaction mass may also experience dermal exposure to the substance. The inhalation and dermal exposure of workers to solid MCP/DCP reaction mass was modelled with the TRA tool. The modelled inhalation and dermal exposure concentrations are given in table 36 and 37 together with the conditions of exposure.

Professional workers may be exposed to elevated concentrations of MCP/DCP reaction mass as a result of the handling of solid substance or mixtures. In formulation processes, workers may be exposed to the pure MCP/DCP reaction mass during transfer activities at dedicated facilities (PROC 8b). Professional workers performing transfer and loading tasks at dedicated facilities may be exposed to airborne concentrations of the pure, powdery MCP/DCP reaction

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mass of 25 mg/m³ in the absence of RMMs and 1.25 mg/m³ in the presence of LEV with a 95% efficiency during a working shift of 8 hours. The use of LEV with an efficiency of at least 90% is required at all professional sites where the powdery material is used in order to keep the dust concentrations at a reasonably low level.

The modelled airborne concentrations of formulated powdery mixtures containing 10% MCP/DCP reaction mass is 1 mg/m³ for the closed processes, 25 mg/m³ without LEV and 1.25 mg/m³ with LEV for filling at dedicated lines. The airborne concentrations of pure, powdery MCP/DCP reaction mass during the activities performed without LEV are thus 0.1 mg/m³ for closed processes, 2.5 mg/m³ for mixing and blending and 2.5 mg/m³ for filling tasks. The modelled airborne concentration for liquid formulations (>25% MCP/DCP reaction mass) is 1.54 mg/m³. The modelled dermal doses of liquid or solid materials (pure MCP/DCP reaction mass for transfer activities and formulated mixture for all other tasks) are 1.37 to 34.3 mg/kg/day (closed processes), 1.371 mg/kg/day (mixing and blending) and 0.686 mg/kg/day (transfer, loading, filling) if no skin protection is taken into account.

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Industrial and professional worker exposure to MCP/DCP reaction mass resulting from formulation of solid fertilisers described as indoor activities

Process Category	Activity Type	LEV	Duration (hours)	PRE	Weight fraction	Airborne MCP/DCP reaction mass conc. 100% (mg/m ³)	Airborne MCP/DCP reaction mass conc. in formulations 10% (mg/m ³)	Dermal dose MCP/DCP reaction mass 100% (mg/kg/day)	Dermal dose MCP/DCP reaction mass in formulations 10% (mg/kg/day)
FORMULATION SOLID FERTILISERS									
2- Used in closed, continuous process with occasional controlled exposure	Industrial	No	>4 hours (default)	No	10%	1	0.1	1.37	0.137
3- Used in closed batch process	Industrial	No	>4 hours (default)	No	10%	1	0.1	34.3	3.43
4- Use in batch and other processes where opportunity for exposure arises	Industrial	No	>4 hours (default)	No	10%	25	2.5	10.4	1.04
4- Use in batch and other processes where opportunity for exposure arises	Industrial	Yes	>4 hours (default)	No	10%	2.5	0.25	10.4	1.04
5- Mixing or blending in batch processes for formulation	Industrial	No	>4 hours (default)	No	10%	25	2.5	13.7	1.37

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Process Category	Activity Type	LEV	Duration (hours)	PRE	Weight fraction	Airborne MCP/DCP reaction mass conc. 100% (mg/m ³)	Airborne MCP/DCP reaction mass conc. in formulations 10% (mg/m ³)	Dermal dose MCP/DCP reaction mass 100% (mg/kg/day)	Dermal dose MCP/DCP reaction mass in formulations 10% (mg/kg/day)
5- Mixing or blending in batch processes for formulation	Industrial	Yes	>4 hours (default)	No	10%	2.5	0.25	0.068	0.0068
8b- Transfer of substances or preparations from/to vessels at dedicated facilities	Industrial	No	>4 hours (default)	No	10%	25	2.5	6.86	0.686
8b- Transfer of substances or preparations from/to vessels at dedicated facilities	Industrial	Yes	>4 hours (default)	No	10%	1.25	0.125	0.686	0.0686
9- Transfer of substances or preparations into small containers	Industrial	No	>4 hours (default)	No	10%	20	2	6.86	0.686
9- Transfer of substances or preparations into small containers	Industrial	Yes	>4 hours (default)	No	10%	2	0.2	0.686	0.0686

