

SAFETY DATA SHEET according to Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Microdacyn60 Hydrogel

Revision date: 02.02.2017

Revision Number 1.0

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

1.1. Product Identifier

Trade name: Microdacyn60 Hydrogel

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

Application of the substance/the mixture: Treatment of wound care

Uses advised against: No further relevant information available

1.3 Details of the supplier of the safety data sheet

Manufacturer:

Oculus Technologies of México S.A. de C.V.

Industria Vidriera No. 81, Industrial Zapopan Norte

Zip Code 45130. Zapopan, Jalisco. México.

Phone: + 52 33 38 33 67 22

www.oculusiseu.com

e-mail: contacto@oculus.com.mx

Authorized Representative:

Oculus Innovative Sciences Netherlands B.V.

Boven de Wolfskuil 3, C30-32, 6049 LX, Herten.

The Netherlands.

Phone: + 31 (0) 475 318666

Fax: + 31 (0) 475 318342

Emergency Telephone number: 01 800 999 45 67

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture according to Regulation (EC) No. 1272/2008

The product is not classified according to the CLP regulation

2.2 Label elements

Labelling according to Regulation (EC) No. 1272/2008

As this product is a medical device in the meaning of Directive 93/42/EEC and intended use by the end consumer and is applied by body contact, it is exempt from the labelling requirements according to regulation 1272/2008

2.3 Other Hazards

Not known.

SECTION 3: Composition/ Information on ingredients

3.2 Mixtures.

Chemical characterization

Hydrogel obtained through electrolysed solution

Hazardous components

Product Identifier type in accordance with Article 18 (2) of Regulation (EC) No. 1272/2008	CAS No.	Identification name	EC number	Classification	
				Hazard Class and Category Code (s)	Hazard statement Code (s)
009-013-00-6	-	Fluorosilicates	-	Acute Tox.4*	H302

Microdacyn60 Hydrogel contain Sodium Magnesium Fluorosilicate. The Biological tests performed for the product demonstrated that the product is non-toxic, non-irritating and non-sensitizing.

SAFETY DATA SHEET according to Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Microdacyn60 Hydrogel

Revision date: 02.02.2017

Revision Number 1.0

SECTION 4: First aid measures

4.1 Description of first aid measures

General Information: If you feel unwell, seek medical advice.

After inhalation

Although this product is not known to cause respiratory problems if breathing is difficult, remove to fresh air and provide oxygen. Seek medical attention if cough or other symptoms develop.

After contact with skin

Although this product is not known to cause skin irritation, is skin becomes irritated, immediately wash skin with plenty of soap and water while removing contaminated clothing and shoes. Seek medical attention if irritation worsens or persists.

After contact with eyes

Although this product is not known to cause eyes irritation, if eyes become irritated, hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Seek medical attention if irritation develops or persists.

After ingestion

Although this product is not known to cause ingestion problems, if ingested, drink plenty of tap water. Seek medical attention if gastric distress develops.

4.2 Most important symptoms and effects, both acute and delayed

In persons with hypersensitive to product ingredients may cause burning sensation.

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

Always have plenty of water available for first aid
Treat patient symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Product does not burn, fire- extinguishing activities according to surrounding

5.2 Especial hazards arising from the substance or mixture

No further relevant information available

5.3 Advice for firefighters

Use breathing apparatus with independent air supply

Additional Information

Store at recommended instructions.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

In case of vapor formation use respirator
For external use, only, not for injection or consumption
Do not use if hypersensitive to product ingredients
Keep container closed when not using
Keep out of the reach and out of sight of children

SAFETY DATA SHEET according to Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Microdacyn60 Hydrogel

Revision date: 02.02.2017

Revision Number 1.0

6.2 Environmental Precautions
No special measures required

6.3 Methods and material for containment and cleaning up
Soak up with inert absorbent material

6.4 Reference to other sections
Information for disposal (see section 13)
Information for Handling and storage (see section 7)

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Advice on safe handling
Keep container closed when not using
Keep out of the reach and out of sight of children
For external use, only, not for injection or consumption

Advice on protection against fire and explosion
No special protective measures against fire required

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage, rooms and vessels
Keep only in original container
Keep container closed when not using

Further information on storage conditions
Ideal Storage is at 2°C to 24°C
Keep away from sunlight.
Keep dry

7.3 Specific end use (s)
Hydrogel for the debridement and moistening of acute and chronic wounds, cuts, abrasions and burns.

