SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Carbinoxamine Maleate Tablets USP, 4 mg, 100 ct Bottle	NDC 64950-211-01

Product Name: CARBINOXAMINE MALEATE Tablets USP

Recommended use: Carbinoxamine Maleate Tablets USP is a prescribed antihistamine with drying and sedative properties, indicated for the symptomatic treatment of seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and foods, mild allergic skin manifestations of urticaria and angioedema, amelioration of the severity of allergic reactions to blood or plasma, and as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.

Restrictions: Carbinoxamine Maleate Tablets USP is contraindicated in children younger than 2 years of age, nursing mothers, and patients who are hypersensitive to the drug or on monoamine oxidase inhibitor therapy. Do not use to treat lower respiratory tract symptoms, including asthma.

Manufacturer Name: Mikart LLC
Manufacturer Address: 1750 Chattahoochee Ave.
Atlanta, GA 30318
Telephone number: (888) 464-5278

Distributor Name: Genus Lifesciences, Inc.
Distributor 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 product CARBINOXAMINE MALEATE Tablets USP is 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, Carbinoxamine Maleate, and **NOT** for the Tablets product itself.

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Physical hazards:	Not classified
Health hazards:	Acute Oral Toxicity Category 3 Skin and Eye Irritation Category 2
Environmental hazards:	Not classified

Signal Word: Warning

Hazard Statement: Deaths have been reported in children less than 2 years of age who were taking antihistamines. Women who are breast feeding should avoid its use since small amounts appear to be into breast milk.

Pictogram:

Precautionary Statement: Antihistamines should be used with considerable caution in patients with narrow angle glaucoma, symptomatic prostatic hypertrophy, or bladder neck obstruction. Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor. Avoid alcoholic beverages while taking this product.

Hazards Not Otherwise Classified: Generally safe at recommended doses.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS

Chemical Identity	Other Names	CAS Number
Anhydrous Lactose	D-(+)-Latose	63-42-3
Carbinoxamine Maleate (Active Ingredient)	N/A	3505-38-2
Magnesium Stearate	Stearic acid, Magnesium Salt	557-04-0
Microcrystalline Cellulose	Avicel	9004-34-6
Sodium Starch Glycolate	Glycolys and Explotab	9063-38-1

* 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.

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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 are urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, hypotension, headache, palpitations, tachycardia, and dryness of mouth, nose and throat.

Recommendations: Immediate medical attention is required if overdose is suspected.

Note to Physician: Carbinoxamine Maleate should be taken on an empty stomach with water. The dosage should be based on the severity of the condition and the needs and response of the patient. The drug is well tolerated in adults in doses as high as 24 mg daily, in divided doses, over prolonged periods. On the other hand, some patients respond to as little as 4 mg daily. Dosing for children 2 to 5 years of age should be based on weight whenever possible.

Antihistamine over dosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Especially in infants and children, antihistamine over dosage may cause hallucinations, convulsions, or death. The treatment of over dosage with Carbinoxamine Maleate is essentially symptomatic and supportive. Vital signs (including respiration, pulse, blood pressure, and temperature) and EKG should be monitored. Induction of vomiting is not recommended. Activated charcoal should be given and gastric lavage should be considered after ingestion of a potentially life-threatening amount of drug.

SECTION 5 – FIREFIGHTING MEASURES

Extinguishing media: Use carbon dioxide, dry chemical, water spay, 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 is safe to do so. Minimize exposure.

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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 of the spill and ask for instructions on how to dispose the material.

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. Avoid freezing. Keep out of reach of children.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There is no exposure limits for the Carbinoxamine Maleate Tablets products. The exposure limits listed below are for the active ingredient Carbinoxamine Maleate and not for the Tablets products itself.

OSHA Permissible Exposure Limits (PELs):	None
Occupational Exposure Limit (OEL's):	Not Available
Acceptable Daily Exposure (ADE):	Not Available
5-Band System Exposure Classification:	Not Available
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.

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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:	White, round tablets	Odor:	None
Density:	Not Available	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:	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: Excessive heat and light.

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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: Oral

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

General effects:	No data available.
Sensitization:	No data available
Mutagenic effects:	No long-term studies in animals have been performed to determine the possible effects.
Reproductive toxicity:	No long-term studies in animals have been performed to determine the possible effects.
Fetotoxic / Teratogenic Effects:	No long-term studies in animals have been performed to determine the possible effects.

Specific target organ toxicity (STOT):

Single exposure:	No data available
Repeated exposure:	No data available

Toxicity (LD_{50}):

The toxicity information listed below is for the active ingredient Carbinoxamine Maleate and not for the Tablets products itself.

Oral LD_{50} Mouse:	162 mg/kg	Intraperitoneal LD_{50} Mouse:	150 mg/kg
Intravenous LD_{50} Mouse:	32 mg/kg	Oral LD_{50} Guinea Pig:	411 mg/kg

Symptoms / Adverse Reactions: The most common adverse reactions are urticaria, drug rash, chills, dryness of mouth, nose and throat, hypotension, headache, palpitations, tachycardia, sleepiness, dizziness, disturbed coordination, fatigue, wheezing, confusion, urinary problems, nausea, vomiting, diarrhea, constipation, and blurred vision.

Carcinogenicity: No long-term studies in animals have been performed to determine the possible effects. Not listed as a carcinogen by OSHA.

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SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects): No information is currently available on the environmental impact of this 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 product is not classified as environmentally hazardous.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers: Dispose used or contaminated containers as a human prescription drug in accordance with the Federal Drug Administration (FDA) guidelines by drop off the container at a drug take back site or program. If there are none available, then follow the FDA instructions to discard the medicine in the trash at home.

Waste Disposal Methods: Dispose used or contaminated containers as a human prescription drug in accordance with the Federal Drug Administration (FDA) guidelines by drop off the medicine at a drug take back site or program. If there are none available, then follow the FDA instructions to discard the medicine in the trash at home.

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.

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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): Not Applicable

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).

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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
Anhydrous Lactose	63-42-3
Carbinoxamine Maleate (Active Ingredient)	3505-38-2
Magnesium Stearate	557-04-0
Microcrystalline Cellulose	9004-34-6
Sodium Starch Glycolate	9063-38-1

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: Jul/31/23, New SDS

Revision Date: N/A

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.