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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 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:

Disodium fluorophosphate

EINECS Number: 233-433-0

CAS Number: 10163-15-2

REACH Registration number: [to be filled in by company]

Other identifiers: IUPAC NAME: Phosphorofluoridic acid disodium salt, SFP

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

Manufacture of SFP
Formulation of SFP into mixtures
Formulation of SFP into materials
Industrial use as an intermediate
Industrial use as a reactive processing aid
Industrial use as a binding agent in ceramic materials and in ceramics, mortars, cements, plasters and mastics
Industrial use as an additive/pigment/auxiliary in paints, varnishes, coatings and inks (no inclusion into or onto article)
Industrial use as an additive/pigment/auxiliary in paints, varnishes, coatings and inks (inclusion into or onto article)
Industrial use in soaps and detergents
Industrial use as a non-reactive processing aid
Professional use as a binding agent in ceramic materials and in ceramics, mortars, cements, plasters and mastics
Professional use as an additive/pigment/auxiliary in paints, varnishes, coatings and inks
Professional use in soaps and detergents
Professional use in non-metal surface treatment
Consumer use of plasters and mastics. Includes coated articles.
Consumer use of an additive/pigment/auxiliary in paints, varnishes, coatings and inks
Consumer use of cosmetics, dentifrice and oral care products
Consumer use of food/feed products, medical and pharmaceutical products
Service life of wood, paper and plastic articles
Service life of ceramic articles or articles containing cement, refractories, plaster or mastics

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]

SECTION 2. Hazards identification

2.1 Classification of the substance

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

Acute toxicity (oral) 4, H302: Harmful if swallowed

2.2 Label elements

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

Name: disodium fluorophosphate
Index Number: Not applicable
CAS Number:10163-15-2



Signal word: Warning

Hazard Statements:

H302: Harmful if swallowed.

Precautionary Statements:

Prevention:

P264: Wash hands thoroughly after handling.
P270: Do not eat, smoke or drink when using this product.

Response:

P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
P330: Rinse mouth.

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

2.3 Other hazards

The material is not considered to be PBT or vPvB.

SECTION 3. Composition / information on ingredients

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3.1 Substance:

Name	EC Number	CAS Number	Typical concentration	Concentration Range
Disodium fluorophosphate	233-433-0	10163-15-2	>90% [Taken from SIP - specific company to update where necessary]	[to be provided by company]

Registration Number (if available): [specific to each registrant – insert number here]

EC name: disodium fluorophosphate

Identification of hazardous impurities (where applicable):

All impurities > 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

All hazardous impurities are < 0.1%

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

4.1 Description of first aid measures

Inhalation

In case of exposure by inhalation, provide fresh air. Consult doctor in case of symptoms

Ingestion

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse out mouth with plenty of water.

Skin Contact

In case of contact with skin, rinse with plenty of water and soap.

Eye Contact

IF IN EYES: Rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation occurs: Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

Disodium fluorophosphate is acutely harmful via the oral route.

4.3 Indication of any immediate medical attention and special treatment needed

No specific information available.

SECTION 5. Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Disodium fluorophosphate is not flammable. Use fire fighting measures that suit the environment; CO₂, extinguishing powder or water spray. Fight larger fires with foam.

Inappropriate extinguishing media:

For safety reasons: water with a full jet.

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5.2 Special hazards arising from the substance or mixture

Fire can cause release of hydrogen fluoride (HF)

5.3 Advice for fire-fighters

In cases where dust particles of disodium fluorophosphate may be present respiratory ventilation is recommended. Wear appropriate eye protection. See Section 8.2.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes. Use personal protection equipment.

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

Shovel up material and recycle if possible. Dispose of contaminated material according to the waste disposal recommendations.

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.

7.2 Conditions for safe storage, including any incompatibilities

Disodium fluorophosphate is to be transported and stored in cool, dry conditions and in the original packaging. Protect from humidity and keep away from water. Store away from foodstuffs.

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 (2009) 3 mg/m³ measured as alveolic part

EU OEL: (Fluorides inorganic) 2.5 mg/m³

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

DNELS (worker):

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Exposure route	Exposure pattern	DNEL (workers)
Inhalation	Acute systemic effects	2.5 mg/m ³ Although no classification was required following an acute inhalation study, a DNEL is still proposed for this endpoint. The Long-term (8-hr TWA) OEL is considered to be sufficiently protective to cover both long-term and short-term exposure. See below for justification for the use of an OEL in place of a DNEL.
	Long term systemic	2.5 mg/m ³ As the effects of inorganic fluorides have been extensively studied, it is therefore not considered to be ethically sound to investigate the effects of disodium fluorophosphate further. To this end it is recommended that the exposure limit for inorganic fluorides (NIOSH, UK HSE) is observed and is used in the risk assessment in place of a DNEL. The OEL is 2.5 mg F/m ³ . This value is considered to be low enough to be protective of any potential effects.
Dermal	Acute systemic effects	Disodium fluorophosphate is unlikely to be absorbed via the dermal route and does not present a systemic toxicity hazard via this route. As such no DNEL is calculated.
	Long term systemic	No hazard identified

