

# SAFETY DATA SHEET

## 1 PRODUCT AND COMPANY IDENTIFICATION

**Product name:** Coricidin Cold and Flu**SDS No:** P00000022139**Synonyms, Trade Names:**

CORICIDIN (acetaminophen (+) chlorpheniramine maleate), SP002505

**Manufacturer:**Merck  
One Merck Drive P.O. Box 100  
Whitehouse Station, NJ, USA 08889-0100**Telephone:** 908-423-1000 (General Information Only)**Fax:** 908-735-1496**Contact Person:** EHS Data Steward**e-mail:** MSDS@merck.com**Emergency telephone:** 1-908-423-6000(24/7/365) English Only  
Transportation Emergency - CANUTEC  
1-613-996-6666 (Canada Only)**Intended Use:** Finished pharmaceutical product.

## 2 HAZARDS IDENTIFICATION

**Emergency Overview:****Appearance:****Color:** Red  
**Form :** Tablets  
**Odor:** Unknown**Signal words** WARNING!**Potential Health Effects:****General**

Finished pharmaceutical product. Harmful if swallowed. Suspected of causing genetic defects. May cause damage to organs through prolonged or repeated exposures. Do not breathe dust. Obtain special instructions before use. Wash thoroughly after handling.

**Potential Physical / Chemical Effects:**

This material may present a dust deflagration hazard if sufficient quantities are or may become suspended in air. In the absence of testing data, all conductive plant items and operations personnel handling this material should be suitably grounded.

**Inhalation:**

None expected with normal handling of finished product. Exposure to crushed tablets or capsules may cause irritation.

**skin:**

None expected with normal handling of finished product. Exposure to crushed tablets or capsules may cause irritation.

**eye:**

None expected with normal handling of finished product. Exposure to crushed tablets or capsules may cause irritation.

<b>Ingestion:</b>	None expected with normal handling of finished product. Intended route for clinical use.
<b>Signs and Symptoms:</b>	Symptoms of exposure may include: skin rashes and other hypersensitivity reactions, decreased blood pressure, and hematological (blood and blood cells) reactions. After high dose exposures, nausea, vomiting, lethargy, and sweating have been reported. Also severe liver and kidney damage after ingestion although this is not expected with normal workplace handling due to the high concentration associated with these effects.
<b>Routes of Exposure:</b>	Ingestion
<b>Target Organs:</b>	kidney, spleen, liver, testes
<b>Environment:</b>	Avoid release to the environment.
<b>OTHER INFORMATION</b>	No additional information

### 3 COMPOSITION / INFORMATION ON INGREDIENTS

**General information:** The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed.

**Hazardous Component(s):**

Chemical name	CAS-No.	Concentration
Acetaminophen	103-90-2	66.4%
Chlorpheniramine Maleate	113-92-8	0.41%

\* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

### 4 FIRST AID MEASURES

<b>Inhalation:</b>	Move into fresh air and keep at rest. For breathing difficulties, oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.
<b>Skin contact:</b>	Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.
<b>Eye contact:</b>	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
<b>Ingestion:</b>	Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.
<b>Notes to the physician:</b>	
<b>Hazards:</b>	See Sections 2 and 11.
<b>Treatment:</b>	Treat supportively and symptomatically.

### 5 FIRE-FIGHTING MEASURES

---

<b>Extinguishing media:</b>	Water spray, fog, CO2, dry chemical, or alcohol resistant foam.
<b>Unsuitable extinguishing media:</b>	None known.
<b>Unusual Fire &amp; Explosion Hazards:</b>	Emits toxic fumes under fire conditions.
<b>Special Fire Fighting Procedures:</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Protective Measures:</b>	Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

## 6 ACCIDENTAL RELEASE MEASURES

<b>Personal precautions:</b>	Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures.
<b>Environmental precautions:</b>	Do not release into the environment.
<b>Spill Cleanup Methods:</b>	Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

## 7 HANDLING AND STORAGE

<b>Handling:</b>	Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.
<b>Storage:</b>	Keep container tightly closed in a cool, well-ventilated place.