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Industrial and professional worker exposure to MCP/DCP reaction mass resulting from formulation of liquid fertilisers described as indoor activities

Process Category	Activity Type	LEV	Duration (hours)	PRE	Weight fraction	Airborne MCP/DCP reaction mass conc. (mg/m ³)	Dermal dose MCP/DCP reaction mass (mg/kg/day)
FORMULATION LIQUID FERTILISERS							
2- Used in closed, continuous process with occasional controlled exposure	Industrial	No	>4 hours (default)	No	>25%	1.54	1.37
3- Used in closed batch process	Industrial	No	>4 hours (default)	No	>25%	1.54	0.34
4- Use in batch and other processes where opportunity for exposure arises	Industrial	No	>4 hours (default)	No	>25%	1.54	6.86
5- Mixing or blending in batch processes for formulation	Industrial	No	>4 hours (default)	No	>25%	1.54	13.7
8b- Transfer of substances or preparations from/to vessels at dedicated facilities	Industrial	No	>4 hours (default)	No	>25%	1.54	6.86

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Process Category	Activity Type	LEV	Duration (hours)	PRE	Weight fraction	Airborne MCP/DCP reaction mass conc. (mg/m ³)	Dermal dose MCP/DCP reaction mass (mg/kg/day)
9- Transfer of substances or preparations into small containers	Industrial	No	>4 hours (default)	No	>25%	1.54	6.86

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Reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate**2.6 Consumer exposure to MCP/DCP reaction mass**

The formulation of fertilisers containing MCP/DCP reaction mass will not result in direct consumer exposure to the substance.

2.7 Indirect exposure of humans via the environment (oral)

No indirect exposure of humans via the environment is expected for MCP/DCP reaction mass. Thus, no assessment of indirect exposure of humans via the environment is required.

2.8 Environmental exposure to MCP/DCP reaction mass due to formulation

MCP/DCP reaction mass will not be present in the environment as MCP/DCP reaction mass but as separate potassium, sodium and orthophosphate (PO₄³⁻) ions, which are found naturally. No direct acute or long-term adverse effects on aqueous or terrestrial organisms are anticipated with orthophosphates in the environment. Because phosphates are a key nutrient for plants, elevated phosphate concentrations in water can lead to excessive growth of algae and other water plants (eutrophication) if phosphates represent the growth-limiting factor. Although in some cases nutrient enrichment will be absorbed and might not have an apparent effect, it can lead to negative effects in other circumstances. These can range from ecosystem modifications, through algal blooms, to in extreme cases (through decomposition of plant biomass) oxygen depletion and collapse of the biocenosis in a surface water. To avoid such undesirable effects, phosphate emissions to surface water via industrial wastewater are regulated in the Council Directive 96/61/EC concerning integrated pollution prevention and control. It states that phosphates have to be taken into account for fixing emission limit values for industrial wastewater. In order to meet the requirements it may be necessary to add a treatment step for phosphate removal from industrial wastewaters before these are released to the aqueous environment. Council directive 91/271/EEC concerning urban waste water treatment requires phosphate removal from sewage, wherever receiving waters are potentially susceptible to eutrophication in agglomerations >10,000 person equivalent. This requirement is confirmed by the EU Water Framework Directive 2000/60, which also further requires phosphate removal in smaller agglomerations where this is necessary to achieve water quality standards. The directive is not yet fully implemented in all new EU member states. This should be done by end of 2018.

Reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate

ES3: Professional and private fertiliser use

The manufacturing processes are described by the ECHA use descriptor system in the following way: SU 1, 10; PC 12; PROC 2, 5, 8a, 8b, 9; ERC 8B, 8E, 9B

3.1 Processes and activities

Solid or liquid fertilisers containing MCP/DCP reaction mass are available to professional and private users in containers of varying size. Professionals and consumers may use the solid fertilisers directly. In most cases, users will transfer the fertiliser into a distribution system (open vessel, irrigation system in greenhouses, fertigation tank of a tractor, watering can for consumer) and may need to dissolve or dilute the fertilisers in water before use, which may include active mixing either by hand or by use of sticks or other appropriate tools. The solid fertiliser or the diluted fertiliser solution is applied to the ground at indoor sites (greenhouses, flower pots) or outdoor sites (fields, parks, public lawns, sport fields, golf courses, gardens). The fertiliser is generally applied by fertigation, manual powder or solution application, or by foliar spraying. The latter form of application results in the formation of aerosols.

