



*Wyeth Consumer
V# 7057
Circ 2257962
2257970
3704178*

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

WHITEHALL-ROBINS

1407 Cummings Drive

Richmond, VA 23220

804-257-2000

24 HR. Emergency Medical Information:

610-688-4400

CHEMTREC(R) USA, CAN, PR: 800-424-9300

International: 202-483-7616

SUBSTANCE: ADVIL TABLETS (BULK)

TRADE NAMES/SYNONYMS:

ADVIL(R) TABLETS (BULK); WHRPC202

PRODUCT USE: pharmaceutical

CREATION DATE: Jun 19 1995

REVISION DATE: Sep 15 2005

2. COMPOSITION, INFORMATION ON INGREDIENTS

COMPONENT: IBUPROFEN

CAS NUMBER: 15687-27-1

EC NUMBER (EINECS): 239-784-6

PERCENTAGE: >1

COMPONENT: SUCROSE

CAS NUMBER: 57-50-1

EC NUMBER (EINECS): 200-334-9

PERCENTAGE: >1

COMPONENT: OXIDIZED STARCH

CAS NUMBER: 65996-62-5

EC NUMBER: Not assigned.

PERCENTAGE: >1

COMPONENT: STARCH

CAS NUMBER: 9005-25-8

EC NUMBER (EINECS): 232-679-6

PERCENTAGE: >1

COMPONENT: CROSCARMELLOSE SODIUM

CAS NUMBER: 74811-65-7

EC NUMBER: Not assigned.

PERCENTAGE: >1

COMPONENT: CELLULOSE

CAS NUMBER: 9004-34-6

EC NUMBER (EINECS): 232-674-9

PERCENTAGE: >1

COMPONENT: WATER

CAS NUMBER: 7732-18-5

EC NUMBER (EINECS): 231-791-2

PERCENTAGE: >1

3. HAZARDS IDENTIFICATION

NFPA RATINGS (SCALE 0-4): HEALTH=1 FIRE=1 REACTIVITY=0

EMERGENCY OVERVIEW:

COLOR: brown

PHYSICAL FORM: coated tablet

ODOR: odorless

MAJOR HEALTH HAZARDS: kidney damage

PHYSICAL HAZARDS: Dust/air mixtures may ignite or explode.

POTENTIAL HEALTH EFFECTS:

INHALATION:

SHORT TERM EXPOSURE: irritation, allergic reactions

LONG TERM EXPOSURE: allergic reactions

SKIN CONTACT:

SHORT TERM EXPOSURE: irritation, allergic reactions, sensitivity to light

LONG TERM EXPOSURE: irritation, allergic reactions, sensitivity to light

EYE CONTACT:

SHORT TERM EXPOSURE: irritation


LONG TERM EXPOSURE: no information is available

INGESTION:

SHORT TERM EXPOSURE: gastrointestinal irritation, rash, itching, changes in blood pressure, ringing in the ears, nausea, vomiting, diarrhea, constipation, stomach pain, irregular heartbeat, headache, drowsiness, dizziness, disorientation, tingling sensation, loss of coordination, hearing loss, visual disturbances, kidney damage, convulsions, coma

LONG TERM EXPOSURE: allergic reactions, rash, itching, sensitivity to light, changes in blood pressure, ringing in the ears, nausea, vomiting, digestive disorders, diarrhea, constipation, stomach pain, asthma, irregular heartbeat, headache, drowsiness, dizziness, fainting, disorientation, emotional disturbances, tingling sensation, loss of coordination, hearing loss, visual disturbances, eye damage, internal bleeding, blood disorders, heart disorders, kidney damage, liver damage, reproductive effects, convulsions, coma

NFPA 704
HEALTH
FIRE
REACTIVITY



EMERGENCY OVERVIEW
COLOR
PHYSICAL FORM
ODOR
MAJOR HEALTH HAZARDS
PHYSICAL HAZARDS

POTENTIAL HEALTH EFFECTS
INHALATION
SHORT TERM EXPOSURE
LONG TERM EXPOSURE
SKIN CONTACT
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LONG TERM EXPOSURE
EYE CONTACT
SHORT TERM EXPOSURE
LONG TERM EXPOSURE
INGESTION
SHORT TERM EXPOSURE
LONG TERM EXPOSURE

CARCINOGEN STATUS:

OSHA: No

NTP: No

IARC: No

4. FIRST AID MEASURES

INHALATION: If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. Get immediate medical attention.

SKIN CONTACT: Wash skin with soap and water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention, if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

EYE CONTACT: Flush eyes with plenty of water for at least 15 minutes. Then get immediate medical attention.

