Material safety data sheet according to regulation (EC) No. 1907/2006

Date prepared: 31/03/2025

Date revised: 08/09/2025 rev. 002.00

Valid from: 08/09/2025

Version: 002.00 **Replaces version: 001.00**

Section 1: Identification of the Substance/Preparation & Company

1.1 Product identifier

Product name.:	Paratec premium
Product No.:	#30010004 // #30010006 // #30010007 // #30010008
Registered name:	-
EG-No.:	see section 3
CAS-No.:	see section 3
REACH registered No.:	see section 3
Other descriptions:	-

1.2 Use of substance

Intended uses:	Tissue embedding
Uses advised against:	no information available

1.3 Supplier details

Manufacturer/supplier:

SLEE medical GmbH

Address:

Am Neuberg 14, 55268 Nieder-Olm, Germany

Technical support:

+496131 95871-8

Phone number / Fax number / Email

+49 (0) 6136 76997-0 / +49 (0) 6136 76997-99 / Email: mail@slee.de

1.4 Emergency number:

+49 (0) 6136 76997-0

Section 2: Hazard Identification

2.1 Classification of the Substance of Mixture:

Does not contain any components which are hazardous according to CLP Regulation 1272/2008/EC

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2.2 Label Elements:

Does not require a hazard-warning label in accordance with CLP Regulation 1272/2008/EC.

2.3 Other Hazards:

PBT: This product is not identified as a PBT/ vPvB substance according to REACH Annex XIII. Hot liquid may cause thermal burns.

Section 3: Composition/Information of the Composition

3.1 Substances

Substance name:	Paraffin Wax
REACH Reg No.	01-02119488076-30
EC-No.:	232-315-6
CAS-No.:	8002-74-2

Substance name:	Polymer
REACH Reg No.	-
EC-No.:	618-360-8
CAS-No.:	9003-27-4 / content < 3%

Impurities, stabilizing additives and single elements: -

3.2 Mixtures

Product description: Substance Not classified as PBT or vPvB. Not included in the EU list with SVHC substances.

Information on substances:

Substance name	Concentration (w/w) (%)	CAS No.	EC No.	Remark	REACH no.
Paraffin waxes and hydrocarbon waxes (Paratec)	100	8002-74-2	232-315-6	MAC	01-02119488076-30
	100	8002-74-2	232-315-6	MAC	01-02119488076-30

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Paraffin waxes and hydrocarbon waxes (Paratec Premium)	3	9003-27-4	204-066-3	----	01-02119488076-30

Substance name	Hazard Class	H-phrases	Pictograms	----	----
Paraffin waxes and hydrocarbon waxes	----	----	----	----	----

Section 4: First Aid Measures

4.1 Description of First Aid Measures

General information: Remove contaminated/saturated clothing. In case of accident or illness, seek medical advice immediately.

Inhalation: Remove the affected person to fresh air, keep warm and rest. If recovery is not rapid, seek medical advice.

Skin Contact: Wash the affected parts of the body with soap and water. No emergency measures are necessary but if adverse skin effects follow, seek medical advice.

Eye Contact: Flush eyes immediately with fresh water for at least 5 minutes while holding the eyelids open. No emergency measures are necessary but if adverse eye effects follow, seek medical advice.

Ingestion: Do not induce vomiting. No emergency measures are necessary but if adverse health effects follow or large amounts are swallowed, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation: High concentration of vapors may induce: Headache, nausea, dizziness. Irritant effect to the respiratory tract.

Skin Contact: May cause slight irritation to the skin. Heated product may cause burns.

Eye Contact: May cause slight irritation to eyes.

Ingestion: May cause nausea.

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4.3 Indication of any immediate medical attention and special treatment needed

In contact with or splashed by melted product, quickly cool area with water.

Section 5: Fire-fighting Measures

5.1 Extinguishing media

Suitable: foam, dry chemical powder, carbon dioxide.

Unsuitable: water.

5.2 Special hazards arising from the substance or mixture

Slight flammability hazard when exposed to heat or flame. During a fire, toxic gases (carbon monoxide, nitrous gases) may be generated by thermal decomposition or combustion.

5.3 Advice for firefighters

Only suitably trained personnel should attempt to tackle fires. Breathing apparatus and protective clothing should be worn. Do not remain in the immediate vicinity without respiratory protective equipment and protective clothing.

