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

1.1. Product identifier

Product form : Article
PRODUCT NAME : RENASYS™ TOUCH - NPWT
Product code : 66802134, 66027721

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

Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : Medical devices

1.3. Details of the supplier of the safety data sheet

Supplier
Smith & Nephew Medical Ltd
101 Hessle Road
HU3 2BN Hull, East Ridings of Yorkshire
T +44 (0) 1482 225181
https://www.smith-nephew.com/en/contact-us#general

EU Authorised Representative
Smith & Nephew Operation B.V.
Bloemlaan 2
2132 NP Hoofddorp
Netherlands

1.4. Emergency telephone number

Emergency number : 999 (UK) or 112 (EU) 24 Hours, +1-703-527-3887 (Chemtrec 24 Hours)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use.

First-aid measures after skin contact : Adverse effects not expected from this product. Wash skin with plenty of water.

First-aid measures after eye contact : Not expected to present a significant eye contact hazard under anticipated conditions of normal use.

First-aid measures after ingestion : Ingestion is not considered a potential route of exposure.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : None known.

Symptoms/effects after skin contact : None under normal conditions.

Symptoms/effects after eye contact : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after ingestion : Ingestion is not considered a potential route of exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Alcohol-resistant foam. dry chemical powder.

Unsuitable extinguishing media : Do not use water jet.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.

Explosion hazard : Heating may cause a fire or explosion.

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Pick up solid material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Use only the AC power cord provided with the device.
Storage conditions : Store in a well-ventilated place. Keep cool. Avoid direct sunlight.
Storage temperature : 5 – 40 °C
Heat and ignition sources : No flames, no sparks. Eliminate all sources of ignition.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:
Ensure good ventilation of the work station.

Personal protection equipment

Personal protective equipment symbol(s):



Skin protection

Hand protection:
Protective gloves

Respiratory protection

Respiratory protection:
In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	Not available
Appearance	:	Special electrical equipment.
Odour	:	Not available
Odour threshold	:	Not available
Melting point	:	Not available
Freezing point	:	Not applicable
Boiling point	:	Not available
Flammability	:	Non flammable.
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	Not applicable
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Not available
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	Not available
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available

9.2. Other information

No additional information available

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.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Heat. Direct sunlight. Overheating.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified
Skin corrosion/irritation : Not classified
Serious eye damage/irritation : Not classified
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

RENASYS™ TOUCH - NPWT	
Viscosity, kinematic	Not applicable

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short–term (acute) : Not classified

Hazardous to the aquatic environment, long–term (chronic) : Not classified

12.2. Persistence and degradability

RENASYS™ TOUCH - NPWT	
Persistence and degradability	Rapidly degradable

12.3. Bioaccumulative 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

No additional information available

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

UN Number : 3481
Proper Shipping Name: Lithium-Ion Cells and Batteries
Contained in Equipment / Packed with Equipment;

Hazard Class : 9

The lithium cells and batteries in the RENASYS TOUCH DEVICE (66802134) are not subject to the full requirements of the Dangerous Goods Regulations as they meet the following listed below and are properly packaged and are classed as a battery contained in equipment, or battery packed with equipment.

1. For batteries, the Watt Hour rating less than or equal to 100 Wh
2. For cells, the Watt Hour rating is less than or equal to 20 Wh
3. Each battery is tested according to UN Manual of Tests and Criteria Part III, Subsection 38.3 and has a test summary.
4. Each battery is manufactured under a quality management program described in IATA DGR 3.9.2.6, ADR 2.2.9.1.7 and IMDG 2.9.4.5

Special provisions listed below apply:

- UN Model Regulations Special Provisions 188 and 230
- International Civil Aviation Organization (ICAO) Technical Instructions
- International Air Transport Association (IATA) Dangerous Goods Regulations Packing Instructions:

  - 967 Section II (UN3481, Lithium-Ion cells and batteries contained in equipment)
    The cells or batteries should be offered for transport at a state of charge (SOC) not exceeding 30% of their rated capacity.
  - 966 Section II (UN3481, Lithium-Ion cells and batteries packed with equipment)
    The cells or batteries must be offered for transport at a state of charge (SOC) not exceeding 30% of their rated capacity

  IATA Lithium Ion Cells and Batteries meeting the requirements of Section II are not subject to the provision of the IATA DGR except for: -

  - Provision of adequate instruction
  - Marking of Packages
  - Reporting of Dangerous Goods accidents, incidents and other occurrences

- International Maritime Dangerous Goods Code (IMDG) Special Provisions 188 and 230
- European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) Special Provisions 188 and 230
- International Carriage of Dangerous Goods by Rail (RID)Special Provision 188 and 230
- U.S. Department of Transportation (DOT) 49 CFR 173.185 and 173.185(c)
- Canadian Transport of Dangerous Goods Regulations (TDGR) Special Provision 34

Cells and Batteries when contained in equipment/packed with equipment shall be protected from damage and short circuit, and the equipment shall be equipped with an effective means of preventing accidental activation. When Cells and Lithium batteries are contained in equipment/packed with equipment, the equipment shall be packed in strong outer packaging's constructed of suitable material of adequate strength and design in relation to the packaging's capacity and its intended use unless the cell or battery is afforded equivalent by protection by the equipment in which it is contained.

