

Issue Date: 10/05/2021  
Last Revision Date: 28/05/2024  
Superseded Date: 10/05/2021  
Version Number: 02

## SAFETY DATA SHEET

Product Code: RO2111

PAGE 1 OF 5

### SECTION 1 PRODUCT IDENTIFICATION

#### Product identifier

**Product Name:** Bepanthen Nappy Rash Ointment  
**Relevant identified uses of the substance or mixture and uses advised against**  
**Use of the Substance/ Mixture** unfinished drug mixture

### SECTION 2 HAZARD IDENTIFICATION

**GHS Classification** Not a hazardous substance or mixture.  
**GHS label elements** Not a hazardous substance or mixture.  
**Other hazards which do not result in classification** None known.

### SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture** Mixtures  
**Hazardous components** No hazardous ingredients

### SECTION 4 FIRST AID MEASURES

**General advice** : Take off all contaminated clothing immediately.  
**If inhaled** : Remove to fresh air.  
Call a physician immediately.  
**In case of skin contact** After contact with skin, wash immediately with plenty of soap and water.  
If skin reactions occur, contact a physician.  
**In case of eye contact** In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
**If swallowed** If swallowed, seek medical advice immediately and show this container or label.  
**Most important symptoms and effects, both acute and delayed** No information available.  
**Notes to physician** No information available.

Issue Date: 10/05/2021  
 Last Revision Date: 28/05/2024  
 Superseded Date: 10/05/2021  
 Version Number: 02

## SAFETY DATA SHEET

Product Code: RO2111

PAGE 2 OF 5

### SECTION 5 FIRE FIGHTING MEASURES

<b>Suitable extinguishing media</b>	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
<b>Unsuitable extinguishing media</b>	High volume water jet
<b>Specific hazards during fire-fighting</b>	Fire may cause evolution of: Carbon monoxide (CO) Carbon dioxide (CO <sub>2</sub> )
<b>Specific extinguishing methods</b>	Prevent fire extinguishing water from contaminating surface water or the ground water system.
<b>Special protective equipment for firefighters</b>	In the event of fire, wear self-contained breathing apparatus.

### SECTION 6 ACCIDENTAL RELEASE MEASURES

<b>Personal precautions, protective equipment and emergency procedures</b>	Use personal protective equipment. No special precautions required.
<b>Environmental precautions:</b>	Do not flush into surface water or sanitary sewer system.
<b>Methods and material for containment and cleaning up:</b>	Cover spilled product with liquid-binding material (sand, silica gel, acid binder, universal binder, hybilat). Take up mechanically and fill into labeled, closable containers.
<b>Advice on safe handling</b>	No special precautions required.
<b>Hygiene measures</b>	Cleanliness Guidelines (GMP) for manufacturing of drugs must be observed!

### SECTION 7 HANDLING AND STORAGE

<b>Conditions for safe storage</b>	: For storage suitable stores with adequate product-reception volume must be used. During handling local official regulations must be observed in order to avert impairment of water by the product.
------------------------------------	---

### SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
White mineral oil (petroleum), viscosity >20,5 mm <sup>2</sup> /s	8042-47-5	TWA (Mist)	5 mg/m <sup>3</sup>	AU OEL
		TWA (Inhalable fraction)	5 mg/m <sup>3</sup>	ACGIH
Paraffin oils	8012-95-1	TWA (Mist)	5 mg/m <sup>3</sup>	AU OEL
		TWA (Inhalable fraction)	5 mg/m <sup>3</sup>	ACGIH

Information provided on this document is presented in good faith and believed to be correct based on the best data currently available, Livingstone International makes no representations or warranties, expressed or implied as to the completeness or accuracy of the information. In no event will Livingstone International be liable for any errors or omissions in the information provided herein. Information is supplied upon the condition that any persons or corporate receiving same will make independent determination as to its suitability for their own purposes prior to use, and in no event will Livingstone International be responsible for damages of any nature whatsoever resulting from the use of product or reliance upon information provided. Information is provided on an "as is" basis, no representation or warranties, either expressed or implied of fitness for a particular purpose or of any other nature are made herein with respect to information of the product.

