



SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Goprelto® (cocaine hydrochloride nasal solution), 40 mg/mL (4%), 4 ml Bottle, CII	NDC 64950-359-04
Cocaine Hydrochloride Nasal Solution, 40 mg/ml (4%), 4 mL Bottle, CII	NDC 64950-362-04

Product Name: GOPRELTO®, COCAINE HYDROCHLORIDE Nasal Solution

Recommended use: GOPRELTO® and COCAINE HYDROCHLORIDE Nasal Solution (NS) are indicated for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries of the oral, laryngeal and nasal cavities in adults.

Restrictions: GOPRELTO® and COCAINE HYDROCHLORIDE NS contain Cocaine Hydrochloride (HCl), a Schedule II controlled substance. These products may lower the convulsive threshold. Monitor patients for development of seizures. Monitor vital signs, including heart rate and rhythm, in patients after receiving GOPRELTO® or COCAINE HYDROCHLORIDE NS. Avoid use in patients with a recent or active history of uncontrolled hypertension, unstable angina, myocardial infarction, coronary artery disease, or congestive heart failure.

Manufacturer Name: Genus Lifesciences, Inc.
Manufacturer Address: 514 N. 12th Street
Allentown, PA 18102

Fax number: (610) 782-0244
Telephone number: (610) 782-9780 ext.*100

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

The products GOPRELTO® and COCAINE HYDROCHLORIDE NS are a non-hazardous pharmaceutical mixture and do not meet OSHA's Hazard Communication Standard (HCS) 2012, 29CFR 1910.1200 and OSHA's Globally Harmonized System (GHS) hazard criteria. As per OSHA section 1910.1200(b)(6)(vii), "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient; drugs which are packaged by the chemical manufacturer for sale to



consumers in a retail establishment” are exempt.. The GHS hazards listed below are for the product active ingredient, Cocaine HCl, and not for the Nasal Solution product itself.

- Physical hazards: Not classified
- Health hazards: Acute Oral Toxicity Category 3
Cardiovascular System and Central Nervous System category 1
- Environmental hazards: Not classified

Signal Word: Warning

Hazard Statement: GOPRELTO® and COCAINE HYDROCHLORIDE NS active ingredient, Cocaine HCl, is a stimulant and a narcotic. The products have a high potential for abuse and dependence. It may be harmful. Accidental ingestion of large amounts may be fatal.

Pictogram:



Precautionary Statement: Generally safe at recommended doses. Avoid use in patients with a recent or active history of uncontrolled hypertension, unstable angina, myocardial infarction, coronary artery disease, or congestive heart failure. Avoid use of additional vasoconstrictor agents such as epinephrine or phenylephrine. Seek medical attention in case of accidental exposure or overdose. Resuscitative equipment should be immediately available when local anesthetic is used.

Hazards Not Otherwise Classified: Common effects may include headache and epistaxis.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS

Chemical Identity	Other Names	CAS Number
Anhydrous Citric Acid, USP	2-Hydroxy-1,2,3-propanetricarboxylic acid	77-92-9
Cocaine Hydrochloride (Active Ingredient)	N/A	53-21-4
D&C Yellow #10	N/A	8004-92-0
FD&C Green #3	Fast Green FCF, Food Green 3	2353-45-9
Purified Water, USP	N/A	7732-18-5
Sodium Benzoate, NF	Benzoic acid, sodium salt; Sodium benzoate	532-32-1

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



SECTION 4 – FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses if worn. Seek medical attention.

Skin Contact: Wash with soap and large amount of water. Seek medical attention.

Ingestion: These products are not intended for ingestion. If an overdose, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician or a Poison Control Center (1-800-222-1222) immediately.

Inhalation: Should not pose a hazard. If breathing is difficult, move to fresh air and seek medical attention immediately.

Symptoms or effects: The most commonly reported adverse reactions (>1 patient) were headache and epistaxis. No cases of overdose were reported in clinical trials. Blood pressure and heart rate increases were greater with 8% solutions than with regular 4% solutions. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or a significant dose reduction of a drug. Adverse effects associated with abuse of Cocaine include euphoria, excitation, irritability, restlessness, anxiety, paranoia, confusion, psychosis, hypertension, stroke, seizures, dilated pupils, nausea, vomiting, and abdominal pain.

