

**1. Product and Company Identification**

Product name	FANSIDAR(R) Tablets (500/25 mg)	
Product code	01 3744 8	
Use	- Fansidar is an antimalarial drug.	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	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	white
Odor	odourless
Potential Health Effects	<ul style="list-style-type: none">- Exposure: Ingestion- Target Organs: skin, kidneys, liver, respiratory tract, gastrointestinal system, Hematopoietic/blood system - Acute Effects: May cause eye irritation., May cause skin irritation., May cause allergic reactions., May cause photoallergenicity (sensitivity to light)., May cause mucous membrane irritation (inflammation)., May cause headache., May cause hepatic (liver) system effects., Signs and symptoms may include elevation of liver enzyme levels and jaundice (yellowing of the skin and eyes)., May cause renal (kidney) system effects., Signs and symptoms may include urine retention, increase or decrease in urine production, painful urination and presence of blood in urine., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite., May cause blood system changes. - Chronic Effects: No adverse effects known - Carcinogenicity: formulation not listed by NTP, IARC or OSHA- Carcinogenicity: IARC Gr3 not classifiable

*1

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- Additional Health Information
- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class. Liver conditions and/or impaired liver function. Kidney conditions and/or impaired renal function. Respiratory system conditions.
 - Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure. It is also advisable for nursing mothers to exercise caution regarding potential exposure.
 - Reproductive Toxicity: May cause birth defects based on animal data. ^{*2}

*1 referring to:

Talc

*2 referring to:

Pyrimethamine

3. Composition/Information on ingredients

Characterization	final product
Ingredients	Concentration
Sulfadoxine CAS: 2447-57-6	~ 71 %
Pyrimethamine CAS: 58-14-0	~ 4 %
Corn starch CAS: 9005-25-8	~ 18 %
Talc CAS: 14807-96-6	< 1 %

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

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Special method of fire-fighting - cool endangered containers with water spray

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
 - Secure the drum cover and move the container to a safe holding area
 - Clean spill area thoroughly
 - Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.
 - Check area for residual material and repeat clean up if detected

7. Handling and storage

Handling

- Technical measures
- local exhaust ventilation necessary
 - avoid dust formation; consider dust explosion hazard

Storage

- Storage conditions
- keep containers tightly closed
 - room temperature
 - store in a dry place

8. Exposure controls/Personal protection

- Engineering Measures - see 7.
- Threshold value (USA) air
- ACGIH-TLV: 2 mg/m³ (not classifiable as a human carcinogen, respirable fraction) *1
 - OSHA-PEL: 2 mg/m³ (respirable fraction) *1
 - NIOSH-REL: 2 mg/m³ (respirable fraction) *1
 - ACGIH-TLV: 10 mg/m³ (not classifiable as a human carcinogen) *3
 - OSHA-PEL: 5 mg/m³ (respirable fraction) *3
 - OSHA-PEL: 15 mg/m³ (total dust) *3
 - NIOSH-REL: 5 mg/m³ (respirable fraction) *3
 - NIOSH-REL: 10 mg/m³ (total dust) *3
- Threshold value (Roche) air
- IOEL (Internal Occupational Exposure Limit): 0.5 mg/m³ *4

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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. - respiratory protection not necessary
Hand protection	- protective gloves
Eye protection	- safety glasses
Body protection	- protective clothing
*1 referring to:	Talc
*3 referring to:	Corn starch
*4 referring to:	Sulfadoxine

9. Physical and chemical properties

Color	white
Form	solid
Odor	odourless

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 ₅₀ 5'200 mg/kg (oral, mouse)	*4
	- LD ₅₀ 128 mg/kg (oral, rat)	*2
	- LD ₅₀ 131 mg/kg (oral, mouse)	*2
Local effects	- skin: moderately irritating (rabbit)	*4
	- skin: non-irritant (man; occupational experience)	*4
	- skin, eyes, mucous membranes: irritant	*2
Sensitization	- may be sensitizing (man)	*4
Mutagenicity	- mutagenic (various in vivo and in vitro test systems)	*2
Carcinogenicity	- no indication for carcinogenicity (oral)	*2
Reproduction toxicity	- teratogenic and embryotoxic (several species)	*2
*2 referring to:	Pyrimethamine	
*4 referring to:	Sulfadoxine	

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14. Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

15. Regulatory information

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases 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.
- State and local regulations vary and may impose additional reporting requirements.

16. Other information

Edition documentation - changes from previous version in sections 13

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.