

SAFETY DATA SHEET

Microdacyn60 Hydrogel

Revision date: 07.02.2023

Revision Number 2.0

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 advises 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

1.4 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 Article 1, point 5 letter d.

2.3 Other Hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII.

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII.

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII.

The substance is not included in the list established in accordance with Article 59 (1) of REACH for having endocrine disrupting properties or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission delegated regulation (EU) 2017/2100 or Commission regulation (EU) 2018/605.

SECTION 3: Composition/ Information on ingredients

3.1 Substances.

Not applicable

3.2 Mixtures.

Chemical characterization

Hydrogel obtained through electrolysed solution.

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Hazardous components

None of the ingredients necessary for the manufacturing of finished product, are considered as hazardous or dangerous according to Annex XVII of the Regulation (EC) No. 1907/2206.

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, if 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 gloves, eye and face protection.

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

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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.

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2 Recommended monitoring procedures

Monitoring methods: a specific exposure sampling method is not available

Biological monitoring methods: a specific exposure sampling method is not available

8.1.3 Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available.

8.1.5. Control banding

No additional information available

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8.2 Exposure controls

8.2.1 Appropriate engineering controls

Keep only in original container.
Keep container closed when not using.
Keep away from sunlight.

8.2.2 Personal protection equipment

No specific measures are required.

8.2.2.1 Eye and face protection

No special protective equipment required.

8.2.2.2 Skin protection

No special protective equipment required.

8.2.2.3 Respiratory protection

No special protective equipment required.

8.2.2.4 Thermal hazards

No additional information available

8.2.3 Environmental exposure controls

No additional information available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state:	Gel
Colour:	slightly white
Odour:	Slight chlorine odor
Melting point/ freezing point:	0°C
Boiling point or initial boiling point and boiling range:	>100° C
Flammability:	Non flammable
Lower and upper Explosion limit:	Not available
Flash point:	Not available
Auto-ignition Temperature:	Not available
Decomposition Temperature:	Not available
pH:	6.2 to 7.8
Kinematic viscosity:	Not available
Solubility:	complete soluble in water
Partition coefficient n-octanol/water (log value):	Not available
Vapour pressure:	Not available
Density and/or relative Density:	1.0 g/cm ³
Relative vapour density:	Not available
Particle characteristics:	Not applicable

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9.2 Other Information

9.2.1 Information with regard to physical hazard classes.

Not available

9.2.2 Other safety characteristics.

Not available

SECTION 10: Stability and reactivity

10.1 Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2 Chemical Stability

Stable under normal conditions and recommended use.

10.3 Possibility of hazardous reactions

No hazardous reactions known under normal conditions of use.

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

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral): Not classified (based on available data, the classification criteria are not met).

Skin corrosion/irritation: Not classified (based on available data, the classification criteria are not met).

Respiratory or skin sensitization: Not classified (based on available data, the classification criteria are not met).

Germ cell mutagenicity: Not classified (based on available data, the classification criteria are not met).

Carcinogenicity: Not classified (based on available data, the classification criteria are not met).

Reproductive toxicity: Not classified (based on available data, the classification criteria are not met).

STOT-single exposure: Not classified (based on available data, the classification criteria are not met).

STOT-repeated exposure: Not classified (based on available data, the classification criteria are not met).

Aspiration hazard: Not classified (based on available data, the classification criteria are not met).

Practical experience

Other observations

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

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties:

The mixture does not contain substance(s) included in the list established in accordance with Article 59 (1) of REACH for having endocrine disrupting properties or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1%.

11.2.2. Other information:

No additional information available.

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SECTION 12: Ecological information

12.1 Toxicity

Ecological data are not available.

12.2 Persistence and degradability

No additional information available.

12.3 Bio accumulative potential

No additional information available.

12.4 Mobility in soil

No additional information available.

12.5 Results of PBT and vPvB assessment

No additional information available.

12.6 Endocrine disrupting properties

The mixture does not contain substance(s) included in the list established in accordance with Article 59 (1) of REACH for having endocrine disrupting properties or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0.1%.

12.7 Other adverse effects

No data available.

Further information

No further relevant information

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Empty packaging cannot be reused.
Waste in accordance with local regulation.

SECTION 14: Transport information

In accordance with ADR/IMDG/IATA/ADN/RID

ADR	IMDG	IATA	ADN	RID
14.1 UN Number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2 UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3 Transport hazard class (es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packaging group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5 Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

14.6 Special precautions for user

Overland transport:
Not regulated

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Transport by sea:

Not regulated

Air transport:

Not regulated

Inland waterway transport:

Not regulated

Rail transport:

Not regulated

14.7 Maritime Transport in bulk according to IMO instruments.

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