

**SAFETY DATA SHEET according to Regulation (EC) No. 1907/2006**  
**Microdacyn60 Wound Care**

Revision date: 02.02.2017

Revision Number 1.0

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

**1.1. Product Identifier**

**Trade name:** Microdacyn60 Wound Care

**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](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

**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

**2.3 Other Hazards**

Not known.

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**SECTION 3: Composition/ Information on ingredients**

**3.2 Mixtures.**

**Chemical characterization**

Electrolysed solution

**Hazardous components**

None of the ingredients: Sodium Chloride and Purified water, necessary for the manufacturing of finished product, are considered as hazardous or dangerous according to Annex XVII of the Regulation (EC) No. 1907/2006

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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, 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.

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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 breathing apparatus with independent air supply

**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

**6.2 Environmental Precautions**

No special measures required

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**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)**

Solution 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.

**8.2    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

**Skin protection**

No special protective equipment required

**Respiratory protection**

No special protective equipment required

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**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

Physical state: Liquid  
Colour: Colorless  
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

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**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

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**SECTION 11: Toxicological information**

**11.1 Information on toxicological effects**

**Acute toxicity**

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

**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.

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**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.

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**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

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**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

Advice on disposal

The empty container can be disposal of as a solid waste.

Waste disposal

Flush to drain or sewer

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**SECTION 14: Transport information**

AIR (IATA) Not regulated for air transport

**14.1 UN Number**

No hazardous materials as defined by the transport regulations

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- 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
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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