

# SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

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

#### 1.1. Product identifier

Product name : DEHYDRATING CAPSULES UFI : 4K00-D052-M001-TKS0

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

Capsules for drying and dehydrating hearing systems.

### 1.3. Details of the supplier of the safety data sheet

#### Registered company name : MG DEVELOPPEMENT.

Address : 178 rue Negue-Cat - ZAC « Les Portes de l'aéroport ».34130.MAUGUIO.France.

Telephone : +33 (0)4 67 42 95 24. Fax : +33 (0)4 67 42 88 23.

E-mail : contact@mg-dev.fr

http://www.mg-dev.com

#### 1.4. Emergency telephone number : +33 (0)1 45 42 59 59.

Association/Organisation : INRS / ORFILA http://www.centres-antipoison.net.

### Other emergency numbers

#### MG Développement : +33 (0)4 67 42 95 24 (8h30 - 18h)

National Poisons Information Service of England: http://npis.org - NHS 111: dial 111 - National Poisons Information Centre of Ireland: 353 (1) 809 2166 - LUXEMBOURG : (+352) 8002 5500 - European Emergency Number Association (EENA) : 112

# SECTION 2 : HAZARDS IDENTIFICATION

# 2.1. Classification of the substance or mixture

### In compliance with EC regulation No. 1272/2008 and its amendments.

This substance does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This substance does not present a health hazard with the exception of possible occupational exposure thresholds (see paragraphs 3 and 8).

This substance does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

# 2.2. Label elements

### In compliance with EC regulation No. 1272/2008 and its amendments.

No labelling requirements for this substance.

#### 2.3. Other hazards

The substance does not fulfil the PBT or vPvP criteria in accordance with annexe XIII of the REACH regulations EC 1907/2006.

## SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

# 3.1. Substances

#### **Composition :**

Identification	(EC) 1272/2008	Note	%
CAS: 7631-86-9		[1]	50 <= x % < 100
EC: 231-545-4			
SILICON DIOXIDE			

#### Specific concentration limits:

Identification	Specific concentration limits	ATE
CAS: 7631-86-9		inhalation: $ATE = 2.2 \text{ mg/l } 1\text{ h}$
EC: 231-545-4		(dust/mist)
SILICON DIOXIDE		

# Information on ingredients :

[1] Substance for which maximum workplace exposure limits are available.

#### **SECTION 4 : FIRST AID MEASURES**

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

## 4.1. description of first aid measures

#### In the event of exposure by inhalation :

If inhaled, move the patient into the fresh air and keep warm and at rest.

If breathing is irregular or has stopped, proceed with artificial respiration and seek medical attention.

#### In the event of splashes or contact with eyes :

Wash thoroughly with fresh, clean water for 15 minutes holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist.

### In the event of splashes or contact with skin :

Watch out for any remaining product between skin and clothing, watches, shoes, etc.

Remove contaminated clothing and wash the skin thoroughly with soap and water or a recognised cleaner.

# In the event of swallowing :

Seek medical attention, showing the label.

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

No data available.

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

No data available.

## **SECTION 5 : FIREFIGHTING MEASURES**

Non-flammable.

# 5.1. Extinguishing media

#### Suitable methods of extinction

In the event of a fire, use :

- sprayed water or water mist
- foam

- carbon dioxide (CO2)

- powder

### Unsuitable methods of extinction

In the event of a fire, do not use :

- water jet

### 5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

# 5.3. Advice for firefighters

Due to the toxicity of the gas emitted on thermal decomposition of the products, fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

#### 6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

## For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

### 6.2. Environmental precautions

Prevent any material from entering drains or waterways.

## 6.3. Methods and material for containment and cleaning up

Retrieve the product by mechanical means (sweeping/vacuuming).

#### **6.4. Reference to other sections**

No data available.

### **SECTION 7 : HANDLING AND STORAGE**

Requirements relating to storage premises apply to all facilities where the substance is handled.

# 7.1. Precautions for safe handling

Always wash hands after handling.

# Fire prevention :

Prevent access by unauthorised personnel.

**Recommended equipment and procedures :** 

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

## Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the substance is used.

# 7.2. Conditions for safe storage, including any incompatibilities

No data available.

#### Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

# SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

# 8.1. Control parameters

# Occupational exposure limits :

- Germany - AGW (	BAuA - TRGS	900, 08/08/2019	9):		
CAS	VME :	VME :	Excess	Notes	
7631-86-9		4E mg/m <sup>3</sup>			
- Australia (NOHSC: 3008, 1995) :					
CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
7631-86-9	2 mg/m3			А	
- Austria (BGBl. II, 254/2018, 382/2020) :					
CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
7631-86-9	4 mg/m <sup>3</sup>				
- Switzerland (SUVAPRO 2019) :					
CAS	VME	VLE	Valeur plafond	Notations	
7631-86-9	4 ppm				

#### 8.2. Exposure controls

## Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

## - Eye / face protection

Avoid contact with eyes.

Before handling powders or dust emission, wear mask goggles in accordance with standard EN166.

## - Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

Type of gloves recommended :

- Neoprene® (Polychloroprene)
- Natural latex

### - Body protection

Work clothing worn by personnel shall be laundered regularly.

After contact with the product, all parts of the body that have been soiled must be washed.

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# - Respiratory protection

Avoid inhaling dust. Type of FFP mask :

Wear a disposable half-mask dust filter in accordance with standard EN149/A1.

# SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties	
Physical state	
Physical state :	Solid in granules.
-	N/A
Colour	
Colour:	Orange.
Odour	
Odour threshold :	Not stated.
Odour:	Odourless.
Melting point	
Melting point/melting range :	1710 °C.
Freezing point	
Freezing point / Freezing range :	Not stated.
Boiling point or initial boiling point and boiling range	
Boiling point/boiling range :	Not relevant.
Flammability	
Flammability (solid, gas) :	Not stated.
Lower and upper explosion limit	
Explosive properties, lower explosivity limit (%):	Not stated.
Explosive properties, upper explosivity limit (%):	Not stated.
Flash point	
Flash point interval :	Not relevant.
Auto-ignition temperature	
Self-ignition temperature :	Not relevant.
Decomposition temperature	
Decomposition point/decomposition range :	Not relevant.
рН	
pH (aqueous solution) :	3.5 - 8 (20°C - 50 g/l H2O)
pH :	Not relevant.
Kinematic viscosity	
Viscosity :	Not stated.
Solubility	
Water solubility :	Insoluble.
Fat solubility :	Not stated.
Partition coefficient n-octanol/water (log value)	
Partition coefficient: n-octanol/water :	Not stated.
Vapour pressure	
Vapour pressure (50°C) :	Not relevant.
Density and/or relative density	
Density :	0.6 - 0.8
Relative vapour density	
Vapour density :	Not stated.
9.2. Other information	
No data available.	
9.2.1. Information with regard to physical hazard classes	
No data available.	
9.2.2. Other safety characteristics	

No data available.

## SECTION 10 : STABILITY AND REACTIVITY

#### 10.1. Reactivity

No data available.

## 10.2. Chemical stability

This substance is stable under the recommended handling and storage conditions in section 7.

### **10.3.** Possibility of hazardous reactions

No data available.

# 10.4. Conditions to avoid

Avoid :

- formation of dusts

#### **10.5. Incompatible materials**

Keep away from :

- strong oxidising agents

#### 10.6. Hazardous decomposition products

No data available.

# SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

No data available.

### 11.1.1. Substances

## Acute toxicity :

SILICON DIOXIDE (CAS: 7631-86-9)	
Oral route :	

Dermal route :

LD50 > 5000 mg/kg Species : Rat LD50 > 5000 mg/kg Species : Rabbit

Inhalation route (Dusts/mist) :

LC50 = 2.2 mg/l Species : Rat Duration of exposure : 1 h

### 11.2. Information on other hazards

# Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 7631-86-9 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

## **SECTION 12 : ECOLOGICAL INFORMATION**

# 12.1. Toxicity

# 12.1.1. Substances

SILICON DIOXIDE (CAS: 7631-86-9)	
Fish toxicity :	

Crustacean toxicity :

Algae toxicity :

ECr50 = 440 mg/l Duration of exposure : 72 h

Duration of exposure : 48 h

LC50 = 5000 mg/l Duration of exposure : 96 h

EC50 = 7600 mg/l

# 12.2. Persistence and degradability

# 12.2.1. Substances

SILICON DIOXIDE (CAS: 7631-86-9) Biodegradability :

no degradability data is available, the substance is considered as not degrading quickly.

#### 12.3. Bioaccumulative potential

No data available.

### 12.4. Mobility in soil

No data available.

# 12.5. Results of PBT and vPvB assessment

No data available.

12.6. Endocrine disrupting properties

No data available.

# 12.7. Other adverse effects

No data available.

### German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) :

Nicht wassergefährdend : Not hazardous for water.

### **SECTION 13 : DISPOSAL CONSIDERATIONS**

Proper waste management of the substance and/or its container must be determined in accordance with Directive 2008/98/EC.

#### 13.1. Waste treatment methods

Do not pour into drains or waterways.

#### Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

### Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

# **SECTION 14 : TRANSPORT INFORMATION**

Exempt from transport classification and labelling.

# 14.1. UN number or ID 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

## SECTION 15: Regulatory information

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

### - Classification and labelling information included in section 2:

The following regulations have been used:

- EU Regulation No. 1272/2008 amended by EU Regulation No. 2021/643 (ATP 16)
- EU Regulation No. 1272/2008 amended by EU Regulation No. 2021/849 (ATP 17)
- Container information:
- No data available.

### - Particular provisions :

No data available.

- German regulations concerning the classification of hazards for water (WGK, AwSV vom 18/04/2017, KBws) : Nicht wassergefährdend : Not hazardous for water.

## 15.2. Chemical safety assessment

No data available.

### **SECTION 16 : OTHER INFORMATION**

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the substance and not as a guarantee of the properties thereof.

# Abbreviations :

LD50 : The dose of a test substance resulting in 50% lethality in a given time period.

LC50 : The concentration of a test substance resulting in 50% lethality in a given period.

EC50 : The effective concentration of substance that causes 50% of the maximum response.

ECr50 : The effective concentration of substance that causes 50% reduction in growth rate.

REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.

ATE : Acute Toxicity Estimate

UFI : Unique formulation identifier.

STEL : Short-term exposure limit

TWA : Time Weighted Averages

TLV : Threshold Limit Value (exposure)

AEV : Average Exposure Value.

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

WGK : Wassergefahrdungsklasse (Water Hazard Class).

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.