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Issue Date: 25/02/2021

Last Revision Date: N/A Superseded Date: N/A Version Number: 01

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(SECTION 1

PRODUCT IDENTIFICATION

Product identifier SOLUGEL™ Wound Care Gel

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

Wound care gel. This product is only supplied for professional use as a medical device.

(SECTION 2)

HAZARD IDENTIFICATION

Classification of the substance

or mixture

This product is not classified as hazardous in accordance with EU regulation CLP Regulation (EC) No

1272/2008.

Label elements Other hazards No labelling is required in accordance with EU regulations CLP Regulation (EC) No 1272/2008.

This product is not expected to be hazardous under foreseen conditions of use. However, as with all

health care products, care should be taken to carefully read the instructions before use.

Contains no components identified as PBT or vPvB.

(SECTION 3)

COMPOSITION/INFORMATION ON INGREDIENTS

Substances Not applicable. Product is not a substance.

Mixtures An aqueous gel containing the following components:

Name	CAS Number	Classification
Water	7732-18-5	Not classified as hazardous
Propylene Glycol	57-55-6	Not classified as hazardous
Hydroxyethyl cellulose	9004-62-0	Not classified as hazardous
Sodium Chloride	7647-14-5	Not classified as hazardous
Propyl Hydroxybenzoate	94-13-3	Not classified as hazardous
Methyl Hydroxybenzoate	99-76-3	Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects

(SECTION 4)

FIRST AID MEASURES

Description of first aid measures

Eye ContactRinse eye with plenty of water. If irritation or discomfort occurs, seek medical advice. **Inhalation**If any signs of adverse effect, move to area of fresh air and obtain medical advice.

Skin Contact Wash skin with plenty of soap and water. If irritation or discomfort occurs, seek medical advice.

Ingestion If swallowed, rinse mouth thoroughly and drink small quantity of water (500 ml). If discomfort occurs,

seek medical advice.

Most important symptoms and effects, both acute and delayed

No effects from skin or eye contact are anticipated. Ingestion may cause mild abdominal discomfort.

Indication of any immediate medical attention and special treatments needed

Symptomatic treatment as required.

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SECTION 5 FIRE FIGHTING MEASURES

Extinguishing media No known adverse reactions with any extinguishing media. Use extinguisher appropriate to

surrounding conditions.

Special hazards arising from the

substance or mixture Advice for fire fighters Normal combustion products are considered to be carbon dioxide, although incomplete combustion

may lead to the formation of organic decomposition products.

No special precautions required. Wear normal fire-fighting kit and breathing apparatus as appropriate.

(SECTION 6) **ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures

No special precautions required for unused dressings.

Environmental precautions

Methods and materials for containment and clearing up No special precautions required.

Small quantities of spilled gel can be absorbed using paper towels. For larger spills, cover with a suitable absorbent, and collect for disposal.

Wash spill area with soap and water.

References to other sections

None.

(SECTION 7) HANDLING AND STORAGE

Precautions for safe handling

Conditions for safe storage, including any incompatibilities Normal sterile working procedures will provide adequate protection.

Store in a cool dry place. Avoid extremes of temperature.

Specific end uses(s) None.

EXPOSURE CONTROLS/PERSONAL PROTECTION SECTION 8

Control parameters

Substance	8 hour exposure limit	15 minute exposure limit	Source, Type
Propan-1,2-diol (propylene glycol) - total vapour and particulates - particulates	150 ppm (474 mg/m3) - (10 mg/m3)	-	EH40, 2011

Exposure controls Engineering controls are not required.

Respiratory protection No special precautions required. Inhalation is not likely to occur.

Hand Protection Surgical gloves should be worn in accordance with normal working procedures.

Eye protection No special precautions required. Skin protection No special precautions required.

Environmental exposure controls None required.

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(SECTION 9) P

PHYSICAL/CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance Clear gel
Odour None

Odour threshold Not available pH 5.0-7.5

Melting point Similar to water **Boiling point** Similar to water Flash point Not flammable **Evaporation rate** Similar to water **Flammability** Not flammable **Upper/lower flammability limits** Not applicable Vapour pressure Similar to water Vapour density Not available Relative density Not available Solubility in water Miscible in water Solubility in other solvents Not available Partition coefficient (log Kow) Not available No data

Autoignition temperature No data

Decomposition temperature No data

Viscosity Not available

Explosive properties Not considered explosive
Oxidising properties Not considered oxidising

Other information None

SECTION 10 STABILITY AND REACTIVITY

Reactivity No reactive hazards known.

Chemical stability Stable under normal conditions of use. **Possibility of hazardous** No hazardous reactions expected.

reactions

Conditions to avoid Avoid extremes of temperature

Incompatible materials Avoid contact with strong oxidizing agents

Hazardous decomposition

products

Normal combustion products.

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SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

This product has not been tested. Judgements on the expected toxicity of this product have been made based upon consideration of its major components.

(a) acute toxicity
 No effects are anticipated from the product as supplied.
 b) skin corrosion/irritation
 (c) serious eye damage/irritation
 No effects are anticipated from the product as supplied.

(d) respiratory/skin sensitisation May cause irritation and sensitivity in certain susceptible individuals.

(e) germ cell mutagenicityContains no known mutagens(f) carcinogenicityContains no known carcinogens

(g) reproductive toxicity Contains no known reproductive toxins

(h) STOT-single exposure No effects are anticipated from the product as supplied.

(i) STOT-repeated exposure No effects are anticipated from the product as supplied.

(j) aspiration hazard Not applicable to this product

SECTION 12 ECOLOGICAL INFORMATION

ToxicityNo effects are anticipated from the product as supplied.Persistence and degradabilityThis product will biodegrade slowly in the environment.Bioaccumulative potentialNone of the components are known to be bioaccumulative.

Mobility in soil The components of this product are soluble and are expected to partition into the aqueous compartment.

Results of PBT and vPvB assessment None of the components are known to be PBT or vPvB.

Other adverse effects None known.

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods Disposal should be in accordance with local and national regulations.

Used dressings should be disposed of as clinical waste.

(SECTION 14) TRANSPORT INFORMATION

Not regulated as hazardous for transport.

	ADR	IMDG	ICAO
14.1 UN Number	None	None	None
14.2 UN Proper shipping name	None	None	None
14.3 Transport hazard class(es)	None	None	None
14.4 Packing group	None	None	None
14.5 Environmental hazards	None	None	None
14.6 Special precautions for user	None	None	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	None	None	None

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SECTION 15

REGULATORY INFORMATION

Safety, health and environmental regulations/ legislation specific for the substance or mixture All components are listed as existing substances in Europe

Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out for this product.

(SECTION 16)

OTHER INFORMATION

Revision information Inclusion of KCI Australia contact telephone number

Approved for use as a medical device. Refer to full Instructions For Use.

Special training no specialist training required with respect to chemical hazards

List of Abbreviations used in this SDs

CAS Chemical Abstracts Service

CLP Classification, Labelling and Packaging Regulation (EC) no 1272/2008

EC European Community/Commission

PBT Persistent, Bioaccumulative and Toxic

REACH Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) no 1907/2006

vPvB very Persistent, very Bioaccumulative

References:

ECHA CHEM database EH40, 2011

END OF SDS