

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

Version: 2 Language: EN Revision date: 18.03.2016

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

1.1 Product identifier

Oxydens

CAS number: EC number (EINECS/ELINCS): **EC** index number: **REACH registration number:**

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

Identified uses of the Cleaning tabletts for denta splints

substance or mixture:

Not recommended uses of the

Other

substance or mixture:

1.3 Details of the supplier of the safety data sheet

Manufacturer

ERKODENT Erich Kopp GmbH

Siemensstrasse 3 **Telephone:** 07445 8501 0

Fax: 07445 2092

72285 Pfalzgrafenweiler

Supplier

ERKODENT Erich Kopp GmbH

Siemensstrasse 3 **Telephone:** 07445 8501 0

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D 72285 Pfalzgrafenweiler

Information contact

ERKODENT Erich Kopp GmbH Information Telephone: 07445 8501 21

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National contact

ERKODENT Erich Kopp GmbH Information Telephone: 07445 8501 0

Information fax:

E-mail (competent person): info@erkodent.com

Website:

1.4 Emergency telephone number

ERKODENT Erich Kopp GmbH **Telephone:** 07445 8501 0

Only available during office hours.

1.5 Dept. responsible for information

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2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008:

Skin Corr. 1B; H314, Acute Tox. 4; H302

Directive 67/548/EEC: Xn; R22, C; R34

2.2 Label elements

2.2.1 Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms:



GHS07

Signal word: Danger

H phrases: 302 Harmful if swallowed.

Causes severe skin burns and eye damage.

P phrases: 101 If medical advice is needed, have product container or label at hand.

102 Keep out of reach of children.

Wear protective gloves/protective clothing/eye protection/face protection.

301+330+331 IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

303+361+353 IF ON SKIN (or hair): Remove/Take off immediately all contaminated

clothing. Rinse skin with water/shower.

305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

310 Immediately call a POISON CENTER or doctor/physician.

405 Store locked up.

501 Dispose of contents/container to .?.

2.2.2 Labelling according to Directive 67/548/EEC

Hazard symbols:





C Corrosive.

Xn Harmful.

R phrases: 22 Harmful if swallowed.

34 Causes burns.

S phrases:

2.3 Other hazards

none

3. Composition/information on ingredients

3.1 Chemical characterization of the substance or mixture

Preparation related information

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3.2 Composition of the substance or mixture

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH- no.:	Concentratio n:	Classification: EC 1272/2008(CLP):	Classificatio n: 67/548/EEC:
Citric Acid	201-069-1	77-92-9			15 %	STOT SE 3; H335 Skin Irrit. 2; H315 Eye Dam. 1; H318	Xi; R37/38 Xi; R41
Disodium carbonate	207-838-8	497-19-8	011-005-00-2		10 %	Eye Irrit. 2; H319	Xi; R36
Potassium Caroate		70693-62-8			40 %	Acute Tox. 4; H302 Skin Corr. 1B; H314	Xn; R22 -; R33

Ingredients with EC exposure limits

Substance:	EC-no.:	CAS-No.:	INDEX no.:	REACH-	Concentratio	Classification: EC	Classificatio
				no.:	n:	1272/2008(CLP):	n:
						, ,	67/548/EEC:

(The wording of the listed risk phrases is given in Chapter 16)

3.3 Additional information

none

4. First aid measures

4.1 Description of first aid measures

General information: Remove contaminated clothing immediatley and dispose off safely. Symptoms

of poisoning may develop several hours following exposure. Victim should be under medical observation for at least 48 hours after exposure. Remove

contaminated clothing immediatley and dispose off safely.

Following inhalation: Provide fresh air. If victim is at risk of losing consciousness, position and

transport on their side.

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

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

physician.

Following 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.

After ingestion: If accidentally swallowed rinse the mouth with plenty of water (only if the person

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

Self-protection: First aid assistant: Pay attention to self-protection!

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: No information available. **Nature of Hazard:** No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Emergency aid: No information available. **Treatment:** Treat symptomatically.

5. Fire fighting measures

5.1 General information

The product itself is not combustible.

