



MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
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+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:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Simethicone Oral Suspensions/Drops

Trade Name: SAB Simplex
Chemical Family: Not determined
Intended Use: Pharmaceutical product used for gastrointestinal disorders

2. HAZARDS IDENTIFICATION

Appearance: White suspension

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: May cause eye and skin irritation (based on components) .
EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings 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	Classification	%
Citric acid	77-92-9	201-069-1	Xi; R36	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Simethicone	8050-81-5	Not listed	Not Listed	7

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Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Sorbic acid	110-44-1	203-768-7	Not Listed	*
Sodium citrate	68-04-2	200-675-3	Not Listed	*
Sodium cyclamate	139-05-9	205-348-9	Not Listed	*
Flavor	NOT ASSIGNED	Not listed	Not Listed	*
Sodium saccharin	128-44-9	204-886-1	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*
Carbomer	9007-16-3	Not listed	Not Listed	*
Hypromellose	9004-65-3	Not listed	Not Listed	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

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

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

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

6. ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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

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.

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7. HANDLING AND STORAGE

General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8).
Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: 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. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment:

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: Respiratory protection is recommended as a precaution to minimize exposure when handling this material in bulk.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Suspension	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
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

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11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Sodium benzoate

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

Sorbic acid

Rat Oral LD50 7360 mg/kg
Mouse Oral LD50 3200 mg/kg

Citric acid

Rat Oral LD50 3000 mg/kg

Sodium cyclamate

Rat Oral LD50 1280 mg/kg

Sodium saccharin

Mouse Oral LD50 17.5 g/kg
Rat Oral LD50 14.2 - 17 g/kg
Rat Intraperitoneal LD50 7100 mg/kg

Hypromellose

Rat Oral LD50 > 10,000 mg/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)

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

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

Sodium saccharin

36 Week(s) Rat Oral 756 g/kg LOAEL Kidney, Ureter, Bladder
54 Day(s) Rat Oral 32400 mg/kg LOAEL Immune system

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

Carcinogen Status:

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below :

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11. TOXICOLOGICAL INFORMATION

Sodium cyclamate

IARC: Group 3 (Not Classifiable)

Sodium saccharin

IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered.

14. TRANSPORT INFORMATION

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

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15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Simethicone

Australia (AICS): Present

Sodium benzoate

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS/ELINCS List 208-534-8

Sorbic acid

Inventory - United States TSCA - Sect. 8(b) T

Australia (AICS): Present

EU EINECS/ELINCS List 203-768-7

Citric acid

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS/ELINCS List 201-069-1

Sodium citrate

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

Standard for the Uniform Scheduling

for Drugs and Poisons: Schedule 5

EU EINECS/ELINCS List 200-675-3

Sodium cyclamate

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS/ELINCS List 205-348-9

Sodium saccharin

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Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-886-1
Water, purified	
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
Hypromellose	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R36 - Irritating to eyes.

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

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet