

Safety Data Sheet

Issuing date: 03/16/2015

Revision date: 03/06/2017

Revision number: 01

1. Identification of the substance/preparation and the company/undertaking

GHS product identifier

Product name: Hydrocodone Bitartrate and Acetaminophen Oral Solution

Other means of identification

Product code(s): 0121-0772-04, 0121-0772-16, 0121-4772-05, 0121-4772-40, 0121-1544-10,
0121-1544-40, 0121-2316-15, 0121-2316-40

UN-Number: NA

Synonyms: Compare to Lortab®

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical product used for the relief of moderate to moderately severe pain

Uses advised against: Do not use except as prescribed.

Supplier address/information

Pharmaceutical Associates, Inc.
201 Delaware Street
Greenville, SC 29605 (864) 277 -7282

Emergency telephone number: CHEMTREC 800.424.9300

2. Hazards Identification

Classification

This product is a mixture and is a pharmaceutical product. It is considered non-Hazardous according to the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Chemical family: Mixture

Statement of Hazard: May be harmful if swallowed.

Additional Hazard Information:

Short term:

Acetaminophen has been associated with cases of acute liver failure resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed 4000 milligrams per day, and often involve more than one acetaminophen containing product.

Hydrocodone may cause lightheadedness, sedation, dizziness, pinpoint pupils, nausea and vomiting. Other side effects include constipation, rash and itching. May be habit forming.

Long term:

Known Clinical Effects:

Therapeutic use of this substance has resulted in liver failure, serious skin reactions such as acute generalized exanthematous pustulosis, Stevens-Johnson syndrome and toxic epidermal necrolysis.

Ingestion of this material may cause effects similar to those seen in clinical use including dry mouth, drowsiness, headache, dizziness, nausea, vomiting, weakness, anxiety, blurred vision and dilated pupils. Cases of overdose may also lead to respiratory depression, hypotension, coma, convulsions, cardiac

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arrhythmia, and tachycardia. Additionally, symptoms of dependence / withdrawal may occur.

EU Indication of danger: Not classified.

Emergency overview

Seek medical attention in case of accidental exposure or overdose. The product is generally safe when used as prescribed.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential of exposure in your workplace.

Precautionary statements

General advice: Seek medical attention in case of accidental exposure or overdose.

Eyes: Avoid contact with eyes.

Skin Contact: Avoid skin contact.

Inhalation: Not intended for inhalation.

Ingestion: Generally safe at recommended doses. In case of overdose, seek medical attention immediately.

Storage: There are no special storage conditions for safety. For product integrity, store under conditions specified on the label.

Disposal: Dispose of in accordance with applicable laws and regulations.

3. Composition/Information on ingredients

Chemical name	CAS-No	mg/mL	Trade Secret
Acetaminophen	103-90-2	325 mg/15 mL	
Hydrocodone Bitartrate	34195-34-1	7.5 mg/15 mL	
Alcohol 190 Proof	Mixture 64-17-5 (200 proof)	7% v/v	
Methylparaben	99-76-3		X
Edetate Disodium	6381-92-6		X
Sodium Saccharin	6155-57-3		X
Sucrose	57-50-1		X
Propylene Glycol	57-55-6		X
Glycerin	56-81-5		X
Sorbitol Solution	Mixture		X
D&C Yellow No. 10	8004-92-0		X
Fruit Flavor	Mixture		X

4. First aid measures

Description of necessary first-aid measures

Eye contact:

Flush with running water for 15 minutes holding eyelids open. Contact medical personnel if irritation persists.

Skin contact:

Wash contaminated area thoroughly. If irritation persists, contact medical personnel.

Inhalation:

Remove to fresh air and contact medical personnel.

Ingestion:

Overdosage or accidental ingestion – Toxicity may result from acetaminophen or hydrocodone bitartrate overdosage. Contact medical personnel or poison control immediately if overdosage is suspected.

Most important symptoms/effects, acute and delayed

Overdosage from hydrocodone poisoning includes the opioid triad of pinpoint pupils, respiratory depression and loss of consciousness. Convulsions may occur. In acetaminophen overdosage – dose-dependent, potentially fatal hepatic necrosis is the most serious adverse effect. Renal tubular necrosis may occur. Hypoglycemic coma and thrombocytopenia may also occur.

Indication of immediate medical attention and special treatment needed, if necessary

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Overdosage represents a polydrug overdose. Immediate medical attention is required if overdose is suspected.

