

Product Number: E-N520S-2oz
Revision Date: October 3, 2024

Product Name: Numb520 Spray
Revision Number: 2.0

Ebanel

Safety Data Sheet

1. IDENTIFICATION

Product Identifier

Product Name: Numb520 Spray
Item Number: E-N520S-2oz

Other Means of Identification

Synonyms (Product Benefit): Topical Anorectal Spray
Active Ingredient(s): Lidocaine (5%), Phenylephrine HCl (0.25%)

Specific Uses

Specific Uses: Local anesthetic. For the temporary relief of local and anorectal itching and discomfort associated with anorectal disorders and anorectal inflammation. For the temporary relief of pain, burning and soreness. Temporarily shrinks hemorrhoidal tissue. Temporarily reduces the swelling associated with irritation in hemorrhoids and other anorectal disorders.

Uses advised against: Use only as directed.
Target Use Body Part: Body
Item Form: Spray
Age Range: Adult
Unit Count: 2.4 fl. oz per each bottle
Container Type: Plastic spray bottle, child resistant cap
Flavor: Does not apply

Manufacturer Information

Clinical Resolution Laboratory, Inc.
1530 Moonstone
Brea, CA 92821 USA
Phone: 213-384-0500 (M-F 8am-5pm PST)

24-Hour Emergency Telephone Number (Chemtrec)

USA: 1-800-424-9300
International: 703-527-3887

2. HAZARDS IDENTIFICATION

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Classification

This product does not contain any chemicals considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122).

Signal Word

Warning

GHS/CLP Label Elements, including Precautionary Statements

Emergency Overview

The product contains no substances which at their given concentration are considered to be hazardous to health.

Appearance: Clear colorless liquid

Physical State: Water thin liquid

Odor: Characteristic odor to match standard

Precautionary Statements – Prevention

Obtain special instructions before use

Precautionary Statements – Response

None

Precautionary Statements – Storage

None

Precautionary Statements – Disposal

None

Hazards not otherwise classified (HNOC)

Not Applicable

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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Active Ingredients		
Ingredient Name	CAS-No	Percentage Range
Lidocaine	7732-18-5	5%
Phenylephrine	56-81-5	0.25%

Inactive Ingredients		
Ingredient Name	CAS-No	Percentage Range
Alcohol Denat.	64-17-5	0-1%
Allantoin	97-59-6	0-2%
Aloe Barbadensis Leaf Juice	85507-69-3	0-2%
Arginine HCl	1119-34-2	0-2%
Benzyl Alcohol	100-51-6	1-3%
Chamomilla Recutita (Matricaria) Flower Extract	84082-60-0	0-2%
Citric Acid	77-92-9	1-3%
Disodium EDTA	6381-92-6	0-0.5%
Ethoxydiglycol	111-90-0	1-3%
Glycerin	56-81-5	0-2%
Hamamelis Virginiana (Witch Hazel) Water	84696-19-5	0-2%
Polysorbate 20	9005-64-5	1-4%
Propylene Glycol	57-55-6	10-15%
Sodium Benzoate	532-32-1	0-0.5%
Sodium Chloride	7647-14-5	0-0.5%
Sodium Citrate	68-04-2	0-0.5%
Sodium Hydroxide	1310-73-2	0-1%
Sodium Metabisulfite	7681-57-4	0-0.5%
Sodium Sulfite	7757-83-7	0-0.2%
Water	7732-18-5	50-70%

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4. FIRST-AID MEASURES

Route	Common Symptoms	First Aid
Inhalation	Dizziness, trouble breathing	Move to fresh air. If affected person is not breathing, apply artificial respiration. If breathing is difficult, give oxygen. If symptoms persist, get medical attention.
Ingestion	Vomiting, cramps, diarrhea	Do not induce vomiting. If material is swallowed, get medical attention.
Skin Contact	Dermal irritation	If irritation occurs, wash with soap and water. If irritation or allergic reactions persist, get medical attention.
Eye Contact	Irritation	Immediately flush eyes with water for at least 15 minutes, while holding eyelids open. If symptoms persist, get medical attention.

Indication of any immediate medical attention and special treatment needed

Notes to Physician 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

CAUTION: Use of water spray when fighting fire may be inefficient.

Specific Hazards Arising from the Chemical

No information available.

Hazardous Combustion Products

No information available.

Explosion Data

Sensitivity to Mechanical Impact No

Sensitivity to Static Discharge No

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, Protective Equipment, and Emergency Procedures

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Personal Precautions

Avoid contact with eyes.

Other Information

Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions

Environmental Precautions

Refer to protective measures listed in Sections 7 and 8.

Methods and Material for Containment and Cleaning Up

Methods for Containment

Prevent further leakage or spillage if safe to do so.

Methods for Cleaning Up

Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Keep in suitable and closed containers for disposal. Wash spill area with water.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes.

Conditions for Safe Storage, including any Incompatibilities

Storage

Keep in tightly closed containers in a dry and cool place. Keep in properly labeled containers.

Incompatible Products

None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Appropriate Engineering Controls

Engineering Measures

Showers
Eyewash Stations
Ventilation Systems

Individual Protection Measures, such as Personal Protective Equipment

Eye/Face Protection

No special protective equipment required.

