

Non-aspirin Pain Relief Extra Strength, Non-aspirin Pain Relief

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 03/17/2015 Date of issue: 03/17/2015

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Non-aspirin Pain Relief Extra Strength, Non-aspirin Pain Relief

Product Code: 010, 012

Synonyms: Tylenol

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutical

Use only as directed

Refer to product insert for usage instructions and product information.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Allegiant Health

75 North Industry Court

Deer Park, New York 11729

1-631-940-9000

1.4. Emergency Telephone Number

Emergency Number : 1-631-940-9000 (Monday-Friday: 9:00 AM–4:00PM EST)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Classification (GHS-US)

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.). It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(5)(iii)

2.2. Label Elements

GHS-US Labeling

No labelling applicable

2.3. Other Hazards

Exposure to dust may aggravate those with pre-existing eye, skin, or respiratory conditions.

Contains combustible dusts.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
Acetaminophen	(CAS No) 103-90-2	90	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1B, H317 Aquatic Acute 3, H402
Starch	(CAS No) 9005-25-8	4 - 40	Comb. Dust
Starch, 2-hydroxyethyl ether	(CAS No) 9005-27-0	3 - 40	Comb. Dust
Corn Starch Diphosphate	(CAS No) RR-36136-4	4 - 40	Not classified
Starch, hydrolyzed	(CAS No) 68412-29-3	3 - 35	Comb. Dust
2-Pyrrolidinone, 1-ethenyl-, homopolymer	(CAS No) 9003-39-8	1 - 6	Comb. Dust
N-Vinyl-2-pyrrolidone	(CAS No) 88-12-0	1 - 6	Acute Tox. 4 (Oral), H302 Acute Tox. 3 (Dermal), H311 Acute Tox. 4 (Inhalation:dust,mist), H332 Aquatic Acute 3, H402
Stearic acid	(CAS No) 57-11-4	1 - 5	Comb. Dust

Non-aspirin Pain Relief Extra Strength, Non-aspirin Pain Relief

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Croscarmellose sodium	(CAS No) 74811-65-7	2 - 5	Not classified
Sodium carboxymethyl cellulose	(CAS No) 9004-32-4	2 - 5	Comb. Dust
Octadecanoic acid	(CAS No) 85404-83-7	1 - 5	Not classified
Starch, food, modified: Starch sodium octenyl succinate	(CAS No) 66829-29-6	0 - 1	Not classified

Full text of H-phrases: see section 16

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: The risk of inhalation exposure is negligible when product is in its final packaged form. When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if symptoms persist.

First-aid Measures After Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

First-aid Measures After Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

First-aid Measures After Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention. Do NOT induce vomiting.

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

Symptoms/Injuries: Please refer to the package insert for more detailed information.

Symptoms/Injuries After Inhalation: None expected under normal conditions of use. Dust may cause respiratory irritation.

Symptoms/Injuries After Skin Contact: None expected under normal conditions of use. Dust causes skin irritation. Dust may cause an allergic skin reaction. Symptoms may include redness, pain, swelling, itching, burning, dryness, and dermatitis.

Symptoms/Injuries After Eye Contact: May cause minor eye irritation. Dust causes serious eye irritation. Symptoms may include redness, pain, swelling, itching, burning, tearing, and blurred vision.

Symptoms/Injuries After Ingestion: Harmful if swallowed. Potent pharmaceutical- ingestion may be harmful or have adverse effects.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not flammable.

Explosion Hazard: Product is in pill form, but contains substances that are combustible dusts. Product itself is not explosive but if dust is generated, dust clouds suspended in air can be explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Fire may produce irritating and/or toxic gases. Risk of dust explosion.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not allow product to spread into the environment. Avoid all contact with skin, eyes, or clothing. Avoid generating or breathing dust.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Eliminate ignition sources. Stop leak/dust if safe to do so. Ventilate area.

Non-aspirin Pain Relief Extra Strength, Non-aspirin Pain Relief

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

Methods for Cleaning Up: For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal. If dust is present: vacuum clean-up is preferred. Use explosion proof vacuum during cleanup, with appropriate filter, and do not mix with other materials. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection. For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Heating of product can release toxic or irritating fumes; ensure proper ventilation is employed, proper precautions are enforced, and applicable regulations are followed. Accumulation and dispersion of dust with an ignition source can cause a combustible dust explosion. Keep dust levels to a minimum and follow applicable regulations.

Hygiene Measures: This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin, and clothing. Avoid breathing dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store in a dry, cool, and well-ventilated place. Keep/Store away from extremely high or low temperatures, ignition sources, direct sunlight, incompatible materials.

