# SAFETY DATA SHEET



MUCINEX® Multi-Action™ - Cold, Flu, & Sore Throat Caplets

## 1. Product and company identification

Product name : MUCINEX® Multi-Action™ - Cold, Flu, & Sore Throat Caplets

Distributed by : RB Health (US) LLC

Morris Corporate Center IV

399 Interpace Parkway (P.O. Box 225) Parsippany, New Jersey 07054-0225

+1 973 404 2600

: 1-800-338-6167

Emergency telephone

number (Medical)

Emergency telephone : 1-800-424-9300 (U.S. & Canada) CHEMTREC

number (Transport) Outside U.S. and Canada (North America), call Chemtrec:703-527-3887

Website: : http://www.rbnainfo.com

Product use : Cough Suppressant, Analgesic and Nasal decongestant

This SDS is designed for workplace employees, emergency personnel and for other conditions and situations where there is greater potential for large-scale or prolonged exposure, in accordance with the requirements of USDOL Occupational Safety and Health Administration.

This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations, and shown in Section 15 of this SDS.

**SDS** # : D0375357 v5.0 **Formulation** # : FF3051621 v1.0

Relevant identified uses of the substance or mixture and uses advised against

**Identified uses** 

Medicinal product

## 2. Hazards identification

Classification of the substance or mixture

: Not classified.

**GHS label elements** 

Hazard pictograms : Not applicable.

Signal word : No signal word.

**Hazard statements** : No known significant effects or critical hazards.

**Precautionary statements** 

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## 2. Hazards identification

General : Read label before use. Keep out of reach of children. If medical advice is needed,

have product container or label at hand.

Prevention: Not applicable.Response: Not applicable.Storage: Not applicable.Disposal: Not applicable.

Supplemental label

elements

: None known.

**Hazards not otherwise** 

classified

: None known.

# 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
paracetamol guaifenesin DEXTROMETHORPHAN HBR USP phenylephrine hydrochloride	≥30 - ≤60 ≥10 - ≤30 ≤5 ≤1	103-90-2 93-14-1 125-69-9 61-76-7

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

## 4. First aid measures

## **Description of necessary first aid measures**

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower

eyelids. Check for and remove any contact lenses. Get medical attention if irritation

occurs.

**Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get

medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under

medical surveillance for 48 hours.

**Skin contact**: Flush contaminated skin with plenty of water. Remove contaminated clothing and

shoes. Get medical attention if symptoms occur.

Ingestion
 Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is

conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

#### Most important symptoms/effects, acute and delayed

#### Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 Ingestion
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.
 No known significant effects or critical hazards.

#### Over-exposure signs/symptoms

Eye contact : No specific data.

## 4. First aid measures

Inhalation : No specific data. **Skin contact** : No specific data. Ingestion : No specific data.

#### Indication of immediate medical attention and special treatment needed, if necessary

: In case of inhalation of decomposition products in a fire, symptoms may be delayed. Notes to physician

The exposed person may need to be kept under medical surveillance for 48 hours.

**Specific treatments** : No specific treatment.

**Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training.

## See toxicological information (Section 11)

# 5. Fire-fighting measures

## **Extinguishing media**

Suitable extinguishing

media

Unsuitable extinguishing

media

: Use an extinguishing agent suitable for the surrounding fire.

: None known.

Specific hazards arising from the chemical

Hazardous thermal decomposition products : No specific fire or explosion hazard.

: No specific data.

Special protective actions for fire-fighters

: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

**Special protective** equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

# 6. Accidental release measures

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

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders: If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For nonemergency personnel".

**Environmental precautions** 

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

## Methods and materials for containment and cleaning up

**Small spill** 

Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

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## 6. Accidental release measures

Large spill

: Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

# 7. Handling and storage

#### Precautions for safe handling

**Protective measures** 

: Put on appropriate personal protective equipment (see Section 8).

including any incompatibilities

Conditions for safe storage, : Store between the following temperatures: 5 to 35°C (41 to 95°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

# 8. Exposure controls/personal protection

#### **Control**

#### Occupational exposure limits

Not applicable.