Skin and Body Protection

No special protective equipment required.

Respiratory Protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

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Physical and Chemical Properties

Physical State	Water thin liquid
Appearance	Clear colorless liquid
Color	White opaque
Odor	Characteristic odor to match standard
Odor Threshold	No information available

<u>Property</u>	<u>Values</u>
pH	5.5
Melting/Freezing Point	Not applicable
Boiling Point/Range	Not applicable
Flash Point	Not applicable
Evaporation Rate	Not applicable
Flammability (solid, gas)	Not applicable
Flammability Limits in Air	Not applicable
Upper flammability limit	Not applicable
Lower flammability limit	Not applicable
Vapor Pressure	Not applicable
Vapor Density	Not applicable
Specific Gravity	Not applicable
Water Solubility	Not applicable
Solubility in other solvents	Not applicable
Partition Coefficient:	Not applicable
n-octanol/water	Not applicable
Autoignition Temperature	Not applicable
Decomposition Temperature	Not applicable
Kinematic Viscosity	Not applicable
Dynamic Viscosity	Not applicable
Explosive Properties	Not applicable
Oxidizing Properties	Not applicable

Other Information

Softening Point	Not applicable
VOC Content (%)	Not applicable

10. STABILITY AND REACTIVITY

Reactivity

Not reactive.

Chemical Stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing

When used in accordance with the directions.

Hazardous Polymerization

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Hazardous polymerization does not occur.

Conditions to Avoid

Freezing and extreme heat.

Incompatible Materials

None known.

Hazardous Decomposition Products

No information available.

11. TOXICOLOGICAL INFORMATION

There is no data for this product. The information included in this section describes the potential hazards of the individual ingredients.

Information on Likely Routes of Exposure

Product Information

Inhalation	There is no data available for this product.
Eye Contact	There is no data available for this product.
Skin Contact	There is no data available for this product.
Ingestion	There is no data available for this product.

Information on Toxicological Effects

Symptoms No information available.

Delayed and Immediate Effects as well as Chronic Effects from Short and Long-Term Exposure

Sensitization	No information available.
Mutagenic Effects	No information available.
Carcinogenicity	Contains no ingredient listed as a carcinogen.
Reproductive Toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Chronic Toxicity	No known effect based on information supplied.
Target Organ Effects	No adverse health effects on target organs expected for finished product.
Symptoms Associated with Exposure	None expected: may cause skin irritation to sensitive people.
Aspiration Hazard	No information available.
OSHA	Not listed
NTP	Not listed
IARC	Not listed

12. ECOLOGICAL INFORMATION

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There is no ecological data on the Product. The Product ingredients are expected to be safe for the environment at concentrations predicted under normal use and accidental spill scenarios. Packaging components are compatible with the conventional solid waste management practices.

Ecotoxicity

No information available.

Persistence and Degradability

No information available.

Bioaccumulation

No information available.

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods

Waste Disposal Methods

This material, as supplied, is not a hazardous waste according to Federal Regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of in accordance with federal, state, and local laws and regulations

California Hazardous

Waste Code:

331

14. TRANSPORT INFORMATION

DOT

Not regulated/non-hazardous

Proper Shipping Name

Non regulated

Hazard Class

N/A

UN Number

Not applicable

Proper Shipping Name

Not regulated

TDG

Not regulated

MEX

Not regulated

ICAO

Non regulated

IATA

Non regulated

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Proper Shipping Name	Non regulated
Hazard Class	N/A
<u>MDG/IMO</u>	Not regulated
Hazard Class	N/A
<u>RID</u>	Not regulated
<u>ADR</u>	Not regulated
<u>AND</u>	Not regulated
<u>Packing Group Number</u>	Not applicable
<u>Environmental Hazards</u>	Not applicable
<u>Special Precautions</u>	Do not freeze, avoid extreme heat

15. ADDITIONAL REGULATORY INFORMATION

While this finished product is not considered hazardous as defined by OSHA in 29 CFR 1910.1200, this SDS contains valuable information critical to the safe handling and proper use of the product.

U.S. Federal

The product described in this SDS is regulated under the Federal Food, Drug and Cosmetics Act and is safe to use as per directions on container, box, or accompanying literature (where applicable).

CERCLA reportable quantity (RQ): None
SARA 313/302/304/311/312 Chemicals: None

U.S. States

This product is not subject to warning labeling under California Proposition 65.

16. OTHER INFORMATION

General Disclaimer

The information provided in this 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 guidance for safe handling, use, processing, storage, transportation, disposal and release 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.

Approved and Updated by Ebanel Laboratories, Inc.

Disclaimer

The information and recommendations contained in the Safety Data Sheet (SDS) are supplied pursuant to 29 CFR 1910.1200 of the Occupational Safety and Health Standards Hazard Communication Rule. The information and recommendations set forth herein are presented in good faith and believed to be correct as of this date hereof.

Ebanel, however, makes no representation as to the completeness or accuracy thereof, and information is supplied upon the express condition that the persons receiving the information will be required to make their own

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determination as to its suitability for their purposes prior to use. In no event will Ebanel be responsible for any damages of any nature whatsoever resulting from the use of, reliance upon, or the misuse of this information.

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END OF SAFETY DATA SHEET