

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

Issue Date 22-Mar-2018

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Version 1

1. IDENTIFICATION

Product identifier

Product Name Children's Tylenol Oral Suspension Grape Flavor / Children's Tylenol Oral Suspension (Paraben-Free) Grape Flavor / Infants' Tylenol Oral Suspension (Paraben-Free) Grape Flavor

Other means of identification

Safety Data Sheet Code MCNEIL-NA-C-1358-2

Reference document No. C-1358-2

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended Use Pain reliever. 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 McNeil Consumer Healthcare, Division of McNeil-PPC, Inc.
7050 Camp Hill Road, Fort Washington, PA 10934-2299
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:

None

Hazard statements

None

Precautionary Statements - Prevention

None

Precautionary Statements - Response

Eyes: None

Skin: None

Inhalation: None

Ingestion: None

Fire: None.

Spill: None

Precautionary Statements - Storage

None

Precautionary Statements - Disposal

None

Other hazards

None

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)
Glycerin	56-81-5	7- 13	-	-
Acetaminophen USP	103-90-2	1 - 5	-	-

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

4. FIRST AID MEASURES

Description of first aid measures

Inhalation

It is unlikely that emergency treatment will be required. Move victim to fresh air. 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.

Skin contact If skin irritation or rash occurs: Get medical advice/attention.

Ingestion None under normal use conditions. See clinical drug insert information for treatment of overdose. Call a POISON CENTER or doctor if you feel unwell.

Most important symptoms and effects, both acute and delayed

Symptoms Ingestion above therapeutic dose: May cause vomiting, Abdominal pain, nausea, jaundice.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical No information available.

Hazardous combustion products None known.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

Special protective equipment for fire-fighters 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 Store in accordance with: product packaging

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH	
Glycerin 56-81-5	No data available	TWA: 15 mg/m ³ mist, total particulate TWA: 5 mg/m ³ mist, respirable fraction (vacated) TWA: 10 mg/m ³ mist, total particulate (vacated) TWA: 5 mg/m ³ mist, respirable fraction	-	
Chemical name	Alberta	British Columbia	Ontario	Quebec
Glycerin 56-81-5	TWA: 10 mg/m ³	TWA: 10 mg/m ³ TWA: 3 mg/m ³	-	TWA: 10 mg/m ³

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.

Hand protection None under normal use conditions.

Skin and body protection None under normal use conditions.

Respiratory protection None under normal use conditions.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state Liquid

Appearance Liquid

Color purple
 Odor Grape
 Odor threshold No information available

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

10. STABILITY AND REACTIVITY

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation No known effects under normal use conditions.

Eye contact Avoid contact with eyes.

Skin contact No known effects under normal use conditions.

Ingestion No known effects under normal use conditions. Ingestion above therapeutic dose: May cause adverse liver effects; May cause adverse kidney effects.

Information on toxicological effects

Symptoms Ingestion above therapeutic dose: May cause vomiting, Abdominal pain, nausea, jaundice.

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

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No known effects under normal use conditions.

STOT - repeated exposure None under normal use conditions. Ingestion above therapeutic dose: May cause adverse liver effects; May cause adverse kidney effects.

Other adverse effects Ingestion above therapeutic dose: May cause nausea, vomiting, Abdominal pain, jaundice.

Aspiration hazard No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Glycerin 56-81-5	-	LC50: 51 - 57mL/L (96h, Oncorhynchus mykiss)	-	EC50: >500mg/L (24h, Daphnia magna)
Acetaminophen USP 103-90-2	-	LC50: =814mg/L (96h, Pimephales promelas)	-	EC50: 6.1 - 14mg/L (48h, Daphnia magna)

Persistence and degradability Available upon request.

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Glycerin 56-81-5	-1.76
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
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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

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

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

California Proposition 65

This product is not subject to warning labeling under California Proposition 65.

U.S. State Right-to-Know Regulations

Chemical name	New Jersey	Massachusetts	Pennsylvania
Glycerin 56-81-5	X	X	X
Microcrystalline Cellulose 9004-34-6	X	X	X

16. OTHER INFORMATION

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Revision Note Not applicable.

Disclaimer

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End of Safety Data Sheet