3.2 Operational conditions

Information about the professional use of MCP/DCP reaction mass solutions applied by fertigation during crop-growing season is available. The use may occur regularly up to 4 to 5 months a year. The total quantity of MCP/DCP reaction mass applied during the season is approximately 5 to 30 kg per ha, which corresponds to an amount of 1 to 6 kg per ha per use if a monthly use is considered. In the first-tier assessment of exposure a frequency of once a day and an exposure duration of 8 hours will be considered for professional users. The concentration in the undiluted fertiliser products will be set to 10% w/w, the concentration in the working solution to 1% w/w, respectively.

3.3 Risk management measures

Professional users should wear appropriate personal protection equipment, such as gloves and safety glasses during the transfer and dilution of liquid or solid fertilisers and during manual spraying.

3.4 Exposure estimation

Worker exposure

The substance has a very low vapour pressure. A vapour pressure of 0.00001 was taken into account for the calculations. The TRA tool tends to overestimate exposure to low-volatile substances from liquids for hand mixing activities. To model occupational exposure to MCP/DCP reaction mass resulting from manual mixing (PROC 19) of liquids, the substance was characterised as a solid with low dustiness as suggested in ECETOC Technical Report Nr. 93 (ECETOC, 2004, Appendix C). Airborne concentrations of the mixture of 0.3 mg/m³ are predicted for this activity. Workers may be in dermal contact with MCP/DCP reaction mass solutions or liquid mixtures containing the substance, and the ECETOC TRA tool (ECETOC 2010) was used to model potential dermal doses of MCP/DCP reaction mass occurring during the activities described in the exposure scenario. The handling of MCP/DCP reaction mass in form of powdery or granular solid materials may generate airborne dusts that can be inhaled. No information about measured workplace concentrations of MCP/DCP reaction mass-containing dusts occurring during the manufacture and handling of the solid substance are

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available. Workers handling solid MCP/DCP reaction mass may also experience dermal exposure to the substance. The inhalation and dermal exposure of workers to solid MCP/DCP reaction mass was also modelled with the TRA tool. The modelled inhalation and dermal exposure concentrations are given in Table 38 together with the conditions of exposure. Professional exposure to fertiliser spray containing MCP/DCP reaction mass was predicted with the UK POEM model using a 1% solution of MCP/DCP reaction mass with a default spray time of 6 hours. Inhalation exposure during spraying activities was 0.02 ml/h. This is converted to a total daily dose of 1.2×10^{-7} m³/day.

Professional workers can come into contact with the solid, formulated fertiliser containing up to 10% MCP/DCP reaction mass during indoor and outdoor activities. In the present assessment, contact with solid products during transfer and loading operations (PROC 8a) and hand-mixing (PROC 19) was considered. The modelled dust concentration of the mixture occurring during both activities involving the powdery product was 3.0 mg/m³ indoors and 2.1 mg/m³.

The dermal doses of solid and liquid mixtures are 6.8 mg/kg/day for transfer, loading and filling activities at dedicated facilities and 13.7 mg/kg/day for transfer activities at non-dedicated facilities.

Professional exposure to fertiliser spray containing MCP/DCP reaction mass was predicted with the UK POEM model using a 1% solution with a default spray time of 6 hours. Inhalation exposure during spraying activities was 0.02 ml/h. This is converted to a total daily dose of 1.2×10^{-7} m³/day.

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Worker exposure to MCP/DCP reaction mass resulting from professional use of fertilisers

Process Category	Location	LEV	Duration (hours)	PRE	Weight fraction	Skin surface area (cm ²)	Airborne conc. Product (mg/m ³)	Airborne conc. MCP/DCP reaction mass (mg/m ³)	Dermal dose, product (mg/kg/day)	Dermal dose, unprotected (mg/kg/day)
USE OF SOLID, POWDERY FERTILISER, LOW DUSTINESS										
8a –Transfer of chemicals from/to vessels/ large containers at non dedicated facilities	Indoors	No	4 to 8	No	100%	960	0.5	0.05	13.71	1.371
	Outdoors	30%	4 to 8	No	100%	960	0.35	0.035	13.71	1.371
8b- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	Indoors	No	4 to 8	No	100%	960	0.5	0.05	6.8	0.68
	Outdoors	30%	4 to 8	No	100%	960	0.35	0.035	6.8	0.68
9- Transfer of substance or preparation into small containers (dedicated	Indoors	No	4 to 8	No	100%	960	0.5	0.05	6.8	0.68
	Outdoors	30%	4 to 8	No	100%	960	0.35	0.035	6.8	0.68

