

SAFETY DATA SHEET (EC 1907/2006)**Oxynon**

Version: **2.10 / GB**
 Revision date: **01.10.2020**
 Issue date: **03.09.2001**
 replaces version: **2.9**
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Material no.
 Specification **102877**
 VA-Nr **01906661**

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

Trade name Oxynon
 REACH Registration No.: if available listed in Chapter. 3

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

Relevant applications identified For dental use only.

1.3. Details of the supplier of the safety data sheet

Company DeguDent GmbH
 Postfach 1364
 D-63403 Hanau
 Telephone +49 (0)6181/59-5576
 Telefax +49 (0)6181/59-5879
 Email address SDB.Degudent-DE@dentsplysirona.com

1.4. Emergency telephone number

Emergency information +49 (0)6181/59-50 (This telephone number is available during office hours only.)

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

| | | |
|-----------------------|------------|-------|
| Acute toxicity | Category 4 | H302 |
| Reproductive toxicity | Category 2 | H361d |

2.2. Label elements**Labelling as per (EU) 1272/2008****hazard-defining component(s) (GHS)**

- Potassium difluorodihydroxyborate(1-)

Hazard pictograms



Signal word Warning

Hazard statement H302 - Harmful if swallowed.
 H361d - Suspected of damaging the unborn child.

Precautionary statement: Prevention P202 - Do not handle until all safety precautions have been read and understood.
 P264 - Wash hands thoroughly with soap and water after handling.
 P280 - Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement: Reaction P308 + P313 - IF exposed or concerned: Get medical advice/ attention.

Precautionary statement: Disposal P501 - Dispose of contents/container in accordance with local regulation.

2.3. Other hazards

A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out.

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SECTION 3: Composition/information on ingredients

Information on ingredients / Hazardous components as per EU-CLP Regulation (EC) No. 1272/2008

| | | | | |
|--|------------|-----------|------------|-------|
| • Potassium difluorodihydroxyborate(1-) | | 60% - 80% | | |
| CAS-No. | 85392-66-1 | EC-No. | 286-925-2 | |
| Acute toxicity (oral) | | | Category 4 | H302 |
| Reproductive toxicity (oral) | | | Category 2 | H361d |
| • Boron | | < 2% | | |
| CAS-No. | 7440-42-8 | EC-No. | 231-151-2 | |

Texts of H phrases, see in Chapter 16

SECTION 4: First aid measures

4.1. Description of first aid measures

Remove contaminated or saturated clothing.

Inhalation

Move victims into fresh air.

Upon formation of vapours / fumes are formed:

Possible discomfort:

irritation of mucous lining (nose, throat, eyes)

cough, sneezing, flow of tears

If breathing difficulties occur:

Keep patient half sitting with upper body raised.

Call a physician immediately.

Skin contact

Remove product immediately with cellucotton (or similar material).

Wash off with soap and plenty of water.

Consult a physician in case of eye irritation.

Eye contact

With eye held open, thoroughly rinse immediately with plenty of water for at least 10 minutes.

Remove contact lenses.

In case of persistent discomfort:

Consult an ophthalmologist.

Ingestion

Induce vomiting immediately and call a physician.

Keep respiratory tract clear.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician.

Take victim immediately to hospital.

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

Symptoms

Ingestion may provoke the following symptoms:

Stomach/intestinal disorders

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

No information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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Suitable extinguishing media: All extinguishing substances suitable.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media: High volume water jet

5.2. Special hazards arising from the substance or mixture

Danger of decomposition under influence of heat.

In case of combustion or decomposition of the product, the fumes produced lead to irritations or inflammations of the respiratory tract.

5.3. Advice for firefighters

Water for fire fighting must not be introduced in the sewer system, subsoil, or surface waters. Assure that there are sufficient fire water retaining facilities Contaminated fire fighting water must be disposed of in conformity with the regulations of the local authorities.

Fire residues should be disposed of in accordance with the regulations.

In the event of fire, wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

In case product dust is released:

Do not breathe dust.

Avoid formation of dust. Ensure sufficient ventilation.

Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Introduction into soil, natural water bodies or sewerage must be prevented.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

Wear personal protective equipment; see section 8.

Disposal considerations; see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Ensure suitable suction/aeration at the work place and with operational machinery.

If necessary: Local ventilation.

Do not breathe vapours/dust.

Avoid contact with skin, eyes and clothing.

7.2. Conditions for safe storage, including any incompatibilities

Storage

Keep tightly closed in a dry, cool and well-ventilated place.

Store in original container.

Protect from direct sunlight.

German storage class

12 - Non Combustible Liquids

Storage stability

Keep at temperatures of between 5 °C and 30 °C.

