SAFETY DATA SHEET

1. Identification

Product identifier Naropin Solution

Other means of identification

Synonyms Ropivacaine hydrochloride solution

Recommended use Local anaesthetic. **Recommended restrictions** None known.

Manufacturer/Importer/Supplier/Distributor information Aspen Global Incorporated Company name

Address GBS Plaza, Cnr La Salette et Royal Road

Grand Bay, Mauritius

Telephone N/A

SDSRequest@aspengl.com E-mail Toll free access: 1 866 519 4752

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number

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Access Code: 333974

2. Hazard identification

Not classified. Physical hazards Not classified. **Health hazards Environmental hazards** Not classified.

Label elements

Hazard symbol None. None. Signal word

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statements

Prevention Observe good industrial hygiene practices.

Wash hands after handling. Response

Store away from incompatible materials. **Storage**

Disposal Dispose of waste and residues in accordance with local authority requirements.

Other hazards None known.

Supplemental information None.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Ropivacaine hydrochloride monohydrate	132112-35-7	1 - 2.5

Composition comments All concentrations are in percent by weight unless otherwise indicated. The exact concentrations of

the above listed chemicals are being withheld as a trade secret. Components not listed are either

non-hazardous or are below reportable limits.

4. First-aid measures

Inhalation Remove victim from source of exposure. Get medical attention for any breathing difficulty.

Wash skin with soap and water. Remove contaminated clothing and shoes. If skin irritation or rash Skin contact

occurs: Get medical advice/attention. For minor skin contact, avoid spreading material on

unaffected skin.

Naropin Solution SDS Canada

944091 Version #: 01 Revision date: - Issue date: 01-June-2018

Flush thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to Eye contact

do. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth and then drink 200-300 ml of water. Do not induce vomiting without advice from

medical personnel. Get medical attention.

Most important

symptoms/effects, acute and

delayed

Direct contact with eyes may cause temporary irritation. May cause tingling/numbness in exposed areas (paraesthesia). High atmospheric concentrations may lead to anaesthetic effects.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to

protect themselves.

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing media

Water spray. Foam. Dry powder. Carbon dioxide.

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

Special protective equipment and precautions for firefighters During fire, gases hazardous to health may be formed.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Fire fighting

equipment/instructions

Move containers from fire area if you can do so without risk.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Methods and materials for containment and cleaning up Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Use a non-combustible material like vermiculite, sand or earth to soak up the product and place into a container for later disposal. Following product recovery, flush area with water.

Small Spills: Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Do not handle until all safety precautions have been read and understood. Observe good industrial hygiene practices. Do not taste or swallow. When using, do not eat, drink or smoke. Avoid contact with skin and eyes. Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities Store in a closed container. Keep container tightly closed. Keep out of the reach of children.

Storage temperature: between 15 and 30°C. Protect from light. Do not freeze.

8. Exposure controls/personal protection

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

No biological exposure limits noted for the ingredient(s).

Exposure guidelines

No exposure standards allocated.

Appropriate engineering controls

Select controls based on a risk assessment of local circumstances. Engineering controls should

2/6

be used as the primary means to control possible exposures.

Individual protection measures, such as personal protective equipment

Risk of contact: Wear safety glasses with side shields (or goggles). Eye/face protection

Skin protection

Hand protection Wear protective gloves. Suitable gloves can be recommended by the glove supplier. Frequent

change is advisable.

Other Wear suitable protective clothing.

Naropin Solution SDS Canada Respiratory protection When isolation is not possible, respiratory protective equipment (RPE) should be combined with

applicable protective equipment.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing

should not be allowed out of the workplace.

9. Physical and chemical properties

Appearance

Physical state Liquid.

Form Aqueous solution.
Colour Not available.
Odour Not available.
Odour threshold Not available.

pH 4 - 6

Melting point/freezing point Not available.

Initial boiling point and boiling Not available.

range

Flash point Will not burn.

Evaporation rate Not available.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not applicable.

Flammability limit - upper

(%)

Not applicable.

Vapour pressureNot available.Vapour densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Not available.

Partition coefficient Not available.

(n-octanol/water)

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Density 1.00 g/cm³ (20°C)

Explosive properties Not explosive.

Oxidising properties Not oxidising.

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Protect from light. Do not freeze.

Incompatible materials None known.

Hazardous decomposition

products

No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation May be harmful if inhaled.

Naropin Solution SDS Canada

Skin contactMay cause slight skin irritation.Eye contactMay cause slight eye irritation.IngestionMay cause discomfort if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. May cause tingling/numbness in exposed

areas (paraesthesia). High atmospheric concentrations may lead to anaesthetic effects.

Information on toxicological effects

Acute toxicity Not expected to be acutely toxic.

Skin corrosion/irritation Not classified.
Serious eye damage/eye Not classified.

irritation

Respiratory or skin sensitisation

Respiratory sensitisation Not classified.

Skin sensitisationThe product contains a small amount of sensitising substance which may provoke an allergic

reaction among sensitive individuals after repeated contact.

Germ cell mutagenicity

Carcinogenicity

Reproductive toxicity

Specific target organ toxicity
Not classified.

Not classified.

Not classified.

single exposure

Specific target organ toxicity -

Not classified.

repeated exposure

Aspiration hazard

Due to the physical form of the product it is not expected to be an aspiration hazard.

Further information Prolonged exposure may cause chronic effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components Species Test Results

Ropivacaine hydrochloride monohydrate (CAS 132112-35-7)

Aquatic Acute

 Algae
 EC50
 Green algae
 59 mg/l, 72 hours (OECD 201)

 Crustacea
 EC50
 Daphnia magna
 34 mg/l, 48 hours (OECD 202)

 Fish
 LC50
 Zebrafish (Danio rerio)
 38 mg/l, 96 hours (OECD 203)

Persistence and degradability

The product is not expected to be readily biodegradable.

Bioaccumulative potential

Potential to bioaccumulate is low.

Mobility in soil

This product is water soluble and may disperse in soil.

Other adverse effects None known.

13. Disposal considerations

Disposal instructionsCollect and reclaim or dispose in sealed containers at licensed waste disposal site. This material

and its container must be disposed of as hazardous waste. Dispose of contents/container in

accordance with local/regional/national/international regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

Naropin Solution SDS Canada

14. Transport information

TDG

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to

Not applicable.

Annex II of MARPOL 73/78 and the IBC Code

15. Regulatory information

Canadian regulations

This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Greenhouse Gases

Not listed.

Precursor Control Regulations

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto Protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes

^{*}A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

Toxic Substances Control Act (TSCA) Inventory

16. Other information

01-June-2018 Issue date

Revision date

United States & Puerto Rico

Naropin Solution 5/6

944091 Version #: 01 Revision date: -Issue date: 01-June-2018 No

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Version No. 01

References Supplier's SDS

While the information and recommendations contained in this safety data sheet are believed to be correct at the time of issue, liability for its accuracy, adequacy or completeness is excluded to the maximum extent permissible by law and no express or implied warranty is given. This exclusion extends to liability for any statement, opinion or conclusion contained in or any omission from this safety data sheet (including its annexes and references) and for any other related written or oral communication. No representations or warranties are made for these statements, opinions or conclusions and the user must determine the correct and proper use of the material described in

this safety data sheet.

Naropin Solution SDS Canada 944091 Version #: 01 Revision date: - Issue date: 01-June-2018 6 / 6