Recommendations: Immediate medical attention is required if overdose is suspected. Cocaine is detected in human breastmilk in chronic abuse situations and is expected to be at higher concentrations in milk than in maternal blood. Because of the potential for serious adverse reactions in breastfed infants, advise nursing women that breastfeeding is not recommended during treatment with GOPRELTO[®] or COCAINE HYDROCHLORIDE NS, and to pump and discard breastmilk for 48 hours after use or treatment with of GOPRELTO[®] or COCAINE HYDROCHLORIDE NS.

Note to Physician: Central nervous system stimulants, including Cocaine HCl, have a high potential for abuse and dependence. Because Cocaine is significantly distributed to tissues and rapidly metabolized; dialysis and hemoperfusion are not effective. Acidification of the urine does not significantly enhance cocaine elimination.

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media: Use carbon dioxide, dry chemical, water spray, foam, or any material appropriate for fire in the surrounding area.

Specific hazards arising from the mixture: Formation of toxic gases is possible during fire. (Refer to Section 10)



Advice to the firefighters: Wear self-contained breathing apparatus for the firefighting and full protective clothing.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Personal Precautions:** Clean the spill if it is safe to do so. Minimize exposure. Avoid inhalation of dust.
- Protective Equipment:** Safety Glasses or goggles, gloves, protecting clothes with long sleeves.
- Emergency procedures:** Evacuate the area and keep unauthorized personnel away. Prevent further leakage or spillage if safe to do so. Keep upwind.
- Containment Precautions:** Isolate area around spill as specified by site procedures.
- Clean Up Procedures:** Collect spill with absorbent material and place it in a clearly labeled compatible container for waste. Decontaminate the area with water. Notify the manager in charge of DEA affairs to inform the spill and for instructions on how to dispose the material as a controlled substances waste.

SECTION 7 – HANDLING AND STORAGE

- Precaution for safe handling:** Observe safe industrial practices. Avoid breathing mist or vapors, and contact with eyes, skin, and clothing. Do not taste or swallow. Wash thoroughly after handling.
- Conditions for safe storage:** Store upright at 20°C to 25°C (68° to 77°F) in proper labeled containers. Excursions permitted to 15° to 30°C (59° to 86°F). Avoid freezing. Keep out of reach of children.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There is no exposure limits for the Nasal Solution products. The exposure limits listed below are for the active ingredient Cocaine HCl and not for the Nasal Solution products itself.

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|--|---------------------|
| OSHA Permissible Exposure Limits (PELs): | None |
| Occupational Exposure Limit (OEL's): | 6 µg/m ³ |



Acceptable Daily Exposure (ADE):	30 µg/day
5-Band System Exposure Classification:	Category 3 – High Risk
ACGIH Short Term Exposure Limits (STEL):	Not Available
ACGIH Threshold Limit Values (TLVs):	Not Available
NIOSH Immediately Dangerous to Life or Health (IDLH):	None

Engineering Controls: Good ventilation should be use. Ventilation should be matched to conditions.

Personal Protective Measures:

Respiratory protection:	Not required under normal conditions of use.
Eye protection:	Wear safety glasses or goggles if eye contact is possible. Provide an eye wash station when needed.
Protective gloves:	Chemical compatible when needed.
Skin and body protection:	Not required under normal conditions of use. Chemical compatible when needed.
Hygiene measures:	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking.
Other personal protection:	None required

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:	Clear, green liquid	Odor:	Not Available
Density:	1 g/ml	Boiling Point:	Not Available
Melting Point:	Not Applicable	Solubility:	Water
Viscosity:	Not Available	Specific Gravity:	Not Available
Evaporation Rate:	Not Available	Conductivity:	Not Available

Chemical Properties:

pH:	Between 2.0 and 4.0	Flash Point:	Not Available
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Reactivity: Refer to section 10

Toxicity: Refer to section 11

SECTION 10 – STABILITY AND REACTIVITY

Reactivity: None expected under normal conditions of use.

Chemical stability: Stable under normal conditions of use.

Other:

Conditions to avoid: Excessive heat and light.

Incompatible materials: As a precautionary measure, keep away from strong acids and bases.

Hazardous decomposition products: Oxides of Carbon, Oxides of Nitrogen, Hydrogen Chloride.

SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Nasal

Delayed, immediate and chronic effects for short and long term exposure:

General effects: Can increase blood pressure and heart rate or lower convulsive threshold.

