SAFETY DATA SHEET



MUCINEX® SINUS-MAX® - Pressure, Pain & Cough Caplets

1. Product and company identification : MUCINEX® SINUS-MAX® - Pressure, Pain & Cough Caplets **Product name 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 : http://www.rbnainfo.com Website:

Product use : Cough Suppressant and Analgesic.

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 #	:	D0375358 v5.0
Formulation #:	:	FF0390598 v6.0; FF8040338 v 5.0

(D0375358) US

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 statement	t <u>s</u>
General	: Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

2. Hazards identification	
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		
glycerol paracetamol diphenhydramine hydrochloride phenylephrine hydrochloride Propylene glycol	15 - 30 2.5 - 5 0.1 - 1.0 0.1 - 1.0 15 - 30	56-81-5 103-90-2 147-24-0 61-76-7 57-55-6		

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

(D0375358) US

Description of necess	ary 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.

	oms/effects, acute and delayed	
Potential acute health		
Eye contact	: May cause eye irritation upon direct contact with eyes.	
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.	
Over-exposure signs	/symptoms	
Eye contact	: No specific data.	
Inhalation	: No specific data.	
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4. First aid measures		
Skin contact	: No specific data.	
Ingestion	: No specific data.	

Indication of immediate medical attention and special treatment needed, if necessaryNotes to physician: 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.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	: Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	: None known.
Specific hazards arising from the chemical	: No specific fire or explosion hazard.
Hazardous thermal decomposition products	: 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

contractor.

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 non-emergency 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 co	ont	ainment 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

6. Accidental release measures

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Large spill
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: 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).	
Conditions for safe storage, including any incompatibilities	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.	

8. Exposure controls/personal protection

<u>Control</u>	
Occupational exposure limits	
Not applicable.	
Appropriate engineering controls	: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
Environmental exposure controls	: 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 measure	<u>S</u>
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 side-shields.
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.

8. Exposure controls/personal protection

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Respiratory protection
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: 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

Appearance	
Physical state	: Solid.
Color	: Orange.
Odor	: None.
Odor threshold	: Not available.
рН	: Not available.
Melting point	: Not available.
Boiling point	: Not available.
Flash point	: Not available.
Evaporation rate	: Not available.
Flammability (solid, gas)	: Not available.
Lower and upper explosive (flammable) limits	: Not available.
Vapor pressure	: Not available.
Vapor density	: Not available.
Relative density	: Not available.
Solubility	: Easily soluble in the following materials: cold water and hot water.
Partition coefficient: n- octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Flow time (ISO 2431)	: Not available.

10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: 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.

11. Toxicological information

Information on toxicological effects

Acute toxicity

rritation/Corrosion	LD50 Oral LD50 Oral LD50 Oral			Rat	1944 mg/kg	-
phenylephrine hydrochloride Conclusion/Summary rritation/Corrosion						1
Conclusion/Summary				Rat Rat	1510 mg/kg 350 mg/kg	-
rritation/Corrosion	Based		data the elec	sification criteria		
	. Daseu Of	i avaliable	uala, ine cias	Sincation Chieffa	a are not met.	
Not available.						
Conclusion/Summary						
Skin		-		ritical hazards.		
Eyes	•	se eye irrita				
Respiratory	: No know	n significan	t effects or c	ritical hazards.		
Sensitization						
Not available.						
Conclusion/Summary						
Skin	: No know	n significar	t effects or c	ritical hazards.		
Respiratory	: No know	n significar	t effects or c	ritical hazards.		
<u>Autagenicity</u>						
Not available.						
Conclusion/Summary	: No know	n significan	t effects or c	ritical hazards.		
Carcinogenicity		-				
Not available.						
Conclusion/Summary	: No know	n significar	t effects or c	ritical hazards.		
Classification		in olgriniour				
Product/ingredient name	OSHA	IARC	NTP			
paracetamol	-	3	-			
Reproductive toxicity						
Not available.						
		n oignificon	t offecte er e	sitical borarda		
Conclusion/Summary <u>Feratogenicity</u>	. NO KHOW	n signincar		ritical hazards.		
Not available.						
		· · · · · · · · · · · · · · · · · · ·	1 - f f1			
Conclusion/Summary	NO KNOW	n significan	it effects of cl	ritical hazards.		
Specific target organ toxicity	<u>(single ex</u>	<u>posure)</u>				
Not available.						
Specific target organ toxicity	(repeated	<u>exposure)</u>				
Not available.						
Aspiration hazard						
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11. Toxicological information

Not available.