Section 6: Measures in Case of Accidental Release

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Wear suitable protective clothing. See section 8. Stop leak if safe to do so. Remove sources of ignition.

For emergency responders: Wear suitable protective clothing and breathing apparatus. See section 8.

Stop leak if safe to do so. Remove sources of ignition

6.2 Environmental precautions

Water may be used to flush spills away from sources of ignition. Prevent spreading by damming. Do not allow the product to enter public drainage system or open water course. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Containment: Stop leak if safe to do so. Use damming system to prevent spreading.

Cleaning up: Use sand or active clay to absorb spilled substance and remove to containers for disposal. When in liquid state, cool and allow to solidify.

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6.4 Reference to other sections

See sections 8 and 13.

Section 7: Handling and Storage

7.1 Precautions for safe handling

Recommendations:	Handle in accordance with GMP and safety procedures. The molten product can cause severe burns. Use molten product in well-ventilated areas. Use personal protective equipment as required.
General advice:	Do not eat or drink in immediate vicinity. Wash hands after use. Remove any contaminated clothing before eating or drinking.

7.2 Conditions for safe storage including any incompatibilities

Keep material sealed, dry and out of direct sunlight. Avoid heat and ignition sources. Store in original containers or other high-density polyethylene containers which are sealed and clearly labelled. Clean up spilled material immediately.

7.3 Specific end use(s)

No data available.

Section 8: Exposure Controls/Personal Protection

8.1 Control parameters

TWA TLV (ACGIH):	2mg/m³ (paraffin wax fumes). However, in all circumstances, exposure should be kept as low as possible by sufficient ventilation and safe work practices.
DNEL:	No data available
PNEC:	No data available
PEL:	No data available
REL:	No data available

8.2 Exposure controls

Appropriate engineering measures:	Facilities storing or utilizing this material should be equipped with an eyewash facility.
Eye protection:	Wear appropriate eye protection with side shields (EN166).
Skin protection:	Use impervious gloves (EN374). PVC is suitable for casual contact. If direct contact for more than 2 hours then

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	Neoprene or nitrile gloves recommended.
Respiratory protection:	Inhalation of the vapor, fumes or mists should be avoided by safe working practices and good ventilation.
Thermal Hazards:	Thermal hazards only applicable when material is heated. Use appropriate heat resistant gloves.
Environmental Exposure Controls:	See sections 6, 7, 12 and 13.

Section 9: Physical and Chemical Properties

9.1 Information on basic chemical and physical properties

Appearance:	Liquid (at elevated temperature) Solid (at ambient temperature)
Odor:	Typical
Odor threshold:	No data available
pH:	Neutral
Melting point/congealing point:	54-57°C
Initial boiling point/range:	>300°C
Flash point:	>200°C
Evaporation rate:	No data available
Flammability (solid, gas):	May be combustible at high temperatures
Explosion limits:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density (at 15°C):	0.83-0.86g/cm³
Solubility in water:	Insoluble
Solubility in other solvents:	Petroleum Ether, Ethyl Acetate
Partition coefficient n-octanol/water:	No data available
Auto-ignition temperature:	>200°C
Decomposition temperature:	No data available
Viscosity (Kinematic, at 100°C):	~4.0cSt
Explosive properties:	No data available
Oxidizing properties:	No data available

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9.2 Other information

No data available

Section 10: Stability and reactivity

Not reactive under normal storage and handling conditions (see section 7). May react with strong oxidizing agents, especially at high temperatures.

10.1 Chemical stability

Stable under normal storage and handling conditions.

10.2 Possibility of hazardous reactions

No hazardous reactions are expected to occur under normal storage and handling conditions.

10.3 Conditions to avoid

Extremes of temperature (preferably, store between 5 and 39°C). The product is combustible when heated >300°C.

10.4 Incompatible materials

May react with strong oxidants (e.g. chlorates, peroxides).

10.5 Hazardous decomposition products

Thermal decomposition or incomplete combustion may produce carbon monoxide, nitrous gases and irritating fumes.

Section 11: Toxicological Information

11.1 Information on toxicological effects

This mixture does not meet the criteria for classification in accordance with Regulation No 1272/2008/EC.

