SAFETY DATA SHEET

Issue Date 25-Nov-2014 **Revision Date** 18-Sep-2015 **Version** 1.1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION

Product Name Hysingla® ER (hydrocodone bitartrate) extended-release tablets

Synonyms Hydrocodone Bitartrate Film Coated Tablets 20, 30, 40, 60, 80, 100, and 120 mg Tablets CII; HYD

Other Information **This is a controlled substance under Schedule II of the Controlled Substances Act.**

Recommended Use Opioid analgesic

Uses advised against Do not use without a prescription.

Manufacturer Address Purdue Pharma L.P.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901-3431
(888) 726-7535

24 Hour Emergency Phone Number Chemtrec (800) 424-9300
For all international transportation emergencies, call Chemtrec collect at (703) 527-3887.

2. HAZARDS IDENTIFICATION

Drugs when in solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard, 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

Emergency Overview

Appearance Tablet **Physical state** Solid **Odor** Odorless

Hazards Not Otherwise Classified (HNOC)
Not Applicable.

Other Information
No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Family Opioid analgesic.

Chemical Name	CAS No	Weight %
Hydrocodone bitartrate	143-71-5	15-20
Hydroxypropyl cellulose	9004-64-2	1-5
Cellulose, Powdered (microcrystalline)	9004-34-6	1-5
Polyethylene oxide	25322-68-3	75-80

4. FIRST AID MEASURES

First aid measures

Eye contact In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

Skin contact In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.

Inhalation In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.

Ingestion In case of accidental ingestion, wash out mouth with copious amounts of water. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Self-protection of the first aider Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms and effects, both acute and delayed

Symptoms 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.

Indication of any immediate medical attention and special treatment needed

Note to physicians This material is an opioid or derivative. Reduced sensation of pain, CNS effects, and opioid related effects may occur, including respiratory depression. Naloxone has been known to counter the effects of opioids.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media No information available.

Specific hazards arising from the chemical
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Explosion Data
Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Evacuate personnel to safe areas. Use personal protection recommended in Section 8.

Other Information Do not break or crush tablets. Avoid procedures that will generate dust. Local exhaust is recommended to avoid exposure to significant airborne dust levels from broken or crushed tablets. Avoid contact with eyes, skin, or clothing. Wash thoroughly after handling. Wash contaminated clothing after use.

Environmental precautions

Environmental precautions See section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Wear suitable protective clothing and equipment. Sweep up intact tablets or vacuum up cut, broken or crushed tablets and place collected material into a suitable container for reclamation or disposal. Thoroughly wash area with detergent and water. Hydrocodone bitartrate is a Schedule II controlled substance. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented. Notify appropriate company regulatory personnel. Dispose of all solid waste and wash and rinse water in accordance with federal, state, and local regulations.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Avoid contact with skin, eyes or clothing. Wash thoroughly after handling. Wash contaminated clothing before reuse. Avoid generation of dust and accumulation. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.

Conditions for safe storage, including any incompatibilities

Storage conditions Hydrocodone hydrochloride is a Schedule II Controlled Substance and requires DEA-compliant storage. Keep containers tightly closed. Protect from light. To maintain potency, store at 25°C (77°F) and control temperature excursions to between 15-30°C (59-86°F).

Incompatible materials None known based on available information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Cellulose, Powdered (microcrystalline) 9004-34-6	TWA: 10 mg/m³ Upper respiratory irritant	TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction	TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust TWA: 1 mg/m³

Chemical Name	Performance-Based Exposure Band (PBEB)	Company OEG (ug/m³)
Hydrocodone bitartrate	None	40

Engineering Controls None under normal use conditions.

Individual Protection Measures (Personal Protective Equipment)

Eye/face protection	None required for consumer use. In laboratory or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting or possibility of splashing. Contact a health and safety professional for specific information.
Skin and body protection	None required for consumer use. In laboratory or industrial settings, gloves and lab coats are recommended. Contact a health and safety professional for specific information.
Respiratory protection	Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. In the United States of America, if respirators are used, they are to be NIOSH-approved and part of a respiratory protection program instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.
General Hygiene Considerations	Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties

Physical state	Solid
Appearance	Tablet
Odor	Odorless
Color	Green 20 mg, yellow 30 mg, grey 40 mg, beige 60 mg, pink 80 mg, blue 100 mg, white 120 mg.
Odor threshold	No information available.