INGESTION: If a large amount is swallowed, get medical attention.

5. FIRE FIGHTING MEASURES

FIRE AND EXPLOSION HAZARDS: Slight fire hazard. Dust/air mixtures may ignite or explode.

EXTINGUISHING MEDIA: carbon dioxide, regular dry chemical, regular foam, water

FIRE FIGHTING: Move container from fire area if it can be done without risk. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

6. ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL RELEASE:

Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers.

7. HANDLING AND STORAGE

STORAGE: Store and handle in accordance with all current regulations and standards. Keep separated from incompatible substances. Store at room temperature. Avoid contact with temperatures above 40 C. See original container for storage recommendations.

HANDLING: Use methods to minimize dust.

8. EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE LIMITS:

IBUPROFEN:

800 ug/m³ recommended TWA 8 hour(s) (OEG)

SUCROSE:

5 mg/m³ OSHA TWA (respirable dust fraction)

15 mg/m³ OSHA TWA (total dust)

10 mg/m³ ACGIH TWA

10 mg/m³ NIOSH recommended TWA 10 hour(s) (total particulate)

5 mg/m³ NIOSH recommended TWA 10 hour(s) (respirable fraction)

10 mg/m³ UK WEL TWA

20 mg/m³ UK WEL STEL

MEASUREMENT METHOD: Particulate filter; Gravimetric; NIOSH IV # 0500, Nuisance Dust (total), # 0600 (respirable)

STARCH:

5 mg/m³ OSHA TWA (respirable dust fraction)

15 mg/m³ OSHA TWA (total dust)

10 mg/m³ ACGIH TWA

10 mg/m³ NIOSH recommended TWA 10 hour(s) (total particulate)

5 mg/m³ NIOSH recommended TWA 10 hour(s) (respirable fraction)

10 mg/m³ UK WEL TWA (total inhalable dust)

4 mg/m³ UK WEL TWA (respirable dust)

MEASUREMENT METHOD: Particulate filter; Gravimetric; NIOSH IV # 0500, Nuisance Dust (total), # 0600 (respirable)

CELLULOSE:

5 mg/m³ OSHA TWA (respirable dust fraction)

15 mg/m³ OSHA TWA (total dust)

10 mg/m³ ACGIH TWA

5 mg/m³ NIOSH recommended TWA 10 hour(s) (respirable fraction)

10 mg/m³ NIOSH recommended TWA 10 hour(s) (total particulate)

10 mg/m³ UK WEL TWA (total inhalable dust)

4 mg/m³ UK WEL TWA (respirable dust)

20 mg/m³ UK WEL STEL (total inhalable dust)

MEASUREMENT METHOD: Particulate filter; Gravimetric; NIOSH IV # 0500, Nuisance Dust (total), # 0600 (respirable)

VENTILATION: Ventilation equipment should be explosion-resistant if explosive concentrations of material are present. Provide local exhaust ventilation system. Ensure compliance with applicable exposure limits.

EYE PROTECTION: Eye protection not required under normal conditions.

CLOTHING: Protective clothing is not required.

GLOVES: Wear appropriate chemical resistant gloves.

RESPIRATOR: Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum.

Consider warning properties before use.

Any dust and mist respirator.

Any air-purifying respirator with a high-efficiency particulate filter.

For Unknown Concentrations or Immediately Dangerous to Life or Health -

Any supplied-air respirator with full facepiece and operated in a pressure-demand or other positive-pressure mode in combination with a separate escape supply.

Any self-contained breathing apparatus with a full facepiece.

9. PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE: solid

COLOR: brown

PHYSICAL FORM: coated tablet

ODOR: odorless

BOILING POINT: Not applicable

MELTING POINT: Not available

VAPOR PRESSURE: Not applicable

VAPOR DENSITY: Not applicable

SPECIFIC GRAVITY: Not available

WATER SOLUBILITY: Not available

PH: Not applicable

VOLATILITY: Not applicable

ODOR THRESHOLD: Not available

EVAPORATION RATE: Not applicable

COEFFICIENT OF WATER/OIL DISTRIBUTION: Not available

10. STABILITY AND REACTIVITY

REACTIVITY: Stable at normal temperatures and pressure.

CONDITIONS TO AVOID: Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

INCOMPATIBILITIES:

May be incompatible with acids, bases, and oxidizers.

HAZARDOUS DECOMPOSITION:

Thermal decomposition products: miscellaneous decomposition products

POLYMERIZATION: Will not polymerize.