Notes to Physician: NA

5. Fire-fighting measures

Suitable extinguishing media:	Use carbon dioxide, dry chemical or water spray.
Specific hazards arising from the chemical	Not Applicable
Explosion data:	Not applicable
Protective equipment and precautions for firefighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (See Section 8). Minimize exposure.
Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and materials for containment and cleaning up

- Methods for containment: Isolate area around spill as specified by site procedures.
- Methods for cleaning up: Absorb the liquid with suitable material. Dispose of spill material in accordance with applicable federal, state or local regulations.

7. Handling and storage

Precautions for safe handling

Handling: No special handling required for hazard control under conditions of normal product use.

Conditions for safe storage, including any incompatibilities

Storage: No special storage required for hazard control. For product protection, follow storage recommendations on the case label, primary product label and insert.

Incompatible products: As a precautionary measure, keep away from strong oxidizers.

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8. Exposure controls/personal protection

Control parameters

Exposure guidelines: The exposure guidelines listed below are for the individual components and not the product itself.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Acetaminophen	Not Available	Not Available	Not Available
Hydrocodone Bitartrate	Not Available	Not Available	Not Available
Ethanol	Not Available	1900 mg/m ³ TWA	1000 ppm TWA
Methylparaben	Not Available	Not Available	Not Available
Edetate Disodium	Not Available	Not Available	Not Available
Sodium Saccharin	Not Available	Not Available	Not Available
Sucrose	10 mg/m ³	15 mg/m ³	10 mg/m ³ TWA
Propylene Glycol	Not Available	10 mg/m ³ TWA (WEEL)	Not Available
Glycerin	10 mg/m ³ TWA	10 mg/m ³ TWA	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
D&C Yellow No. 10	Not Available	Not Available	Not Available
Fruit Flavor	Not Available	Not Available	Not Available

Appropriate engineering controls

Engineering measures: Engineering controls should be used to limit exposure.

Individual protection measures, such as personal protective equipment

Eye/face protection: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin and body protection: Not required under normal conditions of use. Wear protective clothing when working with large quantities.

Respiratory protection: Not required under normal use of the product. If the applicable PEL (Permissible Exposure Limit) is exceeded use an appropriate respirator.

Hygiene measures: Wash hands thoroughly after use.

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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: Solution
 Odor: Fruit
 Appearance: Clear yellow liquid
 Odor threshold: Not available

Property	Values	Remarks/Method
pH	4.0 – 5.0	Current USP
Melting point/range	Not applicable	
Boiling point/boiling range	Not available	
Flash point	Not applicable	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability limits in air	Not applicable	
-upper flammability limit	Not applicable	
-lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	1.0 - 1.2	Current USP
Water solubility	Not applicable	
Solubility in other solvents	Not applicable	
Partition coefficient: n-octanol/water	Not applicable	
Autoignition temperature	Not applicable	
Decomposition temperature	Not applicable	
Viscosity	Not available	
Flammable properties	Not applicable	
Explosive properties	Not applicable	
Oxidizing properties	Not applicable	

Other information VOC content (%)

Alcohol 7%v/v

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10. Stability and reactivity

Reactivity	Stable at normal conditions
Chemical stability	Stable at normal conditions
Possibility of hazardous reactions	Stable at normal conditions
Conditions to avoid	None known
Incompatible materials	As a precautionary measure, keep away from strong oxidizers.
Hazardous decomposition products	None known

11. Toxicological information

Information on likely routes of exposure

Product information:

- Inhalation: Not Available
- Eye contact: Not Available
- Skin contact: Not Available
- Ingestion: Not Available

The information in the table below is for the individual components and not the product.

Chemical name	LD50 oral	LD50 dermal	LC50 inhalation
Acetaminophen	1944 mg/kg Rat	Not Available	Not Available
Hydrocodone Bitartrate	375mg/kg Rat	Not Available	Not Available
Ethanol	3632 mg/kg Mouse	Not Available	20000 ppm 10h Rat
Methylparaben	2100 mg/kg Rat	No skin irritation 24 hr. Rabbit	Not Available
Edetate Disodium	>2000 mg/kg Rat	Not Available	Not Available
Sodium Saccharin	14200 mg/kg Rat	Not Available	Not Available
Sucrose	29700 mg/kg Rat	Not Available	Not Available
Propylene Glycol	20000 mg/kg Rat	20800 mg/kg Rabbit	Not Available
Glycerin	12600 mg/kg Rat	10000 mg/kg Rabbit	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available
D&C Yellow No. 10	Not Available	Not Available	Not Available
Fruit Flavor	Not Available	Not Available	Not Available

Symptoms related to the physical, chemical and toxicological characteristics

Overdose from hydrocodone poisoning includes the opioid triad of pinpoint pupils, respiratory depression and loss of consciousness. Convulsions may occur. In acetaminophen overdose – dose-dependent, potentially fatal hepatic, necrosis is the most serious adverse effect. Renal tubular necrosis may occur. Hypoglycemic coma and thrombocytopenia may also occur.