## 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Exposure limits:</b>	OEB (Occupational Exposure Band) is an internal Merck control band.
-------------------------	---

Chemical name	Type	Exposure Limit values	Source
Cellulose Microcrystalline - Total dust.	TWA	10 mg/m <sup>3</sup>	Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment) (12 2008)
Cellulose Microcrystalline	TWA	10 mg/m <sup>3</sup>	Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2) (10 2006)
Cellulose Microcrystalline - Total dust.	TWA	10 mg/m <sup>3</sup>	Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended) (07 2007)
Cellulose Microcrystalline - Respirable fraction.	TWA	3 mg/m <sup>3</sup>	Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended) (07 2007)
Cellulose Microcrystalline	TWAEV	10 mg/m <sup>3</sup>	Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents) (11 2010)
Starch - Total dust.	TWA	10 mg/m <sup>3</sup>	Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment) (12 2008)
Starch	TWA	10 mg/m <sup>3</sup>	Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2) (10 2006)
Starch - Respirable fraction.	TWA	3 mg/m <sup>3</sup>	Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended) (07 2007)
Starch - Total dust.	TWA	10 mg/m <sup>3</sup>	Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended) (07 2007)
Starch	TWAEV	10 mg/m <sup>3</sup>	Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents) (11 2010)
Acetaminophen	TWA	2 ug/m <sup>3</sup> (OEB 1)	Merck
Chlorpheniramine Maleate	TWA	10 ug/m <sup>3</sup> (OEB 3) <sup>a</sup>	Merck
	Wipe Limit	100 ug/100 cm <sup>2</sup>	Merck
Magnesium Stearate	TWA	10 mg/m <sup>3</sup>	Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2) (10 2006)
	TWA	10 mg/m <sup>3</sup>	Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended) (07 2007)
	TWA	10 mg/m <sup>3</sup>	Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2) (07 2009)
	TWAEV	10 mg/m <sup>3</sup>	Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents) (11 2010)

OEB (Occupational Exposure Band) is an internal Merck control band.

- A skin notation has been assigned to this compound because cutaneous exposure may contribute significantly to the overall exposure and produce systemic effects.
- Listed.
- Listed.
- Listed.
- Listed.

<b>Protective Measures:</b>	Observe occupational exposure limits and minimize the risk of inhalation of dust. Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
<b>Respiratory Protection:</b>	Use an appropriate approved air-purifying respirator equipped with HEPA cartridges/canisters where there is the potential for exceeding established occupational exposure limits or occupational exposure bands. Powered air filter respirator. Use a positive pressure, air-supplied, pressure demand tight fitting respirator (e.g., SCBA or airline equipped with emergency escape bottle) where there is a potential for uncontrolled releases in excess of the respirator's capabilities, where exposure levels are unknown or where air-purifying respirators may not provide adequate protection.
<b>Hand protection:</b>	Chemical resistant gloves. Consider double gloving.
<b>Eye protection:</b>	Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
<b>Skin and Body Protection:</b>	Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
<b>Hygiene measures:</b>	Wash skin thoroughly with soap and water.

## 9 PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

**Appearance:**

<b>Physical State:</b>	Solid
<b>Form:</b>	Tablets
<b>Color:</b>	Red
<b>Odor:</b>	Unknown

## 10 STABILITY AND REACTIVITY

<b>Stability:</b>	Stable
<b>Possibility of hazardous reactions:</b>	Stable
<b>Conditions to avoid:</b>	Excessive heat. Moisture.
<b>Incompatible materials:</b>	No data available.
<b>Hazardous decomposition products:</b>	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

<b>11 TOXICOLOGICAL INFORMATION</b>
-------------------------------------

**General information:** The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

**Specified substance(s):**

**Acute Toxicity (Oral);**

**Name**

Acetaminophen

**Test results**

LD50 (Mouse): 338 mg/kg Harmful if swallowed.  
 LD50 (Rat): 2,400 mg/kg Practically non-toxic if swallowed.  
 LD50 (Guinea pig): 2,620 mg/kg

Chlorpheniramine Maleate

LD50 (Rat): 118 - 306 mg/kg Effects observed included lacrimation, excitement, and convulsions.  
 LD50 (Mouse): 130 mg/kg

**Acute Toxicity (Dermal):**

**Name**

Acetaminophen

**Test results**

No data available.

Chlorpheniramine Maleate

LD50 (Rat): 365 mg/kg

**Acute Toxicity (Inhalation):**

**Name**

Acetaminophen

**Test results**

No data available.

Chlorpheniramine Maleate

MAC (Rat, 4 h): 0.61 mg/l No mortality observed.

