



SAFETY DATA SHEET

Revision date: 06-Jun-2016

Version: 1.0

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: Robitussin Maximum Strength Cough and Chest Congestion DM Daytime (Project Accelerate)

Trade Name: Robitussin
Compound Number: WH-1719-0001
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Consumer healthcare product used as Cough and cold remedy

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
1 Giralda Farms
Madison, NJ 07940

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

Label Elements

Signal Word: Not required
Hazard Statements: Non-hazardous in accordance with international standards for workplace safety.

Other Hazards

Note: No data available
This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Citric acid, anhydrous	77-92-9	201-069-1	Not Listed	*
Dextromethorphan hydrobromide	6700-34-1	Not Listed	Acute Tox.4 (H302) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)	0.1
Glycerin, USP	56-81-5	200-289-5	Not Listed	*
Polyethylene glycol	25322-68-3	Not Listed	Not Listed	*
Propylene glycol	57-55-6	200-338-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Carboxymethylcellulose sodium	9004-32-4	Not Listed	Not Listed	*
FD & C Blue No. 1	3844-45-9	223-339-8	Not Listed	*
FD & C Red No. 40	25956-17-6	247-368-0	Not Listed	*
Flavor	NOT ASSIGNED	Not Listed	Not Listed	<1.0
Liquid glucose	8027-56-3	Not Listed	Not Listed	*
Menthol-L	1490-04-6	216-074-4	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Sodium Citrate	6132-04-3	Not Listed	Not Listed	*
Sucralose	56038-13-2	259-952-2	Not Listed	*
Triacetin	102-76-1	203-051-9	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Xanthan gum	11138-66-2	234-394-2	Not Listed	*

Additional Information:

* Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions: None known

Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

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5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO₂, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Consumer healthcare product used for Upper respiratory

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Dextromethorphan hydrobromide

Pfizer OEL TWA-8 Hr: 0.2 mg/m³

Glycerin, USP

Australia TWA 10 mg/m³

Belgium OEL - TWA 10 mg/m³

Czech Republic OEL - TWA 10 mg/m³

Estonia OEL - TWA 10 mg/m³

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Finland OEL - TWA	20 mg/m ³
France OEL - TWA	10 mg/m ³
Germany (DFG) - MAK	50 mg/m ³
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Switzerland OEL -TWAs	50 mg/m ³

Polyethylene glycol

Austria OEL - MAKs	1000 mg/m ³
Germany - TRGS 900 - TWAs	1000 mg/m ³
Germany (DFG) - MAK	1000 mg/m ³ average molecular weight 200-600
Slovakia OEL - TWA	1000 mg/m ³
Slovenia OEL - TWA	1000 mg/m ³
Switzerland OEL -TWAs	1000 ppm

Propylene glycol

Australia TWA	150 ppm 474 mg/m ³ 10 mg/m ³
Ireland OEL - TWAs	150 ppm 470 mg/m ³ 10 mg/m ³
Latvia OEL - TWA	7 mg/m ³
Lithuania OEL - TWA	7 mg/m ³

Exposure Controls

Engineering Controls:	Keep airborne contamination levels below the exposure limits listed above in this section. Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
Eyes:	Wear safety glasses or goggles if eye contact is possible.
Skin:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.
Respiratory protection:	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Liquid	Color:	Translucent red
Odor:	Cherry Vanilla	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		

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9. PHYSICAL AND CHEMICAL PROPERTIES

pH: No data available.

