

SAFETY DATA SHEET

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING**Product identifier**

Product Name Acetaminophen 500mg Phenylephrine HCl 5mg Tablets; Allegiant Health Code 261

Other means of identification

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Medicinal products

Uses advised against No information available

Details of the supplier of the safety data sheet

Supplier Name Allegiant Health

Supplier Address 75 North Industry Court
Deer Park
New York
11729
US

Supplier Phone Number Phone:631-940-9000
Fax:631-940-9591

Supplier Email dporti@allegiant-health.com

Emergency telephone number

Company Emergency Phone Number 631-940-9000

2. HAZARDS IDENTIFICATION**Classification**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Skin sensitization	Category 1
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GHS Label elements, including precautionary statements

Emergency Overview

Signal word	Warning
Hazard Statements May cause an allergic skin reaction	
	
Appearance White	Physical state Solid
Odor Odorless	

Precautionary Statements - Prevention

Avoid breathing dust/fume/gas/mist/vapors/spray
Contaminated work clothing should not be allowed out of the workplace
Wear protective gloves

Precautionary Statements - Response

Specific treatment (see supplemental first aid instructions on this label)

Skin

IF ON SKIN: Wash with plenty of soap and water
If skin irritation or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse

Precautionary Statements - Storage

None

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Hazards not otherwise classified (HNOC)

Not applicable

Unknown Toxicity

0 % of the mixture consists of ingredient(s) of unknown toxicity

Other information

May be harmful if swallowed
Toxic to aquatic life with long lasting effects
Repeated or prolonged skin contact may cause allergic reactions with susceptible persons

Interactions with Other Chemicals

No information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No	Weight-%	Trade Secret
Acetaminophen (4-Hydroxyacetanilide)	103-90-2	60 - 100	*
Microcrystalline cellulose	9004-34-6	7 - 13	*
Phenylephrine hydrochloride	61-76-7	0.1 - 1	*

*The exact percentage (concentration) of composition has been withheld as a trade secret

4. FIRST AID MEASURES

First aid measures

General Advice

Show this safety data sheet to the doctor in attendance.

Eye contact

Rinse thoroughly with plenty of water, also under the eyelids. If symptoms persist, call a physician.

Skin contact

Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

Inhalation

Remove to fresh air.

Ingestion

Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed

Most Important Symptoms and Effects

Itching. Rashes. Hives.

Indication of any immediate medical attention and special treatment needed

Notes to Physician

May cause sensitization in susceptible persons. Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media

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

Unsuitable extinguishing media

CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical

Product is or contains a sensitizer. May cause sensitization by skin contact.

Uniform Fire Code

Sensitizer: Solid

Hazardous Combustion Products

Carbon oxides.

Explosion Data

Sensitivity to Mechanical Impact No.

Sensitivity to Static Discharge No.

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

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Environmental precautions

Environmental precautions

Refer to protective measures listed in Sections 7 and 8.

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

Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.

Incompatible Products None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Microcrystalline cellulose 9004-34-6	TWA: 10 mg/m ³	TWA: 15 mg/m ³ total dust TWA: 5 mg/m ³ respirable fraction (vacated) TWA: 15 mg/m ³ total dust (vacated) TWA: 5 mg/m ³ respirable fraction	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits NIOSH IDLH Immediately Dangerous to Life or Health

Other Exposure Guidelines Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992)

Appropriate engineering controls

Engineering Measures Showers
Eyewash stations
Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin and body protection Wear protective gloves and protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

Hygiene Measures Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical and Chemical Properties



Physical state	Solid		
Appearance	White	Odor	Odorless
Color	No information available	Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	No data available	None known	
Melting / freezing point	No data available	None known	
Boiling point / boiling range	No data available	None known	
Flash Point	No data available	None known	
Evaporation Rate	No data available	None known	
Flammability (solid, gas)	No data available	None known	
Flammability Limit in Air			
Upper flammability limit	No data available		
Lower flammability limit	No data available		
Vapor pressure	No data available	None known	
Vapor density	No data available	None known	
Specific Gravity	No data available	None known	
Water Solubility	No data available	None known	
Solubility in other solvents	No data available	None known	
Partition coefficient: n-octanol/water	No data available	None known	
Autoignition temperature	No data available	None known	
Decomposition temperature	No data available	None known	
Kinematic viscosity	No data available	None known	
Dynamic viscosity	No data available	None known	
Explosive properties	No data available		
Oxidizing properties	No data available		

Other Information

Softening Point	No data available
VOC Content (%)	No data available
Particle Size	No data available
Particle Size Distribution	

10. STABILITY AND REACTIVITY

Reactivity

No data available.

Chemical stability

Stable under recommended storage conditions.

Possibility of Hazardous Reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

None known based on information supplied.

Incompatible materials

None known based on information supplied.

Hazardous Decomposition Products

Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure



Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Acetaminophen (4-Hydroxyacetanilide) 103-90-2	= 1944 mg/kg (Rat)	-	-
Microcrystalline cellulose 9004-34-6	> 5 g/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h

Information on toxicological effects

Symptoms Itching. Rashes. Hives.

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

Sensitization May cause sensitization in susceptible persons. May cause sensitization by skin contact.

Mutagenic Effects No information available.

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical Name	ACGIH	IARC	NTP	OSHA
Acetaminophen (4-Hydroxyacetanilide) 103-90-2		Group 3		
Microcrystalline cellulose 9004-34-6		-	-	-

*IARC (International Agency for Research on Cancer)
Group 3 - Not Classifiable as to Carcinogenicity in Humans*

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Chronic Toxicity No known effect based on information supplied. Contains a known or suspected carcinogen.

Target Organ Effects Skin.

Aspiration Hazard No information available.

Numerical measures of toxicity Product Information

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

ATEmix (oral)
2,238.00 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxic to aquatic life with long lasting effects.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Acetaminophen (4-Hydroxyacetanilide) 103-90-2		96h LC50: = 814 mg/L (Pimephales promelas)	EC50 = 1000 mg/L 30 min EC50 = 1050 mg/L 15 min EC50 = 1120 mg/L 5 min	48h EC50: 6.1 - 14 mg/L

Persistence and Degradability

No information available.

Bioaccumulation

Chemical Name	Log Pow
Acetaminophen (4-Hydroxyacetanilide) 103-90-2	0.51

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal methods

This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261). This material could become a hazardous waste if it is mixed with or otherwise comes in contact with a hazardous waste, if chemical additions are made to this material, or if the material is processed or otherwise altered. Consult 40 CFR 261 to determine whether the altered material is a hazardous waste. Consult the appropriate state, regional, or local regulations for additional requirements.

Contaminated Packaging

Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION

<u>DOT</u>	NOT REGULATED
Proper Shipping Name	NON REGULATED
Hazard Class	N/A

<u>TDG</u>	Not regulated
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<u>MEX</u>	Not regulated
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<u>ICAO</u>	Not regulated
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IATA	Not regulated
Proper Shipping Name	NON REGULATED
Hazard Class	N/A
IMDG/IMO	Not regulated
Hazard Class	N/A
RID	Not regulated
ADR	Not regulated
ADN	Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Complies
DSL	All components are listed either on the DSL or NDSL.

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.

Chemical Name	California Proposition 65
Microcrystalline cellulose - 9004-34-6	-

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Rhode Island	Illinois
Microcrystalline cellulose	X	X	X	-	X



9004-34-6					
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International Regulations

Mexico

National occupational exposure limits

Component	Carcinogen Status	Exposure Limits
Microcrystalline cellulose 9004-34-6 (7 - 13)		Mexico: TWA 10 mg/m ³ Mexico: STEL 20 mg/m ³

Mexico - Occupational Exposure Limits - Carcinogens

Canada

WHMIS Hazard Class

Not determined

16. OTHER INFORMATION

NFPA	Health Hazards 2	Flammability 0	Instability 0	Physical and Chemical Hazards -
HMIS	Health Hazards 2	Flammability 0	Physical Hazard 0	Personal Protection X

Prepared By Product Stewardship
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27-Sep-2015

Revision Note

No information available

Disclaimer

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End of Safety Data Sheet