MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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1-212-573-2222

Pfizer Ltd
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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: Mefenamic Acid Oral Suspension

Trade Name: Ponstan; Ponstyl
Chemical Family: Not determined
Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

2. HAZARDS IDENTIFICATION

Appearance: Off-white creamy suspension

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

Additional Hazard Information:

Short Term: May be harmful if swallowed. May cause allergic reactions in susceptible individuals. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on gastrointestinal system, liver, kidneys, heart.

Known Clinical Effects: Adverse effects associated with the therapeutic use of mefenamic acid include serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Dizziness, headaches, anemia, increased bleeding time, rashes, and liver effects have also been reported. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

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 product or its ingredients 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	%
Mefenamic Acid	61-68-7	200-513-1	Repr. Cat.3;R63 Xn;R22	1
Sodium hydroxide	1310-73-2	215-185-5	C;R35	<1
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	<1
Sucrose	57-50-1	200-334-9	Not Listed	*
Alcohol	64-17-5	200-578-6	F;R11	0.5

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Povidone	9003-39-8	Not listed	Not Listed	*
Gluconolactone	90-80-2	202-016-5	Not Listed	*
Magnesium aluminum silicate	1327-43-1	215-478-8	Not Listed	*
Sodium benzoate	532-32-1	208-534-8	Not Listed	*
Sodium saccharin	128-44-9	204-886-1	Not Listed	*
Carboxymethylcellulose sodium	9004-32-4	Not listed	Not Listed	*
Sorbitol solution	50-70-4	200-061-5	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*
Flavor	NOT ASSIGNED	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.

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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Carbon dioxide, dry chemical, or foam

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

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 spill with absorbent material. 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.

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). Wash thoroughly after handling.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Mefenamic Acid

Pfizer OEL TWA-8 Hr:	3000 µg/m^3

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	= 2 mg/m^3 Ceiling
Australia PEAK	= 2 mg/m^3 Peak
Austria OEL - MAKs	= 2 mg/m^3 MAK
Belgium OEL - TWA	= 2 mg/m^3 TWA
Bulgaria OEL - TWA	= 2.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 1 mg/m^3 TWA
Finland OEL - TWA	= 2 mg/m^3 TWA
France OEL - TWA	= 2 mg/m^3 VME
Greece OEL - TWA	= 2 mg/m^3 TWA
Hungary OEL - TWA	= 2 mg/m^3 TWA
Latvia OEL - TWA	= 0.5 mg/m^3 TWA
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	= 0.5 mg/m^3 NDS
Slovakia OEL - TWA	= 2 mg/m^3 TWA
Slovenia OEL - TWA	= 2 mg/m^3 TWA
Sweden OEL - TWAs	= 1 mg/m^3 LLV

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	= 2 ppm Ceiling
Australia PEAK	= 5 ppm Peak = 7.5 mg/m^3 Peak
Austria OEL - MAKs	= 5 ppm MAK = 8 mg/m^3 MAK
Belgium OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Bulgaria OEL - TWA	= 8.0 mg/m^3 TWA
Cyprus OEL - TWA	= 5.0 ppm TWA = 8.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 8 mg/m^3 TWA
Estonia OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Germany - TRGS 900 - TWAs	= 2 ppm TWA = 3 mg/m^3 TWA
Greece OEL - TWA	= 5 ppm TWA = 7 mg/m^3 TWA
Hungary OEL - TWA	= 8 mg/m^3 TWA
Ireland OEL - TWAs	= 5 ppm TWA = 7 mg/m^3 TWA
Italy OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Latvia OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Lithuania OEL - TWA	= 5 ppm IPRV = 8 mg/m^3 IPRV
Luxembourg OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Malta OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Netherlands OEL - TWA	= 5 ppm MAC = 8 mg/m^3 MAC
Poland OEL - TWA	= 5 mg/m^3 NDS
Romania OEL - TWA	= 5 ppm TWA = 8 mg/m^3 TWA
Slovakia OEL - TWA	= 5 ppm TWA = 8.0 mg/m^3 TWA
Slovenia OEL - TWA	= 5 ppm TWA anhydrous = 8 mg/m^3 TWA anhydrous
Spain OEL - TWA	= 5 ppm VLA-ED = 7.6 mg/m^3 VLA-ED

Magnesium aluminum silicate

Bulgaria OEL - TWA	= 1.5 mg/m^3 TWA = 10.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 10.0 mg/m^3 TWA except for gamma Al2O3
Slovakia OEL - TWA	= 6 mg/m^3 TWA except .gamma.-Aluminum oxide

Sucrose

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA
Australia TWA	= 10 mg/m^3 TWA
Belgium OEL - TWA	= 10 mg/m^3 TWA
Bulgaria OEL - TWA	= 10.0 mg/m^3 TWA
Estonia OEL - TWA	= 10 mg/m^3 TWA
France OEL - TWA	= 10 mg/m^3 VME

