Kovanaze™ Nasal Spray
(6 mg Tetracaine Hydrochloride and 0.1 mg Oxymetazoline Hydrochloride per 0.2 mL spray)

1. IDENTIFICATION OF SUBSTANCE

Name:	**Kovanaze™ Nasal Spray** (6 mg tetracaine hydrochloride and 0.1 mg oxymetazoline hydrochloride)
Product Code:	NDC # 69803-100-10
Recommended use:	Kovanaze is a nasal spray containing an ester local anesthetic with a vasoconstrictor indicated for regional anesthesia when performing a restorative procedure on teeth.
Restrictions on use:	Refer to the package insert or label for contraindications and warnings regarding use of this product.
Manufacturer:	St. Renatus, LLC 1000 Centre Avenue Fort Collins, CO 80526
Emergency Information:	The SP Group, LLC 720-837-7128

2. HAZARD IDENTIFICATION

Emergency Overview: Product contains two active pharmaceutical ingredients that can affect body functions; handle with caution.

Classified According to: UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS)
Classification of Substance: Not available

Classification of Mixture:

Toxicity	Classification Category
Acute toxicity	5
Skin corrosion/irritation	3
Serious eye damage/irritation	2A
Skin sensitization	1
Aquatic toxicity, chronic	4

Label Elements:
Pictogram:



Signal Word: Warning

2. HAZARD IDENTIFICATION (continued)

Toxicity	Hazard Code	Hazard statements
Acute toxicity	H303	May be harmful if swallowed
	H313	May be harmful in contact with skin
	H333	May be harmful if inhaled
Skin corrosion/irritation	H316	Causes mild skin irritation
Serious eye damage/irritation	H319	Causes serious eye irritation
Skin sensitization	H317	May cause an allergic skin reaction
Aquatic toxicity, chronic	H413	May cause long-lasting, harmful effects to aquatic life

Precautionary Statements:

Prevention:	P264	Wash hands thoroughly after handling.
	P280	Wear protective gloves, eye protection, and face protection.
	P261	Avoid breathing vapors/spray.
	P272	Contaminated work clothing should not be allowed out of the workplace.
Response:	P312	Call a poison center or doctor if the exposed individual feels unwell following inhalation, ingestion or dermal contact with the product.
	P332, P313	If skin irritation occurs: Get medical attention or advice.
	P305, P351, P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337, P313	If eye irritation persists: Get medical attention or advice.
	P302, P352	IF ON SKIN: Wash with plenty of water.
	P333, P313	If skin irritation or rash occurs: Get medical attention or advice.
	P362, P363	Take off contaminated clothing. Wash contaminated clothing before reuse.
Disposal:	P501	Dispose of contents and container in accordance with local, regional, national and international regulations.

Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Characterization/Description: Tetracaine hydrochloride/oxymetazoline hydrochloride solution

Components of Drug Product:

CAS Number:	Chemical Name:	Percent:
7732-18-5	Water	>93%
136-47-0	Tetracaine hydrochloride	3% w/v
6132-04-3	Sodium citrate, dihydrate	<1.5% w/v
77-92-9	Citric acid, anhydrous	1% w/v
100-51-6	Benzyl alcohol	<1% w/v
9004-62-0	Hydroxyethylcellulose	<0.1% w/v
2315-02-8	Oxymetazoline hydrochloride	0.05% w/v

4. FIRST AID MEASURES

Inhalation: If exposed to excessive levels of mists or vapors, remove victim to fresh air. Give oxygen or artificial respiration if necessary. Seek medical attention if warranted.

Skin Contact: If exposed to a large volume of the drug product, IMMEDIATELY flood affected skin with water removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. Seek medical attention if warranted.

Eye Contact: First check the victim for contact lenses and remove if present. IMMEDIATELY flush victim's eyes with water or normal saline solution for 20 to 30 minutes and contact a hospital or poison control center. Do not put any ointments, oils, or medication in the victim's eyes without specific instructions from a physician. Transport the victim to a hospital if symptoms (such as redness or irritation) develop.

Ingestion: DO NOT INDUCE VOMITING.

If large quantities are ingested and if the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center. IMMEDIATELY transport the victim to a hospital.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Agents: Carbon dioxide, dry powder, alcohol-resistant foam, or water spray.

Protective Equipment: Self-contained breathing apparatus and protective equipment for fire-fighting.

Special Hazards Arising from the Mixture: None known, product not flammable or combustible.

6. ACCIDENTAL RELEASE MEASURES

Personnel Precautions: Wear gloves (disposable surgical) and eye protection (chemical splash glasses or goggles) to prevent contamination of skin and eyes in the event of large spills.

Environmental Precautions: Do not discharge into drains, surface waters, or groundwater.

Measures for Cleaning/Containment: Use absorbent material to pick up all liquid spill material. Seal the contaminated material, including contaminated clothing, in a vapor-tight plastic bag for disposal. Wash all contaminated surfaces with a soap and water solution.

7. HANDLING AND STORAGE

Handling: Wear personal protective equipment when handling this material. Wash hands after handling. For bulk spills, wear suitable personal protective eyewear, clothing, boots, and gloves.

Storage: Store under refrigerated conditions.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Control Parameters:

Engineering Controls:	None necessary under conditions of normal use.

