



# SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 11

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** Nitroglycerine Ointment

### Other means of identification

**Product Code** FG00091

**Synonyms** Rectiv

### Recommended use of the chemical and restrictions on use

**Recommended Use** Vasodilator indicated for the treatment of moderate to severe pain associated with chronic anal fissure

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

### Details of the supplier of the safety data sheet

#### **Manufacturer**

Allergan plc  
5 Giralda Farms  
Madison, NJ USA 07940  
+1-800-272-5525

#### **E-mail address**

SDS@Allergan.com

### Emergency telephone number

#### **Emergency Telephone**

Call CHEMTREC Day or Night  
Within USA or Canada: 1-800-424-9300  
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

## 2. HAZARDS IDENTIFICATION

### Classification

#### **OSHA Regulatory Status**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 4
Acute toxicity - Dermal	Category 3
Carcinogenicity	Category 1B

### Label elements

#### **Emergency Overview**

**Danger**

#### **Hazard statements**

H302 - Harmful if swallowed  
H311 - Toxic in contact with skin  
H350 - May cause cancer



**Appearance** Ointment

**Physical state** Solid

**Odor** No information available

**Chemical Name**  
Nitroglycerin

**Symptoms**

In therapeutic use headache which may be severe and persistent may occur immediately after administration. Vertigo, dizziness, weakness, palpitation, flushing, rash, exfoliative dermatitis and adverse vascular effects have been reported. Allergic reactions to organic nitrates are extremely rare, but they do occur and are manifested by nausea, vomiting, weakness, excessive sweating, pallor, and collapse. Limited evidence of harm to fetus during pregnancy, based on animal data. More serious adverse effects are the result of Nitroglycerin's capacity to induce vasodilatation, venous pooling, reduced cardiac output, and hypotension. Manifested symptoms have included increased intracranial pressure, with any or all of persistent throbbing headache, confusion, and moderate fever, vertigo, palpitations, rapid heart beat, visual disturbances, nausea and vomiting (possibly with colic and even bloody diarrhea), fainting (especially in the upright posture), difficulty breathing, later followed by labored breathing, excessive sweating, with the skin either flushed or cold and clammy, heart block and abnormal slow heart beat, paralysis, coma, seizures, and death. Methemoglobinemia has been rarely reported in association with organic nitrates. Methemoglobinemia is a condition where the blood cannot absorb sufficient oxygen and tissues become hypoxic.

**Chemical Name**  
Nitroglycerin

**Medical Conditions Aggravated by Exposure**

Individuals with early myocardial infarction, severe anemia, increased intracranial pressure, and those with a known sensitivity or hypersensitivity to nitroglycerin or its ingredients, or other nitrates or nitrites. Concomitant use with phosphodiesterase type 5 (PDE5) inhibitors such as sildenafil citrate (VIAGRA<sup>†</sup>) since it has been shown to potentiate the hypotensive effects of nitrates.

**Precautionary statements**

P264 - Wash face, hands and any exposed skin thoroughly after handling  
 P270 - Do not eat, drink or smoke when using this product  
 P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
 P330 - Rinse mouth  
 P312 - Call a POISON CENTER or doctor if you feel unwell  
 P361 - Remove/Take off immediately all contaminated clothing  
 P363 - Wash contaminated clothing before reuse  
 P302 + P352 - IF ON SKIN: Wash with plenty of soap and water  
 P322 - Specific measures (see supplemental first aid instructions on this label)  
 P201 - Obtain special instructions before use  
 P202 - Do not handle until all safety precautions have been read and understood  
 P281 - Use personal protective equipment as required  
 P308 + P313 - IF exposed or concerned: Get medical advice/attention  
 P405 - Store locked up  
 P501 - Dispose of contents/ container to an approved waste disposal plant  
 P280 - Wear protective gloves/protective clothing/eye protection/face protection

