SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Clemastine Fumarate Tablets USP, 2.68 mg, 100 Ct Bottles	NDC 64950-268-10
Clemastine Fumarate Tablets USP, 2.68 mg, 30 Ct Bottles	NDC 64950-268-03

Product Name: Clemastine Fumarate Tablets USP

Recommended use: Clemastine Fumarate Tablets USP, 2.68 mg is an antihistamine indicated for the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation. Clemastine Fumarate Tablets USP, 2.68 mg are also indicated for the relief of mild, uncomplicated allergic skin manifestations of urticaria and angioedema. It should be noted that Clemastine Fumarate is indicated for the dermatologic indications at the 2.68 mg dosage level only.

Restrictions: Do not drink alcohol while using Clemastine Fumarate since it has additive effects with alcohol and other CNS depressants. Because of the higher risk for infants, newborns, and premature babies in particular, antihistamine therapy is contraindicated in nursing mothers. Antihistamines should not be used to treat lower respiratory tract symptoms including asthma.

Manufacturer Name:
Manufacturer Address:
PEL Healthcare LLC.
650 Cathill Road
Sellersville, PA 18960

Telephone number: 215-799-5000

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

Telephone number: (610) 782-9780
Fax number: (610) 782-9781

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

The product Clemastine Fumarate Tablets USP is a non-hazardous pharmaceutical mixture and does 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 active product ingredient (API), Clemastine Fumarate USP, and **NOT** for the Tablet product itself.

Physical hazards:	Not classified
Health hazards:	Oral Acute Toxicity Category 3 Dermal Acute Toxicity Category 3 Inhalation Acute Toxicity Category 3
Environmental hazards:	Aquatic environment Acute Category 1 Aquatic environment Chronic Category 1

Signal Word: Warning

Hazard Statement: Clemastine has additive effects with alcohol and other CNS depressants. Antihistamines should be used with caution in patients with narrow angle glaucoma, peptic ulcer, prostatic hypertrophy, and bladder neck obstruction.

Pictogram:

Precautionary Statement: Generally safe at recommended doses. The maximum recommended dosage is one tablet three times daily. Antihistamine overdose reactions may vary. Drugs that treat depression and other nervous system disorders prolong and intensify the anticholinergic (drying) effects of antihistamines.

Hazards Not Otherwise Classified: None known.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

Chemical Identity	Other Names	CAS Number
Clemastine Fumarate	N/A	14976-57-9
Colloidal Silicon Dioxide	Silica, Aerosil	7631-86-9
Corn Starch	Maize MIR162	9005-25-8
Lactose Monohydrate	Pharmatose DCL 14, Lactose hydrate	64044-51-5
Povidone K30	Crospovidone	9003-39-8
Stearic Acid	Cetylacetic acid, Octadecanoic acid	57-11-4

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

SECTION 4 – FIRST AID MEASURES

Eye Contact: As a finished product is not an expected route of exposure. If contact suspected, flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses if worn. Seek medical attention if irritation or discomfort persists.

Skin Contact: Wash with soap and large amount of water. Contact medical personnel if irritation persists.

Ingestion: This product is intended for ingestion. If an overdose, taken not as prescribed, or an accidental ingestion of large amounts occurs, call a physician immediately.

Inhalation: As a finished product is not an expected route of exposure. If breathing is difficult, move to fresh air and seek medical attention.

Symptoms or effects: Antihistamine overdose reactions may vary from depression to stimulation. The most frequent symptoms are urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, and dryness of the mouth, nose, and throat.

Recommendations: Immediate medical attention is required if an overdose is suspected. Call a Poison Control Center (1-800-222-1222) or 911 if you feel unwell. No action shall be taken involving any personal risk or without suitable training. If needed and if possible, give artificial respiration and/or CPR. Administer activated charcoal as slurry.

Note to Physician: Inform patients or their caregivers to discontinue and contact a healthcare provider immediately if serious reactions occur. Clemastine fumarate should be used with caution in patients with: history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease, and hypertension. Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc. Antihistamines should not be used to treat lower respiratory tract symptoms including asthma.

Dosage should be individualized according to the needs and response of the patient. There is no specific therapy for acute overdose with antihistamines. The latent period from ingestion to appearance of toxic effects is characteristically short (1/2-2 hours). Since overdoses of other classes of drugs (i.e., tricyclic antidepressants) may also present anticholinergic symptomatology, appropriate toxicological analysis should be performed as soon as possible to identify the causative agent. If vomiting has not occurred spontaneously, the conscious patient should be induced to vomit. This is best done by having him drink a glass of water or milk after which he should be made to gag. Precautions against aspiration must be taken, especially in infants and children. If vomiting is unsuccessful gastric lavage is indicated within 3 hours after ingestion and

even later if large amounts of milk or cream were given beforehand. Isotonic and 1/2 isotonic saline is the lavage solution of choice.

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media — Use Water spray, Dry chemical, CO_2, or any material appropriate for fire in the surrounding area. Use water spray to cool unopened containers.

Specific hazards arising from the mixture: — None known for the finished product. (Refer to section 10)

Advice to the firefighters: — Wear appropriate protective clothing and equipment, including self-contained breathing apparatus.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal Precautions: — No action shall be taken involving any personal risk or without suitable training. Clean the spill if is safe to do so. Minimize exposure. Keep unnecessary personnel away. Do not touch or walk through spilled material.

Protective Equipment: — Safety Glasses or goggles, gloves, protecting clothes. (Refer to section 8)

Emergency procedures: — Evacuate the area. Keep unnecessary personnel away. Prevent further spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

Containment Precautions: — Isolate area around spill as specified by site procedures.

Clean Up Procedures: — Collect the material in a compatible container and dispose according to applicable regulations (Refer to section 13). Decontaminate the area with water.

