

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION
1.1 Product identifier

Product name: Hydrocodone Bitartrate and Acetaminophen Oral Solution CII

Product code(s): Hydrocodone Bitartrate and Acetaminophen Oral Solution CII

Synonym(s): Active ingredient (1) - Hydrocodone Bitartrate; 4,5 α -epoxy-3-methoxy-17-methylmorphinan-6-one tartrate (1:1) hydrate (2:5)
Active ingredient (2) - Acetaminophen; Paracetamol; APAP; N-(4-Hydroxyphenyl)acetamide; N-(4-Hydroxyphenyl)acetanilide

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Hydrocodone Bitartrate and Acetaminophen Oral Solution CII is indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Restrictions on use: Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

1.3 Details of the supplier and of the safety data sheet
Manufactured By

VistaPharm, Inc.
7265 Ulmerton Road
Largo, FL 33771 USA
+1-888-655-15051-727-530-1633

1.4 Emergency telephone number

In the continental USA: +1-888-655-1505

SECTION 2 - HAZARDS IDENTIFICATION
2.1 Classification of substance or mixture

Product definition: Mixture

Classification in accordance with 29 CFR 1910 (OSHA HCS) and Regulation (EC) No 1272/2008

Not a dangerous substance or mixture according to OSHA or to European Union Legislation

2.2 Label elements

Not a dangerous substance or mixture according to GHS

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS
3.1 Substances

Not applicable

3.2 Mixtures

Concentration	Ingredient	CAS Number	EC Number	Index Number	GHS Classification
25 mg/5 mL	Hydrocodone Bitartrate	34195-34-1	205-608-1	-----	H302
108 mg/5 mL	Acetaminophen	103-90-2	203-157-5	-----	H302, H412
8.6%/5 mL	Ethanol	64-17-5	200-578-6	603-005-00-1	H225

Inactive ingredients: Citric Acid Anhydrous; Ethyl Maltol; Glycerin; Methylparaben; Propylene Glycol; Propylparaben; Purified Water; Saccharin; Sodium; Sodium Citrate Dihydrate; Sorbitol Solution; Sucrose; FD&C Red #40; Artificial Wild Cherry Flavor

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

SECTION 4 - FIRST AID MEASURES
4.1 Description of first aid measures

Inhalation: If product mist causes respiratory irritation or distress, move the exposed person to fresh air immediately. If breathing is difficult or irregular, administer oxygen; if respiratory arrest occurs, start artificial respiration by trained personnel. Get immediate medical attention. If unconscious place in the recovery position and get immediate medical attention. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. Ensure that medical personnel are aware of the material involved. If respiratory irritation persists or if other symptoms develop, seek medical attention.

Eyes: Immediately flush eyes with large amounts of water for 15 minutes, occasionally lifting the upper and lower eyelids. Remove contact lenses after the first 2 minutes and continue rinsing. If irritation persists seek medical attention, preferably from an ophthalmologist.

Skin: Rinse skin with water while removing contaminated clothing. Wash affected area with soap and water. Wash contaminated clothing and shoes thoroughly before reuse. In the event of any complaints or symptoms, avoid further exposure and seek medical attention.

Ingestion: Rinse mouth with water if the victim is conscious. Remove dentures, if present. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept lower than the waist so that vomit does not enter into the lungs. Never give anything by mouth to an unconscious or convulsing person. Do not leave the victim unattended. If the victim is unconscious, place in the recovery position and get immediate medical attention. Immediately contact a POISON CONTROL CENTER or doctor if adverse health effects persist or are severe.

4.2 Most important symptoms and effects, both acute and delayed
Potential health symptoms and effects

Eyes: May cause eye irritation.

Skin: May cause skin irritation.

Inhalation: Inhalation of mist may cause upper respiratory tract irritation.

Ingestion: May cause nausea, vomiting, loss of appetite or severe stomach pain. May cause headache, dizziness, fatigue, sweating, drowsiness, fainting or weakness. May cause serious, life-threatening respiratory depression, which may be fatal. May cause trouble in urination and changes in the amount and color of urine. May cause unusual bruising or bleeding. May cause yellowing of the eyes. May cause a severe allergic reaction characterized by itching or hives, swelling or tingling of the mouth or throat, swelling of skin or the face or hands, chest tightness and breathing difficulty. May cause kidney damage. Refer to product insert for complete side effect data.

