



SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Cocaine Hydrochloride (CII) Nasal Solution, 40 mg/ml (4%), 4 mL	NDC 64950-362-04
---	------------------

Recommended use and restrictions: Cocaine Hydrochloride Nasal Solution is 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.

Manufacturer Name: Genus Lifesciences, Inc.

Manufacturer Address: 514 N. 12th Street
Allentown, PA 18102

Fax number: (610) 782-0244

Emergency telephone number: (610) 782-9780 ext.100

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification of the substance or mixture (GHS):

Pictogram:



Signal Word: Warning

Hazard Statement: May be harmful. Accidental ingestion of large amounts may be fatal. Resuscitative equipment should be immediately available when local anesthetic is used.



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)	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

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: Call a physician or poison control center immediately.

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

SECTION 5 – FIREFIGHTING MEASURES

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

Special hazards arising from the mixture: Formation of toxic gases is possible during fire.

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

Further information: Use water spray to cool unopened containers



SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Exposure Limits: Not Available

Respiratory Protection: Not required

Personal Protection: Safety Glasses or goggles, gloves, protecting clothes with long sleeves

Environmental Precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and Materials for containment and clean up: Collect spill with absorbent material and place it in a compatible container. Dispose according to applicable regulations.

SECTION 7 – HANDLING AND STORAGE

Precaution for safe handling: Observe safe industrial practices. Avoid breathing mist or vapors. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. Use with adequate ventilation. Wash thoroughly after handling.

Conditions for safe storage: Store 20°C to 25°C in proper labeled containers. Keep container closed tightly and away from heat or flames. Protect from light. Store away from foodstuffs. Keep from freezing. Keep out of reach of children.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Respiratory protection: None required

Ventilation: Normal room ventilation

Protective gloves: Chemical compatible

Eye protection: Safety glasses or goggles

Other personal protection: Protect exposed skin



SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, blue-green liquid	Evaporation rate:	Not available
Odor:	Not available	Flammability:	Not applicable
pH:	Between 2.0 and 5.0	Vapor density:	Not available
Boiling Point:	Not available	Relative density:	Not available
Solubility:	In water	Viscosity:	Not available

SECTION 10 – STABILITY AND REACTIVITY

Reactivity:	Not available
Chemical stability:	Stable
Possibility of hazardous reactions:	Not available
Conditions to avoid:	Excessive heat and light
Incompatible materials:	Strong acids, strong bases
Hazardous decomposition products:	Oxides of Carbon, Oxides of Nitrogen, Hydrogen Chloride

SECTION 11 – TOXICOLOGICAL INFORMATION

Carcinogenicity:	Long-term animal studies to evaluate the carcinogenic potential of cocaine have not been conducted.
Routes of exposure:	Nasal
Symptoms related to the toxicological characteristics:	Possible headache and epistaxis.
Delayed, immediate and chronic effects:	Can increase blood pressure and heart rate, may lower convulsive threshold.



SECTION 12 – ECOLOGICAL INFORMATION

No information is currently available on the environmental impact of this product. Releases to the environment should be avoided.

SECTION 13 – DISPOSAL INFORMATION

Dispose of waste in accordance with the Drug Enforcement Administration (DEA) guidelines.

SECTION 14 – TRANSPORT INFORMATION

This product is not regulated for the safe transport of hazardous chemicals under USDOT regulations.

SECTION 15 – REGULATORY INFORMATION

Drug Enforcement Administration (DEA): Schedule II controlled substance

Federal Drug Administration (FDA): Approved prescription medication

SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences, Inc.

Preparation Date: May/22/18, New SDS

Revision Date: N/A

This Safety Data Sheet cancels and replaces all preceding SDS for this product.

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.