

# SAFETY DATA SHEET

## Microdacyn60 Hydrogel

Revision date: 07.02.2023

Revision Number 2.0

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### 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](http://www.oculusiseu.com)

e-mail: [contacto@oculus.com.mx](mailto: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

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### 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.

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### 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.

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## 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.

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## 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.

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## 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)

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### 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.

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### 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.

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## 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
Partion coefficient n-octanol/water (log value):	Not available
Vapour pressure:	Not available
Density and/or relative Density:	1.0 g/cm <sup>3</sup>
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

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## 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.

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## 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

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#### 12.7 Other adverse effects

No data available.

#### Further information

No further relevant information

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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

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

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### SECTION 14: Transport information

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

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

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### 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.

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### 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