

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Product form : Mixture
Trade name : Triphasix
Product code : 002011

1.2. Relevant identified uses of the substance or mixture and uses advised against**1.2.1. Relevant identified uses**

Industrial/Professional use spec : For professional use only
Use of the substance/mixture : Alginate for dental impression material.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Parkell Inc.
300 Executive Drive
Edgewood, NY 11717
T (631) 249-1134

Authorized Representative in Europe (Regulatory affairs only)

Directa AB
P.O. Box 723, Finvids väg 8
SE-194 27 Upplands Väsby
Sweden

1.4. Emergency telephone number

Emergency number : 1-352-323-3500 (Infotrac) (International, 24 hours)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Serious eye damage/eye irritation, Category 2 H319
Hazardous to the aquatic environment — Chronic Hazard, Category 3 H412
Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning
Hazard statements (CLP) : H319 - Causes serious eye irritation
H412 - Harmful to aquatic life with long lasting effects
Precautionary statements (CLP) : P264 - Wash hands thoroughly after handling
P273 - Avoid release to the environment
P280 - Wear eye protection
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337+P313 - If eye irritation persists: Get medical advice/attention
P501 - Dispose of contents to comply with applicable local, national and international regulation.

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2.3. Other hazards not contributing to the classification

Dust may form explosive mixture in air.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Titanate(2-), hexafluoro-, dipotassium, (OC-6-11)-	(CAS-No.) 16919-27-0 (EC-No.) 240-969-9	1 - 3	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318
Zinc oxide, dust	(CAS-No.) 1314-13-2 (EC-No.) 215-222-5 (EC Index-No.) 030-013-00-7	0,5 - 2,5	Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Acetic acid substance with a Community workplace exposure limit	(CAS-No.) 64-19-7 (EC-No.) 200-580-7 (EC Index-No.) 607-002-00-6	0 - 0,2	Flam. Liq. 3, H226 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Acetic acid	(CAS-No.) 64-19-7 (EC-No.) 200-580-7 (EC Index-No.) 607-002-00-6	(10 =<C < 25) Skin Irrit. 2, H315 (10 =<C < 25) Eye Irrit. 2, H319 (25 =<C < 90) Skin Corr. 1B, H314 (C >= 90) Skin Corr. 1A, H314

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Allow victim to breathe fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: Dust of the product, if present, may cause respiratory irritation after an excessive inhalation exposure
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after skin contact	: May cause slight temporary irritation
Symptoms/effects after ingestion	: Abdominal pain, nausea

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Not classified as flammable but will burn.
Explosion hazard	: Accumulation of airborne dusts may present an explosion hazard in the presence of an ignition source.
Reactivity in case of fire	: Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Hazardous decomposition products in case of fire	: Combustion may produce irritating fumes.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
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Protective equipment for firefighters : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection. For disposal of residues refer to section 13 : Disposal considerations.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Provide adequate ventilation.

Hygiene measures : Wash hands thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool, well ventilated place away from: Heat sources and incompatible materials. Keep container closed when not in use.

Incompatible materials : Carbonates, oxides, phosphates, oxidising substances and bases.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Zinc oxide, dust (1314-13-2)		
EU	Local name	Zinc oxide
Belgium	Short time value (mg/m ³)	10 mg/m ³
Croatia	GVI (granična vrijednost izloženosti) (mg/m ³)	5 mg/m ³
Croatia	KGVI (kratkotrajna granična vrijednost izloženosti) (mg/m ³)	10 mg/m ³
Czech Republic	Expoziční limity (PEL) (mg/m ³)	2 mg/m ³
Czech Republic	Expoziční limity (NPK-P) (mg/m ³)	5 mg/m ³
Finland	HTP-arvo (8h) (mg/m ³)	2 mg/m ³
Finland	HTP-arvo (15 min)	10 mg/m ³
France	Local name	Oxyde de zinc
Ireland	OEL (8 hours ref) (mg/m ³)	5 mg/m ³
Ireland	OEL (15 min ref) (mg/m ³)	10 mg/m ³
Lithuania	IPRV (mg/m ³)	5 mg/m ³
Poland	NDS (mg/m ³)	5 mg/m ³
Poland	NDSch (mg/m ³)	10 mg/m ³
Portugal	OEL TWA (mg/m ³)	2 mg/m ³ (respirable fraction)
Portugal	OEL STEL (mg/m ³)	10 mg/m ³ (respirable fraction)
Slovakia	NPHV (priemerná) (mg/m ³)	1 mg/m ³
Slovakia	Upozornenie (SK)	krátkodobý kategória I. , respirabilná frakcia
Sweden	nivågränsvärde (NVG) (ppm)	5 ppm
Sweden	Anmärkning (SE)	total dust 1
United Kingdom	WEL TWA (mg/m ³)	5 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	10 mg/m ³
United Kingdom	Remark (WEL)	(fume)