Incompatible Products: Strong acids. Strong bases. Strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical. Refer to product insert for usage instructions and product information.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Starch (9005-25-8)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)
N-Vinyl-2-pyrrolidone (88-12-0)		
USA ACGIH	ACGIH TWA (ppm)	0.05 ppm
USA ACGIH	ACGIH chemical category	Confirmed Animal Carcinogen with Unknown Relevance to Humans

8.2. Exposure Controls

Appropriate Engineering Controls

: Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective goggles. Protective clothing.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear chemically resistant protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: Use a NIOSH-approved respirator whenever exposure may exceed established Occupational Exposure Limits.

Non-aspirin Pain Relief Extra Strength, Non-aspirin Pain Relief

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: Tablet
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. **Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. **Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight. Extremely high or low temperatures. Sources of ignition. Incompatible materials
- 10.5. **Incompatible Materials:** Strong oxidizers. Strong bases. Strong acids.
- 10.6. **Hazardous Decomposition Products:** Thermal decomposition generates: Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Oral: Harmful if swallowed.

Non-aspirin Pain Relief Extra Strength, Non-aspirin Pain Relief	
ATE (Oral)	534.11 mg/kg body weight
Acetaminophen (103-90-2)	
ATE (Oral)	500.00 mg/kg body weight
Sodium carboxymethyl cellulose (9004-32-4)	
LD50 Oral Rat	27000 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 5800 mg/m ³ (Exposure time: 4 h)
Starch, 2-hydroxyethyl ether (9005-27-0)	
LD50 Oral Rat	> 50000 mg/kg
N-Vinyl-2-pyrrolidone (88-12-0)	
LD50 Oral Rat	830 mg/kg
LD50 Dermal Rabbit	560 mg/kg
LC50 Inhalation Rat	3.07 mg/l/4h
Octadecanoic acid (85404-83-7)	
LD50 Oral Rat	> 2000 mg/kg

Skin Corrosion/Irritation: Not classified. Dust causes skin irritation

Serious Eye Damage/Irritation: Not classified. Dust causes serious eye irritation

Non-aspirin Pain Relief Extra Strength, Non-aspirin Pain Relief

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Respiratory or Skin Sensitization: Not classified. Dust may cause an allergic skin reaction

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Acetaminophen (103-90-2)	
IARC group	3
2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)	
IARC group	3
N-Vinyl-2-pyrrolidone (88-12-0)	
IARC group	3

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: None expected under normal conditions of use. Dust may cause respiratory irritation

Symptoms/Injuries After Skin Contact: None expected under normal conditions of use. Dust causes skin irritation. Dust may cause an allergic skin reaction. Symptoms may include redness, pain, swelling, itching, burning, dryness, and dermatitis

Symptoms/Injuries After Eye Contact: May cause minor eye irritation. Dust causes serious eye irritation. Symptoms may include redness, pain, swelling, itching, burning, tearing, and blurred vision

Symptoms/Injuries After Ingestion: Pharmaceutical. Ingestion is likely to be harmful or have adverse effects.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Acetaminophen (103-90-2)	
LC50 Fish 1	814 mg/l (Exposure time: 96 h - Species: Pimephales promelas [flow-through])
EC50 Daphnia 1	6.1 - 14 mg/l (Exposure time: 48 h - Species: Daphnia magna)
N-Vinyl-2-pyrrolidone (88-12-0)	
EC50 Daphnia 1	45 mg/l (Exposure time: 48 h - Species: Daphnia species)

12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential

Acetaminophen (103-90-2)	
Log Pow	0.51
N-Vinyl-2-pyrrolidone (88-12-0)	
Log Pow	0.4 (at 25 °C)

12.4. Mobility in Soil

Stearic acid (57-11-4)	
Log Koc	51.05

12.5. Other Adverse Effects

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Sewage Disposal Recommendations: Do not dispose of waste into sewer.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

Acetaminophen (103-90-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Starch (9005-25-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

Non-aspirin Pain Relief Extra Strength, Non-aspirin Pain Relief

Safety Data Sheet

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Starch, hydrolyzed (68412-29-3)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
2-Pyrrolidinone, 1-ethenyl-, homopolymer (9003-39-8)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Stearic acid (57-11-4)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Sodium carboxymethyl cellulose (9004-32-4)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Starch, 2-hydroxyethyl ether (9005-27-0)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
N-Vinyl-2-pyrrolidone (88-12-0)
Listed on the United States TSCA (Toxic Substances Control Act) inventory
Octadecanoic acid (85404-83-7)
Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2 US State Regulations

Starch (9005-25-8)
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) List
N-Vinyl-2-pyrrolidone (88-12-0)
U.S. - New Jersey - Right to Know Hazardous Substance List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date	: 03/17/2015
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 3 (Dermal)	Acute toxicity (dermal) Category 3
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
Skin Sens. 1B	Skin sensitization Category 1B
Comb. Dust	May form combustible dust concentrations in air
H302	Harmful if swallowed
H311	Toxic in contact with skin
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H332	Harmful if inhaled
H402	Harmful to aquatic life

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.

SDS US (GHS HazCom)