

This safety data sheet was created pursuant to the requirements of:  
US OSHA Hazard Communication Standard 1910.1200, Canada WHMIS 2015

**Issue Date** 21-Apr-2020

**Revision Date** 21-Apr-2020

**Version** 1

## 1. IDENTIFICATION

### Product identifier

**Product Name** Tylenol Extra Strength Coated Tablets / Tylenol Extra Strength Tylenol Coated Tablets

### Other means of identification

**Safety Data Sheet Code** MCNEIL-NA-C-1425-1

**Reference document No.** PR-0000484, C-1425-1

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended Use** This SDS is only intended for occupational use and not for consumer use (see packaging label and or insert). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished product. For health and safety information during manufacturing of this product, please refer to the appropriate SDS for each component.

**Uses advised against** None if used in accordance with product label.

### Details of the supplier of the safety data sheet

United States of America Johnson & Johnson Consumer Inc.  
McNeil Consumer Healthcare Division  
7050 Camp Hill Road, Fort Washington, PA 19034  
215-273-7000

Canada Johnson & Johnson Inc.  
88 McNabb Street, Markham, Ontario, Canada  
L3R 5L2  
Canada 1-877-223-9807

### Emergency telephone number

**24 Hour Emergency Phone Number:** Call 3E company at 1-877-236-9871. Provide Technician with the following tracking code: 2277, Hours Open: 24 hours emergency assistance.

**Restrictions on emergency number:** None

## 2. HAZARDS IDENTIFICATION

### Classification

**Regulatory information** Over the counter drugs in their solid final form (e.g. capsules, tablets or pills) or packaged for sale to consumers in a retail establishment are considered exempt under the criteria of the U.S. Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 and Canada WHMIS 2015. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous

**Label elements**

**Signal word:**  
Not applicable

**Hazard statements**  
Not applicable

**Precautionary Statements - Prevention**  
Not applicable

**Precautionary Statements - Response**

**Eyes:** Not applicable  
**Skin:** Not applicable  
**Inhalation:** Not applicable  
**Ingestion:** Not applicable  
**Fire:** Not applicable.  
**Spill:** Not applicable

**Precautionary Statements - Storage**  
Not applicable

**Precautionary Statements - Disposal**  
Not applicable

**Other hazards**  
Not applicable

**Numerical measures of toxicity**      The acute toxicity of all ingredients has been evaluated for all applicable exposure routes associated with the product's intended use.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Mixture**

Chemical name	CAS No.	Weight-%	Hazardous Material Information Review Act registry number (HMIRA registry #)	Date HMIRA filed and date exemption granted (if applicable)
Acetaminophen USP	103-90-2	60 - 100	-	-
Pregelatinized Starch NF	9005-25-8	5 - 10	-	-
Microcrystalline Cellulose NF	9004-34-6	3-7	-	-
Titanium Dioxide	13463-67-7	0.1 - 1	-	-

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

**4. FIRST AID MEASURES**

**Description of first aid measures**

**Inhalation**      If the product is crushed: Do not breathe dust. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. If symptoms persist, call a physician.

**Eye contact**      Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician.

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<b>Skin contact</b>	If skin irritation or rash occurs: Get medical advice/attention.
<b>Ingestion</b>	None under normal use conditions. See clinical drug insert information for treatment of overdose. Call a POISON CENTER or doctor if you feel unwell.
<b><u>Most important symptoms and effects, both acute and delayed</u></b>	
<b>Symptoms</b>	Ingestion above therapeutic dose: May cause vomiting, nausea, Abdominal pain, jaundice.
<b><u>Indication of any immediate medical attention and special treatment needed</u></b>	
<b>Note to physicians</b>	Treat symptomatically.

## 5. FIRE-FIGHTING MEASURES

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	No information available.
<b>Hazardous combustion products</b>	None known.
<b>Explosion data</b>	
<b>Sensitivity to Mechanical Impact</b>	None.
<b>Sensitivity to Static Discharge</b>	None.
<b>Special protective equipment for fire-fighters</b>	As in any fire, wear self-contained breathing apparatus pressure-demand and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

### **Personal precautions, protective equipment and emergency procedures**

**Personal precautions** In the event of an accidental release, the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.

### **Environmental precautions**

**Environmental precautions** Avoid release to the environment.

### **Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so. Clean contaminated surface thoroughly.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

## 7. HANDLING AND STORAGE

### **Precautions for safe handling**

**Advice on safe handling** No special precautions are needed in handling this material.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep at temperatures between 20 and 25 °C (68 and 77 °F). Store in accordance with product packaging.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Control parameters**

**Exposure Limits**

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH	
Pregelatinized Starch NF 9005-25-8	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust	
Microcrystalline Cellulose NF 9004-34-6	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust	
Titanium Dioxide 13463-67-7	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 10 mg/m <sup>3</sup> total dust	IDLH: 5000 mg/m <sup>3</sup> TWA: 2.4 mg/m <sup>3</sup> CIB 63 fine TWA: 0.3 mg/m <sup>3</sup> CIB 63 ultrafine, including engineered nanoscale	
Chemical name	Alberta	British Columbia	Ontario	Quebec
Pregelatinized Starch NF 9005-25-8	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
Microcrystalline Cellulose NF 9004-34-6	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>
Titanium Dioxide 13463-67-7	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup> TWA: 3 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>	TWA: 10 mg/m <sup>3</sup>

**Other Information**

ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value. NIOSH IDLH: National Institute for Occupational Safety and Health - Immediately Dangerous to Life or Health. OSHA PEL: Occupational Safety and Health Administration - Permissible Exposure Limits. TWA (Time-Weighted Average). 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 controls**

All personal protective equipment should be based on a risk assessment. Consult an Environmental Health and Safety Expert if necessary.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

None under normal use conditions. Avoid contact with eyes.

**Hand protection**

None under normal use conditions.

<b>Skin and body protection</b>	None under normal use conditions.
<b>Respiratory protection</b>	None under normal use conditions.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	tablet
<b>Color</b>	red
<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	No data available	
<b>Melting point / freezing point</b>	No data available	
<b>Boiling point / boiling range</b>	No data available	
<b>Flash point</b>	No data available	
<b>Evaporation rate</b>	No data available	
<b>Flammability (solid, gas)</b>	No data available	
<b>Flammability Limit in Air</b>		
<b>Upper flammability limit:</b>	No data available	
<b>Lower flammability limit:</b>	No data available	
<b>Vapor pressure</b>	No data available	
<b>Vapor density</b>	No data available	
<b>Relative density</b>	No data available	
<b>Water solubility</b>	No data available	
<b>Solubility in other solvents</b>	No data available	
<b>Partition coefficient</b>	No data available	
<b>Autoignition temperature</b>	No data available	
<b>Decomposition temperature</b>	No data available	
<b>Kinematic viscosity</b>	No data available	
<b>Dynamic viscosity</b>	No data available	
<b>Explosive properties</b>	No information available	
<b>Oxidizing properties</b>	No information available	

### Other Information

<b>Softening point</b>	No information available
<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

#### Product Information

<b>Inhalation</b>	If the product is crushed: Do not breathe dust. May cause irritation of respiratory tract.
<b>Eye contact</b>	If the product is crushed: Contact with eyes may cause irritation.
<b>Skin contact</b>	If the product is crushed: Substance may cause slight skin irritation.
<b>Ingestion</b>	Ingestion above therapeutic dose: May cause adverse liver effects; May cause adverse kidney effects.

### Information on toxicological effects

<b>Symptoms</b>	Ingestion above therapeutic dose: May cause vomiting, nausea, Abdominal pain, jaundice.
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### Delayed and immediate effects as well as chronic effects from short and long-term exposure

<b>Skin corrosion/irritation</b>	If the product is crushed: May cause Skin irritation.
<b>Serious eye damage/eye irritation</b>	If the product is crushed: May be irritating to the eyes.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	Titanium dioxide has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group 2B) and a potential carcinogen by OSHA by inhalation in powder form. This is not applicable to this product.

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

Chemical name	ACGIH	IARC	NTP	OSHA
Titanium Dioxide 13463-67-7	-	Group 2B	-	X

#### Legend

**IARC (International Agency for Research on Cancer)**

Group 2B - Possibly Carcinogenic to Humans

**OSHA (Occupational Safety and Health Administration of the US Department of Labor)**

X - Present

<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	Ingestion above therapeutic dose: May cause adverse liver effects; May cause adverse kidney effects.
<b>STOT - repeated exposure</b>	Ingestion above therapeutic dose: May cause adverse liver effects; May cause adverse kidney effects.
<b>Other adverse effects</b>	Ingestion above therapeutic dose: May cause vomiting, nausea, Abdominal pain, jaundice.
<b>Aspiration hazard</b>	No information available.

## 12. ECOLOGICAL INFORMATION

**Ecotoxicity** .

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Acetaminophen USP 103-90-2	-	LC50: =814mg/L (96h, Pimephales promelas)	-	EC50: 6.1 - 14mg/L (48h, Daphnia magna)

**Persistence and degradability** No information available.

**Bioaccumulation** .

Component Information

Chemical name	Partition coefficient
Acetaminophen USP 103-90-2	0.51

**Other adverse effects** No information available.

**13. DISPOSAL CONSIDERATIONS**

**Waste treatment methods**

**Waste from residues/unused products** Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging** Do not reuse empty containers. Disposal should be in accordance with applicable regional, national and local laws and regulations.

**14. TRANSPORT INFORMATION**

**Note:** The information provided in section 14 is intended to provide the user with guidance only on the proper shipping requirements for the finished product in the final packaging - NOT BULK. Transport classifications may vary by container volume and may be influenced by regional or country variations in regulations. It is the responsibility of the Shipper to ensure this product is shipped in accordance with all applicable regulations. Consult your company's Hazardous/Dangerous Goods Expert for information specific to your situation.

**DOT**

UN/ID no.	Not applicable
Proper shipping name	Not applicable
Hazard Class	Not applicable
Packing Group	Not applicable
Environmental Hazards	Not applicable
Special Provisions	Not applicable

**TDG**

UN/ID no.	Not applicable
Proper shipping name	Not applicable
Hazard Class	Not applicable
Packing Group	Not applicable
Environmental Hazards	Not applicable
Special Provisions	Not applicable

**IMDG**

UN/ID no.	Not applicable
Proper shipping name	Not applicable
Hazard Class	Not applicable
Packing Group	Not applicable
Marine pollutant	Not applicable
Special Provisions	Not applicable

**ICAO, TI, IATA**

UN/ID no.	Not applicable
Proper shipping name	Not applicable
Hazard Class	Not applicable
Packing Group	Not applicable
Environmental hazards	Not applicable
Special Provisions	Not applicable

Transport in bulk according to Annex II of MARPOL and the IBC Code Not applicable

**15. REGULATORY INFORMATION**

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

**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**

See Section 2 for any applicable physical or health hazard categories.

**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**

**U.S. State Right-to-Know Regulations**

Chemical name	New Jersey	Massachusetts	Pennsylvania
Pregelatinized Starch NF 9005-25-8	-	X	X
Microcrystalline Cellulose NF 9004-34-6	X	X	X
Titanium Dioxide 13463-67-7	X	X	X

**16. OTHER INFORMATION**

Issue Date 21-Apr-2020



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Revision Note Not applicable

**Disclaimer**

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**End of Safety Data Sheet**