



SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

| | |
|---|------------------|
| Clemastine Fumarate, 0.5 mg/5 mL, Syrup, 120 ml. Bottle | NDC 64950-324-12 |
|---|------------------|

Recommended use:

Indicated for the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus and lacrimation. It is also indicated for the relief of mild uncomplicated allergic skin manifestations of urticaria and angioedema at the 2 mg dosage level only. Clemastine Fumarate Syrup is indicated for use in pediatric population age 6 years through 12 and adults.

Restrictions:

Clemastine Fumarate Syrup should be used with caution in patients with history of increased intraocular pressure, hyperthyroidism, cardiovascular disease, bronchial asthma, and hypertension. Antihistamine therapy is contraindicated in nursing mothers. Do not use with CNS stimulants.

Manufacturer Name:

Piramal Pharma Limited

Manufacturer Address:

650 Cathill Road
Sellersville, PA 18960

Telephone number:

215-799-5000

Distributor Name:

Genus Lifesciences Inc.

Distributor Address:

514 N. 12th Street
Allentown, PA 18102

Telephone number:

(610) 782-9780

Fax number:

(610) 782-9781

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

This product is a pharmaceutical mixture and does not meet OSHA's Globally Harmonized System (GHS) hazard criteria; however the active ingredient Clemastine Fumarate Classification, Signal Word, Hazard Statement, and Pictogram is considered as follow:

- Health Hazard – Category 3 narcotic effects
- Aquatic Acute – Category 1

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Signal Word: Warning

Hazard Statement: May cause drowsiness or dizziness. Hazardous to the aquatic environment.

Pictogram:



Precautionary Statement: Generally safe at recommended Syrup doses. Avoid contact with eyes. Seek medical attention in case of accidental exposure or overdose. Clemastine Fumarate Syrup has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.)

Hazards Not Otherwise Classified: Product common effects may include sedation, sleepiness, dizziness, and disturbed coordination. Other effects may include fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, blurred vision, vertigo, tinnitus, nausea, vomiting, diarrhea, constipation.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS*

| Chemical Identity | Other Names | CAS Number |
|---|-----------------------------------|------------|
| Alcohol | Ethyl Alcohol, Ethanol | 64-17-5 |
| Clemastine Fumarate (Active Ingredient) | N/A | 14976-57-9 |
| Maleic Acid | Toxic acid, Maleinic acid | 110-16-7 |
| Methylparaben | Methyl 4-hydroxybenzoate | 99-76-3 |
| Passion Fruit Flavor | N/A | N/A |
| Propylene Glycol | 1,2-propanediol, Propane-1,2-diol | 57-55-6 |
| Propylparaben | Propyl 4-hydroxybenzoate | 94-13-3 |
| Saccharin Sodium | Cristallose, Sucromat | 128-44-9 |
| Sodium Hydroxide | Sodium Hydrate, Soda Lye | 1310-73-2 |
| Sorbitol Solution 70% | Esasorb, Glucitol, D-, Gulitol | 50-70-4 |

* 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 if irritation or discomfort persists.



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- 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:** Not an expected route of exposure.
- Symptoms or effects:** Antihistamine overdose reactions may vary from depression to stimulation. In children, stimulation predominates initially in a syndrome which may include excitement, hallucinations, incoordination, muscle twitching, hyperthermia, convulsions, and tremors followed by postictal depression and cardio respiratory arrest. Dry mouth, fixed dilated pupils, flushing of the face, and fever are common. In adults, CNS depression, ranging from drowsiness to coma, is more common. The convulsing dose of antihistamines lies near the lethal dose.
- Recommendations:** Immediate medical attention is required if overdose is suspected. Call a Poison Control Center (1-800-222-1222) if you feel unwell.
- Note to Physician:** 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.

SECTION 5 – FIREFIGHTING MEASURES

- Extinguishing media** Use Water, Foam, Dry chemical or CO₂. Use water spray to cool unopened containers.
- Specific hazards arising from the mixture:** None known. (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:** Clean the spill if it is safe to do so. Minimize exposure.



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- Protective Equipment:** Safety Glasses or goggles, gloves, protecting clothes.
- Emergency procedures:** Evacuate the area. Prevent further leakage or spillage if safe to do so.
- Containment Precautions:** Isolate area around spill as specified by site procedures.
- Clean Up Procedures:** Use suitable absorbent material. Collect the material in a compatible container. Dispose according to applicable regulations (Refer to section 13). Decontaminate 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 at Controlled Room Temperature, 20°C to 25°C (68°F to 77°F).

