



BIO-PHARM Incorporated

# Robafen DM Syrup

## Safety Data Sheet

Prepared according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date: 09/02/2015

Supersedes: N/A

Version: 1.0

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product name : Robafen DM Syrup  
Product form : Mixture  
Other means of identification : Pharmaceutical  
Active Ingredients: Each 5mL contains:  
Guaifenesin (Gliceryl Guaiacolate), USP 100 mg  
Dextromethorphan Hydrobromide, USP 10 mg

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Cough Suppressant; Expectorant

#### 1.3. Details of the supplier of the safety data sheet

BIO-PHARM INC.  
2091 HARTEL STREET  
LEVITTOWN, PA 19057  
PHONE: (215) 949-3711

#### 1.4. Emergency telephone number

Emergency number : 1-866-845-1611

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### GHS-US classification

Not classified

#### 2.2. Label elements

##### GHS-US labelling

No labelling applicable

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

No data available

### SECTION 3: Composition/information on ingredients

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Product identifier	%
Contains no hazardous ingredients at levels requiring disclosure by the OSHA Hazard Communication Standard (29 CFR 1910.1200).	N/A	100

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a comfortable position for breathing.

First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes.

First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Continue rinsing.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center or medical professional. Get medical attention if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries : Not expected to present a significant acute hazard under anticipated conditions of normal use.

Symptoms/injuries after inhalation : May cause respiratory irritation.

Symptoms/injuries after skin contact : May cause skin irritation.

Symptoms/injuries after eye contact : Direct contact with the eyes is likely to be irritating.

Symptoms/injuries after ingestion : May cause gastrointestinal irritation.

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### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Foam. Carbon dioxide. Dry powder. Sand.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.

Explosion hazard : Product is not explosive.

Reactivity : No dangerous reactions known under normal conditions of use.

### 5.3. Advice for firefighters

Precautionary measures fire : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

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

General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained clean-up crews properly equipped with respiratory equipment and full chemical protective gear (see Section 8).

#### 6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.

#### 6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air respirator, in case of emergency.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for cleaning up : Take up liquid spill into absorbent material. Place in a suitable container for disposal in accordance with the waste regulations (see Section 13).

### 6.4. Reference to other sections

See Sections 8 and 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep the container tightly closed. Store in a dry, cool and well-ventilated place. Avoid freezing. Protect from light.

Storage temperature : 15 - 30 °C

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No data available

### 8.2. Exposure controls

Appropriate engineering controls : Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Use explosion-proof equipment with flammable materials. Ensure adequate ventilation, especially in confined areas.

Personal protective equipment : Gloves. Protective goggles.



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Hand protection	: Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. Suitable gloves for this specific application can be recommended by the glove supplier.
Eye protection	: Use eye protection suitable to the environment. Avoid direct contact with eyes.
Skin and body protection	: Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.
Respiratory protection	: Use NIOSH-approved dust/particulate respirator. Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: Reddish pink
Odor	: No data available
Odor Threshold	: No data available
pH	: 2.3 – 3.0
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 1.2 – 1.3
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

#### 9.2. Other information

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No dangerous reactions known under normal conditions of use.

#### 10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

#### 10.3. Possibility of hazardous reactions

None known.

#### 10.4. Conditions to avoid

None known.

#### 10.5. Incompatible materials

None known.

#### 10.6. Hazardous decomposition products

None known.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified

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Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: May cause respiratory irritation.
Symptoms/injuries after skin contact	: May cause skin irritation.
Symptoms/injuries after eye contact	: Direct contact with the eyes is likely to be irritating.
Symptoms/injuries after ingestion	: May cause gastrointestinal irritation.

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : No information available.

#### 12.2. Persistence and degradability

Robafen DM Syrup	
Persistence and degradability	No information available.

#### 12.3. Bioaccumulative potential

Robafen DM Syrup	
Bioaccumulative potential	No information available.

#### 12.4. Mobility in soil

Robafen DM Syrup	
Ecology - soil	No information available.

#### 12.5. Other adverse effects

Other adverse effects : No data available.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste treatment methods : Obtain the consent of pollution control authorities before discharging to wastewater treatment plants.

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

### SECTION 14: Transport information

In accordance with DOT

Not hazardous for transport

#### Additional information

Other information : No supplementary information available.

#### Transport by sea

No additional information available

#### Air transport

No additional information available

### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

Robafen DM Syrup	
All chemical substances in this product are listed in the EPA (Environment Protection Agency) TSCA (Toxic Substances Control Act) Inventory or are exempt	
SARA Section 311/312 Hazard Classes	None

#### 15.2. International regulations

No additional information available.

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### 15.3. US State regulations

#### California Proposition 65

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm.

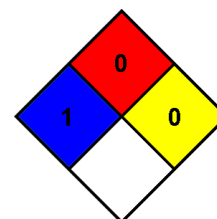
#### Glycerol (56-81-5)

U.S. - Massachusetts - Right To Know List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

### SECTION 16: Other information

Indication of changes : Revision 1.0: New SDS Created.  
Revision date : 09/02/2015  
Other information : Author: BCS.

NFPA health hazard : 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.  
NFPA fire hazard : 0 - Materials that will not burn.  
NFPA reactivity : 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



#### HMIS III Rating

Health : 1  
Flammability : 0  
Physical : 0  
Personal Protection : B

The information contained in this Safety Data Sheet has been compiled from reliable sources and is believed to be correct as of the date issued. It is the responsibility of the user to determine the appropriateness and applicability to their situation. BIO-PHARM INC. disclaims any expressed or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental, or consequential damages, from use or reliance on the above information.