7.3. Specific end use(s)

We are unaware of any specific end uses which go beyond the data reported in Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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• Potassium difluorodihydroxyborate(1-)

| | | | |
|--------------------|-------------------------------------|--------|--------------------------------------|
| CAS-No. | 85392-66-1 | EC-No. | 286-925-2 |
| Control parameters | 2.5 mg/m ³ Indicative | | Time Weighted Average (TWA):(EU ELV) |

8.2. Exposure controls

Engineering measures

hydrogen fluoride is released during processing., Ensure suitable suction/aeration at the work place and with operational machinery.

Personal protective equipment

Respiratory protection

In case of working with / without sufficient object exhaustion:, If workplace exposure limit is exceeded apply respirator with ABEK-P3 combination filter.

Hand protection

Wear protective gloves made of the following materials:

Glove material Nitrile rubber/Nitrile latex (NBR)

Material thickness 0.4 mm

Break through time > 240 min

Eye/face protection

Safety glasses with side-shields

Skin and body protection

suitable protective clothing recommended

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice., If there is the possibility of skin/eye contact, the indicated hand/eye/body protection should be used., When using, do not eat, drink or smoke. Wash face and/or hands before break and end of work., After contact with skin, wash immediately with plenty of water., Do not inhale smoke, dust, vapor., Draw off hydrogen fluoride vapours., Do not swallow product., Apply adequate skin protection agents before handling the product. Assure skin cleaning and skin care after work. Preventive skin protection is recommended.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Form dispersion

Colour brown

Odour odourless

Odour threshold: not applicable

pH ca. 5.5

Melting point/range not known

Boiling point/range not known

Flash point Method: closed cup
does not flash

Evaporation rate No data available

Flammability (solid, gas) not flammable

Lower explosion limit not applicable

Upper explosion limit not applicable

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| | |
|--|---|
| Vapour pressure | not applicable |
| Density | ca. 1.6 g/cm ³ |
| Water solubility | ca. 500 g/l (20 °C) |
| Partition coefficient: n-octanol/water | no data available |
| Autoinflammability | Not capable of spontaneous combustion or heating. |
| Thermal decomposition | No data available |
| Viscosity, dynamic | no data available |
| Explosiveness | not applicable |
| Oxidizing properties | not oxidizing |

9.2. Other information

Other information No further physicochemical data were determined.

SECTION 10: Stability and reactivity

10.1. Reactivity

no data available

10.2. Chemical stability

The product is chemically stable.

10.3. Possibility of hazardous reactions

Stability Stable at room temperature.
Possibility of hazardous reactions No hazardous reactions are known if properly handled and stored.

10.4. Conditions to avoid

Traces of hydrogen fluoride vapours are formed if heated above melting point.

10.5. Incompatible materials

Avoid contact with acids., Reaction with sulphuric acid.

10.6. Hazardous decomposition products

decomposition products on heating sulphuric acid
Hydrogen fluoride

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute oral toxicity LD50 Rat(female): 608 mg/kg
Method: OECD Guide-line 401
Test substance: Potassium difluorodihydroxyborate(1-)

Test substance: Boron
no data available

Acute inhalation toxicity LC50 Rat(male and female): > 2.04 mg/l / 4 h / dust/mist
Method: OECD Test Guideline 403
Test substance: Potassium difluorodihydroxyborate(1-)
Assessment: The substance or mixture has no acute inhalation toxicity
The data are derived from the evaluations or test results achieved with

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similar products (conclusion by analogy).

Test substance: Boron
no data available

Acute dermal toxicity LD50 Rabbit(male and female): > 2000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity
This information is derived from evaluation of or a test result for a similar compound (conclusion based on analogy).

Test substance: Boron
no data available

Skin irritation not irritating

Eye irritation not irritating

Sensitization no data available

Repeated dose toxicity no data available

Assessment of STOT single exposure no data available

Assessment of STOT repeat exposure no data available

Risk of aspiration toxicity no data available

Mutagenicity assessment no data available

Carcinogenicity No data available

Toxicity to reproduction Studies in laboratory animals have given indications of developmental disturbances.

SECTION 12: Ecological information**12.1. Toxicity**

No ecotoxicological studies are available.

