



SAFETY DATA SHEET

Revision date: 01-Nov-2014

Version: 2.0

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

Product Identifier

Material Name: Mefenamic Acid Suppositories

Trade Name: PONSTAN; PONTAL; PARKEMED; COSLAN; PONSTYL; Mefenamin Pfizer

Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

Details of the Supplier of the Safety Data Sheet

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Pfizer Pharmaceuticals Group
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CHEMTREC (24 hours): 1-800-424-9300
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International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 2

EU Classification:

EU Indication of danger: Toxic to Reproduction: Category 3

EU Risk Phrases:

R63 - Possible risk of harm to the unborn child.

Label Elements

Signal Word: Warning

Hazard Statements: H361d - Suspected of damaging the unborn child

Precautionary Statements:

P201 - Obtain special instructions before use
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

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Other Hazards No data available
Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods.

Note: 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	EU Classification	GHS Classification	%
Mefenamic Acid	61-68-7	200-513-1	Repr. Cat.3;R63 Xn;R22	Acute Tox.4 (H302) Repr.2 (H361d)	10

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Hard fat	Not assigned	Not Listed	Not Listed	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 R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Contact: Remove contaminated clothing and wash exposed area with soap and water. Obtain medical assistance if irritation occurs.

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.

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Medical Conditions None known
Aggravated by Exposure:

Indication of the Immediate Medical Attention and Special Treatment Needed
Notes to Physician: None

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: Emits toxic fumes of carbon monoxide and oxides of nitrogen.

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 the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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

Use appropriate ventilation. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. 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): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Mefenamic Acid

Pfizer OEL TWA-8 Hr: 3000 µg/m³

Exposure Controls

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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:	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:	Wear protective clothing when working with large quantities.
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:	Suppository	Color:	White to creamy-white
Odor:	No data available.	Odor Threshold:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture
Solvent Solubility:	No data available		
Water Solubility:	No data available		
pH:	No data available.		
Melting/Freezing Point (°C):	No data available		
Boiling Point (°C):	No data available.		
Partition Coefficient: (Method, pH, Endpoint, Value)			
Mefenamic Acid			
No data available			
Hard fat			
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		

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

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11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

Short Term:

Long Term:

Known Clinical Effects:

The information included in this section describes the potential hazards of the active ingredient.

May cause allergic reactions in susceptible individuals.

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

Adverse effects associated with 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.

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

Mefenamic Acid

Mouse Oral LD50 525 mg/kg

Rat Oral LD50 740mg/kg

Mouse IV LD50 96mg/kg

Rat IV LD50 112mg/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.

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

Reproduction & Development Toxicity: (Duration, 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

Carcinogen Status:

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

12. ECOLOGICAL INFORMATION

Environmental Overview:

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

Toxicity:

No data available

Persistence and Degradability:

No data available

Bio-accumulative Potential:

No data available

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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.

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Hard fat

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

Mefenamic Acid

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2
EU EINECS/ELINCS List	Schedule 4
	200-513-1

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16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Reproductive toxicity-Cat.2; H361d - Suspected of damaging the unborn child

Xn - Harmful
Toxic to Reproduction: Category 3

R22 - Harmful if swallowed.
R63 - Possible risk of harm to the unborn child.

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

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

Revision date: 01-Nov-2014

Prepared by: Product Stewardship Hazard Communication
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