SECTION 7 – HANDLING AND STORAGE

Precaution for safe handling: Observe safe industrial practices. No special handling requirements for normal use of this material. Dispense content with a child resistant closure and in a tight, light-resistant container as defined in the USP/NF.

Conditions for safe storage: Store in original container at 25°C (77°F). Protect from Moisture and Light. Keep container tightly closed. Keep out of reach of children. Do not use if seal under cap is missing or broken. For more information follow directions in product packaging.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There are no exposure limits for the Clemastine Fumarate Tablet products. The exposure limits listed below are for the Active Product Ingredient (API) Clemastine Fumarate and not for the finished Tablet product itself.

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 Threshold Limit Values (TLVs):	
Short Term Exposure Limits (STEL) – 15 min:	Not Available
Time Weight Average (TWA) – 8 Hours:	Not Available
NIOSH Immediately Dangerous to Life or Health (IDLH):	None

Engineering Controls: Good ventilation should be use and should be matched to conditions. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Clean work areas routinely to prevent accumulation of product as appropriate.

Personal Protective Measures:

Respiratory protection:	Not required under normal conditions of use for finished product. If it found to be necessary, wear a mask or an appropriate NIOSH approved respirator.
Eye protection:	Not required under normal conditions of use for finished product. If it found to be necessary, wear safety glasses or goggles as appropriate for the task.
Protective gloves:	Not required under normal conditions of use for finished product. If it found to be necessary, wear chemical compatible gloves.

Skin and body protection:	Not required under normal conditions of use for finished product. During manufacture or other similar industrial operations, wear the necessary protection for the process.
Hygiene measures:	Wash hands, wrist, forearms and face thoroughly after handling chemicals and products, before eating, and at the end of working period. Contaminated clothing should not be allowed out of the workplace. Wash clothing before reusing.
Other personal protection:	None required

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:	Round Tablet	Odor:	None
Density:	Not Available	Boiling Point:	Not available
Color:	White	Solubility:	Water, Alcohol
Viscosity:	Not Available	Specific Gravity:	Not Available
Evaporation Rate:	Not Available	Conductivity:	Not Available

Chemical Properties:

pH:	Not Available	Flash Point:	Not Available
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:	Moisture, light, and heat.
Incompatible materials:	As a precautionary measure, keep away from strong oxidizers.

Hazardous decomposition products: None known

SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Ingestion

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

General effects: Common side effects might include drying and sedative side effects.

Sensitization: No known significant effects.

Carcinogenicity: There was no evidence of carcinogenesis in rats receiving an oral dosage of 84 mg/kg (about 500 times the usual human adult dosage) for 2 years or in mice receiving 206 mg/kg (about 1300 times the usual human adult dosage) for 85 weeks. Product not listed as a carcinogen by OSHA.

Mutagenic effects: No known significant effects or critical hazards.

Reproductive toxicity: Oral dosage of 312 times the usual human adult dosage have decreased mating ability in male rats, but dosages 156 times the usual human adult dosage had no effect on mating.

Fetotoxic / Teratogenic Effects: Reproduction studies in rats and rabbits using oral dosages up to 312 and 188 times the usual human adult dosage, respectively, have not revealed evidence of harm to the fetus.

Specific Target Organ Toxicity (STOT):

Single exposure: No data available

Repeated exposure: No data available

Toxicity (LD50):

Toxicity studies have not been conducted with the Clemastine Fumarate Tablets product. The exposure limits listed below are for the active product ingredient (API) Clemastine Fumarate and not for the finished Tablet product itself.

Oral LD_{50} Rat:	3550 mg/kg	Intravenous LD_{50} Rat:	82 mg/kg
Oral LD_{50} Mouse:	730 mg/kg	Intravenous LD_{50} Mouse:	43 mg/kg

Adverse Reactions: Clemastine Fumarate Tablets may cause sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor,

irritability, insomnia, euphoria, diplopia, vertigo, blurred vision, tinnitus, hysteria, neuritis, convulsions.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects): Ecotoxicity studies have not been conducted with the Isoniazid Tablets USP product.

Persistence and Degradability: Not Available

Bioaccumulation: Not Available

Leaching studies: Not Available

Other adverse effects: The pharmaceutical product is not classified as environmentally hazardous. No studies to aquatic organisms or environment were found, however; is highly recommended to avoid any environmental releases since the active ingredient Clemastine Fumarate is considerate toxic to aquatic life.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers: Dispose used or contaminated containers in accordance with the federal, state or local regulatory requirements.

Waste Disposal Methods: Dispose all the product waste in accordance with the federal, state or local regulatory requirements.

Special Precautions: Discard away from children's reach. Releases to the sewer 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 / IATA - International Civil Aviation Organization / 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 ICAO / 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

Drug Enforcement Administration (DEA): Not Listed as Controlled Substances.

Food and Drug Administration (FDA): Approved prescription medication.

Occupational Safety and Health Administration (OSHA):

GHS symbols in consumer packaged form are not required per OSHA 29 CFR 1910.1200(b)(5) and OSHA 29 CFR 1910.1200(b)(5)(iii).

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.

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

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

SARA 311/312 Hazard Categories:

Immediate Hazard – No
Delayed Hazard – No
Fire Hazard – No
Pressure Hazard – No
Reactivity Hazard – No

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

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).

Toxic Substances Control Act (TSCA):

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

Ingredient	CAS Number
Colloidal Silicon Dioxide	7631-86-9
Corn Starch	9005-25-8
Isoniazid	54-85-3
Povidone K30	9003-39-8
Stearic Acid	57-11-4

SECTION 16 – OTHER INFORMATION

See current package insert for further information.

SDS prepared by Genus Lifesciences Inc.

Creation Date: Sep/03/24, New SDS

Revision Date: N/A

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