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

The exposure limits listed below are for the active ingredient Clemastine Fumarate and not for the Syrup 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 Short Term Exposure Limits (STEL): | Not Available |
| ACGIH Threshold Limit Values (TLVs): | Not Available |
| NIOSH Immediately Dangerous to Life or Health (IDLH): | None |



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Engineering Controls: Not required when handling liquid or containers. Good ventilation should be used. Ventilation should be matched to conditions.

Personal Protective Measures:

Respiratory protection: None required when handling liquids.

Eye protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Protective gloves: Not required under normal conditions of use. Chemical compatible when needed.

Skin and body protection: Not required under normal conditions of use.

Hygiene measures: Wash hands thoroughly.

Other personal protection: None required

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

| | | | |
|-------------------|------------------------|-------------------|------------------------|
| Appearance: | Clear colorless liquid | Odor: | Citric (Passion fruit) |
| Density: | Not Available | Boiling Point: | Not available |
| Melting Point: | Not Applicable | Solubility: | In water |
| Viscosity: | Not Available | Specific Gravity: | Not Available |
| Evaporation Rate: | Not Available | Conductivity: | Not Available |

Chemical Properties:

| | | | |
|-------------|---------------------|--------------|---------------------|
| pH: | Approximate 6.2 | 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.



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Chemical stability: Stable under normal conditions of use.

Other:

Conditions to avoid: Excessive cold, freezing.

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: Anticholinergic (drying) and sedative side effects.

Sensitization: No data available

Mutagenic effects: No data available

Reproductive toxicity: Oral doses of Clemastine Fumarate Syrup in the rat produced a decrease in mating ability of the male at 312 times the adult human dose. This effect was not found at 156 times the adult human dose.

Fetotoxic / Teratogenic Effects: There are no adequate and well-controlled studies of Clemastine Fumarate Syrup in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed.

Oral reproduction studies performed with Clemastine Fumarate Syrup in rats and rabbits at doses up to 312 and 188 times the adult human doses respectively, have revealed no evidence of teratogenic effects.

Specific Target Organ Toxicity (STOT):

Single exposure: No data available

Repeated exposure: No data available



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Toxicity (LD50):

The toxicity information listed below is for the active ingredient Clemastine Fumarate and not for the Syrup product itself.

| | |
|-------------------|------------|
| Oral LD50 Rat: | 3550 mg/kg |
| Oral LD50 Mouse: | 730 mg/kg |
| Oral LD50 Rabbit: | 1000 mg/kg |

Symptoms / Adverse Reactions:

Urticaria, rash, anaphylactic shock, photosensitivity, chills, excessive perspiration, dryness of mouth, nose and throat. This product is known to be excreted by the kidney.

Carcinogenicity:

Not listed as a carcinogen by OSHA.

In a 2-year oral study in the rat at a dose of 84 mg/kg (about 500 times the adult human dose) and an 85-week oral study in the mouse at 206 mg/kg (about 1300 times the adult human dose), Clemastine Fumarate Syrup showed no evidence of carcinogenesis.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects):

Environmental properties have not been thoroughly evaluated for the product. 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 pharmaceutical product is not classified as environmentally hazardous. No major harmful effects to aquatic organisms are expected, however; is highly recommended to avoid environmental releases.



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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 of 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 - 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

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



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

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).

Toxic Substances Control Act (TSCA):

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

| Ingredient | CAS No |
|-----------------------|-----------|
| Alcohol | 64-17-5 |
| Maleic Acid | 110-16-7 |
| Methylparaben | 99-76-3 |
| Propylene Glycol | 57-55-6 |
| Propylparaben | 94-13-3 |
| Saccharin Sodium | 128-44-9 |
| Sodium Hydroxide | 1310-73-2 |
| Sorbitol Solution 70% | 50-70-4 |

Environmental Response Compensation and Liability Act (CERCLA):

Not applicable for the product. This product, as supplied, contains substances regulated as hazardous substances under CERCLA (40 CFR 302). The following are the components listed and their CERCLA Reportable Quantities (RA) in pounds:



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| Component | CAS No | CERCLA RQ (pounds) |
|------------------|-----------|--------------------|
| Maleic Acid | 110-16-7 | 5,000 |
| Sodium hydroxide | 1310-73-2 | 1,000 |

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: Nov/22/24, New SDS

Revision Date: N/A

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

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