SAFETY DATA SHEETS

This SDS packet was issued with item:

078948228

N/A

SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Hycodan®(Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg) (CII), Tablets, 30 count, Bottle	NDC 64950-205-03
Hycodan®(Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg) (CII), Tablets, 100 count, Bottle	NDC 64950-205-10
Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII), Tablets, 30 count, Bottle	NDC 64950-206-03
Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII), Tablets, 100 count, Bottle	NDC 64950-206-10

Product Name: Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets

Recommended use: Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets is a combination of Hydrocodone, an opioid agonist; and Homatropine, a muscarinic antagonist, indicated for the symptomatic relief of cough in patients 18 years of age and older. Homatropine is a drug that works against the narcotic Hydrocodone to prevent an overdose of this medication.

Restrictions: Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets is contraindicated for patients who are sensitive to Hydrocodone or Homatropine, or children younger than 6 years of age. Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Do not use except as prescribed. Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets is not recommended for use in pregnant women or during breastfeeding.

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

Fax number: (610) 782-9781
Emergency telephone number: (610) 782-9780 ext.*100

SECTION 2 – HAZARD (S) IDENTIFICATION

Classification (GHS):

The product Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets 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, Hydrocodone Bitartrate, and not for the tablet product itself.

Physical hazards:	Not classified
Health hazards:	Acute Oral Toxicity Category 2 Cardiovascular System and Central Nervous System category 3 Narcotic Effects
Environmental hazards:	Not classified

Signal Word: Warning

Hazard Statement: Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets active ingredient, Hydrocodone, is a stimulant and a narcotic. The product has a high potential for abuse and dependence. It may be harmful. Accidental ingestion of large amounts may be fatal. May be habit forming. Tolerance may develop upon repeated administration. It should be prescribed and administered with the same degree of caution of other narcotic drugs.

Pictogram:

Precautionary Statement: Generally safe at recommended doses. Because of the risks of addiction, abuse, and misuse with opioids, reserves Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets for use in adult patients for whom the benefits of cough suppression are expected to outweigh the risks. Seek medical attention in case of accidental exposure or overdose.

Hazards Not Otherwise Classified: Common effects may include somnolence, mental clouding, lightheadedness, dizziness, headache, dry mouth, nausea, vomiting, and constipation.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS

Chemical Identity	Other Names	CAS Number
Colloidal Silicon Dioxide NF	Cab-O-Sil® M-5P	7631-86
Dibasic Calcium Phosphate Dihydrate, USP	Emcompress®	7789-77-7
Homatropine Methylbromide, USP (Active Ingredient)	Methylhomatropine	80-49-9
Hydrocodone Bitartrate, USP (Active Ingredient)	Hydrocodone Acid Tartrate	34195-34-1
Lactose Monohydrate, NF Spray Dried	SuperTab® 11SD	10039-26-6
Magnesium Stearate, NF	Magnesium Distearate	557-04-0
Pregelatinized Starch, NF	Starch 1500®	9005-25-8
Stearic Acid, NF	Hystrene® 5016 NF	57-11-4

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

SECTION 4 – FIRST AID MEASURES

Eye Contact: Should not pose a hazard. If needed, flush with water while holding eyelids open for at least 15 minutes. Remove contact lenses if worn. Seek medical attention.

Skin Contact: Should not pose a hazard. If needed, wash with soap and large amount of water. Seek medical attention.

Ingestion: If an overdose occurs, 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 include: sedation (somnolence, mental clouding, and lethargy), impaired mental and physical performance, lightheadedness, dizziness, headache, dry mouth, nausea, vomiting, and constipation. 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.

Recommendations: Immediate medical attention is required if overdose is suspected. Always use an accurate milliliter measuring device when measuring and administering Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets. A household teaspoon is not an accurate measuring device and such use could lead to overdose and serious adverse reactions.

Note to Physician: Advise patients not to increase the dose or dosing frequency of Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets because serious adverse events such as respiratory depression may occur with overdose. Monitor patients closely for respiratory

depression, especially within the first 24-72 hours of initiating therapy. Prescribe Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets for the shortest duration that is consistent with individual patient treatment goals. Do not abruptly discontinue Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets in a physically-dependent patient. Instruct patients not to consume alcoholic beverages or use prescription or nonprescription products containing alcohol while on Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets therapy.

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.

Protective Equipment: Use containment equipment to prevent access to drains and sewer, such as spill blockers, and drain covers. Refer to section 8 for Personal Protective Equipment.

