1. Identification

Product identifier Tylenol Extra Strength Caplet

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.

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

2. Hazard(s) identification

Not classified.

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.

3. Composition/information on ingredients

Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>103-90-2</td>
<td>80-90</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>5-10</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>5-10</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose (CAS 9004-34-6)</td>
<td>PEL</td>
<td>5 mg/m³</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m³</td>
<td>Total dust.</td>
</tr>
<tr>
<td>Starch (CAS 9005-25-8)</td>
<td>PEL</td>
<td>5 mg/m³</td>
<td>Respirable fraction.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15 mg/m³</td>
<td>Total dust.</td>
</tr>
</tbody>
</table>

US. ACGIH Threshold Limit Values

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose (CAS 9004-34-6)</td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Starch (CAS 9005-25-8)</td>
<td>TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

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. 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**

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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen (CAS 103-90-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>Rat</td>
<td>1944 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
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

09-October-2013
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

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