



Safety Data Sheet

Acetaminophen and Codeine Phosphate Tablets, USP 300mg/15mg, 300mg/30mg and 300mg/60mg

Date: 07/26/2019 Revision: 00

SECTION 1: Identification

1.1. Identification

Product form : Tablet
Product name : Acetaminophen and Codeine phosphate Tablets, USP

1.2. Recommended use and restrictions on use

Recommended use : Pharmaceuticals (Pain Management)
Restrictions on use : No additional information available.

1.3. Supplier

WES Pharma Inc
1221 Tech Court
Westminster, MD- 21157
USA
+1 (410) 861-6444

1.4. Emergency telephone number

Emergency number : +1 (888) 212-6921

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Physical Hazards : Not Classified
Health Hazards : Not Classified
OSHA Defined Hazards : Not Classified

Label Element

- Hazard Symbol : None
- Signal Word : Warning

- Hazard 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.

Precautionary Statement

- Prevention : Observe good industrial hygiene practices.
- Response : Wash hands after handling
- Storage : Store away from incompatible materials. Protect from moisture. Store at 20 – 25 °C (68 - 77°F).
- Disposal : Dispose of in accordance with applicable laws and regulations.

2.2. Other hazards which do not result in classification

No additional information available



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SECTION 3: Composition/Information on Ingredients

3.1. Substances

Chemical Name	Product Identifier	%
Acetaminophen	(CAS-No.) 103-90-2	~67%
Codeine Phosphate	(CAS-No.) 41444-62-6	3-12%

SECTION 4: First-Aid Measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: call a poison center or a doctor.
First-aid measures after skin contact	: Wash skin with plenty of water. Wash contaminated clothing before reuse. If skin irritation or rash occurs get medical advice/attention. Keep work clothing separately.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. DO NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor if you feel unwell. If vomiting occurs, keep head low so that stomach content doesn't get into lungs. Never give anything by mouth to an unconscious person. Do not apply mouth-to-mouth resuscitation. Apply artificial respiration if victim is not breathing.

4.2. Most important symptoms and effects (acute and delayed)

Potential adverse human health effects and symptoms	: Dizziness, headaches, nausea. May cause stomach cramps and vomiting. Drowsiness. Lethargy. Impaired concentration. Impaired memory. Impairment of the nervous system. Anxiety, fear, dysphoria, psychic dependence, mood changes. Respiratory depression.
Symptoms/effects	: Abuse, Addition and Misuse. May cause damage to organs. May cause damage to organs through prolonged or repeated exposure.
Symptoms/effects after inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause respiratory irritation. This material or its emissions may affect the central nervous system and/or aggravate pre-existing disorders. May cause drowsiness or dizziness.
Symptoms/effects after skin contact	: Causes skin irritation. May cause an allergic skin reaction, rash, urticarial.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Swallowing a large quantity of this material will result in serious health hazard. May cause a light irritation of the linings of the mouth, throat, and gastrointestinal tract. Dizziness, headaches, nausea. Vomiting. Diarrhea. May cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, respiratory depression, tolerance, dependence, and withdrawal.
Chronic symptoms	: Respiratory arrest, shock, cardiac arrest



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4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically. Give activated charcoal.

SECTION 5: Fire-Fighting Measures

5.1. Immediate medical attention and special treatment, if necessary

Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Specific hazards arising from the chemical

Fire hazard : Combustible Dust.
Explosion hazard : Dust may form explosive mixture in air.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering the environment.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal Precaution, protective equipment and emergency

General measures : Avoid contact with skin, eyes and clothing. Do not breathe dust. Eliminate every possible source of ignition.

For non-emergency personnel

Protective equipment : Refer to Section 8.3
Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Refer to Section 8.3.
Emergency procedures : Ventilate area.

6.2. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.
Other information : All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented following DEA guidelines.
Prevent entry to sewers and public waters. Avoid release to the environment.
Environmental Precaution : Prevent entry to sewers and public waters. Avoid release to the environment

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.



