ProCut/ProCut⁺ SAFETY DATA SHEET VELOPEX ALUMINIUM OXIDE



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name I/PDR 8025F (29 Cut) Aluminium Oxide

I/PDR 8024F (53 cut) Aluminium Oxide

Synonyms PROCUT, PROCUT⁺, Alumina

1.2 Uses of the product

Identified Uses Dental abrasive for professional use

Uses Advised Against None known

1.3 Details of the supplier of the safety data sheet

Supplier Medivance Instruments Ltd.

Barretts Green Road

Harlesden London NW10 7AP

T +44 (0) 20 8965 2913 F +44 (0) 20 8963 1270 enquiries@velopex.com

1.4 Emergency telephone number

020 8965 2913

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification

Not applicable

2.2 Label elements

Does not require labeling under the CLP Regulation (EC) No. 1272/2008. But please take note of this product information. No risk of silicosis during application.

<u>Safety Instructions</u> Possible dust exposure due to fine dust particles.

Do not breathe dust.

Avoid contact with eyes.

2.3 Other hazards

Not known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Mean Values		
Alumina (Al ₂ O ₃)	99.69%		
Titanium dioxide (TiO ₂)	-/-		

Chemical Characteristation	EINECS	CAS No.	(1) REACH Registration No. (2) CLP Notification No.	Classification according to CLP Regulation EC No. 1272 / 2008	
				Hazard classes / Hazard categories	Hazard statements
Alumina (Al ₂ O ₃)	215-691-6	1344-28-1	(1) 01-2119529248-35-0010	-/-	-/-
			(2) 02-2119709295-38-0000		
Titanium dioxide (TiO ₂)	236-675-5	13463-67-7	(2) 02-2119879066-28-0000	-/-	-/-

Hazardous substances

No dangerous ingredients

Substances with prescribed EC exposure limits

Does not contain substances with EC exposure limits

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General Information

Consult a doctor in case of health disorders.

After Inhalation

Provide the affected person with fresh air. Consult a doctor in case of irritation of the respiratory tract.

After eye contact

Remove contact lenses and Irrigate with water for at least 15 minutes. If irritation persists, then consult doctor

After skin contact

No harmful effects Remove contaminated clothing Wash with soap and plenty of water

After swallowing

Rinse mouth and drink plenty of water. Do not induce vomiting. If you feel unwell, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Not known

4.3 Indication of any immediate medical attention and special treatment need

Treat symptomatically

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Product does not burn. Match extinguishing measures to ambient situation.

Unsuitable extinguishing media

Not known

5.2 Special hazards arising from the product

Not known

5.3 Advice for firefighters

Match the firefighting measures to the environmental conditions.

Additional information

Not known

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 personal precautions

Avoid dust formation

6.2 Environmental protection precautions

Not known

6.3 Methods and material for containment and cleaning up

Pick up mechanically and dispose of properly.

6.4 References to other sections

Refer to protective measures in sections 7 and 8.

Additional Information

Not known

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Information on safe handling

Avoid dust formation

Information on fire and explosion protection

No special fire protection measures are neccessary

Additional Information

Not known

7.2 Conditions for safe storage, including any incompatibilities

Information on storage conditions

Always store product in dry conditions.

Requirements for storage rooms and containers

No special requirements needed.

Storage class VCI

LGK 13 (non-combustible solids)

7.3 Specific end use(s)

Dental air abrasion powder for cutting, caries removal and cavity preparation.

SECTION 8: LIMITATION AND MONITORING OF EXPOSURE/PERSONAL PROTECTICE EQUIPMENT

8.1 Control parameters

Occupational exposure limit values in the workplace and/or biological limit values

Occupational Exposure Limits (OEL) in Germany for dusts

Inhalable fraction (E) Respirable fracton (A) with exceeding factor 2 each, ref. TRGS 900 10 mg/m3 1.25 mg /m3

Community exposure limits

Country specific. Please inquire in individual cases.

8.2 Exposure Controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over the use of personal protective equipment. Provide adequate ventilation. This can be achieved by local suction or general air extraction.

Aluminium Oxide is not a hazardous substance, thus only the general dust limit value applies.

Suitable assessment methods tap verify the effectiveness of the protective measures taken include metrological and non-metrological determination methods as described in the Technical Rules for hazardous Substances (TRGS) 4021 and BS EN 14042 "Workplace areas, Guidelines for the implementation and application of processes for assessment of exposure to chemical and biological agents".

Personal protective equipment

The use of personal protective equipment is dependent on the concentrations and quantity of hazardous substances and their use in specific workplaces.

Respiratory protection

Normally, no personal respiratory protective equipment is necessary. In case of insufficient ventilation or exceeded workplace limits, a protective breathing mask should be worn (FFP filtering half mask depending on the existing concentration).

Hand protection

Wear appropriate gloves

Eye protection

Tight-sealing protective eyewear (dust-protection goggles) in accordance with EN 166:2001.

Body protection

With normal use, no body protection by half or full-body coverall and boots is required.

Information on industrial hygiene

Minimum standards for protective measure when handling Working materials are listed in TRGS 500.

Do not eat, drink, smoke or take drugs while using this product.

Avoid contact with skin, eyes and clothing.