SECTION 8: Exposure controls/persons protection

8.1 Control parameters
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls
Protective and hygiene measures
Keep only in original container
Keep container closed when not using
Do not use if hypersensitive to product ingredients

Eye/Face protection
No special protective equipment required

Hand protection
No special equipment required

SAFETY DATA SHEET according to Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Microdacyn60 Hydrogel

Revision date: 02.02.2017

Revision Number 1.0

Skin protection

No special protective equipment required

Respiratory protection

No special protective equipment required

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: Hydrogel
Colour: Slightly white
Odour: Slight chlorine odor
pH value: 6.2 to 7.8
Changes in the physical state
Flash point: n.a.
Lower explosion limits: n.a.
Upper explosion limits: n.a.
Ignition temperature: n.a.
Bulk density: 1.0
Water solubility: complete soluble in water

9.2 Other Information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No decomposition if stored and applied as directed

10.2 Chemical Stability

Stable under normal conditions and recommended use

10.2 Possibility of hazardous reactions

No hazardous reactions known

10.4 Conditions to avoid

This product is safe under normal storage and handling conditions
Keep away from sunlight.
Keep dry

10.5 Incompatible materials

No materials to be specially mentioned

10.6 Hazardous decomposition products

No hazardous decomposition products known

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Based on the available data, the classification criteria are not met.

SAFETY DATA SHEET according to Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Microdacyn60 Hydrogel

Revision date: 02.02.2017

Revision Number 1.0

Irritation and corrosivity

Based on the available data, the classification criteria are not met.

Sensitizing effects

Based on the available data, the classification criteria are not met.

STOT- single exposure

Based on the available data, the classification criteria are not met.

Severe effects after repeated or prolonged exposure

Based on the available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on the available data, the classification criteria are not met.

Aspiration hazards.

Based on available data, the classification criteria are not met.

Additional information on test

Biological test for the finished product demonstrated that the product is safe for the intended use under the recommended use.

Practical experience

Other observations

In persons with hypersensitive to product ingredients may cause burning sensation.

SECTION 12: Ecological information

12.1 Toxicity

Ecological data are not available

12.2 Persistence and degradability

No data available

12.3 Bio accumulative 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 Other adverse effects

No data available

Further information

No further relevant information

SAFETY DATA SHEET according to Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Microdacyn60 Hydrogel

Revision date: 02.02.2017

Revision Number 1.0

SECTION 13: Disposal considerations

13.1 Waste treatment methods

The empty container can be disposed of as a solid waste.
For unused or expired products follow the local regulation.

SECTION 14: Transport information

AIR (IATA) Not regulated for air transport

14.1 UN Number

No hazardous materials as defined by the transport regulations

14.2 UN proper shipping name

No hazardous materials as defined by the transport regulations

14.3 Transport hazard class (es):

No hazardous materials as defined by the transport regulations

14.4 Packaging group

No hazardous materials as defined by the transport regulations

14.5 Environmental hazards

No hazardous materials as defined by the transport regulations

14.6 Special precautions for user

No hazardous materials as defined by the transport regulations

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory Information

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

No further relevant information available

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16. Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the IFU.

Abbreviations and acronyms

IATA= International Air transport association

IBC-Code= International Code for the construction and equipment of ships carrying dangerous chemicals in bulk

CAS= Chemical Abstract service

VPvB= Very persistent and very bio-accumulative

n.a.= not applicable