**Other Information**

Unknown Acute Toxicity 1.6% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
Paraffin Wax	8002-74-2	232-315-6	60 - 100*
White Petrolatum	8009-03-8	232-373-2	7 - 13*
Lanolin	8006-54-0	232-348-6	7 - 13*
sorbitan sesquioleate	8007-43-0	232-360-1	1 - 5*
Nitroglycerin	55-63-0	200-240-8	0.1 - 1*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### 4. FIRST AID MEASURES

#### First aid measures

<b>General advice</b>	If symptoms persist, call a physician. Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing.
<b>Eye contact</b>	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. If symptoms persist, call a physician.
<b>Skin Contact</b>	Consult a physician if necessary. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	Remove to fresh air. Call a physician. If breathing is irregular or stopped, administer artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
<b>Ingestion</b>	Rinse mouth. Drink plenty of water. If symptoms persist, call a physician. Do NOT induce vomiting.

**Chemical Name**  
Nitroglycerin

**Note to physicians**  
Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

#### **Suitable extinguishing media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

#### **Unsuitable extinguishing media**

None known.

#### **Specific hazards arising from the chemical**

Fire may produce irritating, corrosive and/or toxic gases.

#### **Explosion data**

**Sensitivity to Mechanical Impact** Not impact sensitive.

**Sensitivity to Static Discharge** Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

#### **Protective equipment and precautions for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions** Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

<b>Environmental precautions</b>	Prevent entry into waterways, sewers, basements or confined areas. Do not flush into surface water or sanitary sewer system. See Section 12 for additional ecological information.
<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

**7. HANDLING AND STORAGE**

<b>Advice on safe handling</b>	Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.
<b>Storage Conditions</b>	Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.
<b>Incompatible materials</b>	None known based on information supplied.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control parameters**

**Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m <sup>3</sup> )
Parrafin Wax 8002-74-2	TWA: 2 mg/m <sup>3</sup> fume	(vacated) TWA: 2 mg/m <sup>3</sup>	TWA: 2 mg/m <sup>3</sup> fume	N/A
Nitroglycerin 55-63-0	TWA: 0.05 ppm S*	(vacated) STEL: 0.1 mg/m <sup>3</sup> not in effect as a result of reconsideration (vacated) S* Ceiling: 0.2 ppm Ceiling: 2 mg/m <sup>3</sup> S*	IDLH: 75 mg/m <sup>3</sup> STEL: 0.1 mg/m <sup>3</sup>	140 ug/m <sup>3</sup>

*NIOSH IDLH Immediately Dangerous to Life or Health*

**Other Information** Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

**Appropriate engineering controls**

**Engineering Controls** The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

**Individual protection measures, such as personal protective equipment**

<b>Eye/face protection</b>	No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.
<b>Skin and body protection</b>	During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).
<b>Respiratory protection</b>	Respiratory protection is generally not needed during routine conditions of use of this

product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid	<b>Appearance</b>	Ointment
<b>Color</b>	No information available	<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available		

### Property

pH

Melting point/freezing point

Boiling point / boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

Flammability Limit in Air

Upper flammability limit:

Lower flammability limit:

Vapor pressure

Vapor density

Specific Gravity

Water solubility

Solubility in other solvents

Partition coefficient

Autoignition temperature

Decomposition temperature

Explosive properties

Oxidizing properties

### Values

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

No information available

### Other Information

Molecular weight

VOC Content (%)

Density

Bulk density

No information available

No information available

No information available

No information available

## 10. STABILITY AND REACTIVITY

### Reactivity

Not defined As Reactive substance

### Chemical stability

Stable under normal conditions.

### Possibility of Hazardous Reactions

None under normal processing.

### Conditions to avoid

Aerosol formation.

### Incompatible materials

None known based on information supplied.