Remove soiled or soaked clothing immediately.

Wash hands before breaks and at end of work.

Protect skin by using skin creams.

Environmental protection measures

See sections 6 and 7; no further action is required

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Appearance Angular
Physical state Solid
Colour White
Odour Odourless

Safety data

Explosion hazard The product itself is not explosive; however, formation of explosive air/dust mixtures is possible.

Lower explosion limit
Upper explosion limit
Vapour pressure

Not known
Not relevant

Specific gravity approx. 3.9 to 4.1g/cm3

Flow time
Water solubility
pH value
Boling point/range

Not relevant
Insoluble in water
Not applicable
>3000 °C

Flash point Not determined as product is not flammable

Melting point approx. 2000 °C

Ignition temperature Not determined as product is not flammable

9.2 Other Information

None

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Alumina is non-reactive and does not change with proper handling and storage.

10.2 Chemical stability

Alumina is chemically stable and does not change with proper handling and storage.

10.3 Possibility of hazard reactions

No hazardous reactions known.

10.4 Conditions to avoid

None.

10.5 Incompatible materials

No hazardous reactions known.

10.6 Hazardous decomposition products

No known hazardous decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

According to current IFA reports the product contains no silicosis-inducing, toxic or carcinogenic components. The indications given in section 8 of this product information must be observed.

Acute ToxicityNo data on the product availableIrritationNo data on the product availableCorrosivityNo data on the product availableSensitisationNo data on the product availableRepeated dose toxicityNo known toxicity of Alumina

CMR effects (carinogenic, mutagenic and toxic to reproduction)

No carcinogenic effect according to IFA reports

Summarised evaluation of the CMR properties No known CMR properties

Practical experience (relevant for classification and other observations)

No data on the product available

 Carcinogenicity
 No known carcinogenicity of Alumina

 Mutagenicity
 No data on the product available

 Reproductive toxicity
 No data on the product available

Other information Not known

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No known effects

Ecotoxicity

For Aluminium Oxide no environmental problems are to be expected when handled and used properly.

Fish toxicity

Harmful effects for aquatic organisms are not expected.

Aquatic invertebrates

Harmful effects for aquatic organisms are not expected.

Water plants

Harmful effects for aquatic organisms are not expected.

12.2 Persistence and degradability

Based on current experience, this product is inert and not degradable.

12.3 Bioaccumulative potential

No data available. Accumulation in biological materials is rather unlikely, as it is inert and insoluble.

12.4 Mobility in soil

Potential not known

12.5 Results of PBT and vPvB assessment

Not relevant. The substances in this product do not meet the criteria for classification as PBT or vPvB.

12.6 Other harmful effects

None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Alumina. If recycling is not possible, waste must be disposed of in compliance with national and local regulations. Confirm the exact waste code with the disposer.

13.2 Packaging

National and local regulations must be followed.

Contaminated packaging

Packaging with Aluminium Oxide residues can be recycled.

Cleaned packaging

Packaging can be reused after being cleaned or recycled.

SECTION 14: TRANSPORT INFORMATION

Alumina is not dangerous goods.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislations specific for the product

EU Legislation

Not known

National regulations

Water hazard class

Not hazardous to water; classification according to VwVwS, Annex 4.

Technical instruction on air quality (TA-Luft)

Substances not mentioned by name.

<u>Hazardous Incident Ordinance (12. BlmSchV [German Federal Immission Control Regulation])</u>

Substances not mentioned by name.

Chemicals Prohibition Ordinance

Substances not mentioned by name.

Relevant Technical Rules for Hazardous Substances

Contains no hazardous substances.

Employment Restrictions

Not known

Miscellaneous

Aluminium Oxide is not subject to the VOC Regulation.

International regulations

All Aluminium Oxide ingredients are listed with TSCA, A1CS, DSL (NDSL), NEPA and PICCS and registered with MITI / ENCS under 1-23

15.2 Chemical Safety Assessment

Not relevant

SECTION 16: OTHER INFORMATION

Further applicable EC directives

Not known

Restrictions on use recommended by the manufacturer

For Dental application only.

Literature and data sources

Regulations

REACH Regulation (EC) No. 1907/2006 CLP Regulation (EC) No. 1272/2008 Hazardous Substances Ordinance (GefStoffV) Commission Decision 2000/532/EC (AVV) Transport Regulations according to ADR, RID and IATA TRGS 900 VOC Regulation (ChemVOCFarbV)

Hazard statements, referred to in section 2 and 3 according to Regulation (EC) No. 1272/2008:

None

Legend

ADR European agreement concerning the international carriage of dangerous goods by road

AVV/EWC European Waste Catalogue

BlmSchV Regulation on the Implementation of the (German) Federal Immission Control Ordinance

CAS Chemical Abstracts Service
EC European Community
EN European Standard

IATA-DGR International Air Transport Association-Dangerous Goods Regulations

PBT persistent, bioaccurnulative, toxic

RID Regulations concerning the International Carriage of Dangerous Goods

TRGS Technical Rules For hazardous Substances

TSCA Toxic Substances Control Act
VOC Volatile Organic Compounds (VOCs)
vPvB very persistent and very bioaccumulative

VwVwS Administrative Regulation on Substances Hazardous to Water

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