GENERAL HANDLING INSTRUCTIONS
Packaging's should be handled with care. Rough handling may result in batteries being short circuited or damaged. This may cause leakage, explosion, or fire.

DAMAGED LITHIUM BATTERIES ARE FORBIDDEN FOR TRANSPORT IN ANY MODE

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

ADR	IMDG	IATA	ADN	RID	US DOT
14.1. UN number or ID number					
UN 3481	UN 3481	UN 3481	UN 3481	UN 3481	UN 3481
14.2. UN proper shipping name					
LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT	LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT	Lithium ion batteries contained in equipment	LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT	LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT	LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT
Transport document description					

ADR	IMDG	IATA	ADN	RID	US DOT
UN 3481 LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT, 9, (E)	UN 3481 LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT, 9	UN 3481 Lithium ion batteries contained in equipment, 9	UN 3481 LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT, 9	UN 3481 LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT, 9	UN 3481 LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT
14.3. Transport hazard class(es)					
9	9	9	9	9	Not applicable
					Not applicable
14.4. Packing group					
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards					
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No EmS-No. (Fire): F-A EmS-No. (Spillage): S-I	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary information available					

14.6. Special precautions for user

Overland transport

Classification code (ADR)	:	M4
Special provisions (ADR)	:	188, 230, 310, 348, 360, 376, 377, 387, 390, 670, 677
Limited quantities (ADR)	:	0
Excepted quantities (ADR)	:	E0
Packing instructions (ADR)	:	P903, P908, P909, P910, P911, LP903, LP904, LP905, LP906
Transport category (ADR)	:	2
Tunnel restriction code (ADR)	:	E
EAC code	:	2Y

Transport by sea

Special provisions (IMDG)	:	188, 230, 310, 348, 360, 376, 377, 384, 387, 390
Limited quantities (IMDG)	:	0
Excepted quantities (IMDG)	:	E0
Packing instructions (IMDG)	:	P903, P908, P909 , P910, P911, LP903, LP904, LP905, LP906
Stowage category (IMDG)	:	A
Stowage and handling (IMDG)	:	SW19
Properties and observations (IMDG)	:	Electrical batteries containing lithium ion may react (e.g. flame, heat, emission of toxic, corrosive or flammable gases or vapours) or disassemble due to damage, defects or short circuit.

Air transport

PCA Excepted quantities (IATA)	:	E0

PCA Limited quantities (IATA)	:	Forbidden
PCA limited quantity max net quantity (IATA)	:	Forbidden
PCA packing instructions (IATA)	:	967
PCA max net quantity (IATA)	:	5kg
CAO packing instructions (IATA)	:	967
CAO max net quantity (IATA)	:	35kg
Special provisions (IATA)	:	A48, A88, A99, A154, A181, A185, A213, A220
ERG code (IATA)	:	12FZ

Inland waterway transport

Classification code (ADN)	:	M4
Special provisions (ADN)	:	188, 230, 310, 348, 360, 376, 377, 387, 390, 670, 677
Limited quantities (ADN)	:	0
Excepted quantities (ADN)	:	E0
Equipment required (ADN)	:	PP
Number of blue cones/lights (ADN)	:	0

Rail transport

Classification code (RID)	:	M4
Special provisions (RID)	:	188, 230, 310, 348, 360, _376, 377, 387, 390, 670, 677
Limited quantities (RID)	:	0
Excepted quantities (RID)	:	E0
Packing instructions (RID)	:	P903, 908, 909, P910, P911, LP903, LP904, LP905, LP906
Transport category (RID)	:	2
Colis express (express parcels) (RID)	:	CE2
Hazard identification number (RID)	:	90

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

EU-Regulations

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (2024/590)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 2024/590 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Not listed on the COUNCIL REGULATION (EC) of dual-use items.

Explosives Precursors Regulation (EU 2019/1148)

Not listed on the Explosives Precursors list (EU)

Drug Precursors Regulation (EC 273/2004)

Not listed on the Drug Precursors list (EU)

National regulations

France

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

The classification complies with : ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.