### Hazardous Decomposition Products

None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

Acute toxicity

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Nitroglycerin	See Symptoms for more information.	Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.	Very toxic in contact with skin.	Very toxic if swallowed.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Paraffin Wax	> 5000 mg/kg ( Rat )	> 3600 mg/kg ( Rabbit )	N/A
White Petrolatum	N/A	= 3600 mg/kg ( Rabbit )	N/A
Lanolin	> 5000 mg/kg ( Rat )	N/A	N/A
sorbitan sesquioleate	> 39800 mg/kg ( Rat )	N/A	N/A
Nitroglycerin	= 100 mg/kg ( Rat )	> 280 mg/kg ( Rabbit )	N/A

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Nitroglycerin	Not mutagenic in the standard battery of tests.	This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B). Rats developed dose-related fibrotic and neoplastic changes in liver, including carcinomas, and interstitial cell tumors in testes.	Studies in rats and rabbits have not shown teratogenicity or harm to the fetus.	It is not known whether this drug is excreted in human milk. Because most drugs are excreted in human milk, if use of this drug is deemed essential, the patient should stop nursing.

Chemical Name	STOT - single exposure	STOT - repeated exposure
Nitroglycerin	No information available.	Cardiovascular.

**Target Organ Effects** Eyes, Respiratory system, Skin.

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity** 1.6% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document .

- ATEmix (oral) 982 mg/kg
- ATEmix (dermal) 960 mg/kg
- ATEmix (inhalation-dust/mist) 12.5 mg/l

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

98.6% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Nitroglycerin 55-63-0	N/A	1.6 - 2.6: 96 h Pimephales promelas mg/L LC50 static 0.87 - 3.25: 96 h Lepomis macrochirus mg/L LC50 flow-through 0.87 - 2.21: 96 h Lepomis macrochirus mg/L LC50 static 2 - 3.8: 96 h Oncorhynchus mykiss mg/L LC50 static 2.2 - 3.7: 96 h Pimephales promelas mg/L LC50 flow-through	38 - 55: 48 h Daphnia magna mg/L EC50 Static 46 - 55: 48 h Daphnia magna mg/L EC50

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Nitroglycerin 55-63-0	N/A	Based on the BCF, the potential for bioaccumulation in aquatic organisms is low.	Expected to have moderate mobility in soil.	N/A

**Other adverse effects** No information available

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Disposal of wastes** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse container. Dispose of contents/containers in accordance with local regulations.

**US EPA Waste Number** P081

Chemical Name	RCRA	RCRA - Basis for Listing	RCRA - D Series Wastes	RCRA - U Series Wastes
Nitroglycerin 55-63-0	P081	-	-	-

Chemical Name	RCRA - Halogenated Organic Compounds	RCRA - P Series Wastes	RCRA - F Series Wastes	RCRA - K Series Wastes
Nitroglycerin 55-63-0	-	P081	-	-

This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical Name	California Hazardous Waste Status
Nitroglycerin 55-63-0	Toxic Ignitable Reactive

**14. TRANSPORT INFORMATION**

**DOT** Not regulated

**TDG** Not regulated

**ICAO (air)** Not regulated

**IATA** Not regulated

**IMDG** Not regulated

**ADR** Not regulated

**ADN** Not regulated

**15. REGULATORY INFORMATION**

**International Inventories**

**TSCA** Listed  
**DSL/NDSL** Listed  
**EINECS/ELINCS** Listed

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**US Federal Regulations**

**Carcinogenicity** The table below indicates whether each agency has listed any ingredient as a carcinogen  
 This product contains one or more substances which are classified by IARC as

carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B)

Chemical Name	ACGIH	IARC	NTP	OSHA
Nitroglycerin 55-63-0	-	Group 2A	-	X

IARC (International Agency for Research on Cancer)

Group 2A - Probably Carcinogenic to Humans

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

X - Present

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

**SARA 311/312 Hazard Categories**

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

**CERCLA**

This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Nitroglycerin 55-63-0	10 lb	-	RQ 10 lb final RQ RQ 4.54 kg final RQ

**US State Regulations**

**California Proposition 65**

This product does not contain any Proposition 65 chemicals

**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Paraffin Wax 8002-74-2	X	X	X
Lanolin 8006-54-0	-	-	X
PROPYLENE GLYCOL USP 57-55-6	X	-	X
Nitroglycerin 55-63-0	X	X	X

**16. OTHER INFORMATION**

Revision Date 02-Oct-2018  
Revision Note No information available

**Disclaimer**

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

**End of Safety Data Sheet**