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SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Precautions for safe handling	: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor. Avoid creating or spreading dust. Avoid contact with skin, eyes and clothing. Do not breathe dust. Eliminate all ignition sources if safe to do so. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep out of direct sunlight.
Hygiene measures	: Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep only in the original container in a cool well-ventilated place.
Incompatible products	: Strong bases. Strong acids. Strong oxidizers.
Incompatible materials	: Sources of ignition. Direct sunlight.
Storage area	: Controlled substances. Location of storage area must comply with all Drug Enforcement Agency regulations.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

Acetaminophen (103-90-2)

Not applicable

Codeine Phosphate (41444-62-6)

Not applicable

8.2. Appropriate engineering controls

Appropriate engineering controls	: Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Provide local exhaust or general room ventilation.
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8.3. Individual protection measures/Personal protective equipment

Personal protective equipment	: Avoid all unnecessary exposure.
Hand protection	: Wear protective gloves.
Eye protection	: Chemical goggles or safety glasses
Skin and body protection	: Wear suitable protective clothing
Respiratory protection	: In case of inadequate ventilation wear respiratory protection.
Other information	: Do not eat, drink or smoke during use.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Tablets
Color	: Variable
Odor	: Odorless
Odor threshold	: No data available
pH	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available



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Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: Non-flammable
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log P _{ow}	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Explosive limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and Reactivity

10.1. Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport

10.2. Chemical stability

Material is stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures. Avoid dust formation.

10.5. Incompatible materials

As a precautionary measures, keep away from strong oxidizers.

10.6. Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological Information

11.1. Information on toxicological effects

Likely routes of exposure	: Ingestion; Skin and Eye contact
Acute toxicity	: Oral: Harmful if swallowed in large quantities.

Components	Species	Test Results
Acetaminophen (CAS 103-90-2)		
Acute Oral LD ₅₀	Rat	1944mg/kg
Codeine Phosphate (CAS 1)		
Acute Oral LD ₅₀	Rat	85mg/kg

Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitization	: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified.



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Carcinogenicity : Not classified.

Acetaminophen (103-90-2)	
IARC group	3 - Not classifiable

Reproductive toxicity : Not classified

Specific target organ toxicity

- Single Exposure : May cause damage to organs (kidneys, liver).
 - Repeated Exposure : May cause damage to organs (liver) through prolonged or repeated exposure.
- Aspiration hazard : Due to the physical form of the product it is not an aspiration hazard
- Symptoms/Effects after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause drowsiness or dizziness.
- Symptoms/Effects after skin contact : Causes skin irritation. May cause an allergic skin reaction, rash, urticarial.
- Symptoms/effects after ingestion : Swallowing a small quantity of this material will result in serious health hazard. May cause a light irritation of the linings of the mouth, throat, and gastrointestinal tract. Dizziness, headaches, nausea, vomiting, diarrhea. May cause sedation, pinpoint pupils, mood alterations, nausea, vomiting, respiratory depression, tolerance, dependence, and withdrawal
- Chronic symptoms : Respiratory arrest, shock, cardiac arrest

SECTION 12: Ecological Information

12.1. Toxicity

The product is not classified as environmentally hazardous. Release to the environment should be avoided

12.2. Persistence and degradability

No data is available on the degradability of this product

12.3. Bio accumulative potential

No data available.

12.4. Mobility in soil

No additional information available.

12.5. Other adverse effects

None

SECTION 13: Disposal Considerations

13.1. Disposal methods

- Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.
- Additional information : Notify site Controlled Substance Compliance officer and local DEA office or competent authority for appropriate disposal procedures.
- Ecology - waste materials : Avoid release to the environment.



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SECTION 14: Transport Information

Department of Transportation (DOT)

In accordance with DOT : Not regulated
Transport by sea : Not regulated.
Air transport : Not regulated.

SECTION 15: Regulatory Information

15.1. US Federal regulations

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DEA: Listed under DEA Schedule III controlled substances.

FDA: Acetaminophen and Codeine Phosphate Tablets USP, CIII are an approved prescription medication.

Acetaminophen (CAS 103-90-2)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Codeine Phosphate (CAS 41444-62-6)

EPA TSCA Regulatory Flag Exempt from TSCA: Pharmaceutical/drug substance

15.2. International Regulations

CANADA

Canada

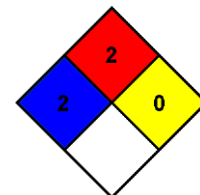
Listed on the Canadian DSL (Domestic Substances List) inventory.

United States and Puerto Rico

Toxic Substances Control Act (TSCA) Inventory is not applicable for this product

SECTION 16: Other information

NFPA health hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.
NFPA fire hazard : 2 - Materials that must be moderately heated or exposed to relatively high ambient temperatures before ignition can occur.
NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and not reactive with water.



Abbreviations and Acronyms:

CAS	Chemical Abstracts Service number
CLP	Classification, Labelling, Packaging
EC50	Environmental Concentration associated with a response by 50% of the test population
GHS	Globally Harmonized System of Classification and Labeling of Chemicals
LD50	Lethal Dose for 50% of the test population
OSHA	Occupational Safety & Health Administration
TSCA	Toxic Substances Control Act



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