SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION

Product Identification:

Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12 mg per 5 mL, 16 oz (473 mL) Bottle	NDC 64950-374-16
Acetaminophen and Codeine Phosphate Oral Solution USP, 120 mg/12 mg per 5 mL, 4 oz (118 mL) Bottle	NDC 64950-374-04

Product Name: ACETAMINOPHEN AND CODEINE PHOSPHATE Oral Solution USP

Recommended use: Acetaminophen and Codeine Phosphate Oral Solution (OS) USP is a prescribed analgesic used for the relief of mild to moderate pain, when other pain treatments such as non-opioid pain medicines do not treat the pain well enough. It contains a non-opioid pain reliever (Acetaminophen) and an opioid pain reliever (Codeine).

Restrictions: Acetaminophen and Codeine Phosphate Oral Solution (OS) USP should not be administrated to patients that have previously hypersensitivity to Codeine or Acetaminophen. Codeine is habit-forming and potentially abusable. Avoid the use of alcohol and depressant with this product.

Manufacturer Name: Pharmaceutical Associates Inc.
Manufacturer Address: 201 Delaware Street
Greenville, SC 29605

Emergency Telephone number: CHEMTREC 800.424.9300

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 ACETAMINOPHEN AND CODEINE PHOSPHATE Oral Solution 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.

SAFETY DATA SHEET

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, **Codeine Phosphate**, and **NOT** for the OS product itself.

Physical hazards:	Not classified
Health hazards:	Acute Toxicity Category 3 Skin and Respiratory Sensitivity Category 1
Environmental hazards:	Not classified

Signal Word: Warning

Hazard Statement: It may be habit forming. Tolerance may develop upon repeated administration.

Pictogram:

Precautionary Statement: This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment. Because of risks of addiction, abuse, and misuse with opioids, reserves the product for use in adult patients. Accidental ingestion of large amounts may be fatal. Seek medical attention is case of accidental exposure or overdose.

This product active ingredient, Codeine is a DEA Schedule III controlled substance. Substances in the DEA Schedule III have a less potential for abuse than Schedule I and II and may lead to moderate or low physical dependence or high psychological dependence. Contact local state professional licensing board or state controlled substances authority for information on how to prevent and detect addiction, abuse, misuse, or diversion of this product.

Hazards Not Otherwise Classified: Generally safe at recommended doses.

SECTION 3 – COMPOSITION / INFORMATION OF INGREDIENTS

Chemical Identity	Other Names	CAS Number
Acetaminophen	Paracetamol, APAP	103-90-2
Alcohol 190 Proof	Absolute Alcohol, Ethanol, Ethyl Alcohol	64-17-5
Cherry Flavor	N/A	Mixture
Codeine Phosphate	Ardinex, Codeine	41444-62-6
FD&C Red No. 40	Allura Red	25956-17-6
FD&C Yellow No.6	Sunset Yellow	2783-94-0

SAFETY DATA SHEET

Chemical Identity	Other Names	CAS Number
Glycerin	1,2,3-Propanetriol	56-81-5
Propylene Glycol	1,2 Propanediol	57-55-6
Sodium Saccharin	Saccharin	6155-57-3
Sucrose	Saccharose	57-50-1

* 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.

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 constipation, nausea, sleepiness, vomiting, tiredness, headache, sedation, dizziness, and abdominal pain. When overdose, symptoms may include respiratory depression, loss on consciousness, convulsions, necrosis, and pinpoint pupils.

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

Note to Physician: Acetaminophen and Codeine Phosphate OS USP should be prescribed with caution in certain special risk patients, such as the elderly or debilitated, and those with severe impairment of renal or hepatic function, head injuries, elevated intracranial pressure, acute abdominal conditions, hypothyroidism, urethral stricture, Addison's disease, or prostatic hypertrophy.

Immediate overdose treatment includes support of cardiorespiratory function and measures to reduce drug absorption. Vomiting should be induced mechanically or with syrup of ipecac if the patient is alert. Oral activated charcoal should follow gastric emptying. The first dose should be accompanied by an appropriate cathartic. If repeated doses are used, the cathartic might be included with alternate doses as required. Hypotension is usually hypovolemic and should respond to fluids. Vasopressors and other supportive measures should be employed as indicated. A cuffed endo-tracheal tube should be inserted before gastric lavage of the unconscious patient and, when necessary, to provide assisted respiration.

