SECTION 1 Identification

1.1. Product identifier

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

1.2. Other means of identification

No additional information available

1.3. Recommended use of the chemical and restrictions on use

Use of the substance/mixture : Medical devices

1.4. Supplier's details

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

1.5. Emergency phone number

Emergency number : 911 (24 Hours), 1-800-424-9300 (Chemtrec 24 Hours)

SECTION 2 Hazard Identification

2.1. Classification of the substance or mixture

GHS US classification

Not classified

2.2. Label elements

GHS US labeling

No labeling applicable

2.3. Hazards associated with known or reasonably anticipated uses

No additional information available

2.4. Hazards not otherwise classified

No additional information available

2.5. Unknown acute toxicity

No additional information available

SECTION 3 Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria for section 3.2 of HCS

SECTION 4 First aid measures

4.1. Description of necessary 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/effects, 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 immediate medical attention and special treatment needed, if necessary

Other medical advice or treatment : Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) 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. Specific hazards arising from the chemical

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. Special protective equipment and precautions for fire-fighters

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".

Environmental precautions : Avoid release to the environment.

6.2. Methods and materials 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.

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 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-ignition : No flames, no sparks. Eliminate all sources of ignition.

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.
Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures, such as personal protective equipment

Hand protection:
Protective gloves

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

Personal protective equipment symbol(s):



SECTION 9 Physical and chemical properties

9.1. Basic physical and chemical properties

Physical state	:	Solid
Appearance	:	Special electrical equipment.
Color	:	No data available
Odor	:	No data available
Odor threshold	:	No data available
pH	:	No data available
Melting point	:	No data available
Freezing point	:	Not applicable
Boiling point	:	No data available
Flash point	:	Not applicable
Flammability (solid, gas)	:	Non flammable.
Vapor pressure	:	No data available
Relative vapor density at 20°C	:	No data available
Relative density	:	No data available
Solubility	:	No data available
Partition coefficient n-octanol/water (Log Pow)	:	No data available
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	No data available
Viscosity, kinematic	:	Not applicable
Explosion limits	:	Not applicable
Particle characteristics	:	No data available

9.2. Data relevant with regard to physical hazard classes (supplemental)

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 toxicological effects

Acute toxicity (oral) : No data available
Acute toxicity (dermal) : No data available
Acute toxicity (inhalation) : No data available
Skin corrosion/irritation : No data available

Serious eye damage/irritation : No data available

Respiratory or skin sensitization : No data available
Germ cell mutagenicity : No data available

Carcinogenicity : No data available

Reproductive toxicity : No data available
STOT-single exposure : No data available
STOT-repeated exposure : No data available
Aspiration hazard : No data available

RENASYS™ TOUCH - NPWT	
Viscosity, kinematic	Not applicable

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.

SECTION 12 Ecological information

12.1. Ecotoxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short–term (acute) : No data available
Hazardous to the aquatic environment, long–term (chronic) : No data available

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. Other adverse effects

Ozone : No data available
Fluorinated greenhouse gases : No

SECTION 13 Disposal considerations

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 DOT / IMDG / IATA

14.1. UN number

UN-No. (DOT)	:	UN3481
UN-No. (IMDG)	:	3481
UN-No. (IATA)	:	3481

14.2. UN Proper Shipping Name

Proper Shipping Name (DOT)	:	Lithium ion batteries contained in equipment
Proper Shipping Name (IMDG)	:	LITHIUM ION BATTERIES CONTAINED IN EQUIPMENT

Proper Shipping Name (IATA) : Lithium ion batteries contained in equipment

14.3. Transport hazard class(es)

DOT

Transport hazard class(es) (DOT) : 9

Hazard labels (DOT) : 9



IMDG

Transport hazard class(es) (IMDG) : 9

Hazard labels (IMDG) : 9



IATA

Transport hazard class(es) (IATA) : 9

Hazard labels (IATA) : 9A



14.4. Packing group

Packing group (DOT) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

14.5. Environmental hazards

Other information : No supplementary information available.