**Appropriate engineering** controls

**Environmental exposure** controls

: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

#### **Individual protection measures**

**Hygiene measures** 

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection

Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with sideshields.

## **Skin protection**

**Hand protection** 

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

**Body protection** 

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

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# 8. Exposure controls/personal protection

**Respiratory protection** 

: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

# 9. Physical and chemical properties

**Appearance** 

**Physical state** : Solid. [Tablet.]

Color : Red.

Odor : None.

: Not available. **Odor threshold** pН : Not available. **Melting point** Not available. **Boiling point** : Not available. Flash point : Not available. : Not available. **Evaporation rate** Flammability (solid, gas) : Not available.

Lower and upper explosive

(flammable) limits

: Not available.

Vapor pressure : Not available. Vapor density : Not available. : Not available. **Relative density** : Not available. Solubility Partition coefficient: n-: Not available.

octanol/water

**Auto-ignition temperature** : Not available. **Decomposition temperature** : Not available. Not available. **Viscosity** 

# 10. Stability and reactivity

**Chemical stability** 

Possibility of hazardous

reactions

Reactivity

: No specific test data related to reactivity available for this product or its ingredients.

: The product is stable.

: Under normal conditions of storage and use, hazardous reactions will not occur.

**Conditions to avoid** : No specific data. **Incompatible materials** : No specific data.

**Hazardous decomposition** 

products

: Under normal conditions of storage and use, hazardous decomposition products should

not be produced.

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# 11. Toxicological information

### Information on toxicological effects

## **Acute toxicity**

Product/ingredient name	Result	Species	Dose	Exposure
paracetamol guaifenesin (9α,13α,14α)-3-methoxy-17-methylmorphinan hydrobromide	LD50 Oral LD50 Oral LD50 Oral	Rat	1944 mg/kg 1510 mg/kg 350 mg/kg	-
phenylephrine hydrochloride	LD50 Oral	Rat	350 mg/kg	-

**Conclusion/Summary** 

: Based on available data, the classification criteria are not met.

#### **Irritation/Corrosion**

Not available.

### **Conclusion/Summary**

Skin : No known significant effects or critical hazards.

**Eyes** : May cause eye irritation upon direct contact with eyes.

: No known significant effects or critical hazards. Respiratory

**Sensitization** 

Not available.

**Conclusion/Summary** 

Skin : No known significant effects or critical hazards. : No known significant effects or critical hazards. Respiratory

**Mutagenicity** 

Not available.

**Conclusion/Summary** 

: No known significant effects or critical hazards.

Carcinogenicity

Not available.

Conclusion/Summary

: No known significant effects or critical hazards.

**Classification** 

Product/ingredient name	OSHA	IARC	NTP
paracetamol	-	3	-

#### Reproductive toxicity

Not available.

**Conclusion/Summary** 

: No known significant effects or critical hazards.

**Teratogenicity** Not available.

**Conclusion/Summary** : No known significant effects or critical hazards.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

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# 11. Toxicological information

### **Aspiration hazard**

Not available.

Information on the likely

routes of exposure

: Not available.

### Potential acute health effects

Eye contact
 Inhalation
 No known significant effects or critical hazards.
 Skin contact
 No known significant effects or critical hazards.
 Ingestion
 No known significant effects or critical hazards.

### Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

## Delayed and immediate effects and also chronic effects from short and long term exposure

#### **Short term exposure**

Potential immediate

effects

: Not available.

Potential delayed effects

: Not available.

Long term exposure

Potential immediate

: Not available.

effects

Potential delayed effects : Not available.

### Potential chronic health effects

Not available.

Conclusion/Summary
 No known significant effects or critical hazards.
 Carcinogenicity
 No known significant effects or critical hazards.
 Mutagenicity
 No known significant effects or critical hazards.
 Teratogenicity
 No known significant effects or critical hazards.
 Developmental effects
 No known significant effects or critical hazards.
 Fertility effects
 No known significant effects or critical hazards.