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Process Category	Location	LEV	Duration (hours)	PRE	Weight fraction	Skin surface area (cm ²)	Airborne conc. Product (mg/m ³)	Airborne conc. MCP/DCP reaction mass (mg/m ³)	Dermal dose, product (mg/kg/day)	Dermal dose, unprotected (mg/kg/day)
filling line, including weighing)										
19- mixing and loading	Indoors	No	1 to 4	No	100%		3	0.3	141.429	14.1429
	Outdoors	30%	1 to 4	No	100%		2.1	0.21	141.429	
USE OF LIQUID FERTILISER										
2- Use in closed, continuous process with occasional controlled exposure	Indoors	No	4 to 8	No	5-25%	960	-	0.925	-	1.371
	Outdoors	30%	4 to 8	No	5-25%	960	-	0.648	-	1.371
5- Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	Indoors	No	4 to 8	No	5-25%	960	-	0.925	-	13.714
	Outdoors	30%	4 to 8	No	5-25%	960	-	0.648	-	13.714

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Process Category	Location	LEV	Duration (hours)	PRE	Weight fraction	Skin surface area (cm ²)	Airborne conc. Product (mg/m ³)	Airborne conc. MCP/DCP reaction mass (mg/m ³)	Dermal dose, product (mg/kg/day)	Dermal dose, unprotected (mg/kg/day)
8a- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	Indoors	No	4 to 8	No	5-25%	960	-	0.925	-	13.714
	Outdoors	30%	4 to 8	No	5-25%	960	-	0.648	-	13.714
8b- Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	Indoors	No	4 to 8	No	5-25%	960	-	0.925	-	6.857
	Outdoors	30%	4 to 8	No	5-25%	960	-	0.648	-	6.857
9- Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	Indoors	No	4 to 8	No	5-25%	960	-	0.925	-	6.857
	Outdoors	30%	4 to 8	No	5-25%	960	-	0.648	-	6.857

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Process Category	Location	LEV	Duration (hours)	PRE	Weight fraction	Skin surface area (cm ²)	Airborne conc. Product (mg/m ³)	Airborne conc. MCP/DCP reaction mass (mg/m ³)	Dermal dose, product (mg/kg/day)	Dermal dose, unprotected (mg/kg/day)
19- mixing and loading	Indoors	No	1 to 4	No	100%		0.3	0.03	141.429	14.1429
SPRAY EXPOSURE TO DILUTE FERTILISER										
Spraying fertiliser	Outdoors	No	6	No	1%	-		1.2x10 ⁻⁷		10.59

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3.6 Consumer exposure

Consumers can come into contact with the solid, formulated fertiliser containing up to 10% MCP/DCP reaction mass during indoor and outdoor activities. In the present assessment, contact with solid products during hand-mixing (PROC 19) was considered. The modelled dust concentration of the solid mixture occurring during activities involving the powdery product was 3.0 mg/m³ (indoors use, worst case scenario) which equates to an exposure of 0.3 mg/m³ MCP/DCP reaction mass. Exposure to the liquid formulation was estimated to be 0.3 mg/m³ which equates to 0.03 mg/m³ MCP/DCP reaction mass. Dermal exposure for both liquid and solid formulations was calculated to be 14.14 mg/kg MCP/DCP reaction mass.

Consumer exposure to the substance during spraying activities was predicted with the UK POEM model. The duration of spraying was 30 minutes/day in the model. The airborne concentration of MCP/DCP reaction mass due to the spraying of fertilisers was 1.2x10⁻⁷ mg/m³ and the dermal dose was 3.3x10⁻⁴ mg/kg/day. These exposure estimations are considered as representative of the potential consumer exposure occurring during the direct use of fertilisers.

