Anoxan

 Version:
 1.9 / GB

 Revision date:
 20.09.2017

 Issue date:
 03.09.2001

 replaces version:
 1.8

 Page:
 1 / 9

 Material no.
 5325290001

 Specification
 102876

 VA-Nr
 01772606



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

1.1. Product identifier

Trade name Anoxan

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)6181/59-5767 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: P202 - Do not handle until all safety precautions have been read and understood.

Prevention P264 - Wash hands thoroughly with soap and water after handling.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement:

Reaction

Disposal

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

Precautionary statement: 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.

Anoxan

 Version:
 1.9 / GB

 Revision date:
 20.09.2017

 Issue date:
 03.09.2001

 replaces version:
 1.8

 Page:
 2 / 9

 Material no.
 5325290001

 Specification
 102876

 VA-Nr
 01772606



SECTION 3: Composition/information on ingredients

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

Potassium difluorodihydroxyborate(1-)			< 80%		
CAS-No. Acute toxic Reproduct	85392-66-1 city (oral) ive toxicity (oral)	EC-No.	286-925-2	Category 4 Category 2	H302 H361d

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

Anoxan

Version: 1.9 / GB Material no.
Revision date: 20.09.2017 Specification
Issue date: 03.09.2001 VA-Nr
replaces version: 1.8
Page: 3 / 9



Suitable extinguishing media: All extinguishing substances suitable.

Use extinguishing measures that are appropriate to local circumstances

5325290001

102876

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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

Anoxan

 Version:
 1.9 / GB

 Revision date:
 20.09.2017

 Issue date:
 03.09.2001

 replaces version:
 1.8

 Page:
 4 / 9

 Material no.
 5325290001

 Specification
 102876

 VA-Nr
 01772606



Potassium difluorodihydroxyborate(1-)

CAS-No. 85392-66-1 EC-No. 286-925-2

Control parameters 2.5 mg/m3 Time Weighted Average (TWA):(EU ELV)

Indicative

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 exeeded 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 paste

Colour white to yellowish

Odour odourless

Odour threshold: not applicable

pH ca. 5.4 (10 g/l) (20 °C)

Melting point/range not known

Boiling point/range not known

Flash point Method: closed cup

not applicable

Evaporation rate No data available

Flammability (solid, gas) not flammable

Lower explosion limit not applicable

Anoxan

 Version:
 1.9 / GB

 Revision date:
 20.09.2017

 Issue date:
 03.09.2001

 replaces version:
 1.8

 Page:
 5 / 9

 Material no.
 5325290001

 Specification
 102876

 VA-Nr
 01772606



Upper explosion limit not applicable

Vapour pressure not applicable

Density ca. 1.5 - 1.6 g/cm3

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

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-)

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

Anoxan

Version: 1.9 / GB Revision date: 20.09.2017 03.09.2001 Issue date: replaces version: 1.8 Page: 6/9

Material no. 5325290001 Specification 102876 VA-Nr 01772606



similar products (conclusion by analogy).

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).

Skin irritation not irritating

Eye irritation not irritating

Sensitization no data available

Repeated dose toxicity no data available

Assessment of STOT single

exposure

Assessment of STOT repeat

exposure

Risk of aspiration toxicity

no data available no data available

no data available

Mutagenicity assessment no data available

Carcinogenicity No data available

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

disturbations.

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

> Potassium difluorodihydroxyborate(1-) Test substance:

OECD TG 203 Method:

NOEC Danio rerio (zebra fish): 560 mg/l / 96 h

Test substance: Potassium difluorodihydroxyborate(1-)

OECD Test Guideline 203 Method:

Toxicity in aquatic EC50 Pseudomonas putida: 240 mg/l / 17 h

invertebrates Potassium difluorodihydroxyborate(1-) Test substance:

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**

12.2. Persistence and degradability

Biodegradability no data available

12.3. Bioaccumulative potential

Anoxan

 Version:
 1.9 / GB

 Revision date:
 20.09.2017

 Issue date:
 03.09.2001

 replaces version:
 1.8

 Page:
 7 / 9

 Material no.
 5325290001

 Specification
 102876

 VA-Nr
 01772606



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 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

Regulatione is required for this product.

SECTION 16: Other information

Relevant H phrases from chapter 3

H302 : Harmful if swallowed.

H361d : Suspected of damaging the unborn child.

Anoxan

 Version:
 1.9 / GB

 Revision date:
 20.09.2017

 Issue date:
 03.09.2001

 replaces version:
 1.8

 Page:
 8 / 9

 Material no.
 5325290001

 Specification
 102876

 VA-Nr
 01772606



Further information

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

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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

LOELLowest observed effect levelNOAELNo observed adverse effect levelNOECno 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

REACH REACH registration

RID Convention concerning International Carriage by Rail

STOT Specific Target Organ Toxicity
SVHC Substances of Very High Concern

TA Technical Instructions

Anoxan

Version:1.9 / GBMaterial no.Revision date:20.09.2017SpecificationIssue date:03.09.2001VA-Nrreplaces version:1.8Page:9 / 9

I no. 5325290001 cation 102876 01772606



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