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5.2 Extinguishing media

Suitable: Extinguishing materials should be selected according to the surrounding area. Unsuitable: Extinguishing materials should be selected according to the surrounding area.

5.3 Special hazards arising from the substance or mixture

Can be released in case of fire: Carbon dioxide (CO2). Carbon monoxide. Sulphur dioxide (SO2).

5.4 Advice for fire fighters

Special protective equipment for fire-fighters

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

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Wear personal protection equipment. Remove all sources of ignition. Avoid contact with skin, eyes and clothes. Avoid generation of dust.

6.2 Environmental precautions

Do not allow to enter into soil/subsoil.

6.3 Methods and materials for containment and cleaning up

Take up mechanically, placing in appropriate containers for disposal.

6.4 References to other sections

See protective measures under point 7 and 8.

7. Handling and storage

7.1 Precautions for safe handling

Information for safe handling

Keep container tightly closed. Avoid generation of dust.

Technical measures

Always close containers tightly after the removal of product. Keep container tightly closed in a cool, wellventilated place.

Precautions against fire and explosion

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

Additional information

none

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions

Handle and open container with care. Store only in original container. Keep/Store only in original container. Keep container tightly closed in a cool, well-ventilated place. Keep away from heat. Protect from sunlight.

Packaging materials

Keep/Store only in original container.

Requirements for storerooms and containers

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

Information about storing together in storage facility

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

Further information concerning storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity. Keep away from heat.

Storage class: 8 B Non-combustible corrosive substances.

7.3 Specific end use(s)

Observe instructions for use.

8. Exposure controls / personal protection

8.1 Control parameters

8.1.1 Limits for occupational exposure

Exposure limit values

Substance:	CAS-No.:	Source:	Occupational exposure limit value:	Limitation of exposure peaks:	Remark:
Potassium Caroate	70693-62-8		3 mg/m3		TWA (8h) / STEL (15 Min.)

EC exposure limit values

Substance:	CAS-No.:	Source:	Occupational	Limitation of	Remark:
			exposure limit value:	exposure peaks:	

8.1.2 DNEL and PNEC values

DNEL-values

Substance:	CAS-No.:	DNEL/DMEL	Industry	Professional	consumer
Disodium carbonate	497-19-8	Ingestion short term (acute)			
		Ingestion Long Term (repeated)			
		Skin contact short term (acute)			
		Skin contact Long Term (repeated)			
		Inhalation short term (acute)			
		Inhalation Long Term (repeated)		10 mg/m3	

PNEC-values

Substance:	CAS-No.:	PNEC	Worker, industry	Worker, professional	consumer

8.1.3 Control-Banding

Control-Banding

none

8.1.4 Additional information

Air limit values: (Dust gerneral) 10 mg/m3; E: inhalable fraction of dust Air limit values: (Dust gerneral) 1,25 mg/m3; A: respirable fraction o dust

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8.2 Exposure controls

Occupational exposure controls

none

Chemical handling

Do not eat, drink, smoke or sneeze at the workplace. Wash hands before breaks and at the end of work. Take off immediately all contaminated clothing.

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.

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 protection

Tightly sealed safety glasses.

Skin 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.

8.3 Exposure scenario

none

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

State of matter: solid

Colour: pigmented white blue

Odour: characteristic
Odour threshold: not determined

Safety relevant basis data

i arameter	value	Oilit	INGIIIAIK
			not determined
			not determined
	5,5-9,0		
			not determined
			not determined
			not determined
			not applicable
			not determined
			not determined
	i arameter		

Parameter

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Value

Unit

Romark

Explosion hazard: not determined
Lower explosion limit: not determined
Upper explosion limit: not determined

Ignition temperature: none Risk of selfignition.

Decomposition temperature:not determinedOxidizing characteristics:not determinedVapour pressure:not determinedRelative vapour density:not determinedSpeed ofnot determined

vaporization/evaporation rate:

Solubility in water:

Fat solubility:

Solubility in

:

not determined

not determined

not determined

viscosity:

not determined

Solvent content: 0 %

9.2 Other information

No information available.