Toxicity to fish LC50 Danio rerio (zebra fish): 750 mg/l / 96 h
Test substance: Potassium difluorodihydroxyborate(1-)
Method: OECD TG 203

NOEC Danio rerio (zebra fish): 560 mg/l / 96 h
Test substance: Potassium difluorodihydroxyborate(1-)
Method: OECD Test Guideline 203

Toxicity in aquatic invertebrates EC50 Pseudomonas putida: 240 mg/l / 17 h
Test substance: Potassium difluorodihydroxyborate(1-)

NOEC Pseudomonas putida: 180 mg/l / 17 h
Test substance: Potassium difluorodihydroxyborate(1-)

Toxicity to algae EC50 Lemna minor (duckweed): 60 mg/l / 96 h
Test substance: Boron

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12.2. Persistence and degradability

Biodegradability no data available

12.3. Bioaccumulative potential

Bioaccumulation no data available

12.4. Mobility in soil

Mobility No data available

12.5. Results of PBT and vPvB assessment

A PBT/vPvB evaluation is not available, since a chemical safety evaluation is not required / has not been carried out.

12.6. Other adverse effects

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product

Disposal according to local authority regulations.

Uncleaned packaging

Do not reuse empty containers and dispose of in accordance with the regulations issued by the appropriate local authorities.

SECTION 14: Transport information

Not dangerous according to transport regulations.

14.1. UN number: --
14.2. UN proper shipping name: --
14.3. Transport hazard class(es): --
14.4. Packing group: --
14.5. Environmental hazards: --
14.6. Special precautions for user: No

SECTION 15: Regulatory information

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

National legislation

employment restriction Note employment restrictions for pregnant and lactating women., Note employment restrictions for minors.

15.2. Chemical safety assessment

Chemical safety assessment No Chemical Safety Report as per Articles 2(8), 2(9) or 14 of the REACH Regulation is required for this product.

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**SECTION 16: Other information****Relevant H phrases from chapter 3**

H302 : Harmful if swallowed.
H361d : Suspected of damaging the unborn child.

Further information

Changes since the last version are highlighted in the margin. This version replaces all previous versions.

This information and all further technical advice is based on our present knowledge and experience. However, it implies no liability or other legal responsibility on our part, including with regard to existing third party intellectual property rights, especially patent rights. In particular, no warranty, whether express or implied, or guarantee of product properties in the legal sense is intended or implied. We reserve the right to make any changes according to technological progress or further developments. The customer is not released from the obligation to conduct careful inspection and testing of incoming goods. Performance of the product described herein should be verified by testing, which should be carried out only by qualified experts in the sole responsibility of a customer. Reference to trade names used by other companies is neither a recommendation, nor does it imply that similar products could not be used.

Legend

| | |
|------------------|---|
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ASTM | American Society for Testing and Materials |
| ATP | Adaptation to Technical Progress |
| BCF | Bioconcentration factor |
| BetrSichV | German Ordinance on Industrial Safety and Health |
| c.c. | closed cup |
| CAS | Chemical Abstract Services |
| CESIO | European Committee of Organic Surfactants and their Intermediates |
| ChemG | German Chemicals Act |
| CMR | carcinogenic-mutagenic-toxic for reproduction |
| DIN | German Institute for Standardization |
| DMEL | Derived minimum effect level |
| DNEL | Derived no effect level |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| EC50 | half maximal effective concentration |
| GefStoffV | German Ordinance on Hazardous Substances |
| GGVSEB | German ordinance for road, rail and inland waterway transportation of dangerous goods |
| GGVSee | German ordinance for sea transportation of dangerous goods |
| GLP | Good Laboratory Practice |
| GMO | Genetic Modified Organism |
| IATA | International Air Transport Association |
| ICAO | International Civil Aviation Organization |
| IMDG | International Maritime Dangerous Goods |
| ISO | International Organization For Standardization |
| LOAEL | Lowest observed adverse effect level |
| LOEL | Lowest observed effect level |
| NOAEL | No observed adverse effect level |
| NOEC | no observed effect concentration |
| NOEL | no observed effect level |
| o. c. | open cup |
| OECD | Organisation for Economic Cooperation and Development |
| OEL | Occupational Exposure Limit |
| PBT | Persistent, bioaccumulative, toxic |
| PEC | Predicted effect concentration |
| PNEC | Predicted no effect concentration |

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| | |
|--------------|--|
| REACH | REACH registration |
| RID | Convention concerning International Carriage by Rail |
| STOT | Specific Target Organ Toxicity |
| SVHC | Substances of Very High Concern |
| TA | Technical Instructions |
| TPR | Third Party Representative (Art. 4) |
| TRGS | Technical Rules for Hazardous Substances |
| VCI | German chemical industry association |
| vPvB | very persistent, very bioaccumulative |
| VOC | volatile organic compounds |
| VwVwS | German Administrative Regulation on the Classification of Substances Hazardous to Waters into Water Hazard Classes |
| WGK | Water Hazard Class |
| WHO | World Health Organization |