



SAFETY DATA SHEET

Issue Date: April 7, 2016

Version 1

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name TYLENOL Extra Strength Rapid Release Gels

Other means of identification

Product Code C-1010-3

Recommended use of the chemical and restrictions on use

Recommended Use Temporarily relieves minor aches and pains due to: the common cold, backache and headache, minor pain of arthritis, toothache, muscular aches, premenstrual and menstrual cramps. Temporarily reduces fever.

Recommended Restrictions None Known.

Details of the supplier of the safety data sheet

Supplier Address

McNeil Consumer Healthcare, Division of McNeil-PPC, Inc.
7050 Camp Hill Rd.
Fort Washington, PA
19034-2299

Emergency telephone number

Company Phone Number (215) 273-7000

24 Hour Emergency Phone Number For 24-hour emergency assistance, call the 3E Company at 1 (877)-236-9871
Provide the technician with the following product tracking code: 2277

2. HAZARDS IDENTIFICATION

Classification

Physical Hazards

Not classified

Health Hazards

Not classified

OSHA Regulatory Status

Over the counter drugs in their solid final form (e.g. tablets, gels 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.

TYLENOL Extra Strength Rapid Release Gels

Label elements

Emergency Overview

Hazard Symbol

None

Signal word

None

Hazard statements

This material does not meet the criteria for classification.

Appearance Red and blue gelcap with gray subcoat/band with black printed "TY" and "500" on gelatin and laser engraved design on subcoat

Physical state Liquid encapsulated in Gelatin shell

Odor Not available.

Precautionary Statements - Prevention

None

Precautionary Statements - Response

None.

Precautionary Statements - Storage

Store at 20 -25 °C (68 - 77 °F) in a dry place.

Precautionary Statements - Disposal

Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards not otherwise classified (HNOC)

Not classified.

Other Information

When used as directed, side effects associated to acetaminophen are rare. If ingested in large doses, long-term chronic use or with alcohol, acetaminophen may cause liver damage, acute renal failure and jaundice.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Weight-%*
Acetaminophen	103-90-2	70-80
Powdered Cellulose NF	9004-34-6	5-10
Pregelatinized Starch NF	9005-25-8	1-5

*The exact percentage is a trade secret.

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

Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing if required, then physically remove as much of the product as possible. Wash affected area with soap and water, then thoroughly flush the area with water. If irritation persists, seek medical advice.

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Inhalation	If symptomatic, move to fresh air. Get medical attention if symptoms persist.
Ingestion	If symptomatic, seek medical advice. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
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Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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5. FIRE-FIGHTING MEASURES

Suitable extinguishing media

Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical

Not applicable.

Explosion data

Sensitivity to Mechanical Impact None known.

Sensitivity to Static Discharge None known.

Protective equipment and precautions for firefighters

Wear self-contained breathing apparatus and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Wear appropriate personal protective equipment (see section 8).

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 Vacuum and place into proper container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Observe good industrial hygiene practices. Minimize dust generation and accumulation.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep only in the original container. Store at 20 - 25 °C (68 - 77 °F). Protect from light. Avoid high humidity. Keep away from food, drink, and animal feedingsuffs. Keep out of reach of children.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines Based on a review of animal and clinical literature, an Occupational Exposure Limit (OEL) of 3000 µg/m³ is recommended as an 8-hour TWA for Acetaminophen.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Pregelatinized Starch NF 9005-25-8	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	TWA: 10 mg/m ³ total dust TWA: 5 mg/m ³ respirable dust

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection None required for consumer use. In laboratory, medical 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. Contact a health and safety professional for specific information.

Skin and body protection None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Hand protection Use protective gloves. None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

Respiratory protection None required for consumer use. 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. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

Thermal hazards Not applicable.

General Hygiene Considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid encapsulated in Gelatin shell	Odor	Not available.
Appearance	Red and blue gelcap with gray subcoat/band with black printed "TY" and "500" on gelatin and laser engraved design on subcoat		
Color	Red and blue gelcap	Odor threshold	Not available.