Acute toxicity

Oral: LD50 >5000mg/kg (OECD 401)

Inhalation: LD50 >2000mg/kg (OECD 402)

Skin corrosion/irritation

Not irritant (OECD 404)

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Serious eye damage/irritation

Not irritant (OECD 405)

Respiratory or skin sensitization

Non-sensitizing (OECD 406)

Germ cell mutagenicity Negative (OECD 476)

Reproductive toxicity

NOAEL >1000mg/kg bw/day (OECD 421 or 422)

- **Specific target organ toxicity – single exposure**
  Not classified as a specific target organ toxicant (single exposure)
- **Specific target organ toxicity – repeated exposure**
  Not classified as a specific target organ toxicant (repeated exposure)

Aspiration hazard

Not classified as presenting an aspiration hazard - based on available data, the classification criteria are not met.

Likely routes of exposure

Skin/eye exposure – no adverse health effects expected.

Symptoms related to the physical, chemical and toxicological characteristics

- **If swallowed**
  Diarrhoea, gastrointestinal complaints
- **If inhaled**
  No data available
- **If on skin**
  No data available

Delayed and chronic effects from short and long-term exposure

No data available

Other information

No data available

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Section 12: Ecological Information

12.1 Toxicity

Aquatic toxicity (Pimephales promelas): LD50 >100mg/l (96h) (OECD203/ISO7346/EEC84/449/V, C1)

Aquatic toxicity (Pseudokirchnerella subcapitata): NOAEL 100mg/l (OECD201)

Aquatic toxicity (Daphnia magna): EL50 >10000mg/l (96h) (OECD202)

12.2 Persistence and degradability

Insoluble in water – can be separated from water in suitable effluent treatment plants.

12.3 Bioaccumulation potential

No data available

12.4 Mobility in soil

Non-volatile and absorption into soil solid phase not expected.

12.5 Results of PBT & vPvB assessment

Not identified as a PBT/ vPvB Substance according to REACH Annex XIII.

12.6 Other adverse effects

No data available

Section 13: Disposal Conditions

13.1 Waste treatment methods

Treat in accordance with EU directive 2008/98/EC. Transport to authorised waste location, or incinerate under controlled conditions (EU Directives 2000/76/EC and 1999/31/EC apply). Do not dispose to drains or sewage systems.

Section 14: Transport Information

14.1 UN number

Not classified

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14.2 UN proper shipping name

Not classified

14.3 Transport hazard class(es)

Not classified

14.4 Packing group

Not classified

14.5 Environmental hazards

None

14.6 Special precautions for user

None

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC code

Not classified

Section 15: Regulatory Information

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

EU Regulations: Regulation [EC] 1272/2008 including amendments

Regulation [EC] 1907/2006 including amendments (EC 2015/830)

15.2 Chemical safety assessment

The supplier has not performed a chemical safety assessment of this substance.

Section 16: Other Information

Indication of changes: All sections revised according to Regulation [EC] No 1272/2008 [CLP] in preparation for the 1 June 2015 deadline.

Rev3 - Reach registration number(s) added to composition.

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16.1 Abbreviations & Acronyms:

ACGIH:	American Conference of Governmental Industrial Hy-
gienists CAS No:	Chemical Abstract Service number
CLP:	Classification Labelling and Packaging Reg-
ulation DNEL:	Derived No Effect Level
EC:	European Commission
EC No:	European Chemical Number – EINECS –
ELINCS ECHA:	European Chemical Agency
EINECS:	European Inventory of Existing Commercial Chemical Sub-
stances ELINCS:	European List of Notified Chemical Substances
ES:	Exposure Scenario
LD50:	Median Lethal Dose
LC50:	Median Lethal Concentra-
tion NOAEL:	No Observed Adverse Ef-
fect Level PEL:	Permissible Exposure Limit
PNEC:	Predicted No Effect Level
REACH:	Registration, Evaluation, Authorisation & re-striction of Chemicals
REL:	Recommended Exposure Limit
TLV:	Threshold Limit Value

TWA: Time Weighted Average

Hazard Statements/Precautionary statements:

None

The information contained herein is for health and safety guidance only and does not constitute a product specification. It is, to the best of our knowledge and belief accurate. However, since the conditions of handling and use are beyond our control, we make no guarantee of results, and assume no liability for damages incurred by use of this material. It is the responsibility of the user to comply with all applicable laws and regulations.