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Delayed and immediate effects and also chronic effects from short and long term exposure

- Sensitization: No data available
- Mutagenic effects: No data available
- Carcinogenicity: Not carcinogenetic
- Reproductive toxicity: No data available
- STOT – single exposure: No data available
- STOT – repeated exposure: No data available
- Aspiration hazard: No data available

Numerical measures of toxicity – product

- No data available

12. Ecological information

Ecotoxicity Environmental properties have not been thoroughly evaluated. Releases to the environment should be avoided.

Persistence and Degradability No data available

Bioaccumulation No data available

Other adverse effects: No data available

The following table lists the data for the individual components, if available.

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to micro-organisms	Daphnia Magna (water flea)
Acetaminophen	Not Available	814 mg/L 96 hr. Pimephales promelas	Not Available	9.2 mg/L 48 hr.
Hydrocodone Bitartrate	Not Available	Not Available	Not Available	Not Available
Ethanol	Not Available	Not Available	Not Available	Not Available
Methylparaben	91 mg/L 72 hr. Pseudokirchneriella subcapitata	59.5 mg/L 89 hr Oryzias latipes	Not Available	41.1 mg/L 48 hr
Edetate Disodium	10 – 100 mg/L 72 hr	>500 mg/kg 96 hr Leuciscus idus	Not Available	>100 mg/L 24 hr.
Sodium Saccharin	Not Available	Not Available.	Not Available	Not Available
Sucrose	Not Available	Not Available	Not Available	Not Available
Propylene Glycol	Not Available	52930 mg/L 96 hr. Pimephales promelas	Not Available	13020 mg/L 48 hr.
Glycerin	Not Available	58.5 ppm 96 hr Trout	Not Available	Not Available
Sorbitol Solution	Not Available	Not Available	Not Available	Not Available
D&C Yellow No. 10	Not Available	Not Available	Not Available	Not Available
Fruit Flavor	Not Available	Not Available	Not Available	Not Available

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13. Disposal considerations

Waste disposal methods

Dispose of waste in accordance with all federal, state and local regulations.

Contaminated packaging

Dispose of waste in accordance with all federal, state and local regulations.

14. Transport information

Notes:

Not regulated for transport under USDOT, IATA, TDG, IMDG or other regulations.

15. Regulatory information

International inventories**Legend****TSCA:**

United States Toxic Substances Control Act 8(b) inventory not applicable for the drug product. The following components are included on the inventory: Acetaminophen, Ethanol, Methylparaben, Glycerin, Propylene Glycol, Sodium Saccharin Dihydrate, Sucrose and D&C Yellow No. 10.

EINECS:

Acetaminophen, Hydrocodone Bitartrate, Ethanol 200 proof, Propylene Glycol, Glycerin, Sodium Saccharin Dihydrate, Sucrose, Methylparaben, Edetate Disodium and D&C Yellow No. 10 are listed on the EINECS inventory.

U.S. Federal regulations**OSHA Label:**

Not Applicable

US DEA:

Schedule II substance

SARA 311/312 Hazard categories:

Not Applicable

Clean Water Act:

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)

CERCLA:

No components are listed under CERCLA.

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California Proposition 65:

This product does contain Ethanol and Sodium Saccharin which are listed as a Proposition 65 chemicals.

U.S. state Right-to-Know regulations

"X" designates that the ingredients are listed on the state Right-to-Know list

Chemical name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Acetaminophen	X		X		
Hydrocodone Bitartrate	X		X		
Ethanol 200 Proof	X	X	X	X	X
Methylparaben	X		X		
Edetate Disodium					
Sodium Saccharin	X	X	X		
Sucrose	X	X	X		
Propylene Glycol	X		X		
Glycerin	X	X	X	X	X
Sorbitol Solution	X		X		
Fruit Flavor					
D&C Yellow No. 10					

U.S. EPA label information:

Not applicable

16. Other information

Prepared by:

Pharmaceutical Associates Regulatory Affairs Department

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Revision note:

Revision 01:

- Deleted NDC numbers 0121-4772-10, 0121-4772-15.
- Added NDC number 0121-4772-40, 0121-1544-10, 0121-1544-40, 0121-2316-15, 0121-2316-40
- Corrected Section 5, Specific Hazards to say "Not Applicable"

General Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet