

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Trade name : Actimask™ Acetaminophen 92M (Taste-Masked)

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

Use of the substance/mixture : Pharmaceutical ingredient

1.3. Details of the supplier of the safety data sheet

SPI Pharma Inc.
Rockwood Office Park
503 Carr Road
Wilmington, Delaware 19809
(302) 360-7200

1.4. Emergency telephone number

Emergency number : Chemtrec (800) 424-9300; Chemtrec (Outside USA) +1 703-527-3887 (24 hours; 7 days/week)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Eye Irrit. 2 H319
Acute Tox. 4 (Inhalation) H332
STOT SE 3 H335

2.2. Label elements

GHS-US labelling

Hazard pictograms :



Signal word : GHS07
Warning

Signal word : Warning

R-phrases : R22 - Harmful if swallowed
R64 - May cause harm to breastfed babies.
R36/37/38 - Irritating to eyes, respiratory system and skin.

S-phrases : S22 - Do not breathe dust
S35 - This material and its container must be disposed of in a safe way
S24/25 Avoid contact with skin and eyes.
S45 In case of accident or you feel unwell seek medical advice immediately (show the label where possible).

Precautionary statements (CLP) : P280 - Wear eye protection, face protection, protective clothing, protective gloves.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS-US)

No data available

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according to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

SECTION 3: Composition/information on ingredients

3.1. Substance

Name : Actimask™ Acetaminophen 92M (Taste-Masked)

Name	Product identifier	%	GHS-US classification
Acetaminophen	(CAS No) 103-90-2	60-95	Xi; R22; R36/37/38; R64 Eye Irrit. 2, H319
Proprietary coating 1	Proprietary	<40	Not classified
Proprietary coating 2	Proprietary	<5	Not classified

3.2. Mixture

Not applicable

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	: Assure fresh air breathing. Allow the victim to rest. In all cases of doubt, or when symptoms persist, seek medical advice.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention if irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. If a large quantity has been ingested : Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries after inhalation	: Overexposure to dusts may produce slight irritation of the respiratory system.
Symptoms/injuries after eye contact	: May cause slight irritation to eyes.
Symptoms/injuries after ingestion	: On ingestion in large quantities : may cause gastrointestinal disturbance.

4.3. Indication of any immediate medical attention and special treatment needed

None known.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Explosion hazard	: Accumulation of airborne dusts may present an explosion hazard in the presence of an ignition source.
Reactivity	: Stable.

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

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6.3. Methods and material for containment and cleaning up

- For containment : Contain the discharged material using dust suppressant.
Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Provide adequate ventilation. Avoid contact with eyes. Avoid generation of dust. Remove all sources of ignition. Use only non-sparking tools. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store at room temperature. Keep container tightly closed.
Incompatible products : Strong bases. Strong acids. Strong oxidizing agents.
Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

- Appropriate engineering controls : Provide local exhaust or general room ventilation to minimize exposure to dust. Exposures should be minimized in accordance with good industrial hygiene practices.
Personal protective equipment : Avoid all unnecessary exposure. Protective goggles. Gloves.



- Hand protection : Wear protective gloves.
Eye protection : Chemical goggles or safety glasses.
Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.
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
Color : White
odor : None
Odor threshold : No data available
pH : No data available
Relative evaporation rate (butylacetate=1) : No data available
Melting point : No data available
Freezing point : No data available
Boiling point : Not applicable
Flash point : No data available
Self ignition temperature : No data available
Decomposition temperature : No data available
Flammability (solid, gas) : Non flammable.
Vapour pressure : Not applicable
Relative vapour density at 20 °C : No data available
Relative density : No data available

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Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Avoid accumulation of airborne dusts, heat, high temperatures, pressure, mechanical shock or other conditions that might result in a hazardous situation.

10.5. Incompatible materials

strong acids. Strong bases.

10.6. Hazardous decomposition products

Upon thermal decomposition, this product emits carbon monoxide, carbon dioxide, nitrogen oxides and hydrocarbon fragments. In the presence of heat and water, acetaminophen will hydrolyze to yield acetic acid and p-aminophenol.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acetaminophen (203-157-5)

LD50 oral rat	1944 mg/kg
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Proprietary component 1 (Proprietary)

LD50 oral rat	>2000 mg/kg
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No additional information available

12.2. Persistence and degradability

Actimask™ Acetaminophen 92M (Taste-Masked)

Persistence and degradability	Not established.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on ozone layer : No additional information available

Effect on the global warming : No known ecological damage caused by this product.

Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Empty containers should be rinsed and discarded in a waste container or offered for recycling if possible. Do not re-use empty containers except for storage and shipment of original product.

Ecology - waste materials : Avoid release to the environment.

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SECTION 14: Transport information

In accordance with DOT

Not regulated for transport

Additional information

Other information : No supplementary information available.

ADR

Transport document description :

Transport by sea

No additional information available

Air transport

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

No additional information available

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

Classification according to Regulation (EC) No. 1272/2008 [CLP]

No additional information available

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

No additional information available

15.2.2. National regulations

No additional information available

15.3. US State regulations

No supplementary information available

SECTION 16: Other information

Abbreviations and acronyms : ATE - acute toxicity estimate. CAS - Chemical Abstracts Service. HCS - Hazard Communication Standard. HMIS - Hazardous Materials Identification System. GHS - Globally Harmonised System. OSHA - Occupational Safety and Health Administration. SDS - Safety Data Sheet.

Date of SDS preparation : 05/01/2015

Other information : None.

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product