Consumer exposure to MCP/DCP reaction mass resulting from formulation of fertilisers (predicted with UK POEM)

	Private spraying of liquid fertilisers with home garden sprayer, 5 L-tank, low-level target	Unit
MIXING AND LOADING		
<i>Liquid fertiliser</i>		
Dermal dose of a.s.	14.14	mg/kg
Inhalation exposure of a.s.	0.03	mg/m ³
<i>Solid, fertiliser</i>		
Dermal dose of a.s.	0.017	mg/kgy
Inhalation exposure to a.s.	0.3	mg/m ³
SPRAY APPLICATION		
Dermal exposure to spray	0.02	mL/day
Dermal exposure to a.s.	0.02	mg/day
Dermal dose of a.s.	3.3x10⁻⁴	mg/kg/day
Inhalation exposure to a.s.	0.01	mg/day
Inhalation exposure concentration of a.s. during event	1.27x10 ⁻⁷	mg/m ³

a.s.: active substance

3.7 Indirect exposure of humans via the environment (oral)

No indirect exposure of humans via the environment is expected for MCP/DCP reaction mass. Thus, no assessment of indirect exposure of humans via the environment is required.

3.8 Environmental exposure to MCP/DCP reaction mass due to fertiliser use

Granular and liquid fertilisers containing MCP/DCP reaction mass are directly applied to the soil surface. In a general exposure scenario describing fertiliser use in the EU (Fertilizer Europe TF Exposure scenario, 2010), it is stated that 400 – 1000 kg fertiliser are applied per hectare per year. This amount may be distributed to the field in several applications.

A simple method to calculate the PEC for soil is given in the guidance document on estimating persistence and degradation kinetics from Environmental Fate Studies on Pesticides in EU Registration (FOCUS, 2006).

Reaction mass of calcium bis(dihydrogenorthophosphate) and calcium hydrogenorthophosphate

$$PEC_{soil,0} = \frac{A}{100 \cdot depth \cdot bd}$$

where

A : application rate (g/ha),

depth : mixing depth (cm),

bd : dry soil bulk density (g/cm³).

The concentration of MCP/DCP reaction mass in soil due to fertiliser use in the present assessment is calculated based on the highest reported fertiliser amount of 1000 kg containing 10% MCP/DCP reaction mass. Taking into account a mixing depth of the soil of 5 cm and a bulk density of the dry soil of 1.5 g/cm³, the predicted concentration in the soil immediately following a single application of 100 kg ($PEC_{soil,0}$) is 133.33 mg MCP/DCP reaction mass per kg soil.

MCP/DCP reaction mass may be dissolved in runoff water and transported from agricultural fields into water bodies. It can travel attached to particles of soil or manure eroded by water into a water body. In a simulation study, the runoff of phosphorus from a fertilised soil was investigated (Tarkalson and Mikkelsen, 2007). Concentrations of phosphorus in runoff water after treatment with broiler litter from birds fed a low phytic-acid corn were measured. Runoff water was collected during a simulated 30 minutes rainfall event. Concentrations of algal-available phosphorus in runoff water at application rates of 8 to 82 kg phosphorus per hectare ranged from 3.4 to 18.7 mg/L. The measured phosphorus concentrations obtained in the simulation study can be taken as a reasonable worst-case for concentrations found in runoff from agricultural land occurring under unfavourable conditions. Phosphorus losses from fertilised soil can be minimised by following a set of recommended safety measures (Lory, 1999):

- Apply phosphorus sources below the surface.
- Surface-apply phosphorus sources during periods of the year when runoff is unlikely.
- Surface-apply phosphorus sources only on fields with a low potential for runoff.
- Do not surface-apply phosphorus sources to frozen or snow-covered soils.
- Maintain buffer strips around water resources where no phosphorus is applied.
- Add alum or similar treatment to manure to reduce the availability of phosphorus.

There is little potential that phosphorus leaches through soil into groundwater. The affinity of soluble phosphorus to adsorb to particles limits its movement through soil as it leaches through soil. Considerable transport of phosphorus to groundwater is not anticipated with fertiliser use under normal conditions.

Sandy soils may have limited capacity to absorb phosphorus and relatively high amounts of phosphorus deposited on such soils may overwhelm the absorption capacity. Cracking soils or areas with karst topography may create channels in the soil which allow direct travel of surface water into groundwater. In both cases elevated phosphorus concentrations in groundwater may occur. Specific risk measures may be required for the described soil properties.