

## SAFETY DATA SHEET AQUACARE ALUMINIUM OXIDE

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

#### 1.1 Product identifier

Product Name I/PDR 8025F (29 µm) Aluminium Oxide  
I/PDR 8024F (53 µm) Aluminium Oxide

Synonyms 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

Class IIa Medical Device Under Directive 93/42 EEC

#### 2.2 Label elements

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

#### Safety Instructions

Possible dust exposure due to fine dust particles.

#### 2.3 Other hazards

Not Known.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	NK (Mean values)	NK Micro (Mean values)	EK (Mean values)	EK Micro (Mean values)	EKR (Mean values)
Aluminium ( $Al_2O_3$ )	95.65%	95.77%	99.73%	99.69%	99.30%
Titanium dioxide ( $TiO_2$ )	2.42%	2.79%	-/-	-/-	-/-

Chemical Characterisation	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
Aluminium ( $Al_2O_3$ )	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	-/-	-/-

Substances listed on the aforesaid 'Candidate list of Substances of Very High Concern (SVHC) for authorisation of the European Chemicals Agency (ECHA) are not intentional ingredients of this product. It is therefore not to be expected that those substances are present in quantities of > 0.1% in the product

### Hazardous Substances

No dangerous ingredients

### Substances with prescribed EC exposure limits

Does not contain substances with EC exposure limits

## SECTION 4: FIRST AID MEASURES

Please also take note of sections 8 and 16 of this product information.

### 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 rinse the eyes with open eyelids for 10 minutes under running water. If necessary, consult an ophthalmologist.

#### After skin contact

Wash with water and rinse.

#### 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 needed

Treat symptomatically

## SECTION 5: FIRE-FIGHTING PROCEDURES

### 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 substance or mixture

Not known.

### 5.3 Advice for fire-fighters

Match the fire-fighting procedures to the environmental conditions.

#### Additional information

Not known.

## SECTION 6: ACCIDENTAL RELEASE PROCEDURES

### 6.1 Personal precautions

Avoid dust accumulation

### 6.2 Environmental protection measures

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 section 7 and 8.

#### Additional information

Not known.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

#### Information on safe handling

Avoid dust accumulation

#### Information on fire and explosion protection

No special fire protection measures are necessary

#### 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.

### 8.1 Control parameters

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

##### Occupational Exposure Limits (OEL) in Germany for dust

Inhalable fraction (E)	10 mg / m <sup>3</sup>
Respirable fraction (A)	1.25 mg / m <sup>3</sup>

with exceeding factor 2 each, ref. TRGS 900

#### Community exposure limits

Country specific. Please inquire in individual cases.

### 8.2 Limitation and monitoring of exposure

#### 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 to 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**

Glove material: Leather

#### **Eye protection**

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

#### **Body protection**

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

#### **Information on industrial hygiene**

Minimum standards for protective measures 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	Not known
Upper explosion limit	Not known
Vapour pressure	Not relevant
Specific gravity	Approx. 3.9 to 4.1g/cm <sup>3</sup>
Flow time	Not relevant
Water solubility	Insoluble in water
pH value	Not applicable
Boiling point/range	>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

The information about the explosion limits refers to Alumina. Please refer to the technical data sheet for other physical and chemical data.

### 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 hazardous reactions

No hazardous reactions known.

### 10.4 Conditions to avoid

No decomposition if used according to specifications.

### 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 toxicity	No data on the product available
Irritation	No data on the product available
Corrosivity	No data on the product available
Sensitisation	No data on the product available
Repeated dose toxicity	No known toxicity of Alumina
CMR effects (carcinogenic, 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 Bioaccumulation 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/legislation 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

#### Hazardous Incident Ordinance (12. BImSchV [German Federal Immission Control Regulation])

Substances not mentioned by name

#### Solvents Ordinance (31. BImSchV [German Federal Immission Control Regulation])

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

No known effects

### 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

### Legends

ADR	European agreement concerning the international carriage of dangerous goods by road
AW/EWC	European Waste Catalogue
BImSchV	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, Bioaccumulative, 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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#### Disclaimer

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