Chronic: Prolonged and repeated ingestion of acetaminophen may cause serious (possibly fatal) liver disease. Refer to product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Hydrocodone Bitartrate, an opioid, exposes users to the risks of addiction, abuse, and misuse. Addiction can occur at recommended dosages and if the drug is misused or abused.

4.3 Indication of any immediate medical attention and special treatment needed

Advice to doctor and hospital personnel

Immediate medical treatment is recommended for unintentional ingestion or overdose.

SECTION 5 - FIRE FIGHTING MEASURES

5.1 Extinguishable media

Suitable methods of extinction: Use extinguishing media suitable for the surrounding fire.

Unsuitable methods of extinction: None known

5.2 Special hazards arising from the substance or mixture

During emergency conditions overexposure to decomposition products may cause a health hazard. Symptoms may not be immediately apparent or may be delayed. Obtain medical attention.

5.3 Advice for firefighters

Full protective equipment including self-contained breathing apparatus should be used. If possible, firefighters should control runoff water contaminated with this material and prevent it from being discharged to any waterway, sewer or drain to prevent environmental contamination.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Evacuate non-essential personnel from the area. Wear appropriate protective clothing designated in Section 8.2. Remove all sources of ignition. Ventilate the area. Clean up spills immediately. Spill creates a slip hazard.

6.2 Environmental precautions

Avoid dispersal of spilled material or runoff and prevent contact with soil and entry into drains, sewers and waterways.

6.3 Methods and materials for containment and cleaning up

Cover drains and contain spill. Small spills can be wiped up with absorbent material (e.g. cloth, paper towel). Cover larger spills with inert absorbent. Do not use combustible material such as sawdust. Collect material and place into an approved, labeled container for proper disposal. Observe possible material restrictions (Sections 7.2 and 10.5). Clean contaminated area with soap and water. Dispose of material via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations.

6.4 Reference to other sections

For symptoms of overexposure and first aid treatment, see Section 4.

SECTION 7 - HANDLING AND STORAGE

7.1 Precautions for safe handling

Observe label precautions. Wear all appropriate protective equipment specified in Section 8.2. Do not get in eyes or on skin or clothing. If normal use presents a respiratory hazard, use only adequate ventilation or wear an appropriate respirator.

Advice on protection against fire and explosion

Not expected to be a fire or explosion hazard.

7.2 Conditions for safe storage, including any incompatibilities

Store at 20 - 25 °C (68 - 77 °F) in a dry, well-ventilated area away from incompatible materials (see Section 10.5), food and drink. Keep container tightly closed when not in use. Protect containers from physical damage. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Containers are hazardous when empty as they contain product residues. Use appropriate to avoid environmental contamination. Ventilate closed areas. Keep locked up and out of reach of children.

7.3 Specific end uses

Apart from the uses mentioned in Section 1.2, no other specific uses are stipulated.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure values.

8.2 Exposure controls

Engineering measures: Use adequate ventilation. Local exhaust is preferable. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Individual protection measures: Not normally required. Wear protective clothing to prevent repeated or prolonged contact with product. Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled.

Hygiene measures: Facilities storing or using this material should be equipped with an eyewash station and safety shower. Change contaminated clothing. Wash hands and forearms thoroughly after use, before eating, drinking, smoking or using the lavatory.

Eye/face protection: None normally required. If there is a danger of splashing wear safety glasses with unperforated side shields during use.

Hand protection: Not normally needed. For prolonged or repeated skin contact wear gloves recommended by supplier for protection against materials in Section 3. Breakthrough time of selected gloves must be greater than the intended use period.

Other protective equipment: Not normally needed. Wear protective clothing and protective boots if the situation requires.

Respiratory protection: No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to vapor/fume at levels exceeding the exposure limits.