## **Numerical measures of toxicity**

**Acute toxicity estimates** 

# 11. Toxicological information

Product/ingredient name	Oral (mg/ kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/ I)
paracetamol	1944	N/A	N/A	N/A	N/A
guaifenesin	1510	N/A	N/A	N/A	N/A
(9α,13α,14α)-3-methoxy-17-methylmorphinan hydrobromide	350	N/A	N/A	N/A	N/A
phenylephrine hydrochloride	350	N/A	N/A	N/A	N/A

# 12. Ecological information

#### **Toxicity**

Product/ingredient name	Result	Species	Exposure
paracetamol	Acute EC50 56.34 mg/l Fresh water Acute EC50 4.8 mg/l Fresh water	Crustaceans - Moina macrocopa Daphnia - Daphnia magna - Neonate	48 hours 48 hours
	Acute LC50 814000 μg/l Fresh water Chronic NOEC 5.72 mg/l Fresh water Chronic NOEC 0.61 to 1.06 μg/l Fresh water	Fish - Pimephales promelas Daphnia - Daphnia magna Fish - Danio rerio - Adult	96 hours 21 days 6 weeks

### Persistence and degradability

Not available.

#### **Bioaccumulative potential**

Product/ingredient name	LogPow	BCF	Potential
paracetamol	0.4	3.162	low
guaifenesin	1.39	-	low
phenylephrine hydrochloride	-0.31	-	low

### **Mobility in soil**

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects

: No known significant effects or critical hazards.

# 13. Disposal considerations

#### **Disposal methods**

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid

# 13. Disposal considerations

dispersal of spilled material and runoff and contact with soil, waterways, drains and

# 14. Transport information

	DOT Classification	TDG Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-			
Environmental hazards	No.	No.	No.	No.

**Additional information** 

**TDG Classification IMDG IATA** 

Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL and

: Not available.

the IBC Code

## 15. Regulatory information

U.S. Federal regulations

Clean Air Act Section 112 : Not listed

(b) Hazardous Air **Pollutants (HAPs)** 

Clean Air Act Section 602

Class I Substances

: Not listed

**Clean Air Act Section 602** 

: Not listed

**Class II Substances** 

**DEA List I Chemicals** (Precursor Chemicals) : Not listed

**DEA List II Chemicals** (Essential Chemicals) : Not listed

**SARA 302/304** 

Composition/information on ingredients

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# 15. Regulatory information

No products were found.

SARA 304 RQ : Not applicable.

**SARA 311/312** 

Classification : Not applicable.

Composition/information on ingredients

Name	%	Classification
paracetamol		COMBUSTIBLE DUSTS ACUTE TOXICITY (oral) - Category 4
guaifenesin (9α,13α,14α)-3-methoxy-17-methylmorphinan hydrobromide		ACUTE TOXICITY (oral) - Category 4 ACUTE TOXICITY (oral) - Category 4
phenylephrine hydrochloride	≤1	ACUTE TOXICITY (oral) - Category 4

#### State regulations

Massachusetts : The following components are listed: CELLULOSE

**New York**: None of the components are listed.

New Jersey : The following components are listed: CELLULOSE

Pennsylvania : The following components are listed: CELLULOSE

**Label elements** 

**Additional information / Recommendations** 

**Additional information**: Read label before use.

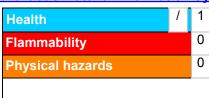
Avoid contact with eyes.

Recommendations : No known significant effects or critical hazards.

Recommendations : No known significant effects or critical hazards.

## 16. Other information

### **Hazardous Material Information System (U.S.A.)**



Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.)



## 16. Other information

NFPA (30B) aerosol Flammability No known significant effects or critical hazards.

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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

**Key to abbreviations** : ATE = Acute Toxicity Estimate

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973

as modified by the Protocol of 1978. ("Marpol" = marine pollution)

UN = United Nations

Date of issue : 18/05/2020 Date of previous issue : 11/01/2019

Version : 5.0

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▼ Indicates information that has changed from previously issued version.

## **Notice to reader**

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.