



MATERIAL SAFETY DATA SHEET

Revision date: 18-Jul-2007

Version: 1.0

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

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Contact E-Mail: Contact E-Mail: pfizer-MSDS@pfizer.com This e-mail address should not be used to report suspected adverse events.

Material Name: Naproxen Tablets

| | |
|-------------------------|---|
| Trade Name: | NAPRONTAG; PONSTANT |
| Synonyms: | NAPRATEC (in combination with Misoprostol tablets) |
| Chemical Family: | Arylacetic acid |
| Intended Use: | Pharmaceutical active used as non-steroidal, anti-inflammatory drug (nsaid) |

2. HAZARDS IDENTIFICATION

Appearance: Yellow tablets
Signal Word: WARNING

Statement of Hazard: Harmful if swallowed.
Suspected of damaging the unborn child.

Additional Hazard Information:
Short Term: Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted. Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: Clinical use of this drug has caused headache dizziness drowsiness skin rash effects on hearing swelling gastrointestinal effects such as nausea, pain, heartburn, bleeding, ulceration, and perforation . 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.

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Australian Hazard Classification (NOHSC): 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 | % |
|--------------------|------------|-----------------------|---------------------------|-------|
| Naproxen Sodium | 26159-34-2 | 247-486-2 | Repr. Cat.3;R63 Xn;R22 | 90-95 |
| Maize starch | 9005-25-8 | 232-679-6 | Not Listed | * |
| Magnesium stearate | 557-04-0 | 209-150-3 | Not Listed | * |

| Ingredient | CAS Number | EU EINECS/ELINCS List | Classification | % |
|-------------------------|------------|-----------------------|----------------|---|
| Povidone | 9003-39-8 | Not listed | Not Listed | * |
| Sodium starch glycolate | 9063-38-1 | Not listed | Not Listed | * |
| Lactose | 63-42-3 | 200-559-2 | Not Listed | * |
| Yellow lake blend | MIXTURE | 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: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire. May include oxides of carbon.

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

Fire / Explosion Hazards: Not applicable

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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Releases to the environment should be avoided.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Maize starch

| | |
|-----------------------------------|----------------------------------|
| 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 |
| Czech Republic OEL - TWA | = 4.0 mg/m ³ TWA |
| Greece OEL - TWA | = 10 mg/m ³ TWA |
| Ireland OEL - TWAs | = 5 mg/m ³ TWA |
| | = 10 mg/m ³ TWA |
| | = 4 mg/m ³ TWA |
| OSHA - Final PELs - TWAs: | = 15 mg/m ³ TWA total |
| | = 5 mg/m ³ TWA |
| Portugal OEL - TWA | = 10 mg/m ³ TWA |
| Spain OEL - TWA | = 10 mg/m ³ VLA-ED |

Magnesium stearate

| | | |
|-----------------------------------|-------------------------------|--|
| ACGIH Threshold Limit Value (TWA) | = 10 mg/m ³ TWA | except stearates of toxic metals |
| Australia TWA | = 10 mg/m ³ TWA | |
| Belgium OEL - TWA | = 10 mg/m ³ TWA | |
| Ireland OEL - TWAs | = 10 mg/m ³ TWA | except lead stearate |
| Lithuania OEL - TWA | = 3 mg/m ³ IPRV | |
| Portugal OEL - TWA | = 10 mg/m ³ TWA | does not include stearates of toxic metals |
| Spain OEL - TWA | = 10 mg/m ³ VLA-ED | not including stearates of toxic metals |
| Sweden OEL - TWAs | = 5 mg/m ³ LLV | |

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The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Naproxen Sodium

Pfizer Occupational Exposure Band (OEB): OEB1 (control exposure to the range of $>1000\mu\text{g}/\text{m}^3$ to $<3000\mu\text{g}/\text{m}^3$)

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.

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 airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

| | | | |
|---------------------------|---------|--------------------------|---------|
| Physical State: | Tablet | Color: | Yellow |
| 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.

11. TOXICOLOGICAL INFORMATION

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

Povidone

Rat Oral LD50 100 g/kg

Lactose

Rat Oral LD50 > 10 g/kg

Naproxen Sodium

Rat Oral LD50 534 mg/kg

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Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Naproxen Sodium

| | | | | | |
|-------------------------------------|--------|------|---------------|------|----------------------------|
| Fertility and Embryonic Development | Rat | Oral | 20 mg/kg/day | NOEL | No effects at maximum dose |
| Fertility and Embryonic Development | Rabbit | Oral | 20 mg/kg/day | NOEL | No effects at maximum dose |
| Fertility and Embryonic Development | Mouse | Oral | 170 mg/kg/day | NOEL | No effects at maximum dose |

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Naproxen Sodium

2 Year(s) Rat No route specified 24 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: Not listed as a carcinogen by IARC, NTP or US OSHA.

Povidone

IARC: Group 3

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.

15. REGULATORY INFORMATION

EU Symbol: Xn

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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.
S36/37/39 - Wear suitable protective clothing, gloves and eye/face protection.

OSHA Label:
WARNING
Harmful if swallowed.
Suspected of damaging the unborn child.

Canada - WHMIS: Classifications

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



Naproxen Sodium
Australia (AICS): Present
EU EINECS/ELINCS List 247-486-2

Maize starch
Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
REACH - Annex IV - Exemptions from the obligations of Register: Present
EU EINECS/ELINCS List 232-679-6

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

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

Magnesium stearate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS/ELINCS List 209-150-3

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

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Australia (AICS):
EU EINECS/ELINCS List

Present
200-559-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

R63 - Possible risk of harm to the unborn child.

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

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

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