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	Not available.	
Melting point/freezing point	Not available.	
Boiling point / boiling range	Not available.	
Flash point	Not available.	
Evaporation rate	Not available.	
Flammability (solid, gas)	Not available.	
Flammability Limit in Air		
Upper flammability limit:	Not available.	
Lower flammability limit:	Not available.	
Vapor pressure	Not available.	
Vapor density	Not available.	
Specific Gravity	Not available.	
Water solubility	Not available.	
Solubility in other solvents	Not available.	
Partition coefficient	Not available.	
Autoignition temperature	Not available.	
Decomposition temperature	Not available.	
Kinematic viscosity	Not available.	
Dynamic viscosity	Not available.	
Explosive properties	Not available.	
Lower explosive limit:	Not available.	
Upper explosive limit:	Not available.	
Oxidizing properties	Not available.	

10. STABILITY AND REACTIVITY

Reactivity

Stable at normal conditions.

Chemical stability

Stable.

Possibility of Hazardous Reactions

Hazardous polymerization does not occur.

Conditions to avoid

Elevated temperatures. Minimize dust generation and accumulation.

Incompatible materials

None known based on information supplied. Strong oxidizing agents.

Hazardous Decomposition Products

None known

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

- Inhalation** Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
- Eye contact** Under normal conditions of intended use, this material is not expected to eye irritation.
- Skin Contact** This product is not expected to be a skin hazard.
- Ingestion** When used as directed, side effects associated to acetaminophen are rare. If ingested in large doses, long-term chronic use or with alcohol, acetaminophen may cause liver damage, acute renal failure and jaundice.

Ingestion of less than 10 mg/kg is unlikely to produce toxicity in a child. Acute dextromethorphan over dosage probably will not result in severe signs and symptoms of intoxication unless massive amounts have been ingested.

Acute Effects

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Acetaminophen 103-90-2	= 1944 mg/kg (Rat) = 338 mg/kg (Mouse)	-	-	-

Information on toxicological effects

Symptoms Not available.

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

- Sensitization** Not expected.
- Germ cell mutagenicity** There is no evidence to suggest that acetaminophen is mutagenic.
- Carcinogenicity** There is no evidence to suggest that acetaminophen is carcinogenic.
- Reproductive toxicity** In rats and mice, high oral doses of acetaminophen impaired spermatogenesis and caused testicular atrophy. At oral doses up to 250 mg/kg/day during gestation, this drug was not teratogenic in mice or rats and did not cause intrauterine growth abnormalities in rats.
- STOT - single exposure** Not classified.
- STOT - repeated exposure** Not classified.
- Aspiration hazard** Due to the physical form of the product it is not an aspiration hazard.

12. ECOLOGICAL INFORMATION

Ecotoxicity

This product's components are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

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Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes

Dispose in accordance with applicable federal, state, and local regulations.

Local disposal regulation

Dispose in accordance with local regulations.

Hazardous waste code

Hazardous waste codes should be determined in accordance with hazardous waste regulatory authorizes.

Waste from residue / unused packaging

Dispose in accordance with applicable regulations

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. TRANSPORT INFORMATION

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

This substance/mixture is not intended to be transported in bulk.

15. REGULATORY INFORMATION

International Inventories

TSCA	Not listed
DSL/NDSL	Not listed
EINECS/ELINCS	Not listed
ENCS	Not listed
IECSC	Not listed
KECL	Not listed
PICCS	Not listed
AICS	Not listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

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AICS - Australian Inventory of Chemical Substances

US Federal Regulations

US OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Over-the-counter drugs in their solid final form (e.g. tablets, gels 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 listed.

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	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

Drug Enforcement Administration (DEA) List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))

Not regulated

DEA Exempt Chemical Mixtures Code Number

Not regulated

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPS) List

Not regulated

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated

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)

Safe Drinking Water Act (SDWA)

Not regulated

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

US State Regulations

This product does not contain a chemical known to the State of California to cause cancer, birth defects, or other reproductive harm.

California Proposition 65

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Pregelatinized Starch NF 9005-25-8	-	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION

Issue Date: April 7, 2016

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet