SAFETY DATA SHEET

LORTAB® ELIXIR CII
Hydrocodone Bitartrate and Acetaminophen Oral Solution

1. IDENTIFICATION

Product Identifier: LORTAB® ELIXIR CII Hydrocodone Bitartrate and Acetaminophen Oral Solution, 10 mg/300 mg per 15 mL

Synonyms: Dihydrocodeione bitartrate hydrate; Paracetamol

National Drug Code (NDC): 17478-450-16

Recommended Use: Pharmaceutical. LORTAB ELIXIR is indicated for the relief of moderate to moderately severe pain.

Company: Akorn, Inc.
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Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. HAZARD(S) IDENTIFICATION

Physical Hazards: Highly flammable liquid and vapors — Category 2

Health Hazards: Not classifiable.

Symbol(s):

Signal Word: Danger.

Hazard Statement(s):

H225 Highly flammable liquid and vapors.

Precautionary Statement(s):

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P241 Use explosion – proof electrical/ ventilating/ lighting/ equipment.

P242 Use only non – sparking tools.

P243 Take precautionary measures against static discharge.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P370 + P378 In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary.

	P403 + P235	Store in a well-ventilated place. Keep cool.
	P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: Not classifiable.

Supplementary Information: Product may be considered a hazardous material according to OSHA 29 CFR 1910.1200 regulatory standards.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Per 5 mL	Per 15 mL
Hydrocodone Bitartrate	Dihydrocodeione bitartrate hydrate	34195-34-1	$C_{18}H_{21}NO_3$• $C_4H_6O_6$• 2½H_2O	494.49	3.33 mg	10 mg
Acetaminophen	Paracetamol	103-90-2	$C_8H_9NO_2$	151.16	100 mg	300 mg
Alcohol	Ethyl alcohol	64-17-5	C_2H_5OH	46.07	7%	7%

In addition, the liquid contains the following inactive ingredients: Citric Acid Anhydrous, Ethyl Maltol, Glycerin, Methylparaben, Propylene Glycol, Propylparaben, Purified Water, Saccharin Sodium, Sorbitol Solution, Sucrose, with D&C Red #33 and FD&C Red #40 as coloring and natural and artificial flavoring.

4. FIRST AID MEASURES

Ingestion: If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact: Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical

	attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	*Hydrocodone:* Serious overdose with hydrocodone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and sometimes bradycardia and hypotension. In severe overdosage, apnea, circulatory collapse, cardiac arrest and death may occur. *Acetaminophen:* In acetaminophen overdosage: dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis, hypoglycemic coma and coagulation defects may also occur. Early symptoms following a potentially hepatotoxic overdose may include: nausea, vomiting, diaphoresis and general malaise. Clinical and laboratory evidence of hepatic toxicity may not be apparent until 48 to 72 hours post-ingestion.
Medical Conditions Aggravated by Exposure:	Respiratory ailments; hypersensitivity or allergic sensitivity; head injury or other intracranial lesions; increased intracranial pressure; impaired hepatic or renal function; hypothyroidism; Addison's disease; prostatic hypertrophy; urethral stricture; pulmonary disease.
WARNING:	May be habit-forming.
Notes to Physician:	Treat supportively and symptomatically. LORTAB ELIXIR contains hydrocodone, an opioid agonist, and is a Schedule II controlled substance. LORTAB ELIXIR can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing LORTAB ELIXIR in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

5. FIREFIGHTING MEASURES

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or foam as necessary.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: Toxic gases and vapors may be released if involved in a fire.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Store away from oxidizing agents and acids.

Specific End Use: Pharmaceuticals.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Hydrocodone Bitartrate	STEL	100 mg/m^3
	TWA	33 mg/m^3
Acetaminophen	TWA	5 mg/m^3
Alcohol	OSHA PEL	1,000 ppm; 1,900 mg/m^3
	NIOSH IDLH	3,300 ppm
	NIOSH REL	1,900 mg/m^3
	ACGIH TWA	1,000 ppm
	ACGIH TLV STEL	1,000 ppm

STEL: Short Term Exposure Limit. TWA: Time Weighted Average. OSHA PEL: Occupational Safety and Health Administration – Permissible Exposure Limits. NIOSH IDLH: National Institute for Occupational Safety and Health – Immediately Dangerous to Life or Health. REL: Recommended Exposure Limits. ACGIH TLV: American Conference of Governmental Industrial Hygienists –Threshold Limit Value.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Chemically compatible gloves should be worn. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

General Hygiene Considerations: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:	Clear red liquid.
Odor:	Fruit punch.
Odor Threshold:	No data available.
pH:	3.7 to 4.7.
Melting Point:	No data available.
Freezing Point:	No data available.
Boiling Point:	173°F.
Flash Point:	55°F.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	No data available.
Partition Coefficient	No data available.
(n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Specific Gravity:	1.13 to 1.19.

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Contact with incompatible materials.
Incompatible Materials:	No data available. This product is a mixture that has not been tested as a whole.
Hazardous Decomposition Products:	Toxic gases and vapors may be released if involved in a fire.

11. TOXICOLOGICAL INFORMATION

Information on the Likely Routes of Exposure

Inhalation:	May cause irritation to the nose and/or respiratory tract. May cause nausea, dizziness, sneezing, breathing difficulties or allergic reaction. May cause lung edema and typical symptoms of narcosis.

Ingestion: May cause nausea, constipation, dizziness. Large dosages can lead to CNS depression, collapse, respiratory or cardiac arrest and death. May produce damage to liver, kidneys, and CNS.

Skin Contact: May be harmful if absorbed through skin. May cause irritation or allergic reaction. Capable of producing narcotic effects if absorbed through breaks, inflamed areas, etc.

Eye Contact: May be harmful if absorbed through this route. May also cause irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Hydrocodone Bitartrate	Rat	Oral	LD_{50}	375 mg/kg
Acetaminophen	Rat	Oral	LD_{50}	2,404 mg/kg

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Does Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

Aspiration Hazard: No data available.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: May result in cirrhosis of the liver, damage to the heart, and kidneys. May cause increased sensitivity, tolerance, habituation and addiction.

Systemic Effects: Analgesic and anti-tussive effects. May cause central nervous system effects and respiratory depression.

Reproductive Effects: Pregnancy Category C. No adequate or well-controlled studies have been conducted with this product.

Carcinogenicity: No adequate studies in animals have been performed to determine the carcinogenic potential of this product.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

Terrestrial Toxicity: No data available.
Persistence and Degradability: No data available.
Bioaccumulative Potential: No data available.
Mobility in Soil: No data available.
Mobility in Environment: No data available.
Other Adverse Effects: No data available.

13. DISPOSAL CONSIDERATIONS

Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

International Air Transport Association (IATA):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Flammable Liquid, n.o.s.	UN1993	Class 3	III

International Maritime Dangerous Good (IMDG):

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Flammable Liquid, n.o.s.	UN1993	Class 3	III

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Hydrocodone Bitartrate	No
Acetaminophen	No
Alcohol	Yes

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Hydrocodone Bitartrate	Not Listed	Not Listed	Not Listed
Acetaminophen	Not Listed	Not Listed	Not Listed
Alcohol	Listed	Listed	Listed

California Proposition 65:	Alcohol is listed to cause cancer and birth defects or other reproductive harm.

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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