10. Stability and reactivity

10.1 Reactivity

No risks worthy of mention. No data available

10.2 Chemical stability

none slow decomposition spontaneous decomposition

10.3 Possibility of hazardous reactions

Reducing agents.

10.4 Conditions to avoid

Keep away from heat.

10.5 Incompatible materials

Reducing agents. Heavy metals. Etchant and acids Alkalis (alkalis).

10.6 Hazardous decomposition products

none Hazardous decomposition products

10.7 Additional information

none

11. Toxicological information

11.1 Information on toxicological effects

Data apply to the principal component. Harmful by inhalation and if swallowed. ATEmix calculated: ATE (oral) 1213,6 mg/kg

Acute toxicity

/ touto toxioity		
Substance:	CAS-No.:	Toxicological information
Substance.	CA3-110	Toxicological information

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Citric Acid	77-92-9	Oral: LD50 >5000 mg/kg Mouse Dermal: LD50 >2000 mg/kg Rabbit
Disodium carbonate	497-19-8	Oral: LD50 2800 mg/kg Rat Dermal: LD50 >2000 mg/kg Rabbit
Potassium Caroate	70693-62-8	Oral: LD50 500 mg/kg Rat Dermal: LD50 >2000 mg/kg Rabbit Inhalative (4h) aerosol: LC50 >5mg/l Rat

Specific symptoms in laboratory animals

Toxicological data are not available.

11.2 Irritation and etching

Irritant effect on the skin

Corrosive

Irritant effect on the eye

highly caustic.

Irritant effect on the respiratory tract

Toxicological data are not available.

Etching

corrosive.

11.3 Sensitization

No symptoms known up to now.

11.4 Repeated dose toxicity

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

Potassium Caroate:

Subchronic oral toxicity (90d Rat). NOAEL: 200 mg/kg literature infomation ECHA Dossier Subacute inhalative toxicity (14d Rat). NOAEC: 0,0014 mg/l literature infomation ECHA Dossier

11.5 CMR effects

Carcinogenicity

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

Mutagenicity

Potassium Caroate:

In-vitro mutagenicity:

OECD Guidline 471 (Bacterial Reverse Mutation Assy) = negative. Literature information: ECHA Dossier

OECD Guidline 473 (In vitro mammalian Cell Gene Mutatation Test) = positive. Literature information:

ECHA Dossier

OECD Guidline 476 (In vitro mammalian Cell Gene Mutatation Test) = positive. Literature information:

ECHA Dossier

In vivo mutagenicity:

OECD Guidline 474 (Mammalian Erythrocyte Micronucleus Test) = negative. Literature information:

ECHA Dossier

Developmental toxicity/teratogenicity:

NOAEL = 250 mg/kg (bw) / day Literature information: ECHA Dossier

Sodium carbonate:

Developmental toxicity/teratogenicity:

NOAEL = 245 mg/kg (bw) / day Literature information: ECHA Dossier

Citric acid:

In-vitro mutagenicity:

OECD Guidline 471 (Bacterial Reverse Mutation Assy) = negative. Literature information: ECHA

OECD Guidline 473 (In vitro mammalian Cell Gene Mutatation Test) = positive. (without metabolic activation) Literature information: ECHA Dossier

In vivo mutagenicity:

OECD Guidline 475 (Mammalian Bone Marrow Chromosome Aberration Test) = negative. Literature

En - 01.12.10 Page: 8 by: 12 information: ECHA Dossier **Reproductive toxicity**No information available.

11.6 General remarks

No information available.

Practical experience

No information available.

Other observations

No information available.

Additional information

No information available.

12. Ecological information

12.1 Toxicity

The information about ecology refers to the main components.