Emergency procedures: Evacuate the area and keep unauthorized personnel away. Prevent further spillage if safe to do so.

Containment Precautions: Prevent material from flush/entering sewer, or public waters. For spills on water, contain and collect. Isolate area around spill as specified by site procedures.

Clean Up Procedures: Collect spill with broom and scoop, 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 contact with eyes, skin, and clothing. Do not taste or swallow. Wash hands thoroughly after handling. Wear protective clothing when handling large quantities.

Conditions for safe storage: Store in the original container with child resistant closure tightly secured at controlled room temperature of 20°C to 25°C (68° to 77°F). Keep out of reach of children. For more information, follow as directed in product packaging. Location of storage must comply with DEA regulations.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There is no exposure limits for the tablet product. The exposure limits listed below are for the active ingredient Hydrocodone and not for the tablet product itself.

OSHA Permissible Exposure Limits (PELs):	None
Occupational Exposure Limit (OEL's):	15 µg/m^3
Acceptable Daily Exposure (ADE):	70 µg/day
5-Band System Exposure Classification:	Category 3 – High Risk
ACGIH Threshold Limit Values (TLVs):	
Short Term Exposure Limits (STEL) – 15 min:	100 mg/m^3
Time Weight Average (TWA) – 8 Hours:	33 mg/m^3
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:	Not required under normal conditions of use.
Protective gloves:	Chemical compatible when needed.
Skin and body protection:	Not required under normal conditions of use.
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:	Round tablet	Odor:	Not Applicable
Density:	Not Available	Boiling Point:	Not Applicable
Melting Point:	Not Applicable	Solubility:	Water
Viscosity:	Not Applicable	Specific Gravity:	Not Applicable
Evaporation Rate:	Not Applicable	Conductivity:	Not Applicable

Chemical Properties:

pH:	Between 2.5 and 5.0	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 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: Oral, Ingestion

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

General effects:	Have a high potential for abuse, misuse, and dependence. It may cause nervous system disorders. Acute overdose with Hydrocodone is characterized by respiratory depression, extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, in some cases, pulmonary edema, partial or complete airway obstruction, atypical snoring, hypotension, circulatory collapse, cardiac arrest, and death.
Sensitization:	Contact with the skin may cause irritation.
Mutagenic effects:	Mutagenicity studies have not been conducted with Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets; however, published information is available for the individual active ingredients or related active ingredients.
Reproductive toxicity:	Fertility and reproductive studies have not been conducted with Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets; however, published information is available for the individual active ingredients or related active ingredients.
Fetotoxic / Teratogenic Effects:	There are no available data with Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets use in pregnant women to inform a drug-associated risk for adverse developmental outcomes. Prolonged use of opioid analgesics during pregnancy for medical or nonmedical purposes can result in physical dependence in the neonate and neonatal opioid withdrawal syndrome shortly after birth.

Specific target organ toxicity (STOT):

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

Toxicity (LD_{50}):

Toxicity studies have not been conducted with Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets. The toxicity information listed below is for the active ingredient Hydrocodone Bitartrate and not for the tablet product itself.

Oral LD_{50} Rat:	375 mg/kg	Subcutaneous LD_{50} Rat:	150 mg/kg
Subcutaneous LD_{50} Mouse:	86 mg/kg		

Symptoms / Adverse Reactions: The most common adverse reactions are Somnolence, mental clouding, impairment of mental and physical performance, dizziness, nervousness, visual

	disturbances, confusion, headache, lightheadedness, dry mouth, and nausea. Have a high potential for abuse and dependence.
Carcinogenicity:	Carcinogenicity studies have not been conducted with Hydrocodone Bitartrate and Homatropine Methylbromide, 5 mg/1.5 mg (CII) Tablets; however, published information is available for the individual active ingredients or related active ingredients. Not listed as a carcinogen by OSHA.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity (Toxicity effects):	No information is currently available on the environmental impact. All releases to terrestrial, atmospheric, and aquatic environments 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. An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers:	Dispose used or contaminated containers in accordance the DEA guidelines.
Waste Disposal Methods:	Dispose in accordance with the 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
Colloidal Silicon Dioxide NF	7631-86
Magnesium Stearate, NF	557-04-0
Homatropine Methylbromide	80-49-9
Pregelatinized Starch, NF	9005-25-8
Stearic Acid, NF	57-11-4

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

Creation Date: June/02/21, New SDS

Revision Date: Jul/28/22

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

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