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Zinc oxide, dust (1314-13-2)		
Norway	Grøenseverdier (AN) (mg/m ³)	5 mg/m ³
Acetic acid (64-19-7)		
EU	Local name	Acetic acid
EU	IOELV TWA (mg/m ³)	25 mg/m ³ (deleted with effect from August 21, 2018)
EU	IOELV TWA (ppm)	10 ppm (deleted with effect from August 21, 2018)
EU	IOELV STEL (mg/m ³)	50 mg/m ³
EU	IOELV STEL (ppm)	20 ppm
Austria	MAK (mg/m ³)	25 mg/m ³
Austria	MAK (ppm)	10 ppm
Austria	MAK Short time value (mg/m ³)	50 mg/m ³
Austria	MAK Short time value (ppm)	20 ppm
Belgium	Limit value (mg/m ³)	25 mg/m ³
Belgium	Limit value (ppm)	10 ppm
Belgium	Short time value (mg/m ³)	38 mg/m ³
Belgium	Short time value (ppm)	15 ppm
Bulgaria	OEL TWA (mg/m ³)	25 mg/m ³
Bulgaria	OEL STEL (mg/m ³)	37 mg/m ³
Croatia	GVI (granična vrijednost izloženosti) (mg/m ³)	25 mg/m ³
Croatia	GVI (granična vrijednost izloženosti) (ppm)	10 ppm
Cyprus	OEL TWA (mg/m ³)	25 mg/m ³
Cyprus	OEL TWA (ppm)	10 ppm
Czech Republic	Expoziční limity (PEL) (mg/m ³)	25 mg/m ³
Denmark	Grænseværdie (langvarig) (mg/m ³)	25 mg/m ³
Denmark	Grænseværdie (langvarig) (ppm)	10 ppm
Estonia	OEL TWA (mg/m ³)	25 mg/m ³
Estonia	OEL TWA (ppm)	10 ppm
Estonia	OEL STEL (mg/m ³)	25 mg/m ³
Estonia	OEL STEL (ppm)	10 ppm
Finland	HTP-arvo (8h) (mg/m ³)	13 mg/m ³
Finland	HTP-arvo (8h) (ppm)	5 ppm
Finland	HTP-arvo (15 min)	25 mg/m ³
Finland	HTP-arvo (15 min) (ppm)	10 ppm
France	Local name	Acide acétique
France	VLE (mg/m ³)	25 mg/m ³
France	VLE (ppm)	10 ppm
France	Note (FR)	Valeurs recommandées/admises
Germany	TRGS 900 Occupational exposure limit value (mg/m ³)	25 mg/m ³ (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed)
Germany	TRGS 900 Occupational exposure limit value (ppm)	10 ppm (The risk of damage to the embryo or fetus can be excluded when AGW and BGW values are observed)
Gibraltar	Eight hours mg/m ³	25 mg/m ³
Gibraltar	Eight hours ppm	10 ppm
Greece	OEL TWA (mg/m ³)	25 mg/m ³
Greece	OEL TWA (ppm)	10 ppm
Greece	OEL STEL (mg/m ³)	37 mg/m ³
Greece	OEL STEL (ppm)	15 ppm
Hungary	AK-érték	25 mg/m ³
Hungary	CK-érték	25 mg/m ³
Ireland	OEL (8 hours ref) (mg/m ³)	25 mg/m ³
Ireland	OEL (8 hours ref) (ppm)	10 ppm
Ireland	OEL (15 min ref) (mg/m ³)	37 mg/m ³
Ireland	OEL (15 min ref) (ppm)	15 ppm