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	1.25 mg/m ³ Although no classification was required following an acute inhalation study, a DNEL is still proposed for this endpoint. The DNEL is based on the long-term (8-hr TWA) OEL of 2.5 mg/m ³ with an assessment factor of 2 applied to account for the differences in workers and the general population, specifically; 24 hrs versus 8 hrs, bodyweight; 60 kg versus 70 kg and inhalation rate; 0.83 m ³ /hr versus 1.25 m ³ /hr. This long-term DNEL is considered to be adequate to cover both short-term and long-term exposure.
	Long term systemic	
Oral	Acute systemic effects	An oral DNEL is not required for consumers using products containing disodium fluorophosphate as the uses that may result in oral exposure are covered by other European legislation: The use of food supplements and pharmaceuticals containing disodium fluorophosphate is covered in Directive 2002/46/EC and directive 2001/83/EC, respectively. In addition the potential risk for consumers from the use of cosmetics and personal care products falls under the EU Cosmetics Directive (Regulation EC 76/768/EEC and Regulation (EC) No 1223/2009), and have been assessed and authorised for use under this Directive.
	Long term systemic	

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Dermal	Acute systemic effects	Disodium fluorophosphate is unlikely to be absorbed via the dermal route and does not present a systemic toxicity hazard via this route. As such no DNEL is calculated.
	Long term systemic	

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

PNECs:

No hazards identified and therefore no PNECs are calculated.

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: Wear protective gloves: Protective gloves: In case of spray contact at least protection index 2 recommended, according to more than 30 min. penetration time (EN 374). 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: chloroprene gloves or equivalent.

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, white granules	Observed
Odour	Odourless	Observed
Odour threshold	Not applicable	
pH	pH 7.1	As measured in the water solubility study (EU Method A.6)
Melting point/freezing point	>450°C	EU Method A1
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 applicable	
Flammability (Solid, gas)	Not flammable	Based on prediction and use based

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		observations
Upper/lower flammability or explosive limits	Not applicable	
Vapour pressure	Not determined	According to Regulation No. 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	3.05 at 23°C	EU Method A3
Solubility(ies)	296 g/L at 20.0 ± 0.5°C	EU Method A.6 The effect of temperature over the range 10 to 30°C has been considered not to have had a significant influence on the observed solubility of the test material. Water solubility of the test material over the pH range 4 to 9 would be constant, essentially due to the low buffering activities seen in the environment.
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 disodium fluorophosphate, 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

Contact with strong acids releases hydrogen fluoride.

10.4 Conditions to avoid

None identified.

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10.5 Incompatible materials

Strong acids.

10.6 Hazardous decomposition products

Hydrogen fluoride (HF)

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Toxicological endpoint	Value (including relevance to CLP criteria)	Method
Acute toxicity		
Oral	LD50 = 570 mg/kg bw/day	Rat, fixed dose procedure. Klimisch reliability 1
Dermal	Although skin contact is likely during production and use of disodium fluorophosphate, inhalation of the substance is also likely and as such an acute inhalation study has been performed. As disodium fluorophosphate is an inorganic chemical with a molecular weight of >100 systemic absorption via the dermal route is unlikely and as such inhalation and oral routes are considered to be a worst-case for systemic absorption. In addition, no signs of systemic toxicity were observed in the acute skin and eye studies conducted on disodium fluorophosphate and therefore it can be reliably assumed that a full characterisation of the acute systemic toxicity profile of disodium fluorophosphate can be derived from the acute oral and inhalation studies and as such further in vivo testing would be unethical and could not be scientifically justified.	
Inhalation	LC50 = >2.1 mg/L	Rat, OECD 403. Klimisch reliability 1
Skin corrosion/irritation	Not irritating to skin	Reconstituted human epidermis, EU method B44. Klimisch reliability 1
Serious eye/damage/irritation	Not irritating	Rabbit, OECD 405. Klimisch reliability 1
Respiratory or skin sensitisation	Not sensitising	Mouse, OECD 429. Klimisch reliability 1
Germ cell mutagenicity	Not considered to be mutagenic.	Disodium fluorophosphate is not expected to produce germ cell genotoxic damage.
Carcinogenicity	Not considered to be a carcinogen.	Not required for REACH. Study on analogous substance (Klimisch reliability 2), sodium fluoride, does not provide evidence of carcinogenic potential.
Reproductive toxicity	NOAEL 70 mg/kg. Not considered to be a reproductive toxicant.	Not classified, weight of evidence approach consisting of Klimisch reliability 1 data on disodium fluorophosphate (OECD 422) and Klimisch reliability 2 data on sodium fluoride is presented (multi-generation studies).
STOT-single exposure – all routes	No STOT SE observed via the oral, dermal or inhalation route	
STOT-Repeated exposure - all routes	Not considered to induce specific organ toxicity after repeated exposure via oral route.	Not classified, weight of evidence approach consisting of Klimisch reliability 1 data on disodium fluorophosphate (OECD 422) and Klimisch reliability 2 data on sodium fluoride

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		(2-year carcinogenicity) is presented.
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. Kimisch reliability 1
Acute <i>Daphnia</i> toxicity	48 hr EC ₅₀ = > 100 mg/L 48 hr NOEC = >100 mg/L	<i>Daphnia magna</i> , OECD 202, EU Method C.2. Kimisch reliability 1
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. Kimisch reliability 1
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. Kimisch reliability 1

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

12.2 Persistence and degradability

Disodium fluorophosphate is an inorganic substance, biodegradation studies are not applicable. No further testing is deemed to be necessary.

12.3 Bioaccumulative potential

The degradation products of disodium fluorophosphate (sodium, fluoride and phosphate ions) 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

12.4 Mobility in soil

No data available:

A batch equilibrium study according to OECD Guideline 106 was deemed to be not applicable to Disodium fluorophosphate for the following reasons:

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.

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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 disodium fluorophosphate 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

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)

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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			

Other Information:

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 disodium fluorophosphate.

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

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- 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
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

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Annex: summary of relevant exposure scenarios

To be attached by each registrant