SAFETY DATA SHEET

Meticulous attention should be given to maintaining adequate pulmonary ventilation. In severe cases on intoxication, peritoneal dialysis, or preferably hemodialysis may be considered. If hypoprothrombinemia occurs, Vitamin K should be administered intravenously. Naloxone can reverse respiratory depression and coma associated with opioid overdose. Naloxone Hydrochloride 0.4 mg to 2 mg is given parenterally. Since the duration of action of Codeine may exceed that of the Naloxone, the patient should be kept under continuous surveillance and repeated doses of the antagonist should be administered as needed to maintain adequate respiration. A narcotic antagonist should NOT be administered in the absence of clinically significant respiratory or cardiovascular depression.

SECTION 5 – FIREFIGHTING MEASURES

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

Specific hazards arising from the mixture: Formation of toxic gases is possible during fire. It may burn emitting Oxides of Chlorine and Nitrogen. (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: Safety Glasses or goggles, gloves, and protecting clothes. (Refer to Section 8)

Emergency procedures: Evacuate the area and keep unauthorized personnel away. Prevent further leakage or spillage if safe to do so. Care should be taken to avoid environmental release.

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 in accordance with applicable regulations, including the DEA.

SAFETY DATA SHEET

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 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.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits:

There is no exposure limits for the Acetaminophen and Codeine Phosphate OS USP products. The exposure limits listed below are for the active ingredient Codeine Phosphate and not for the OS products itself.

OSHA Permissible Exposure Limits (PELs):	200 µg/m^3 TWA
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):	Not Available

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:	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.

SAFETY DATA SHEET

Other personal protection: None required

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Appearance:	Clear orange-yellow solution	Odor:	Cherry
Density:	Not Available	Boiling Point:	Not Available
Melting Point:	Not Applicable	Solubility:	Water
Viscosity:	Not Available	Specific Gravity:	1.2 (USP)
Evaporation Rate:	Not Available	Conductivity:	Not Available

Chemical Properties:

pH:	4.0 – 6.1 (USP)	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 light.
Incompatible materials:	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products:	None known.

SECTION 11 – TOXICOLOGICAL INFORMATION

Routes of exposure: Oral

SAFETY DATA SHEET

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

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 Codeine Phosphate and not for the finished products itself.

Oral LD_{50} Rat:	85 mg/kg	Intraperitoneal LD_{50} Rat:	104 mg/kg
Intravenous LD_{50} Rat:	54 mg/kg	Intramuscular LD_{50} Rat:	208 mg/kg
Oral LD_{50} Mouse:	237 mg/kg	Intraperitoneal LD_{50} Mouse:	110 mg/kg
Intravenous LD_{50} Mouse:	62 mg/kg	Intramuscular LD_{50} Mouse:	191 mg/kg
Oral LD_{50} Guinea Pig:	654 mg/kg	Intraperitoneal LD_{50} Guinea Pig:	352 mg/kg

Symptoms / Adverse Reactions: The most common adverse reactions are drowsiness, dizziness, sedation, shortness of breath, nausea and vomiting. Overdose from Codeine poisoning includes the opioid triad of pinpoint pupils, respiratory depression and loss of consciousness. Convulsions may occur.

SAFETY DATA SHEET

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 information is currently available on the environmental persistence and degradation of this product. Releases to the environment should be avoided.

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

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; is highly recommended to avoid environmental releases.

SECTION 13 – DISPOSAL INFORMATION

Disposal Containers: Dispose used or contaminated containers in accordance with the Drug Enforcement Administration (DEA) and 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 and DEA instructions to discard the medicine in the trash at home.

Waste Disposal Methods: Dispose used or contaminated containers in accordance with the Drug Enforcement Administration (DEA) and 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 and DEA 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.

SAFETY DATA SHEET

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): Listed as Schedule III Controlled Substances (CIII).

Drug Enforcement Administration (DEA): 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).

SAFETY DATA SHEET

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
Acetaminophen	103-90-2
Alcohol 190 Proof	64-17-5
Propylene Glycol	57-55-6
Sucrose	57-50-1
Glycerin	56-81-5
FD&C Red No. 40	25956-17-6
FD&C Yellow No.6	2783-94-0

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: Aug/14/23, 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.

Signature Manifest

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All dates and times are in Eastern Time.

SDS Acetaminophen and Codeine Phosphate Oral Solution USP - 64950

Department Approval

Name/Signature	Title	Date	Meaning/Reason
July Ortiz (JORTIZ)		23 Aug 2023, 09:23:02 AM	Approved

Regulatory Affairs Approval

Name/Signature	Title	Date	Meaning/Reason
Demeitrius Sawickij (DSAWICKIJ)		23 Aug 2023, 12:27:42 PM	Approved

Quality Assurance Approval

Name/Signature	Title	Date	Meaning/Reason
Rama Chitirala (RCHITIRALA)	Vice President of Quality Assurance	24 Aug 2023, 12:37:18 PM	Approved