Melting/Freezing Point (°C): No data available

Boiling Point (°C): No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)

Water, purified

No data available

Glycerin, USP

No data available

Guaifenesin

No data available

Dextromethorphan hydrobromide

Measured 7.4 Log P 1.59

Citric acid, anhydrous

No data available

Carboxymethylcellulose sodium

No data available

FD & C Red No. 40

No data available

FD & C Blue No. 1

No data available

Liquid glucose

No data available

Polyethylene glycol

No data available

Sodium benzoate

No data available

Sodium Citrate

No data available

Sucralose

No data available

Xanthan gum

No data available

Propylene glycol

No data available

Triacetin

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

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10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
Oxidizing Properties: No data available
Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers
Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information: The information included in this section describes the potential hazards of the individual ingredients.
Short Term: Harmful if swallowed (based on components)
Known Clinical Effects: Common adverse reactions associated with the clinical use of dextromethorphan hydrobromide include, drowsiness, dizziness, and nausea and vomiting.

Acute Toxicity: (Species, Route, End Point, Dose)

Glycerin, USP

Mouse Oral LD50 4090 mg/kg
Rat Oral LD50 12.6 g/kg
Rabbit Dermal LD50 > 10 g/kg
Rat Inhalation LC50 1hr > 570 mg/m³
Rat Dermal LD 50 > 21.9 g/kg

Guaifenesin

Rat Oral LD50 1510 mg/kg

Dextromethorphan hydrobromide

Rat Oral LD50 350 mg/kg
Mouse Oral LD50 165mg/kg

Citric acid, anhydrous

Rat Oral LD50 3000 mg/kg

Carboxymethylcellulose sodium

Mouse Oral LD50 > 27,000 mg/kg
Rat Oral LD50 27,000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Sodium benzoate

Rat Oral LD50 4,070 mg/kg
Mouse Oral LD50 1600mg/kg

Xanthan gum

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Rat Oral LD50 > 5000 mg/kg

Propylene glycol

Rat Oral LD 50 22,000 mg/kg
Mouse Oral LD 50 24,900mg/kg
Rabbit Dermal LD 50 20,800mg/kg

Triacetin

Rat Oral LD 50 3000 mg/kg
Mouse Oral LD 50 1100mg/kg

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Glycerin, USP

Eye Irritation Rabbit Mild

Dextromethorphan hydrobromide

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Citric acid, anhydrous

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Polyethylene glycol

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Carboxymethylcellulose sodium

13 Week(s) Rat Oral 227 g/kg LOAEL Liver, Kidney, Ureter, Bladder

Sodium benzoate

10 Day(s) Rat Oral 27370 mg/kg LOAEL Liver, Blood
10 Day(s) Mouse Oral 45 g/kg LOAEL Liver, Kidney, Blood, Ureter, Bladder

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Sodium benzoate

Embryo / Fetal Development Rat Oral 44 g/kg LOEL Developmental toxicity,

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11. TOXICOLOGICAL INFORMATION

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
FD & C Blue No. 1 IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 50 mg/L
Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L

Dextromethorphan hydrobromide

Daphnia magna (Water Flea) OECD EC50 48 Hours 14.5 mg/L
Green algae OECD EbC50 72 Hours 2.4 mg/L
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours 4.9 mg/L

Persistence and Degradability:

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Dextromethorphan hydrobromide

OECD 0% After 28 Day(s) Not Ready

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Dextromethorphan hydrobromide

Measured 7.4 Log P 1.59

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

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14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Carboxymethylcellulose sodium

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Citric acid, anhydrous

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	201-069-1

Dextromethorphan hydrobromide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

FD & C Blue No. 1

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	223-339-8

FD & C Red No. 40

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	247-368-0

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15. REGULATORY INFORMATION

Flavor

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Glycerin, USP

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex V - Exemptions from the obligations of Register:	Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern
EU EINECS/ELINCS List	200-289-5

Liquid glucose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Menthol-L

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	216-074-4

Polyethylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 3
EU EINECS/ELINCS List	Not Listed

Propylene glycol

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-338-0

Sodium benzoate

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CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8
Sodium Citrate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed
Sucralose	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	259-952-2
Triacetin	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-051-9
Water, purified	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Xanthan gum	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	234-394-2

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects

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Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: New data sheet.

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Product Stewardship Hazard Communication

Prepared by: Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet