

SAFETY DATA SHEET

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NGHS / English



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1. IDENTIFICATION

Product identifier

Product Name Emetrol Chewable

Other means of identification

Product Code(s) 1654508

Recommended use of the chemical and restrictions on use

Recommended Use Antiemetic (Vomiting and Nausea)

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Identification WellSpring Pharmaceutical Corporation

Address 5911 N. Honore Ave., Suite 211
Sarasota
FL
34243
US

Telephone Phone:941.312.4727
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E-mail WPCQARA@wellspringpharm.com

Emergency telephone number

Company Emergency Phone Number 941.312.4727

2. HAZARDS IDENTIFICATION

Classification

| | |
|-----------------------|------------|
| Acute toxicity - Oral | Category 4 |
|-----------------------|------------|



Appearance White**Physical state** Solid**Odor** Lemon**GHS Label elements, including precautionary statements****Warning****Hazard statements**

Harmful if swallowed

**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Precautionary Statements - Response**Ingestion**

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

Causes mild skin irritation.

Unknown acute toxicity 79 % of the mixture consists of ingredient(s) of unknown toxicity

79 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

79 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity

79 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)

79 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)

79 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. COMPOSITION/INFORMATION ON INGREDIENTS**Substance**

Not applicable.

Mixture

| Chemical name | CAS No | Weight-% | Hazardous Material Information Review Act registry number (HMIRA) | Date HMIRA filed and date exemption granted (if applicable) |
|---------------|--------|----------|---|---|
| | | | | |

| | | | registry #) | |
|-----------------------|---|----------|-------------|---|
| Supplier Trade Secret | - | 10 - 20% | - | - |
| Supplier Trade Secret | - | 0 - 10% | - | - |
| Supplier Trade Secret | - | 0 - 10% | - | - |
| Supplier Trade Secret | - | 0 - 10% | - | - |

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

4. FIRST AID MEASURES

Description of first aid measures

| | |
|-----------------------|---|
| General advice | Show this safety data sheet to the doctor in attendance. |
| Inhalation | Remove to fresh air. |
| Eye contact | Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician. |
| Skin contact | Wash skin with soap and water. |
| Ingestion | Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician. |

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

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. |
| Large Fire | CAUTION: Use of water spray when fighting fire may be inefficient. |
| Unsuitable extinguishing media | Do not scatter spilled material with high pressure water streams. |
| Specific hazards arising from the chemical | No information available. |
| Hazardous Combustion Products | Carbon oxides. |
| Explosion Data | |
| Sensitivity to Mechanical Impact | None. |
| Sensitivity to Static Discharge | None. |
| Special protective equipment for fire-fighters | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. |

6. ACCIDENTAL RELEASE MEASURES



Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with eyes.

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 Pick up and transfer to properly labeled containers.

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters**Exposure Limits**

| Chemical name | ACGIH TLV | OSHA PEL | NIOSH IDLH | |
|-----------------------|---------------------------|---|--|---------------------------|
| Supplier Trade Secret | 10 mg/m ³ | 20 mppcf TWA; ((80))/(% SiO ₂) mg/m ³) | IDLH: 3000 mg/m ³ TWA: 6 mg/m ³ | |
| Supplier Trade Secret | TWA: 10 mg/m ³ | - | | |
| Chemical name | Alberta | British Columbia | Ontario TWAEV | Quebec |
| Supplier Trade Secret | TWA: 10 mg/m ³ | TWA: 10 mg/m ³ TWA: 3 mg/m ³ | TWA: 10 mg/m ³ TWA: 3 mg/m ³ | TWA: 10 mg/m ³ |

Other Exposure Guidelines 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 Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.



| | |
|---------------------------------------|--|
| Respiratory protection | No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required. |
| 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 | Solid |
| Appearance | White |
| Odor | Lemon |
| Color | No information available |
| Odor Threshold | No information available |

| <u>Property</u> | <u>Values</u> | <u>Remarks</u> | <u>Method</u> |
|---|--------------------------|----------------|---------------|
| pH | No data available | None known | |
| Melting / freezing point | No data available | None known | |
| Boiling point / boiling range | No data available | None known | |
| Flash Point | No data available | None known | |
| Evaporation Rate | No data available | None known | |
| Flammability (solid, gas) | No data available | None known | |
| Flammability Limit in Air | | None known | |
| Upper flammability limit | No data available | | |
| Lower flammability limit | No data available | | |
| Vapor pressure | No data available | None known | |
| Vapor density | No data available | None known | |
| Relative density | No data available | None known | |
| Water Solubility | No data available | | |
| Solubility(ies) | No data available | None known | |
| Partition coefficient: n-octanol/water | No information available | | |
| Autoignition temperature | No data available | None known | |
| Decomposition temperature | No data available | None known | |
| Kinematic viscosity | No data available | None known | |
| Dynamic viscosity | No data available | None known | |

Other Information

| | |
|-----------------------------------|--------------------------|
| Explosive properties | No information available |
| Oxidizing properties | No information available |
| 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 |
| Particle Size | No information available |
| Particle Size Distribution | 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. |
| Hazardous Polymerization | Hazardous polymerization does not occur. |

Conditions to avoid None known based on information supplied.