14.6. Transport in bulk

Not applicable

14.7. Special precautions for user

DOT

UN-No. (DOT) : UN3481

DOT Special Provisions (49 CFR 172.102)	:	181 - When a package contains a combination of lithium batteries contained in equipment and lithium batteries packed with equipment, the following requirements apply: a. The shipper must ensure that all applicable requirements of §173.185 of this subchapter are met. The total mass of lithium batteries contained in any package must not exceed the quantity limits in columns (9A) and (9B) for passenger aircraft or cargo aircraft, as applicable; b. Except as provided in §173.185(c)(3) of this subchapter, the package must be marked “UN 3091 Lithium metal batteries packed with equipment”, or “UN 3481 Lithium ion batteries packed with equipment,” as appropriate. If a package contains both lithium metal batteries and lithium ion batteries packed with and contained in equipment, the package must be marked as required for both battery types. However, button cell batteries installed in equipment (including circuit boards) need not be considered; and c. The shipping paper must indicate “UN 3091 Lithium metal batteries packed with equipment” or “UN 3481 Lithium ion batteries packed with equipment,” as appropriate. If a package contains both lithium metal batteries and lithium ion batteries packed with and contained in equipment, then the shipping paper must indicate both “UN 3091 Lithium metal batteries packed with equipment” and “UN 3481 Lithium ion batteries packed with equipment.” 388 - a. Lithium batteries containing both primary lithium metal cells and rechargeable lithium ion cells that are not designed to be externally charged, must meet the following conditions: i. The rechargeable lithium ion cells can only be charged from the primary lithium metal cells; ii. Overcharge of the rechargeable lithium ion cells is precluded by design; iii. The battery has been tested as a primary lithium battery; and iv. Component cells of the battery must be of a type proved to meet the respective testing requirements of the Manual of Tests and Criteria, part III, subsection 38.3 (IBR, see 171.7 of this subchapter). b. Lithium batteries conforming to paragraph a. of this special provision must be assigned to UN Nos. 3090 or 3091, as appropriate. When such batteries are transported in accordance with 173.185(c), the total lithium content of all lithium metal cells contained in the battery must not exceed 1.5 g and the total capacity of all lithium ion cells contained in the battery must not exceed 10 Wh. 422 - When labelling is required, the label to be used must be the label shown in §172.447. Labels conforming to requirements in place on December 31, 2016 may continue to be used until December 31, 2018. When a placard is displayed, the placard must be the placard shown in §172.560. A54 - Lithium batteries or lithium batteries contained or packed with equipment that exceed the maximum gross weight allowed by Column (9B) of the 172.101 Table may only be transported on cargo aircraft if approved by the Associate Administrator.
DOT Packaging Exceptions (49 CFR 173.xxx)	:	185
DOT Packaging Non Bulk (49 CFR 173.xxx)	:	185
DOT Packaging Bulk (49 CFR 173.xxx)	:	185
DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27)	:	5 kg
DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75)	:	35 kg
DOT Vessel Stowage Location	:	A - The material may be stowed ‘‘on deck’’ or ‘‘under deck’’ on a cargo vessel and on a passenger vessel.

IMDG

Special provision (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
EmS-No. (Fire)	:	F-A - FIRE SCHEDULE Alfa - GENERAL FIRE SCHEDULE

EmS-No. (Spillage)	:	S-I - SPILLAGE SCHEDULE India - FLAMMABLE SOLIDS (REPACKING POSSIBLE)
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.

IATA

Special provision (IATA)	:	A48, A88, A99, A154, A181, A185, A213, A220
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
ERG code (IATA)	:	12FZ

SECTION 15 Regulatory information

15.1. Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory, except for:

RENASYS™ TOUCH - NPWT	CAS-No.	100%

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

National regulations

RENASYS™ TOUCH - NPWT

Small lithium cells and batteries. Lithium cells or batteries, including cells or batteries packed with or contained in equipment, are not subject to any other requirements of this subchapter if they meet all of the following:
a. Primary lithium batteries and cells. (1) Primary lithium batteries and cells are forbidden for transport aboard passenger-carrying aircraft. The outside of each package that contains primary (nonrechargeable) lithium batteries or cells must be marked “PRIMARY LITHIUM BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT” or “LITHIUM METAL BATTERIES—FORBIDDEN FOR TRANSPORT ABOARD PASSENGER AIRCRAFT” on a background of contrasting color. The letters in the marking must be:(i) At least 12 mm (0.5 inch) in height on packages having a gross weight of more than 30 kg (66 pounds); or(ii) At least 6 mm (0.25 inch) on packages having a gross weight of 30 kg (66 pounds) or less, except that smaller font may be used as necessary to fit package dimensions; and(2) The provisions of paragraph (a)(1) do not apply to packages that contain 5 kg (11 pounds) net weight or less of primary lithium batteries or cells that are contained in or packed with equipment and the package contains no more than the number of lithium batteries or cells necessary to power the piece of equipment; b. For a lithium metal or lithium alloy cell, the lithium content is not more than 1.0 g. For a lithium-ion cell, the equivalent lithium content is not more than 1.5 g; c. For a lithium metal or lithium alloy battery, the aggregate lithium content is not more than 2.0 g. For a lithium-ion battery, the aggregate equivalent lithium content is not more than 8 g; d. Effective October 1, 2009, the cell or battery must be of a type proven to meet the requirements of each test in the UN Manual of Tests and Criteria (IBR; see §171.7 of this subchapter); e. Cells or batteries are separated or packaged in a manner to prevent short circuits and are packed in a strong outer packaging or are contained in equipment; f. Effective October 1, 2008, except when contained in equipment, each package containing more than 24 lithium cells or 12 lithium batteries must be:(1) Marked to indicate that it contains lithium batteries, and special procedures should be followed if the package is damaged;(2) Accompanied by a document indicating that the package contains lithium batteries and special procedures should be followed if the package is damaged;(3) Capable of withstanding a 1.2 meter drop test in any orientation without damage to cells or batteries contained in the package, without shifting of the contents that would allow short circuiting and without release of package contents; and(4) Gross weight of the package may not exceed 30 kg (66 pounds). This requirement does not apply to lithium cells or batteries packed with equipment; g. Electrical devices must conform to §173.21; h. For transportation by aircraft, a telephone report in accordance with §171.15(a) is required if a fire, violent rupture, explosion or dangerous evolution of heat (i.e, an amount of heat sufficient to be dangerous to packaging or personal safety to include charring of packaging, melting of packaging, scorching of packaging, or other evidence) occurs as a direct result of a lithium battery. For all modes of transportation, a written report submitted, retained, and updated in accordance with §171.16 is required if a fire, violent rupture, explosion or dangerous evolution of heat occurs as a direct result of a lithium battery or battery-powered device; and i. Lithium batteries or cells are not authorized aboard an aircraft in checked or carry-on luggage except as provided in §175.10.

15.3. State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16 Other information

according to 29 CFR § 1910.1200, Hazard Communication Standard (HCS 2024)
Issue date : 7/21/2026

Safety Data Sheet (SDS), USA

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.