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Acetic acid (64-19-7)		
Latvia	OEL TWA (mg/m ³)	25 mg/m ³
Latvia	OEL TWA (ppm)	10 ppm
Lithuania	IPRV (mg/m ³)	25 mg/m ³
Lithuania	IPRV (ppm)	10 ppm
Luxembourg	OEL TWA (mg/m ³)	25 mg/m ³
Luxembourg	OEL TWA (ppm)	10 ppm
Malta	OEL TWA (mg/m ³)	25 mg/m ³
Malta	OEL TWA (ppm)	10 ppm
Netherlands	Grenswaarde TGG 8H (mg/m ³)	25 mg/m ³
Poland	NDS (mg/m ³)	25 mg/m ³
Poland	NDSch (mg/m ³)	50 mg/m ³
Portugal	OEL TWA (mg/m ³)	25 mg/m ³ (indicative limit value)
Portugal	OEL TWA (ppm)	10 ppm (indicative limit value)
Portugal	OEL STEL (ppm)	15 ppm
Romania	OEL TWA (mg/m ³)	25 mg/m ³
Romania	OEL TWA (ppm)	10 ppm
Slovakia	NPHV (priemerná) (mg/m ³)	25 mg/m ³
Slovakia	NPHV (priemerná) (ppm)	10 ppm
Slovenia	OEL TWA (mg/m ³)	25 mg/m ³
Slovenia	OEL TWA (ppm)	10 ppm
Spain	VLA-ED (mg/m ³)	25 mg/m ³
Spain	VLA-ED (ppm)	10 ppm
Spain	VLA-EC (mg/m ³)	37 mg/m ³
Spain	VLA-EC (ppm)	15 ppm
Sweden	nivågränsvärde (NVG) (mg/m ³)	13 mg/m ³
Sweden	nivågränsvärde (NVG) (ppm)	5 ppm
Sweden	kortidsvärde (KTV) (mg/m ³)	25 mg/m ³
Sweden	kortidsvärde (KTV) (ppm)	10 ppm
Norway	Grenseverdier (AN) (mg/m ³)	25 mg/m ³
Norway	Grenseverdier (AN) (ppm)	10 ppm
Norway	Grenseverdier (Korttidsverdi) (mg/m ³)	37,5 mg/m ³ (value calculated)
Norway	Grenseverdier (Korttidsverdi) (ppm)	15 ppm (value calculated)
Switzerland	MAK (mg/m ³)	25 mg/m ³
Switzerland	MAK (ppm)	10 ppm
Switzerland	KZGW (mg/m ³)	50 mg/m ³
Switzerland	KZGW (ppm)	20 ppm
Turkey	OEL TWA (mg/m ³)	25 mg/m ³
Turkey	OEL TWA (ppm)	10 ppm

8.2. Exposure controls

Appropriate engineering controls:

Provide adequate ventilation. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Hand protection:

Impermeable protective gloves. (to European standard EN 374 or equivalent)

Eye protection:

Chemical goggles or safety glasses. (to European standard EN 166 or equivalent)

Skin and body protection:

Wear suitable protective clothing.

Respiratory protection:

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Wear dust mask in case of dust formation

Other information:

Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Colour	: White
Odour	: Vanilla.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable, but will burn.
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Slightly soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

None under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur. When mixed with air and exposed to an ignition source, dust may burn in the open air or explode if confined.

10.4. Conditions to avoid

Heat sources.

10.5. Incompatible materials

Carbonates, oxides, phosphates, oxidising substances and bases.

10.6. Hazardous decomposition products

Combustion may produce irritating fumes.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

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Titanate(2-), hexafluoro-, dipotassium, (OC-6-11)- (16919-27-0)	
LD50 oral rat	169 mg/kg
Zinc oxide, dust (1314-13-2)	
LD50 oral rat	> 5000 mg/kg
Acetic acid (64-19-7)	
LD50 oral rat	3310 mg/kg
LD50 dermal rabbit	1060 mg/kg
LC50 inhalation rat (mg/l)	11,4 mg/l/4h

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Harmful to aquatic life with long lasting effects.
Ecology - water	: Harmful to aquatic life with long lasting effects.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Harmful to aquatic life with long lasting effects.

Titanate(2-), hexafluoro-, dipotassium, (OC-6-11)- (16919-27-0)	
EC50 96h algae (1)	95 mg/l (Species: Desmodesmus subspicatus)
Acetic acid (64-19-7)	
LC50 fish 1	79 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
LC50 fish 2	75 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 Daphnia 1	65 mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])

12.2. Persistence and degradability

Triphasix	
Persistence and degradability	May cause long-term adverse effects in the environment.

12.3. Bioaccumulative potential

Triphasix	
Bioaccumulative potential	Not established.
Acetic acid (64-19-7)	
Log Pow	-0,31 (at 20 °C)

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations	: Dispose of contents/container to comply with applicable local, national and international regulation.
Ecology - waste materials	: Avoid release to the environment.

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SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

- Overland transport

Not regulated

- Transport by sea

Not regulated

- Air transport

Not regulated

- Inland waterway transport

Not regulated

- Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

VwVwS Annex reference : Water hazard class (WGK) 2, significant hazard to waters (Classification according to VwVwS, Annex 4)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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SECTION 16: Other information

Sources of Key data : According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830. SDS - Safety Data Sheet.

Other information : None.

Full text of H- and EUH-statements:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Flam. Liq. 3	Flammable liquids, Category 3
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
H226	Flammable liquid and vapour
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H319	Causes serious eye irritation
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects
H412	Harmful to aquatic life with long lasting effects

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Eye Irrit. 2	H319	Calculation method
Aquatic Chronic 3	H412	Calculation method

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product