Ireland OEL - TWAs	= 10 mg/m^3 TWA
Lithuania OEL - TWA	= 10 mg/m^3 IPRV
OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA total = 5 mg/m^3 TWA
Portugal OEL - TWA	= 10 mg/m^3 TWA
Slovakia OEL - TWA	= 6 mg/m^3 TWA
Spain OEL - TWA	= 10 mg/m^3 VLA-ED

Alcohol

ACGIH Threshold Limit Value (TWA)	= 1000 ppm TWA
Australia TWA	= 1000 ppm TWA = 1880 mg/m^3 TWA
Austria OEL - MAKs	= 1000 ppm MAK = 1900 mg/m^3 MAK
Belgium OEL - TWA	= 1000 ppm TWA = 1907 mg/m^3 TWA
Bulgaria OEL - TWA	= 1000.0 mg/m^3 TWA
Czech Republic OEL - TWA	= 1000 mg/m^3 TWA
Denmark OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA
Estonia OEL - TWA	= 1000 mg/m^3 TWA = 500 ppm TWA
Finland OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA
France OEL - TWA	= 1000 ppm VME = 1900 mg/m^3 VME
Germany - TRGS 900 - TWAs	= 500 ppm TWA = 960 mg/m^3 TWA
Greece OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA
Hungary OEL - TWA	= 1900 mg/m^3 TWA
Ireland OEL - TWAs	= 1000 ppm TWA = 1900 mg/m^3 TWA
Latvia OEL - TWA	= 1000 mg/m^3 TWA
Lithuania OEL - TWA	= 1000 mg/m^3 IPRV = 500 ppm IPRV
Netherlands OEL - TWA	= 1000 mg/m^3 MAC = 500 ppm MAC
OSHA - Final PELS - TWAs:	= 1000 ppm TWA = 1900 mg/m^3 TWA
Poland OEL - TWA	= 1900 mg/m^3 NDS
Portugal OEL - TWA	= 1000 ppm TWA
Romania OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA
Slovakia OEL - TWA	= 500 ppm TWA = 960 mg/m^3 TWA
Slovenia OEL - TWA	= 1000 ppm TWA = 1900 mg/m^3 TWA
Spain OEL - TWA	= 1000 ppm VLA-ED = 1910 mg/m^3 VLA-ED
Sweden OEL - TWAs	= 1000 mg/m^3 LLV = 500 ppm LLV

Analytical Method: Analytical method available for Mefenamic Acid. Contact Pfizer Inc for further information.

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: 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: Creamy suspension **Color:** Off-white
Molecular Formula: Mixture **Molecular Weight:** Mixture

Solubility: Soluble: Water
pH: 4.9-5.1
Specific Gravity: 1.12-1.14(25 °C)

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

Polymerization: Will not occur

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)

Mefenamic Acid
Mouse Oral LD50 525 mg/kg
Rat Oral LD50 740 mg/kg
Mouse IV LD50 96 mg/kg
Rat IV LD50 112 mg/kg

Sucrose
Rat Oral LD50 29.7 g/kg

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

Alcohol

Rat Inhalation LC50 20,000 mg/L

Povidone
Rat Oral LD50 100 g/kg

Sodium hydroxide
Mouse IP LD50 40 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

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

Sorbitol solution
Rat Oral LD50 15,900 mg/kg
Mouse Oral LD50 17,800 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)

Alcohol
Eye Irritation Rabbit Severe

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Hydrochloric Acid
Skin Irritation Severe
Eye Irritation Severe

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

Mefenamic Acid
78 Week(s) Rat Oral 25 mg/kg/day NOEL Kidney, Gastrointestinal System
1 Year(s) Dog Oral 200 mg/kg/day LOAEL Kidney, Liver
2 Year(s) Monkey No route specified 200 mg/kg/day NOAEL Kidney, Liver, Gastrointestinal system, Heart

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

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

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

Mefenamic Acid
Embryo / Fetal Development Mouse No route specified < 3500 mg/day LOEL Teratogenic
Reproductive & Fertility Rat No route specified 8.75-17.5 g/day NOEL No effects at maximum dose
Embryo / Fetal Development Rat No route specified Not Teratogenic
Embryo / Fetal Development Rabbit No route specified Not Teratogenic

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.

Povidone
IARC: Group 3 (Not Classifiable)

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

Sodium saccharin
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. 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.

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:
Class D, Division 2, Subdivision A

Mefenamic Acid

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 4
EU EINECS/ELINCS List	200-513-1

Povidone

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	215-185-5

Gluconolactone

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-016-5

Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

Magnesium aluminum silicate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-478-8

Sodium benzoate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	208-534-8

Sodium saccharin

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-886-1

Carboxymethylcellulose sodium

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Sucrose

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	200-334-9

Sorbitol solution

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	200-061-5

Alcohol

California Proposition 65	developmental toxicity, initial date 10/1/87 (when in alcoholic beverages)
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-578-6

Water

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

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R11 - Highly flammable.
R22 - Harmful if swallowed.
R23 - Toxic by inhalation.
R35 - Causes severe burns.
R63 - Possible risk of harm to the unborn child.

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