11. TOXICOLOGICAL INFORMATION

IBUPROFEN:

TOXICITY DATA:

180 mg/kg/3 week(s) intermittent oral-man TDLo; 800 mg/kg oral-man TDLo; 1028 mg/kg oral-man TDLo; 8 mg/kg oral-woman TDLo; 120 mg/kg/1 week(s) intermittent oral-man TDLo; 480 mg/kg/17 day(s) intermittent oral-child TDLo; 171 mg/kg oral-man LDLo; 469 mg/kg oral-child LDLo; 429 mg/kg oral-man TDLo; 132 mg/kg/6 day(s) intermittent oral-woman TDLo; 500 mg/kg oral-child TDLo; 96 mg/kg/3 day(s) intermittent unreported-woman TDLo; 636 mg/kg oral-rat LD50; 626 mg/kg intraperitoneal-rat LD50; 740 mg/kg subcutaneous-rat LD50; 530 mg/kg rectal-rat LD50; 740 mg/kg oral-mouse LD50; 320 mg/kg intraperitoneal-mouse LD50; 395 mg/kg subcutaneous-mouse LD50; 620 mg/kg rectal-mouse LD50; 1400 mg/kg oral-rabbit LD50; 830 mg/kg rectal-rabbit LD50; 495 mg/kg oral-guinea pig LD50; 1690 mg/kg oral-hamster LD50; 1 gm/kg oral-mammal LD50; 5 mg/kg oral-cat TDLo; 350 mg/kg unreported-mouse LD50; 100 mg/kg subcutaneous-mouse TDLo; 50 mg/kg skin-mouse TDLo; 50 mg/kg oral-rat TDLo; 30 mg/kg oral-rat TDLo; 103 mg/kg oral-mouse TDLo; 160 mg/kg intraperitoneal-rat TDLo; 1600 mg/kg intraperitoneal-rat LD50; 160 mg/kg oral-rat TDLo; 2 gm/kg oral-woman TDLo; 500 mg/kg intraperitoneal-mouse LDLo; 5 mg/kg oral-cat TDLo; 250 mg/kg unreported-rat LD50; 2 gm/kg oral-woman TDLo; 20.6 mg/kg oral-mouse TDLo; 4 mg/kg skin-rat TDLo; 8 mg/kg oral-woman TDLo; 500 mg/kg oral-mouse LD50; 50 mg/kg intraperitoneal-rat TDLo; 12 gm/kg/30 day(s) continuous oral-rat TDLo; 32760 mg/kg/26 week(s) intermittent oral-rat TDLo; 200 mg/kg/4 day(s) intermittent oral-rat TDLo; 12 gm/kg/30 day(s) continuous rectal-rat TDLo; 1300 mg/kg/2 week(s) intermittent oral-rat TDLo; 480 mg/kg/30 day(s) intermittent oral-dog TDLo; 9 gm/kg/90 day(s) intermittent oral-rat TDLo; 2500 mg/kg/10 day(s) intermittent oral-rat TDLo; 500 mg/kg/10 day(s) intermittent skin-mouse TDLo; 175 mg/kg/1 week(s) intermittent oral-rat TDLo; 84 mg/kg/14 day(s) intermittent intraperitoneal-mouse TDLo; 84 mg/kg/21 day(s) intermittent skin-rat TDLo; 4 gm/kg/5 day(s) intermittent oral-man TDLo; 34.3 mg/kg/5 day(s) intermittent oral-man TDLo

ACUTE TOXICITY LEVEL:

Moderately Toxic: ingestion

TARGET ORGANS: kidneys

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: immune system disorders or allergies, kidney disorders, liver disorders, respiratory disorders, skin disorders and allergies

MUTAGENIC DATA:

cytogenetic analysis - mouse oral 1470 mg/kg 7 day(s); sister chromatid exchange - mouse intraperitoneal 50 mg/kg; sister chromatid exchange - mouse oral 270 mg/kg

REPRODUCTIVE EFFECTS DATA:

8 mg/kg oral-woman TDLo 1 day(s) pre pregnancy continuous; 840 mg/kg oral-rat TDLo 8-14 day(s) pregnant female continuous; 10 mg/kg oral-rat TDLo 21 day(s) pregnant female continuous; 600 mg/kg oral-rat TDLo 3-5 day(s) pregnant female continuous; 9750 mg/kg oral-rat TDLo 65 day(s) male; 2 mg/kg intrauterine-rat TDLo 4 day(s) pregnant female continuous; 270 mg/kg rectal-rat TDLo 17-21 day(s) pregnant female continuous; 891 mg/kg rectal-rat TDLo 17-21 day(s) pregnant female/21 day(s) post pregnancy continuous; 1 gm/kg rectal-rat TDLo 17-21 day(s) pregnant female/4 day(s) post pregnancy continuous; 810 mg/kg rectal-rat TDLo 60 day(s) male day(s) pre pregnancy/2 week(s) pregnant female/7 day(s) continuous; 8100 mg/kg rectal-rat TDLo 60 day(s) male day(s) pre pregnancy/2 week(s) pregnant female/7 day(s) continuous; 420 mg/kg oral-mouse TDLo 7-13 day(s) pregnant female continuous; 1260 mg/kg oral-mouse TDLo 7-13 day(s) pregnant female continuous

ADDITIONAL DATA: May be excreted in breast milk. Interactions with drugs may occur. May cross react with similar compounds.