Personal Protective Equipment:

Respiratory Protection	None necessary under conditions of normal use.
Skin Protection	Wear gloves (disposable surgical) when handling this product. If this product comes into contact with the gloves, or if a tear/puncture develops, remove gloves at once and wash hands.
Eye Protection	Splash-proof safety glasses or goggles should be worn while handling this material.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid	**Color and Odor:** Colorless, odorless
pH: 4.0 to 6.5	**Specific Gravity:** 1.01
Explosion Limit: Not available	**Boiling/Melting/Freezing Points:** Approximately same as water
Flammability: Expected to be non-flammable	**Autoignition Temperature:** Not available
Decomposition Temperature: Not available	**Kinematic Viscosity:** Approximately same as water
Flash Point: Not available	**Solubility:** Product is aqueous solution

Vapor Pressure/Density/Relative Vapor Density: Approximately same as water

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under conditions of normal use and transport.
Chemical Stability:	The product is stable under storage and handling conditions of normal temperature and pressure.
Possibility of Hazardous Reactions:	No hazardous reactions under conditions of normal use.
Conditions to Avoid:	None known.
Incompatible Materials:	None known.
Hazardous Decomposition Products:	None known.

11. TOXICOLOGICAL INFORMATION

No toxicological data are available for the drug product. Information on the potential toxicity for the various components of the mixture is provided below.

Hazard Category	Component	Toxicity or Health Effects Data
Acute Toxicity	No data available for the drug product. Summary of acute toxicity data provided for hazardous components.	
	Tetracaine hydrochloride	LD_{50} (oral) = 160 mg/kg (mouse) LD_{50} (intraperitoneal) = 160 mg/kg (mouse)
	Benzyl alcohol	LD_{50} (oral) = 1360 mg/kg (mouse) LD_{50} (intraperitoneal) = 650 mg/kg (mouse)
	Oxymetazoline hydrochloride	LD_{50} (oral) = 4.7 mg/kg (mouse) LD_{50} (intraperitoneal) = 48 mg/kg (mouse)
Skin Corrosion/ Irritation	No data available for drug product. Summary of data provided for components with potential skin corrosion/irritation hazard.	
	Tetracaine hydrochloride	Non-corrosive. Not irritating to the skin.
	Benzyl alcohol	Skin contact causes irritation.
	Oxymetazoline hydrochloride	Non-corrosive. Not irritating to the skin.
Serious Eye Damage/Irritation	No data available for drug product. Summary of data provided for components with potential skin corrosion/irritation hazard.	
	Tetracaine hydrochloride	May cause serious irritation to eyes.
	Benzyl alcohol	May cause serious irritation and damage to eyes.
	Oxymetazoline hydrochloride	May cause serious damage to eyes.

11. TOXICOLOGICAL INFORMATION (continued)

Hazard Category	Component	Toxicity or Health Effects Data
Respiratory or Skin Sensitization	No data available for drug product. Summary of data provided for components with potential skin sensitization hazard.	
	Tetracaine hydrochloride	May cause an allergic skin reaction.
	Oxymetazoline hydrochloride	Not a skin sensitizer.
Germ Cell Mutagenicity	Classification criteria for germ cell mutagenicity not met.	
Carcinogenicity	Classification criteria for carcinogenicity not met.	
Reproductive Toxicity	Classification criteria for reproductive toxicity not met.	
Systemic Target Organ Toxicity (acute exposure)	Classification criteria for systemic target organ toxicity – acute exposure not met.	
Systemic Target Organ Toxicity (repeat exposure)	Classification criteria for systemic target organ toxicity – repeat exposure not met.	
Aspiration Hazard	No data available.	

The most common adverse reactions reported in clinical trials include: runny nose, nasal congestion, excessive watery eyes, nasal discomfort, and pain or reduced sensitivity in the upper portion of the throat behind the tongue. Transient, asymptomatic elevations in systolic blood pressure (≥25 mm Hg from baseline) and diastolic blood pressure (≥15 mm Hg from baseline) have also been reported.

Potential Health Effects:

Inhalation, acute:	No effects expected under normal conditions of use.
Inhalation, chronic:	No data available.
Skin, acute:	Skin irritation and the associated symptoms may occur (e.g., redness) under normal conditions of use.
Skin, chronic:	No data available.
Eyes, acute:	Eye irritation and transient symptoms of irritation (e.g., stinging, redness) may occur.
Eyes, chronic:	No data available.
Ingestion, acute:	No effects expected under normal conditions of use.
Ingestion, chronic:	No data available.

12. ECOLOGICAL EFFECTS

This drug product has not been tested for aquatic toxicity. However, based on an evaluation of the components of this product, it meets the classification criteria under GHS (2015) and is Category 4 for Aquatic Toxicity, Chronic.

Toxicity:	Not available.
Persistence and degradability:	Not available.
Bioaccumulation potential:	Not available.
Mobility in soil:	Not available.
Other adverse effects:	Not available.

13. DISPOSAL CONSIDERATIONS

Dispose of all waste and contaminated materials associated with this product as specified by existing local, state and federal regulations concerning hazardous waste disposal. Do not discharge into waterways or sewer systems without proper authorization.

14. TRANSPORT INFORMATION

Transport Information:	Not classified as dangerous in the meaning of transport regulations.
Proper shipping name (DOT):	Not regulated by this mode of transportation.

15. REGULATORY INFORMATION

Component:	CAS Number:	Canada DSL/NDSL	EC Inventory	TSCA
Tetracaine hydrochloride	136-47-0	Yes	Yes	No
Benzyl alcohol	100-51-6	Yes	Yes	Yes
Oxymetazoline hydrochloride	2315-02-8	Yes	Yes	No

16. OTHER INFORMATION

This information is based on our present knowledge; however, this shall not constitute a guarantee for any specific product features. No toxicity data are available on this specific formulation; this health hazard assessment is based on information that is available for its components.