Sensitization: No data available

Mutagenic effects: Cocaine was not mutagenic in the in vitro bacterial reverse mutation assay (Ames assay).

Reproductive toxicity: Studies in animals to characterize the effects of Cocaine on fertility have not been completed.

Fetotoxic / Teratogenic Effects: No data available for adverse effect on the fetus.

Specific target organ toxicity (STOT):

Single exposure: No data available

Repeated exposure: No data available

Toxicity (LD₅₀):

The toxicity information listed below is for the active ingredient Cocaine HCl and not for the NS products itself.



Oral LD ₅₀ Mouse:	96 mg/kg	Intravenous LD ₅₀ Rat:	16380 µg/kg
Intravenous LD ₅₀ Mouse:	15 mg/kg	Intravenous LD ₅₀ Guinea Pig:	14562 µg/kg
Intravenous LD ₅₀ Rabbit:	12 mg/kg	Intravenous LD ₅₀ Cat:	10 mg/kg
Intravenous LD ₅₀ Dog:	21 mg/kg		

Symptoms / Adverse Reactions: The most common adverse reactions are headaches and epistaxis. Have a high potential for abuse and dependence.

Carcinogenicity: Long-term animal studies to evaluate the carcinogenic potential of Cocaine have not been conducted. Not listed as a carcinogen by OSHA.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects): No information is currently available on the environmental impact of these products. Releases to the environment should be avoided.

Persistence and Degradability: No data available

Bioaccumulation: No data available

Leaching studies: Not Available

Other adverse effects: The products are not classified as environmentally hazardous.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers: Dispose used or contaminated containers in accordance the Drug Enforcement Administration (DEA) guidelines.

Waste Disposal Methods: Dispose in accordance with the Drug Enforcement Administration (DEA) requirements.

Special Precautions: Discard away from children's reach. Releases to the sewer and the environment should be avoided.



SECTION 14 – TRANSPORT INFORMATION

USDOT - Department of Transportation:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under USDOT.

ICAO - International Civil Aviation Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under ICAO.

IATA - International Air Transport Association:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IATA.

IMDG/IMO - International Maritime Dangerous Goods / International Maritime Organization:

This product is classified as not hazardous and authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals under IMDG/IMO.

Special Precautions: None Known

SECTION 15 – REGULATORY INFORMATION

Food and Drug Administration (FDA): Approved prescription medication

Drug Enforcement Administration (DEA): Listed as Controlled Substances (CII)

SARA 302/304 Extreme Hazardous Substances (EHS): Not Applicable

SARA 311/312 Hazard Categories: Not Applicable

SARA 313 Toxic Chemical Release Inventory (TRI): Not Applicable

Resource Conservation and Recovery Act (RCRA): No Code Applicable



Clean Water Act (CWA):

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).

Clean Air Act (CAA):

This product does not contain any chemicals listed under Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

Environmental Response Compensation and Liability Act (CERCLA):

Not applicable for the product. This product, as supplied, do not contains substances regulated as hazardous substances under CERCLA (40 CFR 302). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

Toxic Substances Control Act (TSCA):

Not applicable for the product. The following product ingredients are included on the TSCA inventory 8(b):

Ingredient	CAS No
Citric Acid Anhydrous	77-92-9
D&C Yellow #10	8004-92-0
FD&C Green #3	2353-45-9
Sodium Benzoate	532-32-1

There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences, Inc.

Creation Date: May/22/18, New SDS

Revision Date: Apr/21/21

This Safety Data Sheet cancels and replaces all preceding SDS for these products.

Genus Lifesciences Inc. believes that the information contained herein is based on the best available data at the date of preparation. However, no warranty is expressed or implied regarding the data's accuracy and completeness. Since the use of this information and the conditions of use of this material are not within the control of Genus Lifesciences Inc., it is the user's obligation to determine the conditions of safe use of this material.

Signature Manifest

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Effective Date: 27 Apr 2021

All dates and times are in Eastern Time.

SDS Cocaine HCl Nasal Solution (NS) - 64950

Department Approval

Name/Signature	Title	Date	Meaning/Reason
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Regulatory Affairs Approval

Name/Signature	Title	Date	Meaning/Reason
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Quality Assurance Approval

Name/Signature	Title	Date	Meaning/Reason
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