

Safety Data Sheet according to Regulation (EU) 2020/878 (REACH)

 Version:
 6
 Revision date:
 15.07.2024

 Replaces version:
 5
 from:
 17.11.2022

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

1.1. Product identifier

Oxydens

CAS No.: -EC No.: -UFI -REACH No.: --

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

Relevant identified uses: Cleaning tablet for plastic dental splints

Uses advised against: Other

1.3. Details of the supplier of the safety data sheet

Manufacturer

Fittydent International GmbH

Carlbergerstrasse 38/Top 3/1 Telephone +43 1 381 81 81

Telefax: +43 1 381 81 82

AT 1230 Wien

Supplier

ERKODENT Erich Kopp GmbH

Siemensstrasse 3 **Telephone** +49 7445 8501 0 **Telefax**: +49 7445 8501-15

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Information contact

ERKODENT Erich Kopp GmbH Information telephone +49 7445 8501 21

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Telephone --

E-mail (competent person) w.heuchert@erkodent.com

Website www.erkodent.com

1.4. Emergency telephone number

Bei Vergiftungserscheinungen, den örtlichen

Giftnotruf oder die 112 (nur in Deutschland)

wählen

Seek medical advice immediately (poison centre).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008:

Ox. Liq./Sol. 2/3, H272; Acute Tox. 4, H302; Skin Corr. 1/1A/1B/1C, H314; Eye Dam. 1, H318

2.2. Label elements

Classification according to Regulation (EC) No 1272/2008 [CLP]

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Hazard pictograms







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GHS03, GHS05, GHS07

Signal word: Danger

Hazard statements:

H272 May intensify fire; oxidiser. H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

Precautionary statements:

P102 Keep out of reach of children.

P301+330+331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P303+361+353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor/.?.

Special labelling of particular preparations:

Enthält: Kaliummonopersulfat, Perborsäure (HBO(=2)), Natriumsalz, Monohydrat; Natriumperoxoborat; [mit einem Gehalt an Teilchen mit einem aerodynamischen Durchmesser von weniger als 50 µm von < 0,1 % (w/w)]

Contains: Potassium monopersulfate, perboric acid (HBO(=2)), sodium salt, monohydrate; sodium peroxoborate; [containing < 0,1 % (w/w) of particles with an aerodynamic diameter of below 50 µm]

2.3. Other hazards

This mixture does not contain any substances presenting a health or environmental hazard within the meanis of Regulation (EC) No. 1272/2008, assigned a Community workplace exposure limit, classified as PBT/vPvB or included in the Candidate List. No known endocrine disrupting properties

SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

Mixture related information

Composition/information on ingredients

Substance:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):	M, ATE, Note
Potassium monopersulfate	10058-23-8		25 - 45 %	Acute Tox. 4, H302; Skin Corr. 1/1A/1B/1C, H314; Eye Dam. 1, H318	ATE (oral) = 500 mg/kg bodyweight
trisodium orthophosphate	10101-89-0		5 - 15 %	Skin Irrit. 2, H315; Eye Irrit. 2, H319	
Sodium carbonate	497-19-8		5 - 15 %	Eye Irrit. 2, H319	
Sulphamic acid	5329-14-6		2,5 - 10	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Aquatic Chronic 3, H412	M = 1 ATE (oral) = 2065 mg/kg bodyweight
perboric acid (HBO(O2)), sodium salt, monohydrate; sodium peroxoborate;	10332-33-9		1 -<6,5 %	Ox. Liq./Sol. 2/3, H272; Acute Tox. 4, H302; Eye Dam. 1, H318; STOT SE 3, H335; Repr. 1A/B, H360Df	ATE (oral) = 500 mg/kg bodyweight
Disodium carbonate, compound with hydrogen peroxide (2:3)	15630-89-4		< 1 %	Ox. Liq./Sol. 2/3, H272; Acute Tox. 4, H302; Eye Dam. 1, H318	ATE (oral) = 500 mg/kg bodyweight
Dinatriumdihydrogenethyl endiamintetraacetat	139-33-3		< 1 %	Acute Tox. 4, H332; STOT RE 2, H373	M = 0 ATE (oral) = 2800 mg/kg bodyweight

(Full text of H- and EUH-statements: see section 16.)

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SECTION 4: First aid measures

4.1. Description of first aid measures

General information: In case of accident or unwellness, seek medical advice immediately

In case of inhalation: Remove casualty to fresh air and keep warm and at rest. In case of respiratory

tract irritation, consult a physician.

Following skin After contact with skin, wash immediately with plenty of water and soap. Seek

contact: medical attention if problems persist. In case of skin irritation, consult a

physician.