Property	**Values**	**Remarks • Method**
pH	No information available.	
Melting point / melting range	No information available.	
Boiling point / boiling range	No information available.	
Flash point	No information available.	
Evaporation rate	No information available.	
Flammability (solid, gas)	No information available.	
Flammability limits in air		
Upper flammability limits		
Lower flammability limits		
Vapor pressure	No information available.	
Vapor density	No information available.	
Specific gravity	No information available.	
Water solubility	No information available.	
Solubility in other solvents	No information available.	
Partition coefficient (n-octanol/water)	No information available.	
Autoignition temperature	No information available.	
Decomposition temperature	No information available.	
Kinematic viscosity	No information available.	
Dynamic viscosity	No information available.	
Explosive properties	No information available.	
Oxidizing properties	No information available.	

Other Information

Softening point	No information available.
Molecular weight	No information available.
VOC content; (%)	No information available.
Density	No information available.
Bulk density	No information available.

10. STABILITY AND REACTIVITY

Chemical stability Stable under recommended storage conditions.

Possibility of hazardous reactions No information available.
Hazardous polymerization Hazardous polymerization does not occur.
Conditions to avoid None known based on available information.
Incompatible materials None known based on available information.
Hazardous decomposition products None known based on available information.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information No data available.

Inhalation No data available.

Eye contact No data available.

Skin contact No data available.

Ingestion No data available.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Hydrocodone bitartrate	375 mg/kg (Rat)	-	-
Hydroxypropyl cellulose	10200 mg/kg (Rat)	-	-
Cellulose, Powdered (microcrystalline)	5 g/kg (Rat)	2 g/kg (Rabbit)	5800 mg/m^3 (Rat) 4 h
Polyethylene oxide	28 g/kg (Rat)	20 mL/kg (Rabbit) 20 g/kg (Rabbit)	-

Information on toxicological effects

Symptoms 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.

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Irritation No information available.

Sensitization No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Germ cell mutagenicity Hydrocodone was negative in the Ames reverse bacterial mutagenicity assay, a Drosophila germ cell test, and a mouse bone marrow micronucleus study.

Carcinogenicity No data found. Not listed by IARC, NTP or USOSHA.

Reproductive toxicity The potential reproductive/embryo toxicity of hydrocodone bitartrate was evaluated in 4 studies (rat and rabbit teratogenicity studies with NOAELs of 10 mg/kg for both studies based on opioid-related pharmacological effects at 30 mg/kg; a rat pre- and post-natal study in 2 generations with a NOAEL of 30 mg/kg, the highest dose tested; and a rat fertility study in both males and females with a NOAEL of 25 mg/kg, the highest dose tested). Collective results from these aforementioned studies suggest that HYD is neither

teratogenic nor a reproductive toxicant to animals.

STOT-single exposure Respiratory system. Central Nervous System (CNS).

STOT-repeated exposure Respiratory system. Central Nervous System (CNS).

Target Organ Effects Respiratory system. Central Nervous System (CNS).

Aspiration hazard No information available.

The following values are calculated based on chapter 3.1 of the GHS document.

Oral LD50 1384 mg/kg
Dermal LD50 2000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity None known

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Polyethylene oxide		LC50 24 h > 5000 mg/L (Carassius auratus)		

Persistence and degradability No information available.

Bioaccumulation No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national, and local laws, and regulations.

Contaminated Packaging Do not reuse container.

14. TRANSPORT INFORMATION

Note: This material is not subject to regulation as a hazardous material for shipping.

DOT Not regulated.

IATA Not regulated.

15. REGULATORY INFORMATION

Hysingla is a DEA Scheduled II controlled substance.

International Inventories

TSCA Not determined.
DSL Not determined.

Legend:
TSCA - United States Toxic Substances Control Act Section 8 (b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

US Federal Regulations

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

CWA (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
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals.

US State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Cellulose, Powdered (microcrystalline) 9004-34-6	X	X	X

US EPA Label Information
EPA Pesticide Registration Number Not Applicable.

16. OTHER INFORMATION

NFPA	**Health Hazards** 1	**Flammability** 0	**Instability** 0	**Physical and Chemical Properties** *
HMIS	**Health Hazards** 1	**Flammability** 0	**Physical Hazards** 0	**Personal protection** X

Chronic Hazard Star Legend * = *Chronic Health Hazard*

General Information In an industrial setting, refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for Safe Handling.

Prepared By This SDS was prepared by the Occupational and Environmental Assessment Section of Purdue Pharma L.P.

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Disclaimer
The information contained in this Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Safety Data Sheet relate only to the specific material designated herein and do not relate to use in

combination with any other material. The data in this Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

End of Safety Data Sheet