MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Ibuprofen Suppository

Trade Name: IPREN
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as analgesic; antipyretic

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Ibuprofen	15687-27-1	239-784-6	125 mg***

Ingredient	CAS Number	EU EINECS List	%
Hard fat	Not assigned	Not listed	*

Additional Information: *** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Suppository
Signal Word: WARNING

Statement of Hazard:
May be harmful if swallowed.
May cause gastrointestinal system effects
May cause allergic reaction in aspirin-sensitive individuals
Possible risk of harm to the unborn child

Additional Hazard Information:

Short Term: Toxicity by breathing dust is not expected, based on animal studies. However, inhalation should be avoided. May be harmful if swallowed. Accidental ingestion may cause effects similar to those seen in clinical use. May cause allergic reaction in sensitive individuals

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus. Acute overdosage and/or chronic abuse of ibuprofen may cause kidney effects.

Known Clinical Effects: Adverse effects associated with the therapeutic use include gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation . It may also cause prolonged bleeding time. Drowsiness, fatigue, or headache are also possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

EU Indication of danger: Harmful
Toxic to Reproduction; Category 3

EU Hazard Symbols:

EU Risk Phrases:

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

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.

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 and shoes and thorougly wash skin with soap or mild detergent and water. If irritation occurs or persists, get 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 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: No special handling requirements for normal use of this material. Avoid contact with eyes, skin and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ibuprofen

Pfizer OEL TWA-8 Hr: 3 mg/m³

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

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Rubber gloves
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. 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:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
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: Thermal decomposition products may include carbon monoxide and carbon dioxide
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

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

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

Ibuprofen
Rat Oral LD 50 1600 mg/kg
Rat Inhalation LC 50 > 20 mg/L
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)

Ibuprofen

4 Day(s)	Rat	Oral	200 mg/kg	Gastrointestinal System
30 Day(s)	Dog	Oral	480 mg/kg	Gastrointestinal system
2 Week(s)	Rat	Oral	1300 mg/kg	Liver

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

Ibuprofen

Fertility and Embryonic Development	Rat	rectal	100 mg/kg/day	Fertility
Fertility and Embryonic Development	Rat	rectal	200 mg/kg/day	Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral	60 mg/kg/day	Not Teratogenic
Embryo / Fetal Development	Rat	Oral	180 mg/kg/day	Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Ibuprofen

Bacterial Mutagenicity (Ames)	*Salmonella*	Negative

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 thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
EU Indication of danger: Harmful
Toxic to Reproduction; Category 3

EU Risk Phrases:

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

EU Safety Phrases:

S22 - Do not breathe dust.
S36 - Wear suitable protective clothing.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May be harmful if swallowed.
May cause gastrointestinal system effects
May cause allergic reaction in aspirin-sensitive individuals
Possible risk of harm to the unborn child

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision A

Ibuprofen

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 3 Schedule 4
EU EINECS List	239-784-6

16. OTHER INFORMATION

Reasons for Revision: Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

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

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End of Safety Data Sheet