After eye contact: In case of contact with eyes, rinse immediately with plenty of flowing water for 10

to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist. If accidentally swallowed rinse the mouth with plenty of water (only if the person

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is conscious) and obtain immediate medical attention. Do NOT induce vomiting.

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

No information available.

After ingestion:

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Water fog. alcohol resistant foam. dry extinguishing powder. Carbon dioxide

extinguishing media (CO2).

Unsuitable High power water jet.

extinguishing media

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon dioxide (CO2). Carbon monoxide. Sulphur dioxide (SO2).

5.3. Advice for firefighters

General information

Move undamaged containers from immediate hazard area if it can be done safely.

Special protective equipment for fire-fighters:

In case of fire: Wear self-contained breathing apparatus. Protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid generation of dust. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil.

6.3. Methods and material for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal. Avoid generation of dust.

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6.4. Reference to other sections

See protective measures under point 7 and 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advices on safe handling

Use only in well-ventilated areas. Keep away from sources of ignition - No smoking. Wear personal protection equipment (refer to section 8).

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Precautions against fire and explosion:

Keep away from sources of ignition - No smoking. Keep away from heat.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep in a cool, well-ventilated place. Put lids on containers immediately after use.

Hints on joint storage

Keep away from food, drink and animal feedingstuffs. Reducing agent. Do not mix with acids. Reducing agent. Alkalis (alkalis).

7.3. Specific end use(s)

Observe instructions for use.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

occupational exposure limit value

Substance:	CAS-No.:	9	Source:	Occupational	Occupational	Limitation of	Remark:
				exposure limit	exposure limit	exposure	
				value:[ppm]	value:[mg/m³]	peaks:	

Substance with a common (EC) occupational exposure limit value.

Substance:	CAS-No.:	So	urce:	Occupat	tional	Occupational	Limitation of	Remark:
				exposur	e limit	exposure limit	exposure	
				value:[pi	pm1	value:[mg/m³]	peaks:	

DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL

PNEC Value

Substance:	CAS-No.:	PNEC
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Additional information

No information available.

8.2. Exposure controls

Occupational exposure controls:

none

General protection and hygiene measures:

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Take off immediately all contaminated clothing.

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Personal protection equipment

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required. Technical ventilation of workplace.

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Hand protection

Suitable gloves type: NBR (Nitrile rubber). NR (Natural rubber (caoutchouc), Natural latex). Butyl rubber. FKM (fluoro rubber). PVC (Polyvinyl chloride) Breakthrough times and swelling properties of the material must be taken into consideration.

Eye/face protection

Tightly sealed safety glasses.

Body protection:

Protective clothing Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

Environmental exposure controls

refer to chapter 7. No further action is necessary.

Consumer exposure controls

refer to chapter 7. No further action is necessary.

Exposure Scenario:

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: solid

Colour: whitish greenish blue

Odour: characteristic **Odour threshold:** not determined

Safety relevant basis data

Partition coefficient: n-

octanol/water:

	parameter	Value	unit	Remark
Melting point/freezing point:	_			not determined
Initial boiling point and boiling				not determined
range:				
Flammability:				not applicable
lower flammability or explosive				not determined
limits:				
Upper flammability or explosive				not determined
limits:				
Flash point:			°C °C °C	not determined
Ignition temperature:				none Risk of selfignition.
Decomposition temperature:				not determined
pH:	approx.	9,0)	
Kinematic viscosity:				not determined
Water solubility (g/L):				

Vapour pressure:

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not determined

not determined

Density:not determinedRelative density:not determinedParticle properties:not determined

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9.2. Other information

There are no data available on the mixture itself.

SECTION 10: Stability and reactivity

10.1. Reactivity

May intensify fire; oxidiser.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4. Conditions to avoid

heat. UV-radiation/sunlight. frost.

10.5. Incompatible materials

Acid Reducing agent

10.6. Hazardous decomposition products

Stable under recommended storage and handling conditions.

SECTION 11: Toxicological information

11.1. Information on hazard classes within the meaning of Regulation (EC) No. 1272/2008

Data apply to the main component. Harmful by inhalation and if swallowed.

M-factor: - Acute toxicity (dermal): - Acute toxicity (oral): - Acute toxicity (inhalative): -

ATE (oral) 1923,077

mg/kg

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Sulphamic acid	5329-14-6	LD50 oral (Rat) 2065 mg/kg
		LD50 Oral 2065 mg/kg
		LD50 dermal > 2000 mg/kg
Dinatriumdihydrogenethylendiamintetraacetat	139-33-3	LD50 oral (Rat) 2800 mg/kg
		NOAEL STOT-RE (Ratte) > 500 mg/kg/d

Skin corrosion/irritation:

Causes severe skin burns and eye damage.

Serious eye damage/irritation:

Causes serious eye damage.

Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

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CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Carcinogenicity:

The ingredients in this preparation do not meet the criteria for classification as CMR category 1 or 2. according to 67/548/EEC.

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Germ cell mutagenicity:

No information available.

Reproductive toxicity:

No information available.

STOT-single exposure:

Based on available data, the classification criteria are not met.

STOT-repeated exposure:

No information available.

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information

11.2. Information about other hazards

11.2.1 Endocrine disrupting properties

11.2.2 Other Information

No information available.

SECTION 12: Ecological information

12.1. Toxicity

Do not allow to enter into surface water or drains.

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Sulphamic acid	5329-14-6	LC50 fish (96 h) 70,3 mg/l
Dinatriumdihydrogenethylendiamintetraacetat	139-33-3	EC50 Daphnia (Daphnia magna) 48 h 140 mg/l EC50 Algae (72 h) > 60 mg/l NOEC/NOEL Daphnia (Daphnia magna) 21 d 25 mg/l NOELR Fish (Brachydanio rerio) 96 h >= 25,7 mg/l LCO Daphnia (Daphnia sp.) 48 h 50 mg/l

12.2. Persistence and degradability

There are no data available on the mixture itself.

12.3. Bioaccumulative potential

There are no data available on the mixture itself.

12.4. Mobility in soil

There are no data available on the mixture itself.

12.5. Results of PBT and vPvB assessment

The components in this formulation do not meet the criteria for classification as PBT or vPvB.

12.6 Endocrine disruptive effect

No known endocrine disrupting properties

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12.7. Other adverse effects

There are no data available on the mixture itself.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Appropriate disposal/Product:

Dispose of waste according to applicable legislation. Send to a physico-chemical treatment facility under observation of official regulations. Send to a hazardous waste incinerator facility under observation of official regulations. Consult the appropriate local waste disposal expert about waste disposal.

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Appropriate disposal / Package

Dispose of waste according to applicable legislation.

List of proposed waste codes / waste designations according to EWC / AVV

Send to a hazardous waste incinerator facility under observation of official regulations.

SECTION 14: Transport information

14.1. UN number

UN No.: 3084

14.2. UN proper shipping name

Land transport (ADR/RID)

ÄTZENDER FESTER STOFF, ENTZÜNDEND (OXIDIEREND) WIRKEND, N.A.G. Kaliummonopersulfat

Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)

CORROSIVE SOLID, OXIDIZING, N.O.S.

(Kaliummonopersulfat)

14.3. Transport hazard class(es)

Hazard label(s) / Label: 8+5.1 Classification code: / Classification CO2 Code:



14.4. Packing group

Packing group/ Packing Group:

14.5. Environmental hazards

ADR/RID / IMDG / ICAO-TI / IATA-DGR:

Marine pollutant:

Yes

X

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14.6. Special precautions for user

Land transport (ADR/RID)

transport category: 2 tunnel restriction code: E
Special provisions: 274 Limited quantity (LQ): 1 kg

Sea transport (IMDG) EmS-No: F-A, S-Q

Special provisions: -- Limited quantity (LQ): 1 kg

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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Remark not applicable

SECTION 15: Regulatory information

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

EU legislation

Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer No information available.

Regulation (EC) No 850/2004 [POP-Regulation]

Regulation (EU) No 649/2012 on the export and import of dangerous chemicals No information available.

The substance/product is registered with strictly controlled conditions as defined in Article 18(4) of Regulation (EC) No. 1907/2006 (REACH Regulation) and must therefore be handled as such. No information available.

National regulations

Observe in addition any national regulations!

Restrictions of occupation

Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC).

Restrictions of occupation **none**

Solvents Regulation (31st BlmSchV)

No information available.

Other regulations, restrictions and prohibition regulations

No information available.

15.2. Chemical Safety Assessment

For this preparation a chemical safety assessment has been carried out.

For this substance a chemical safety assessment has not been carried out.

SECTION 16: Other information

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Relevant H- and EUH-phrases (Number and full text): Hazard statements

H314 Causes severe skin burns and eye damage.

Training advice

none

Recommended restrictions of use:

none

Further remarks:

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storag

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Documentation of changes:

none

Key literature references and sources for data

Data arise from reference works and literature.

Abbreviations and acronyms

Wording of the r-phrases under paragraph 3:

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