

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Version: 1.2 Revision date: 19.04.2011

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GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifiers

Product name Osgide (Resorbable porcine membrane).
 Product numbers OSG1520, OSG2530 and OSG3040.
 CAS-No See section 3

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

Identified uses: The Osgide product is a collagen/elastin membrane and is intended to be used as a medical device. The Osgide product can be implanted in the human body.

1.3 Details of the supplier of the safety data sheet

Company Matricel GmbH,
 Kaiserstrasse 100
 D-52134 Herzogenrath
 Germany
 Telephone +49 2407 5644 0
 Fax +49 2407 5644 10
 E-mail address info@matricel.de

1.4 Emergency telephone number

Emergency telephone number +49 2407 5644 0.

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.
 This substance is not classified as dangerous according to Directive 67/548/EEC.

2.2 Label elements

The product does not need to be labelled in accordance with EC directives or respective national laws.

2.3 Other hazards

- none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Component	CAS-No.	EC-No.	Concentration
Collagen Note: From non-human source (porcine).	9007-34-5	232-697-4	-
Elastin Note: From non-human source (porcine).	9007-58-3	232-701-4	< 30 % (w/w)

4. FIRST AID MEASURES

4.1 Description of first aid measures

If inhaled Inhalation not possible
In case of skin contact No first aid measures needed

In case of eye contact

Rinse with plenty of water and consult physician.

If swallowed

Drink plenty of water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

4.3 Indication of any immediate medical attention and special treatment needed

no data available

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Use dry chemical, CO₂, water spray or foam.

5.2 Special hazards arising from the substance or mixture

Potentially emits toxic fumes under fire conditions.

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use standard personal protective equipment.

6.2 Environmental precautions

Use standard environmental protective measures.

6.3 Methods and materials for containment and cleaning up

Vacuum or sweep the material and place in container for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Personal hygiene measures, such as washing your hands after working with this material are recommended.

7.2 Conditions for safe storage, including any incompatibilities

Protect from contamination. No special precautions required.

7.3 Specific end uses

No data available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

General industrial hygiene practice.

Personal protective equipment

No personal protective equipment is required under normal handling conditions. Standard laboratory protection measures should be respected.

Eye/face protection

No personal protective equipment is required under normal handling conditions. Standard laboratory protection measures should be respected.

Skin protection

No personal protective equipment is required under normal handling conditions. Standard laboratory protection measures should be respected.

Body Protection

No personal protective equipment is required under normal handling conditions. Standard laboratory protection measures should be respected.

Respiratory protection

No personal protective equipment is required under normal handling conditions. Standard laboratory protection measures should be respected.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance Form	Membrane with rectangular shape.
b)	Odour	None.
c)	Odour Threshold	None.
d)	pH	Neutral
e)	Melting point/freezing point	No melting point
f)	Initial boiling point and boiling range	Will decompose before boiling
g)	Flash point	No evaporation
h)	Evaporation rate	No evaporation
i)	Flammability (solid, gas)	Will decompose above 250 °C.
j)	Upper/lower flammability or explosive limits	Not explosive
k)	Vapour pressure	No evaporation
l)	Vapour density	No evaporation
m)	Relative density	No data available
n)	Water solubility	Not soluble in water or organic solvents
o)	Partition coefficient: noctanol/ water	Not soluble in water or organic solvents
p)	Autoignition temperature	Will decompose above 250 °C.
q)	Decomposition temperature	Will decompose above 250 °C.
r)	Viscosity	Solid
s)	Explosive properties	Not explosive
t)	Oxidizing properties	no data available

9.2 Other safety information

no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

Not reactive

10.2 Chemical stability

This material is considered stable under normal processing, storage and handling conditions.

10.3 Possibility of hazardous reactions

no data available

10.4 Conditions to avoid

None.

10.5 Incompatible materials

None.

10.6 Hazardous decomposition products

Other decomposition products - no data available

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Not toxic

Skin corrosion/irritation

Not irritating

Serious eye damage/eye irritation

no data available

Respiratory or skin sensitization

No sensitization

Germ cell mutagenicity

Not mutagenic

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Potential health effects

Inhalation	May be harmful if inhaled. May cause suffocation.
Ingestion	Not harmful
Skin	Not harmful
Eyes	May cause eye irritation by dehydration.

Additional Information

RTECS: Not available

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

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 Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

This material is not considered a hazardous waste. Waste disposal must be in accordance with appropriate regulations. This product, if unaltered by use, may be disposed in landfills or be incinerated

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

14.1 UN number

ADR/RID: -

IMDG: -

IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods

IMDG: Not dangerous goods

IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: -

IMDG: -

IATA: -

14.4 Packaging group

ADR/RID: -

IMDG: -

IATA: -

14.5 Environmental hazards

ADR/RID: no

IMDG Marine pollutant: no

IATA: no

14.6 Special precautions for user

No data available

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

The manufacturer hereby assures and declares that the products specified above, meet the provisions of annex II.4 of Council Directive 93/42/EEC, as amended by Directive 2007/47/EC, concerning medical devices.

15.2 Chemical Safety Assessment

No data available

16. OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Matricel GmbH shall not be held liable for any damage resulting from handling or from contact with the above product.