Incompatible materials None known based on information supplied.

Hazardous Decomposition Products Carbon oxides.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 815.70 mg/kg

Unknown acute toxicity 79 % of the mixture consists of ingredient(s) of unknown toxicity

- 79 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
- 79 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
- 79 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
- 79 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
- 79 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Product Information

Component Information

| Chemical name | Oral LD50 | Dermal LD50 | Inhalation LC50 |
|-----------------------|-----------------------|-------------------------|--------------------------------------|
| Supplier Trade Secret | = 27000 mg/kg (Rat) | - | > 5800 mg/m ³ (Rat) 4 h |
| Supplier Trade Secret | = 7900 mg/kg (Rat) | > 5000 mg/kg (Rabbit) | > 58.8 mg/L (Rat) 4 h |

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.

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

| Chemical name | ACGIH | IARC | NTP | OSHA |
|-----------------------|-------|---------|-----|------|
| Supplier Trade Secret | - | Group 3 | - | X |

Legend

IARC (International Agency for Research on Cancer)

Group 3 - Not Classifiable as to Carcinogenicity in Humans

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

X - Present

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity The environmental impact of this product has not been fully investigated.

| Chemical name | Algae/aquatic plants | Fish | Toxicity to microorganisms | Crustacea |
|-----------------------|---|--|----------------------------|---|
| Supplier Trade Secret | 72h EC50: = 440 mg/L (Pseudokirchneriella subcapitata) | 96h LC50: = 5000 mg/L (Brachydanio rerio) | No data available | 48h EC50: = 7600 mg/L (Ceriodaphnia dubia) |

Persistence and Degradability No information available.

Bioaccumulation No information available.

Mobility No information available.

Other adverse effects No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

California Waste Codes 311

14. TRANSPORT INFORMATION

| | |
|-----------------------------|----------------|
| <u>DOT</u> | NOT REGULATED |
| Proper Shipping Name | NON-REGULATED |
| Hazard Class | N/A |
| <u>TDG</u> | Not applicable |
| <u>MEX</u> | Not applicable |
| <u>ICAO</u> | Not applicable |
| <u>IATA</u> | Not applicable |
| Proper Shipping Name | NON REGULATED |
| Hazard Class | N/A |
| <u>IMDG/IMO</u> | Not applicable |
| Hazard Class | N/A |
| <u>RID</u> | Not applicable |
| <u>ADR</u> | Not applicable |
| <u>ADN</u> | Not applicable |

15. REGULATORY INFORMATION

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

International Regulations

The Montreal Protocol on Substances that Deplete the Ozone Layer Not applicable

The Stockholm Convention on Persistent Organic Pollutants Not applicable

The Rotterdam Convention Not applicable

International Inventories

| | |
|----------------------|---|
| TSCA | Contact supplier for inventory compliance status. |
| DSL/NDSL | Contact supplier for inventory compliance status. |
| EINECS/ELINCS | Contact supplier for inventory compliance status. |
| ENCS | Contact supplier for inventory compliance status. |
| KECL | Contact supplier for inventory compliance status. |
| PICCS | Contact supplier for inventory compliance status. |
| AICS | Contact supplier for inventory compliance status. |

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 |
| KECL | - Korean Existing and Evaluated Chemical Substances |
| PICCS | - Philippines Inventory of Chemicals and Chemical Substances |
| AICS | - Australian Inventory of Chemical Substances |

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

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

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 contains the following Proposition 65 chemicals.

| Chemical name | California Proposition 65 |
|-------------------------|---|
| Supplier Trade Secret - | carcinogen, 10/1/1988 (airborne particles of respirable size) |

U.S. State Right-to-Know Regulations

This product may contain substances regulated by state right-to-know regulations.

| Chemical name | New Jersey | Massachusetts | Pennsylvania | Rhode Island | Illinois |
|-----------------------|------------|---------------|--------------|--------------|----------|
| Supplier Trade Secret | | X | X | | |

16. OTHER INFORMATION

| | | | | |
|--------------------|-------------------------|-----------------------|---------------------------|---|
| <u>NFPA</u> | Health hazards 1 | Flammability 0 | Instability 0 | Physical and Chemical Properties - |
| <u>HMIS</u> | Health hazards 1 | Flammability 0 | Physical hazards 0 | Personal Protection X |

Prepared By Product Stewardship
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Revision Note No information available



Disclaimer

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End of Safety Data Sheet