**Repeated dose toxicity:**

**Name**

Acetaminophen

**Test results**

LOAEL (Rat, Oral, 60 d): 600 mg/kg/day (Target Organ(s): liver, kidney, spleen, blood) This material may produce methemoglobinemia.  
 LOAEL (Rat, Oral, 100 d): 20 mg/kg/day (Target Organ(s): testes) May cause testicular damage. decrease in testicular weights  
 LOAEL (Mouse, Oral, 61 Weeks): 130 ppm May cause reproductive system damage. Effects observed include: some impacts on fertility, gravidity, and offspring. dose-related decreases in lifespan.

Chlorpheniramine Maleate

(Rat, , 14 - 16 Days): 40 - 640 mg/kg No significant findings.  
 (Mouse, , 14 - 16 Days): 25 - 800 mg/kg No significant findings.  
 (Rat, , 13 - 104 Weeks): 3.75 - 60 mg/kg No significant findings.  
 (Mouse, , 13 - 104 Weeks): 25 - 200 mg/kg No significant findings.

**Inhalation:** None expected with normal handling of finished product. Exposure to crushed tablets or capsules may cause irritation.

**Ingestion:** None expected with normal handling of finished product. Intended route for clinical use.

**Skin corrosion/irritation:** None expected with normal handling of finished product. Exposure to crushed tablets or capsules may cause irritation.

**Serious eye damage/eye irritation:** None expected with normal handling of finished product. Exposure to crushed tablets or capsules may cause irritation.

**Respiratory sensitizer/Skin sensitizer:** No data available.

<b>Carcinogenicity:</b>	Active pharmaceutical ingredient: Carcinogenicity studies have shown no evidence of an increase in tumor incidence. IARC Group 3 (Not classifiable as to carcinogenicity to humans).
<b>Mutagenesis:</b>	Active pharmaceutical ingredient: Equivocal results were observed in genotoxicity assays.
<b>Reproductive toxicity:</b>	Active pharmaceutical ingredient: Fetotoxicity was observed in mice. May cause adverse effects on reproduction or fertility.
<b>Other Effects:</b>	Symptoms of exposure may include: skin rashes and other hypersensitivity reactions, decreased blood pressure, and hematological (blood and blood cells) reactions. After high dose exposures, nausea, vomiting, lethargy, and sweating have been reported. Also severe liver and kidney damage after ingestion although this is not expected with normal workplace handling due to the high concentration associated with these effects.

## 12 ECOLOGICAL INFORMATION

**General information:** The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

### Ecotoxicity:

#### Product:

**Chronic Toxicity(Fish):** No data available.

**Chronic Toxicity(Aquatic invertebrates):** No data available.

**Acute toxicity(Aquatic plants):** No data available.

#### Specified substance(s):

##### **Acute toxicity(Fish):**

###### **Name**

###### **Test results**

Acetaminophen

LC50 (Fathead minnow (*Pimephales promelas*), 96 h): 814 mg/l

Chlorpheniramine Maleate

No data available.

##### **Acute toxicity(Aquatic invertebrates):**

###### **Name**

###### **Test results**

Acetaminophen

EC 50 (Water flea (*Daphnia magna*), 48 h): 9.2 mg/l

Chlorpheniramine Maleate

No data available.

**Persistence and degradability:** Active pharmaceutical ingredient: Expected to biodegrade.

**Bioaccumulative potential:** Active pharmaceutical ingredient: Not expected to bioaccumulate.

**Mobility:** Active pharmaceutical ingredient: Expected to be mobile in soil.

## 13 DISPOSAL CONSIDERATIONS

**Disposal Methods:** Disposal must be in accordance with applicable national, state/provincial, and/or local regulations.

**Measures for Avoidance and Recovery:**

Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

**14 TRANSPORT INFORMATION****TDG**

Not regulated.

**IMDG - International Maritime Dangerous Goods Code**

Not regulated.

**IATA - International Air Transport Association**

Not regulated.

**15 REGULATORY INFORMATION****Canadian Controlled Products Regulations:**

This product has been classified according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all required information.

**WHMIS Classification:**

NC: Non-Controlled

**16 OTHER INFORMATION****OTHER INFORMATION**

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

**Revision Information:**

Not relevant.

**Issue Date:**

22.04.2014

**Disclaimer:**

This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.