Environmental exposure controls: Do not empty into drains.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Clear, red liquid
Odor	Cherry
Odor Threshold	No data available
Molecular Weight	494.49 g/mol (Hydrocodone Bitartrate); 151.16 g/mol (Acetaminophen)
Chemical Formula	C ₁₈ H ₂₁ NO ₃ •C ₄ H ₆ O ₆ •2.5 H ₂ O (Hydrocodone Bitartrate); C ₈ H ₉ NO ₂ (Acetaminophen)
pH	No data available
Freezing/Melting Point, Range	No data available
Initial Boiling Point	No data available
Evaporation Rate	No data available
Flammability (solid, gas)	Not applicable
Flash Point	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Lower Explosive Limit (LEL)	No data available
Upper Explosive Limit (UEL)	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	No data available
Viscosity	No data available
Solubility in Water	Dispersible
Partition Coefficient: n-octanol/water	No data available
Volatiles by Weight @ 21° C	No data available

9.2 Other data

No relevant additional information available

SECTION 10 - STABILITY AND REACTIVITY

10.1 Reactivity

No special reactivity has been reported.

10.2 Chemical stability

Product is stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid temperature extremes.

10.5 Incompatible materials

None known

10.6 Hazardous decomposition products

Thermal decomposition products include oxides of carbon.

SECTION 11 - TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute oral toxicity

Expected to have low acute dermal toxicity

Acute inhalation toxicity

Expected to have low acute inhalation toxicity

Acute dermal toxicity

Expected to have low acute dermal toxicity

Skin irritation

May cause skin irritation.

Eye irritation

May cause eye irritation.

Sensitization

No data available

Genotoxicity

No data available

Mutagenicity

No data available

Specific organ toxicity - single exposure

No data available

Specific organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

11.2 Further information

Hydrocodone Bitartrate, an opioid, exposes users to the risks of addiction, abuse, and misuse. Addiction can occur at recommended dosages and if the drug is misused or abused.

Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death.

Prolonged use of Hydrocodone Bitartrate and Acetaminophen Oral Solution during pregnancy can result in withdrawal in the neonate. Neonatal withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts.

Acetaminophen may cause a serious allergic reaction. Chronic ingestion may cause liver damage.

The U.S. Food and Drug Administration (FDA) is informing the public that acetaminophen has been associated with a risk of rare but serious skin reactions. These skin reactions, known as Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), can be fatal. Reddening of the skin, rash, blisters, and detachment of the upper surface of the skin can occur with the use of drug products that contain acetaminophen. These reactions can occur with first-time use of acetaminophen or at any time while it is being taken.

Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4,000 milligrams per day, and often involve more than one acetaminophen-containing product.

Ethanol (CAS #64-17-5): Carcinogen classifications of IARC, ACGIH, NTP, OSHA and California Proposition 65 apply to beverage use only. This product is NOT intended for this use. Ethanol has been shown to produce fetotoxicity in the embryo or fetus of laboratory animals. Prenatal exposure to ethanol is associated with congenital malformations that have collectively been termed "fetal alcohol syndrome".

Handle in accordance with good industrial hygiene and safety practice.

SECTION 12 - ECOLOGICAL INFORMATION**12.1 Toxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulation potential

This product is not expected to bioaccumulate.

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects**Additional ecological information**

Do not allow material to enter into surface waters, wastewater or soil.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

SECTION 13 - DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Methods of disposal: The generation of waste should be avoided or minimized whenever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe way via a licensed pharmaceutical waste contractor and in accordance with FDA and DEA regulations. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Hazardous waste: The classification of this product may meet the criteria for a hazardous waste.

SECTION 14 - TRANSPORT INFORMATION

Note: Transportation information provided is for reference only. Customer is urged to consult 49 CFR 100 - 177, IMDG, IATA, EC, United Nations TDG and WHMIS (Canada) TDG information manuals for detailed regulations and exceptions covering specific container sizes, packaging materials and methods of shipping.

NOT REGULATED FOR TRANSPORT (NOT DANGEROUS GOODS)

SECTION 15 - REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for substance or mixture

U. S. Federal Regulations

OSHA Hazard Communication Standard: This material is not classified as hazardous in accordance with OSHA 29 CFR 1910.1200.

