MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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New York, New York 10017
1-212-573-2222

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

Pfizer Ltd
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Sandwich, Kent
CT13 9NJ
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International CHEMTREC (24 hours): +1-703-527-3887

Material Name: DYNASTAT (Parecoxib sodium) Powder for Injection

Trade Name: DYNASTAT
Chemical Family: Not determined
Intended Use: Pharmaceutical product

2. HAZARDS IDENTIFICATION

Appearance: White crystalline solid
Signal Word: DANGER

Statement of Hazard:
May damage the unborn child.
Causes damage to gastrointestinal system through prolonged or repeated exposure.

Additional Hazard Information:
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on developing fetus and gastrointestinal system.

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation . May cause effects on cardiovascular system. Clinical use may cause Stevens Johnson Syndrome (epidermal necrosis and exfoliative dermatitis). Serious allergic reactions, including anaphylaxis, have been reported.

EU Indication of danger: Toxic to Reproduction: Category 2

EU Hazard Symbols:

T

EU Risk Phrases:
R61 - May cause harm to the unborn child.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

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

2. HAZARDS IDENTIFICATION

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	EU Classification	%
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Phosphoric acid	7664-38-2	231-633-2	C;R34	**
Parecoxib sodium	198470-85-8	Not Listed	Repr.Cat.2;R61 Xn;R48/22	20 or 40 mg****

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium phosphate, dibasic	7558-79-4	231-448-7	Not Listed	*

Additional Information: ** to adjust pH
**** per dose 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: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May burn emitting oxides of: nitrogen sulfur

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.

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 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.

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.

Sodium hydroxide

ACGIH Ceiling Threshold Limit:	2 mg/m^3
Australia PEAK	2 mg/m^3
Austria OEL - MAKs	2 mg/m^3
Bulgaria OEL - TWA	2.0 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
France OEL - TWA	2 mg/m^3
Greece OEL - TWA	2 mg/m^3
Hungary OEL - TWA	2 mg/m^3
Japan - OELs - Ceilings	2 mg/m^3
Latvia OEL - TWA	0.5 mg/m^3
OSHA - Final PELS - TWAs:	2 mg/m^3
Poland OEL - TWA	0.5 mg/m^3
Slovakia OEL - TWA	2 mg/m^3
Slovenia OEL - TWA	2 mg/m^3
Sweden OEL - TWAs	1 mg/m^3

Phosphoric acid

ACGIH Threshold Limit Value (TWA)	1 mg/m^3
ACGIH Threshold Limit Value (STEL)	3 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Australia STEL	3 mg/m^3
Australia TWA	1 mg/m^3
Austria OEL - MAKs	1 mg/m^3
Belgium OEL - TWA	1 mg/m^3
Bulgaria OEL - TWA	1.0 mg/m^3
Cyprus OEL - TWA	1 mg/m^3
Czech Republic OEL - TWA	1 mg/m^3
Denmark OEL - TWA	1 mg/m^3
Estonia OEL - TWA	1 mg/m^3
Finland OEL - TWA	1 mg/m^3
France OEL - TWA	0.2 ppm 1 mg/m^3
Germany - TRGS 900 - TWAs	2 mg/m^3
Germany (DFG) - MAK	2 mg/m^3
Greece OEL - TWA	1 mg/m^3
Hungary OEL - TWA	1 mg/m^3
Ireland OEL - TWAs	1 mg/m^3
Italy OEL - TWA	1 mg/m^3
Latvia OEL - TWA	1 mg/m^3
Lithuania OEL - TWA	1 mg/m^3
Luxembourg OEL - TWA	1 mg/m^3
Malta OEL - TWA	1 mg/m^3
Netherlands OEL - TWA	1 mg/m^3
OSHA - Final PELS - TWAs:	1 mg/m^3
Poland OEL - TWA	1 mg/m^3
Portugal OEL - TWA	1 mg/m^3
Romania OEL - TWA	1 mg/m^3
Slovakia OEL - TWA	1 mg/m^3
Slovenia OEL - TWA	1 mg/m^3
Spain OEL - TWA	1 mg/m^3
Sweden OEL - TWAs	1 mg/m^3

Parecoxib sodium

Pfizer OEL TWA-8 Hr:	100µg/m^3

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.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

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:	Powder	**Color:**	White
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Chemical 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

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 phosphate, dibasic
Rat Oral LD 50 17 g/kg

Sodium hydroxide
Mouse IP LD50 40 mg/kg

Phosphoric acid
Rat Oral LD50 1530 mg/kg
Rabbit Dermal LD 50 2730 mg/kg

Parecoxib sodium
Rat Intravenous Minimum Lethal Dose 45 mg/kg
Dog Para-periosteal Minimum Lethal Dose 100 mg/kg

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

Sodium phosphate, dibasic
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Phosphoric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Parecoxib sodium
Eye Irritation Rabbit Moderate

11. TOXICOLOGICAL INFORMATION

Skin Irritation Rabbit Slight
Skin Sensitization - GPMT Guinea Pig Negative

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

Parecoxib sodium

4 Week(s)	Rat	Intravenous	25/10 mg/kg/day (male/female)	NOAEL	Gastrointestinal System, Kidney
2 Week(s)	Dog	Intravenous	6 mg/kg/day	NOAEL	Gastrointestinal system, Skin
4 Week(s)	Dog	Intravenous	6 mg/kg/day	NOEL	Gastrointestinal system, Skin

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

Parecoxib sodium

Reproductive & Fertility	Rat	Intravenous	12.5 mg/kg/day	NOEL	Maternal toxicity, Developmental toxicity
Reproductive & Fertility	Rabbit	Intravenous	20 mg/kg/day	NOEL	Fetotoxicity
Embryo / Fetal Development	Rabbit	Intravenous	20 mg/kg/day	NOEL	Developmental toxicity

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

Parecoxib sodium

In Vitro Bacterial Mutagenicity (Ames)	*Salmonella*	Negative
In Vitro Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative
In Vitro Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Positive
In Vivo Micronucleus	Rat Bone Marrow	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 investigated. Releases to the environment should be avoided.

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

Phosphoric acid

Gambusia affinis (Mosquitofish)	LC50	96 Hours	3-3.5 mg/L
Daphnia magna (Water Flea)	EC-50	12 Hours	4.6 mg/L

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

EU Symbol: T
EU Indication of danger: Toxic to Reproduction: Category 2

EU Risk Phrases:

R61 - May cause harm to the unborn child.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

EU Safety Phrases:

S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
DANGER
May damage the unborn child.
Causes damage to gastrointestinal system through prolonged or repeated exposure.

Canada - WHMIS: Classifications

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

Sodium phosphate, dibasic

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-448-7

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	1000 lb 454 kg
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

15. REGULATORY INFORMATION

Phosphoric acid

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
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	231-633-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.
R34 - Causes burns.
R35 - Causes severe burns.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 15 - Regulatory Information.

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