Eco toxicity

Substance:	CAS-No.:	Ecotoxicity	
Citric Acid	77-92-9	LC50 440-760 mg/l 96h Leuciccus idus ECHA Dossier ErC50 640 mg/l 96h Scenedesmus quadricauda ECHA Dossier EC50 ca. 120mg/l 48h Daphnia magna	
Disodium carbonate	497-19-8	LC50 300 mg/l 96h Lepomis macrochirus ECHA Dossier EC50 200 - 227 mg/l 48 h Ceriodaphnia sp. ECHA Dossier	
Potassium Caroate	70693-62-8	LC50 53 mg/l 96 h Oncorhynchus mykiss ECHA Dossier ErC50 1 mg/l 72 h Pseudokirchnerella subcapitata ECHA Dossier EC50 3,5 mg/l 48 h Daphnia Magna ECHA Dossier	

12.2 Persistence and degradability

Readily biodegradable (according to OECD criteria). Citric Acid 97% 28d

12.3 Bio accumulative 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

not applicable

12.6 Other adverse effects

There are no data available on the mixture itself.

12.7 Further ecological information

Do not empty into drains or the aquatic environment.

12.8 Further details

There are no data available on the mixture itself.

13. Disposal considerations

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13.1 Waste treatment methods

Appropriate disposal/Product

Waste disposal according to official state regulations. Carry out under observation of official regulations covering a chemical/physical treatment plant. Carry out a burning of harzardous waste according to official regulations. Consult the local waste disposal expert about waste disposal.

Appropriate disposal/ packaging

Waste disposal according to official state regulations.

Control report for waste code/ waste marking according to EAKV

Waste key product: 20 01 29 - Reinigungsmittel, die gefährliche Stoffe enthalten

Waste key packaging: 15 01 10 - Verpackungen, die Rückstände gefährlicher Stoffe enthalten

oder durch gefährliche Stoffe verunreinigt sind

Remark

Waste disposal according to official state regulations.

14. Transport information

14.1 Overland transport (ADR/RID)

Proper Shipping name

UN No.:

Label: Packing Group: Classification code:

Remark: Not a hazardous material with respect to these transportation regulations.

14.2 Transport by sea (IMDG)

Proper Shipping name

UN-No.:

Label: Packing Group:

EmS-No: MFAG: Marine pollutant: Nein

Special Provisions:

Remark: Not a hazardous material with respect to these transportation regulations.

14.3 Air transport (ICAO-TI / IATA-DGR)

Proper Shipping name

UN/ID-No.:

Label: Packing Group:

Remark: Not a hazardous material with respect to these transportation regulations.

14.4 Mail

Not a hazardous material with respect to these transportation regulations.

15. Regulatory information

15.1 Labelling

Hazardous component(s) for labelling

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Special labelling of particular preparations

Classification according to Directive 67/548/EEC or 1999/45/EC

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

EU-Regulations

Directive 1999/13/EC on the limitation of emissions of volatile organic compounds (VOC-RL) No information available.

Regulation (EC) No 2037/2000 on substances that deplete the ozone layer No information available.

Regulation (EC) No 850/2004 on persistent organic pollutants

No information available.

Regulation (EC) No 689/2008 concerning the export and import of dangerous chemicals No information available.

Regulation (EC) No 648/2004 (Detergents regulation)

No information available.

Restrictions under Title VIII of Regulation (EC) No 1907/2006

No information available.

National regulations

Moreover, national legislation has to be observed!

Informations on working limitations

No information available.

Major Accidents Ordinance

No information available.

Storage class according to VCI

Water Hazard Class according to VwVwS

1 weak water pollutant (WGK 1)

Technical Instructions on Air Quality Control (TA-Luft)

No information available.

Further regulations, limitations and legal requirements

No information available.

15.3 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.

16. Other information

16.1 Wording of the H and R-phrases under paragraph 3

Regulation (EC) No 1272/2008

- 302 Harmful if swallowed.
- 314 Causes severe skin burns and eye damage.

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Directive 67/548/EEC

22 Harmful if swallowed.

34 Causes burns.

16.2 Training instructions

none/none

16.3 Recommended restrictions of use

none

16.4 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 storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

16.5 Documentation of changes

none

16.6 Data sources

Data arise from reference works and literature.

16.7 Key and definition

Wording of the r-phrases under paragraph 3:

17. Appendix

17.1 Exposure scenario

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