# SAFETY DATA SHEET

## 1. Identification

**Product identifier** **Tylenol Extra Strength Caplet**

**Other means of identification**

**Product code** McNeil C-85, MCHC-TYEXCP

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

**Recommended restrictions** None known.

**Manufacturer / Importer / Supplier / Distributor information**

**Company name** McNeil Consumer Healthcare, Division of McNeil-PPC, Inc.

**Address** 7050 Camp Hill Rd.
Fort Washington, PA
19034-2299

**Telephone** (215) 273-7000

**Emergency telephone 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. Hazard(s) identification

**Physical hazards** Not classified.

**Health hazards** Not classified.

**OSHA defined hazards** Not classified.

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

**Label elements**

**Hazard symbol** None.

**Signal word** None.

**Hazard statement** The product does not meet the criteria for classification.

**Precautionary statement**

**Prevention** Not applicable.

**Response** No specific first aid measures noted.

**Storage** Store at 20 – 25 ºC (68 - 77ºF).

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

**Hazard(s) not otherwise classified (HNOC)** Not classified.

**Supplemental information**

**Hazard statement** 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

**Mixtures**

| Chemical name | CAS number | % |
|---|---|---|
| Acetaminophen | 103-90-2 | 80-90 |
| Cellulose | 9004-34-6 | 5-10 |
| Starch | 9005-25-8 | 5-10 |

## 4. First-aid measures

**Inhalation** If symptomatic, move to fresh air. Get medical attention if symptoms persist.

**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.

**Eye contact** In case of 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.

**Ingestion** If symptomatic, seek medical advice. If ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms/effects, acute and delayed** May irritate and cause stomach pain, vomiting, diarrhea and nausea.

## 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.

**Special 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** Wear appropriate personal protective equipment (See Section 8).

**Methods and materials for containment and cleaning up** Vacuum and place into proper container for disposal.

## 7. Handling and storage

**Precautions for safe handling** Observe good industrial hygiene practices. Minimize dust generation and accumulation.

**Conditions for safe storage, including any incompatibilities** Keep only in the original container. Store at 20 – 25 ºC (68 - 77ºF). Keep away from food, drink and animal feedingstuffs. Keep out of the reach of children.

## 8. Exposure controls/personal protection

**Occupational exposure limits**

**US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**

| Components | Type | Value | Form |
|---|---|---|---|
| Cellulose (CAS 9004-34-6) | PEL | 5 mg/m3 | Respirable fraction. |
| | | 15 mg/m3 | Total dust. |
| Starch (CAS 9005-25-8) | PEL | 5 mg/m3 | Respirable fraction. |
| | | 15 mg/m3 | Total dust. |

**US. ACGIH Threshold Limit Values**

| Components | Type | Value |
|---|---|---|
| Cellulose (CAS 9004-34-6) | TWA | 10 mg/m3 |
| Starch (CAS 9005-25-8) | TWA | 10 mg/m3 |

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Exposure guidelines** Acetaminophen, CAS # 103-90-2
OEL-TWA = 3000 µg/m3

**Appropriate 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 protection**

**Hand protection** Use protective gloves.

**Other** 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 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. Respirator type: Air-purifying respirator with an appropriate, air-purifying filter, cartridge or canister. 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

| | |
|---|---|
| **Appearance** | White film coated capsule shaped tablet with “TYLENOL 500” logo printed in red on one side. |
| **Physical state** | Solid. |
| **Form** | Tablet. |
| **Color** | White. |
| **Odor** | Odorless. |
| **Odor threshold** | Not available. |
| **pH** | Not available. |
| **Melting point/freezing point** | Not available. |
| **Initial boiling point and boiling range** | Not available. |
| **Flash point** | Not available. |
| **Evaporation rate** | Not available. |
| **Flammability (solid, gas)** | Not available. |
| **Upper/lower flammability or explosive limits** | |
| **Flammability limit - lower (%)** | Not available. |
| **Flammability limit - upper (%)** | Not available. |
| **Explosive limit - lower (%)** | Not available. |
| **Explosive limit - upper (%)** | Not available. |
| **Vapor pressure** | Not available. |
| **Vapor density** | Not available. |
| **Relative density** | Not available. |
| **Solubility(ies)** | Not available. |
| **Partition coefficient (n-octanol/water)** | Not available. |
| **Auto-ignition temperature** | Not available. |
| **Decomposition temperature** | Not available. |
| **Viscosity** | 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** | Strong oxidizing agents. |
| **Hazardous decomposition products** | Carbon oxides. Silicon oxides. Nitrogen oxides (NOx). Sodium oxides. |

## 11. Toxicological information

**Information on likely routes of exposure**

| | |
|---|---|
| **Ingestion** | Expected to be a low ingestion hazard. |
| **Inhalation** | Under normal conditions of intended use, this material is not expected to be an inhalation hazard. |
| **Skin contact** | This product is not expected to be a skin hazard. |
| **Eye contact** | Product dust or powder may cause mechanical eye irritation. |
| **Symptoms related to the physical, chemical and toxicological characteristics** | May irritate and cause stomach pain, vomiting, diarrhea and nausea. |

**Information on toxicological effects**

**Acute toxicity** 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.

| Components | Species | Test Results |
|---|---|---|
| Acetaminophen (CAS 103-90-2) | | |
| **Acute** | | |
| *Oral* | | |
| LD50 | Rat | 1944 mg/kg |

**Skin corrosion/irritation** Skin irritation is not anticipated when used normally.

**Serious eye damage/eye irritation** Product dust or powder may cause mechanical eye irritation.

**Respiratory sensitization** No sensitizing effects known.

**Skin sensitization** This product is not expected to cause skin sensitization.

**Germ cell mutagenicity** This product is not expected to cause mutagenic or genotoxic effects.

**Carcinogenicity**

**IARC Monographs. Overall Evaluation of Carcinogenicity**

| | |
|---|---|
| Acetaminophen (CAS 103-90-2) | 3 Not classifiable as to carcinogenicity to humans. |

**Reproductive toxicity** Not classified.

**Specific target organ toxicity - single exposure** Not classified.

**Specific target organ toxicity - 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 data available.

**Bioaccumulative potential** No data available.

**Mobility in soil** Not available.

**Other adverse effects** Not available.

## 13. Disposal considerations

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

**Local disposal regulations** Dispose of in accordance with local regulations.

**Hazardous waste code** Hazardous waste code should be determined in accordance with hazardous waste regulatory authorities.

**Waste from residues / unused products** 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

**US federal regulations** Over-the-counter drugs in their solid final form (e.g. tablets 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.

All components are on the U.S. EPA TSCA Inventory List.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

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

Not listed.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories** Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance** No

**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**

Not regulated.

**Other federal regulations**

**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.

**Safe Drinking Water Act (SDWA)** Not regulated.

**Food and Drug Administration (FDA)** Not regulated.

**US state regulations** WARNING: This product contains a chemical known to the State of California to cause cancer.

**US. Massachusetts RTK - Substance List**

Cellulose (CAS 9004-34-6)
Starch (CAS 9005-25-8)

**US. New Jersey Worker and Community Right-to-Know Act**

Not regulated.

**US. Pennsylvania RTK - Hazardous Substances**

Cellulose (CAS 9004-34-6)
Starch (CAS 9005-25-8)

**US. Rhode Island RTK**

Not regulated.

**US. California Proposition 65**

**US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance**

Titanium dioxide (CAS 13463-67-7)

**International Inventories**

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|---|---|---|
| Canada | Domestic Substances List (DSL) | Yes |

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|---|---|---|
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | Yes |

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

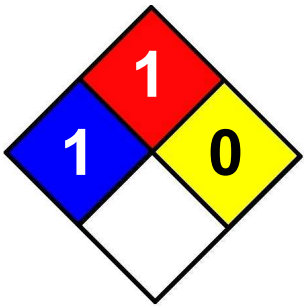
## 16. Other information, including date of preparation or last revision

**Issue date** 16-September-2013

**Revision date** -

**Version #** 01

**NFPA Ratings**




**References**

ACGIH
EPA: AQUIRE database
NLM: Hazardous Substances Data Base
US. IARC Monographs on Occupational Exposures to Chemical Agents
HSDB® - Hazardous Substances Data Bank
IARC Monographs. Overall Evaluation of Carcinogenicity
National Toxicology Program (NTP) Report on Carcinogens
ACGIH Documentation of the Threshold Limit Values and Biological Exposure Indices

**Disclaimer**

The information and recommendations contained herein are based upon tests believed to be reliable. However, Johnson and Johnson does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Johnson and Johnson assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.