

**1. Product and Company Identification**

Product name	ANAPROX(R) Tablets (550 mg)	
Product code	09 8510 4	
Use	- Anaprox is a nonsteroidal anti-inflammatory agent.	
Company information	Enquiries:	Local representation:
	Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	
	Phone	001-973/235 50 00
	E-Mail	info.sds@roche.com
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	

**2. Hazards identification****Emergency Overview**

Form	solid
Color	dark blue
Potential Health Effects	<ul style="list-style-type: none"><li>- Exposure: Ingestion</li><li>- Target Organs: skin, gastrointestinal system, Central nervous system</li><li>- Acute Effects: May cause skin drying, itching, peeling and rashes., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite.</li><li>- Chronic Effects: No adverse effects known</li><li>- Carcinogenicity: formulation not listed by NTP, IARC or OSHA</li><li>- Carcinogenicity: IARC Gr3 not classifiable <sup>*1</sup></li></ul>
Additional Health Information	<ul style="list-style-type: none"><li>- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class. Patients with prior history of ulcer disease or gastrointestinal bleeding and patients with advanced kidney disease.</li></ul>
*1 referring to:	Talc

## ANAPROX(R) Tablets (550 mg)

### 3. Composition/Information on ingredients

Characterization	final product
Ingredients	Concentration
Naproxen sodium CAS: 26159-34-2	~ 76 %
Microcrystalline cellulose CAS: 9004-34-6	~ 15 %
Talc CAS: 14807-96-6	~ 4 %
Magnesium stearate CAS: 557-04-0	~ 0.7 %

### 4. First-aid measures

Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

### 5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	- Toxic emissions may be given off in a fire
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

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### 6. Accidental release measures

- |                          |  |
|--------------------------|--|
| Personal precautions     | - ensure adequate ventilation  |
| Environmental protection | - avoid release to the environment   |
| Methods for cleaning up  | - Scoop or shovel spilled material into a suitable labeled open head drum<br>- Secure the drum cover and move the container to a safe holding area<br>- Clean spill area thoroughly<br>- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.<br>- Check area for residual material and repeat clean up if detected |

### 7. Handling and storage

#### Handling

- |                    |   |
|--------------------|---|
| Technical measures | - local exhaust ventilation necessary<br>- avoid dust formation; consider dust explosion hazard |
|--------------------|---|

#### Storage

- |                    |  |
|--------------------|--|
| Storage conditions | - keep containers tightly closed<br>- room temperature<br>- store in a dry place |
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### 8. Exposure controls/Personal protection

- |                           |  |
|---------------------------|--|
| Engineering Measures      | - see 7.   |
| Threshold value (USA) air | - ACGIH-TLV: 2 mg/m <sup>3</sup> (not classifiable as a human carcinogen, respirable fraction) *1<br>- OSHA-PEL: 2 mg/m <sup>3</sup> (respirable fraction) *1<br>- NIOSH-REL: 2 mg/m <sup>3</sup> (respirable fraction) *1<br>- ACGIH-TLV: 10 mg/m <sup>3</sup> *2<br>- OSHA-PEL: 5 mg/m <sup>3</sup> (respirable dust fraction) *2<br>- OSHA-PEL: 15 mg/m <sup>3</sup> (total dust) *2<br>- NIOSH-REL: 5 mg/m <sup>3</sup> (respirable dust fraction) *2<br>- NIOSH-REL: 10 mg/m <sup>3</sup> (total dust) *2 |

#### Personal protective equipment

- |                        |   |
|------------------------|---|
| Respiratory protection | - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.<br>- respiratory protection not necessary |
| Hand protection        | - protective gloves   |
| Eye protection         | - safety glasses  |

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Body protection - protective clothing

\*1 referring to: Talc

\*2 referring to: Microcrystalline cellulose

### 9. Physical and chemical properties

Color dark blue

Form solid

### 10. Stability and reactivity

Stability - stable under normal conditions

Conditions to avoid - None known

Materials to avoid - None known

### 11. Toxicological information

Acute toxicity - LD<sub>50</sub> 400 mg/kg (oral, rat) \*3

Local effects - skin: irritant \*3  
- eye: slightly irritating \*3

Carcinogenicity - not carcinogenic (several species) \*3

Reproduction toxicity - no toxic reproductive effects (several species) \*3

Note - dosage (oral): 500 to 1'000 mg/d \*3  
- the plasma half-life is about 13 hours; mainly by renal elimination \*3  
- the compound works as an antiinflammatory by inhibiting the prostaglandin synthase \*3  
- the compound is antiinflammatory by inhibiting the prostaglandine synthetase \*3

\*3 referring to: Naproxen sodium

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### 12. Ecological information

Ecotoxicity	- barely toxic for planktonic crustaceans ( <i>Daphnia magna</i> ) EC <sub>50</sub> (24 h) 140 mg/l NOEC (24 h) 51 mg/l	*3
	- barely toxic for planktonic crustaceans ( <i>Hyaella azteca</i> ) EC <sub>50</sub> (96 h) 383 mg/l NOEC (96 h) 120 mg/l	*3
	- barely toxic for fish (rainbow trout) LC <sub>50</sub> (96 h) 690 mg/l NOEC (96 h) 240 mg/l	*3
	- barely toxic for fish (bluegill sunfish) LC <sub>50</sub> (96 h) 560 mg/l NOEC (96 h) 240 mg/l	*3
	- barely toxic for algae ( <i>Scenedesmus (=Desmodesmus) subspicatus</i> ) EC <sub>50</sub> (72 h) > 320 mg/l (EEC, L 383 A, C.3)	*3
	- barely toxic for planktonic crustaceans ( <i>Daphnia magna</i> ) EC <sub>50</sub> (48 h) 174 mg/l (EEC, L 383 A, C.2)	*3
	- moderately toxic for higher plants ( <i>Lemna minor</i> ) EC <sub>50</sub> (7 d) 24.2 mg/l ( <i>Lemna</i> test, ISO/WD 20079)	*3
Air pollution	- observe local/national regulations	*3

\*3 referring to: Naproxen sodium

### 13. Disposal considerations

Waste from residues	- incinerate in qualified installation with flue gas scrubbing - observe local/national regulations regarding waste disposal - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.
Contaminated packaging	- Empty containers must be triple rinsed prior to disposal, recycling or reuse.
RCRA waste	- not regulated under RCRA

### 14. Transport information

Note	- not classified by transport regulations, proper shipping name non-regulated
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### 15. Regulatory information

- |                        |  |
|------------------------|--|
| TSCA Status            | - FDA Exemption - not on inventory   |
| Reporting Requirements | <ul style="list-style-type: none"><li>- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.</li><li>- In New Jersey, report all releases which enter a waterway or into soil, or which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.</li><li>- State and local regulations vary and may impose additional reporting requirements.</li></ul> |

### 16. Other information

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| Edition documentation | - changes from previous version in sections 13 |
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The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.