Information on the likely routes of exposure	Ī	Not available.
Potential acute health effects	5	
Eye contact	1	May cause eye irritation upon direct contact with eyes.
Inhalation	1	No known significant effects or critical hazards.
Skin contact	1	No known significant effects or critical hazards.
Ingestion	:	No known significant effects or critical hazards.
Symptoms related to the phy	sic	al, 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 effect	<u>ts</u>	and also chronic effects from short and long term exposure
Potential immediate effects	:	Not available.
Potential delayed effects	1	Not available.
Long term exposure		
Potential immediate effects	:	Not available.
Potential delayed effects	:	Not available.
Potential chronic health effe	ect	<u>s</u>
Not available.		
Conclusion/Summary		No known significant effects or critical hazards.
General		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		
Fertility effects		No known significant effects or critical hazards.
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Numerical measures of toxicity

Acute toxicity estimates				
Route	ATE value			
Oral	2589.9 mg/kg			

12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
paracetamol	Acute EC50 4.8 mg/l Fresh water	Daphnia - Daphnia magna - Neonate	48 hours
	Acute LC50 814000 μg/l Fresh water	Fish - Pimephales promelas	96 hours

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 : Not available. coefficient (Koc)

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

14. Transport information

(D0375358) US

Regulatory information	UN number	Proper shipping name	Classes	PG*	Label	Additional information
DOT Classification	Not Regulated	Not applicable.	Not available.	-		-
TDG Classification	Not Regulated	Not applicable.	Not available.	-		-

Conforms to USDOL OSF D0375358 v5.0	IA 29CFR 1910.120	00 HAZCOM			
14. Transpo	rt informa	ation			
Mexico Classification	Not Regulated	Not applicable.	Not available.	-	-
IMDG Class	Not Regulated	Not applicable.	Not available.	-	-
IATA-DGR Class	Not Regulated	Not applicable.	Not available.	-	-
Special precautions	u		sure that persons tra		n closed containers that are ne product know what to do in the
PG* : Packing group					
15. Regulato	ory inform	nation			
U.S. Federal regula		SCA 8(a) CDR Exem nited States invento			rmined are listed or exempted.
Clean Air Act Sec (b) Hazardous Air Pollutants (HAPs)	tion 112 : N	ot listed			
Clean Air Act Sect Class I Substance		ot listed			
Clean Air Act Sect Class II Substance		ot listed			
DEA List I Chemic (Precursor Chemic		ot listed			
DEA List II Chemic (Essential Chemic		ot listed			
SARA 302/304	·				
Composition/info	ormation on ing	gredients			
No products were	found.				
SARA 304 RQ	: N	ot applicable.			
SARA 311/312 Classification	: N	ot applicable.			
Composition/info	ormation on ing	gredients			

15. Regulatory information

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
paracetamol guaifenesin phenylephrine hydrochloride	30 - 60 15 - 30 0.1 - 1	Yes. No. No.	No. No. No.	No. No. No.	Yes. Yes. Yes.	No. No. No.

State	regu	lations

Massachusetts New York New Jersey Pennsylvania	 The following components are listed: CELLULOSE None of the components are listed. The following components are listed: CELLULOSE The following components are listed: CELLULOSE
<u>Canada</u>	
WHMIS (Canada)	: Not controlled under WHMIS (Canada).
Canadian lists	
Canadian NPRI	: None of the components are listed.
CEPA Toxic substances	: None of the components are listed.
Canada inventory	: All components are listed or exempted.
Label elements	
Precautionary measures	: Read label before use.
	Avoid contact with eyes.

Keep out of reach of children.

16. Other information



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 are not required on MSDSs 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 mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.) 2

16. Other information



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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 = Internediate 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
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Version	: 5.0
Prepared by	: Reckitt Benckiser India Ltd Plot No 48 Sector - 32 Institutional Area Gurgaon, Haryana India - 122001

Revision comments

: Project gemini-change in business address on section 1

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.