

MATERIAL SAFETY DATA SHEET

Copyright, 2012, Smith & Nephew Medical Limited. All rights reserved.
Copying and/or downloading of this information for the purpose of properly utilising Smith & Nephew Medical Limited products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Smith & Nephew Medical Limited, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

The product is not regulated under, and a material safety data sheet (MSDS) is not required for this product by the Hazard Communication Standard (29 CFR 1910.1200) because, when used as recommended or under ordinary conditions, it should not present a health and safety hazard. However, use or processing of the product not in accordance with the product's recommendations or not under ordinary conditions may affect the performance of the product and may present potential health and safety hazards.

1. Substance/Product identification

Product name:	RENASYS Adhesive gel patch
Company:	Smith & Nephew Medical Limited. Hull HU3 2BN
Preparation/Revision date:	16FEB12
Product type:	Hydrogel adhesive patch
Emergency telephone number:	+44 (0)1482 22518
MSDS No:	XXXXXXX

2. Ingredients

Ingredient	C.A.S. Number	% by Wt
Cross-linked polymer	None	96-98
Siliconised Polyester liner	None	1 - 2
Paper/foil laminate pouch	None	1 - 2

3. Hazard identification

Main Hazards:	Not classified as hazardous.
Routes of Entry:	Eye contact – ingestion – skin contact.
Carcinogenic Status:	Not considered carcinogenic by NTP, IARC and OSHA.
Health Effects – Eyes:	None known. Not expected under

	normal use.
Health Effects – Skin:	This product is intended for skin contact.
Health Effects – Ingestion:	This product is not considered toxic, but as with any material, may be harmful if ingested in large quantities.

4. First Aid measures

Eye contact:	Irrigate thoroughly with water for 5 minutes, holding the eye open. If discomfort persists, obtain medical attention.
Ingestion:	If ingested, obtain medical attention.

5. Fire fighting measures

Flash point:	N/A
Upper flammable limit:	Not determined
Lower flammable limit:	Not determined
Suitable extinguishing media:	Water spray Foam Dry powder Carbon Dioxide
Unusual fire & explosion hazards:	Material will not burn until water has been evaporated. Toxic fumes, gases or vapours may evolve on burning.
Auto-ignition point:	Not determined
Explosion data:	Material does not have explosive properties.

6. Accidental release measures

Not applicable. No specific measures necessary.
Carefully sweep up and dispose of in accordance with local regulations.

7. Handling and storage

Handling procedures:	Keep in sealed pouch as supplied when not in use. Sterile until opened.
Storage:	Store at 5-30°C (and preferably at room temperature 15° to 25°C recommended) in sealed pouch of low MVTR (as supplied). Keep well closed and protected from direct sunlight and moisture. Exposure to extremes of temperature (-15C to +45C) for very

short periods of time will not be detrimental to the hydrogel.

8. Exposure controls/personal protection

As appropriate to quantity handled.

Respirator:	N/A
Ventilation:	N/A
Gloves:	Chemically resistant
Eye protection:	Wear safety glasses
UK exposure limits:	None assigned.

9. Physical and chemical properties

Form:	Hydrogel and plastic covers.
Vapour pressure (mm Hg):	Not determined
Specific gravity:	Not determined
Water solubility:	Swellable/absorbent
Percent volatile:	Not determined
Vapour density:	N/A
Evaporation rate:	Not determined
Odour:	Mild
Viscosity:	N/A
Odour threshold:	Unknown
Boiling point:	N/A
Freezing point:	Hydrogels do not freeze except at exceptionally low temperatures. Temperatures below -5°C should be avoided.
Molecular weight:	N/A (cross-linked polymer)

10. Stability and reactivity

Stability:	Material is normally stable at moderately elevated temperatures and pressures.
-------------------	--

11. Toxicological information

Substantially equivalent material has been tested according to:

International Standard ISO 10993-10(1995) – Biological Evaluation of Medical Devices, Part 10: Acute (Single Exposure) Skin Irritation Testing of the Gel.

International Standard ISO 10993-10(1995) – Biological Evaluation of Medical Devices, Part 10: Maximisation Sensitisation Test.

International Standard ISO 10993-5 – Biological Evaluation of Medical Devices, Part 5: Tests for Cytotoxicity, Extract Method.

No evidence of carcinogenic properties. No evidence of mutagenic or teratogenic effects.

Principle hydrogel component is approved for Use as a Food Contact material by the FDA.

12. Ecological information

No environmental hazard is anticipated provided that the material is handled and disposed of with due care and attention.

13. Disposal considerations

Chemical residues are generally classified as special waste and as such are covered by regulations which vary according to location. Contact your local waste disposal authority for advice or pass to a chemical disposal company.

14. Transport information

Not regulated.

UN number:	N/A
IMDG:	N/A
ICAO:	N/A
ADR/RID Hazard:	N/A

15. Regulatory information

Symbol(s):	N/A
Indication of danger:	N/A
Precautionary labels:	This material has no known hazards as defined by local laws.
EEC number:	N/A

16. Other information

HMIS Codes	Health 0, Fire 0, Reactivity 0.
------------	---------------------------------

Relevant R phrases	Not applicable
--------------------	----------------

Revision Indicators

Section	Changed
1 Substance /Product Identification	4 April 2009
2 Hazard Identification	4 April 2009
3 Composition/Information on Ingredients	4 April 2009
7 Handling and Storage	4 April 2009
8 Exposure Controls/Personal Protection	4 April 2009
16 Other Information	4 April 2009

As the conditions or method of use are beyond our control, we do not assume any responsibility and expressly disclaim any liability for use of this product. Information contained herein is believed to be true and accurate but all statements and suggestions are made without warranty, expressed or implied, regarding accuracy of the information, the hazards connected with the use of the material or the results or the results to be obtained from the use thereof. Compliance with all applicable federal, state, and local regulations remains the responsibility of the user.