Issue Date: 10/05/2021  
 Last Revision Date: 28/05/2024  
 Superseded Date: 10/05/2021  
 Version Number: 02

## SAFETY DATA SHEET

Product Code: RO2111

PAGE 3 OF 5

### Personal protective equipment

#### Respiratory protection

Recommended respiratory protection: full mask with filter ABEK-ST (ABEK-P3)

#### Hand protection Material

Hand protection: protective gloves for chemicals made of Baypren, nitrile rubber or PVC wear

#### Remarks

Breakthrough time not tested; dispose of immediately after contamination. Advice: The gloves should not be reused.

#### Eye protection

Safety glasses

#### Protective measures

No special safety precautions are required during handling of pharmaceuticals in their intended finished form (tablets or liquid formulations) by chemists, the hospital's medical staff or patients. For the intake of ready for use pharmaceuticals or the external use on the skin please read the label and the package leaflet. Wear suitable protective equipment. The personal protective equipment is applicable for the handling of bulk material without packaging and for incidents if an exposure by the active ingredient or hazardous components can be expected.

### SECTION 9

### PHYSICAL/CHEMICAL PROPERTIES

Appearance:	cream
Colour:	white
Odour:	pleasant
Solubility(ies)	
Water solubility	practically insoluble (20 °C)
Decomposition temperature	No data available
Explosive properties:	No statements available.
Oxidizing properties	No statements available.
Impact Sensitivity	No data available

### SECTION 10

### STABILITY AND REACTIVITY

Reactivity	No data available
Chemical stability	No data available
Possibility of hazardous reactions	None known.
Conditions to avoid	No data available
Incompatible materials:	Oxidizing agents
Hazardous decomposition products:	Carbon monoxide (CO) Carbon dioxide (CO2)

Issue Date: 10/05/2021  
 Last Revision Date: 28/05/2024  
 Superseded Date: 10/05/2021  
 Version Number: 02

## SAFETY DATA SHEET

Product Code: RO2111

PAGE 4 OF 5

### SECTION 11 TOXICOLOGICAL INFORMATION

#### Respiratory or skin sensitisation

##### Product:

Assessment: An acute toxic effect is not expected.

#### Chronic toxicity

##### Product:

Repeated dose toxicity - Assessment: An acute toxic effect is not expected.

### SECTION 12 ECOLOGICAL INFORMATION

#### Ecotoxicity

##### Product:

#### Ecotoxicology Assessment

Acute aquatic toxicity: This product has no known ecotoxicological effects.

Persistence and degradability: No data available

Bioaccumulative potential: No data available

Mobility in soil: No data available

#### Other adverse effects

##### Product:

Additional ecological information: Do not allow to enter surface waters or groundwater.

### SECTION 13 DISPOSAL CONSIDERATIONS

#### Disposal methods

Contaminated packaging: Contaminated, empty containers are to be treated in the same way as the contents.

### SECTION 14 TRANSPORT INFORMATION

#### International Regulations

IATA-DGR: Not regulated as a dangerous good

IMDG-Code: Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable for product as supplied.

National Regulations: Not regulated as a dangerous good

Issue Date: 10/05/2021  
 Last Revision Date: 28/05/2024  
 Superseded Date: 10/05/2021  
 Version Number: 02

# SAFETY DATA SHEET

Product Code: RO2111

PAGE 5 OF 5

## SECTION 15 REGULATORY INFORMATION

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

No statements available

**Standard for the Uniform Scheduling of Medicines and Poisons**

No poison schedule number allocated

**The components of this product are reported in the following inventories:**

AICS Not in compliance with the inventory

## SECTION 16 OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**Reason for Revision:** To bring to date

# END OF SDS

Information provided on this document is presented in good faith and believed to be correct based on the best data currently available, Livingstone International makes no representations or warranties, expressed or implied as to the completeness or accuracy of the information. In no event will Livingstone International be liable for any errors or omissions in the information provided herein. Information is supplied upon the condition that any persons or corporate receiving same will make independent determination as to its suitability for their own purposes prior to use, and in no event will Livingstone International be responsible for damages of any nature whatsoever resulting from the use of product or reliance upon information provided. Information is provided on an "as is" basis, no representation or warranties, either expressed or implied of fitness for a particular purpose or of any other nature are made herein with respect to information of the product.