TSCA Status: All of the components of this product are listed on the Toxic Substance Control Act (TSCA) Inventory. This product is not subject to TSCA 12(b) Export Notification.

DEA Schedule II (29 CFR 1308.12): Hydrocodone Bitartrate, DEA No. 9193

Superfund Amendments and Reauthorization Act (SARA)

SARA Section 311/312 Hazard Categories: None known

SARA 313 Information: None of the chemicals in this product exceed the threshold (de minimis) reporting levels established by Section 313 of the Emergency Planning and Community Right-to Know Act of 1986.

SARA 302/304 Extremely Hazardous Substance: None of the components of the product are subject to the reporting requirements of these sections of Title III of SARA.

SARA 302/304 Emergency Planning & Notification: None of the components of the product are subject to the reporting requirements of these sections of Title III of SARA.

Comprehensive Response Compensation and Liability Act (CERCLA): None of the components of the product exceed the threshold (de minimis) reporting levels for hazardous wastes established by CERCLA.

Clean Air Act (CAA)

This product does not contain Hazardous Air Pollutant (HAP) designated in CAA Section 112 (b).

This product does not contain Class 1 Ozone depletors.

This product does not contain Class 2 Ozone depletors.

Clean Water Act (CWA)

This product does not contain Hazardous Substances under the CWA.

This product does not contain Priority Pollutants under the CWA.

This product does not contain Toxic Pollutants under the CWA.

U.S. State Regulations

California Prop 65, Safe Drinking Water and Toxic Enforcement Act of 1986

Carcinogen classification for Ethanol (CAS #64-17-5) applies to *beverage use only*. This product is NOT intended for this use.

Other U.S. State Inventories

Ethanol (CAS #64-17-5) is listed on the following the State Hazardous Substance Inventories, Right-to-Know lists and/or Air Quality/Air Pollutants lists: CA, ID, MA, MN, NJ, PA, RI, WA.

Canada

WHMIS Hazard Classification: Uncontrolled product according to WHMIS classification criteria

Canadian National Pollutant Release Inventory (NPRI): None of the components of this product are not listed on the NPRI.

European Economic Community

WGK, Germany (Water danger/protection): No data available

Global Chemical Inventory Lists

Country	Inventory Name	Inventory Listing*
Canada	Domestic Substance List (DSL)	Yes
Canada	Non-Domestic Substance List (NDSL)	No
Europe	Inventory of New and Existing Chemicals (EINECS)	Yes
United States	Toxic Substance Control Act (TSCA)	Yes
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
New Zealand	New Zealand Inventory of Chemicals (NZIoC)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (KECI)	Yes
Philippines	Philippines Inventory of Chemicals and Chemical Substances (PICCS)	Yes

*Yes - All components of this product are in compliance with the inventory requirements administered by the governing country.

No - One or more components of this product are not on the inventory or are exempt from listing.

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16 - OTHER INFORMATION

Hazardous Material Information System (HMIS)

Health	<input type="checkbox"/> 0
Flammability	<input type="checkbox"/> 0
Physical Hazard	<input type="checkbox"/> 0
Personal Protection	<input type="checkbox"/>

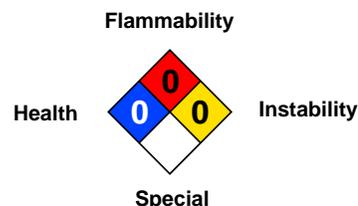
HMIS Hazard Rating Legend

0 = Minimal 1 = Slight 2 = Moderate 3 = Serious
4 = Severe * = Chronic Health Hazard

NFPA Hazard Rating Legend

0 = Insignificant 1 = Slight 2 = Moderate
3 = High 4 = Extreme

National Fire Protection Association (NFPA)



Full text of GHS Hazard Phrases referenced in Section 3 (not covered in Section 2)

H302 - Harmful if swallowed

H412 - Harmful to aquatic life with long lasting effects

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Revision date: 05 September 2018, Version 2

Supersedes SDS dated: 25 June 2018, Version 1