HEALTH EFFECTS:

INHALATION:

ACUTE EXPOSURE:

IBUPROFEN: May cause respiratory tract irritation. Allergic reactions may occur in previously exposed persons.

CHRONIC EXPOSURE:

IBUPROFEN: Repeated or prolonged exposure may cause sensitization.

SKIN CONTACT:

IBUPROFEN: May cause irritation. Sufficient contact with the skin may result in an allergic reaction in previously exposed and sensitive persons. See information on nonsteroidal anti-inflammatory drugs.

ACUTE EXPOSURE:

NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID): Skin exposure to UV light may result in phototoxic or photoallergic reactions in sensitive individuals who have systemically absorbed nonsteroidal anti-inflammatory drugs.

CHRONIC EXPOSURE:

NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID): May cause effects as in acute exposure.

EYE CONTACT:

ACUTE EXPOSURE:

IBUPROFEN: May cause irritation.

CHRONIC EXPOSURE:

IBUPROFEN: No data available.

INGESTION:

IBUPROFEN: Unilateral decreases in visual acuity with central scotomata and aseptic meningitis have been reported from therapeutic use. Reproductive effects have been reported in animals. See information on nonsteroidal anti-inflammatory drugs.

ACUTE EXPOSURE:

NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID): Overdosing may cause gastrointestinal effects such as nausea, vomiting, diarrhea, constipation, indigestion, and epigastric pain. Central nervous system effects may include drowsiness, dizziness, disorientation, lethargy, paresthesia, numbness, intense headache, blurred vision, tinnitus, decreased auditory acuity, ataxia, muscle twitching, convulsions, stupor, and coma. Other effects such as sweating, fluid retention, oliguria or anuria, tachycardia, hypertension or hypotension, rash, and pruritis may occur. Elevated serum creatinine and BUN may indicate renal damage. Peptic ulceration may also develop.

CHRONIC EXPOSURE:

NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAID): In addition to the effects of acute exposure, prolonged administration may cause gastrointestinal irritation, erosion, ulceration, perforation, frank or occult bleeding, diarrhea or constipation, and blood in the vomit or stool. Renal effects may include

hematuria, pyuria, proteinuria, urinary casts, nocturia, polyuria, dysuria, oliguria or anuria, renal insufficiency including renal failure, papillary necrosis, nephrosis, nephrotic syndrome, and glomerular and interstitial nephritis. Edema, metabolic acidosis, hyperkalemia, azotemia, cystitis, and urinary tract infections may occur. Hepatotoxic effects may occur rarely and include abnormal liver function tests, jaundice, hepatocellular injury, and possibly fatal hepatitis. Visual and hearing disturbances may occur including conjunctivitis, corneal deposits, retinal degeneration, ear pain, and rarely, deafness. Effects on the heart, various blood dyscrasias, interference with platelet function, and phototoxic or photoallergic skin reactions may occur. Anaphylactoid reactions such as maculopapular rash, urticaria, pruritus, bronchospasm, and syncope may develop. Idiosyncratic reactions may involve asthma, allergic interstitial nephritis, hypersensitivity hepatitis, hepatic necrosis, agranulocytosis, aplastic anemia, and exfoliative dermatitis.

12. ECOLOGICAL INFORMATION

Not available

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all applicable regulations.

14. TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: No classification assigned.

CANADIAN TRANSPORTATION OF DANGEROUS GOODS: No classification assigned.

LAND TRANSPORT ADR: No classification assigned.

LAND TRANSPORT RID: No classification assigned.

AIR TRANSPORT IATA: No classification assigned.

AIR TRANSPORT ICAO: No classification assigned.

MARITIME TRANSPORT IMDG: No classification assigned.

15. REGULATORY INFORMATION

U.S. REGULATIONS:

CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4): Not regulated.

SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30): Not regulated.

SARA TITLE III SECTION 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40): Not regulated.

SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):

ACUTE: Yes
CHRONIC: Yes
FIRE: No
REACTIVE: No
SUDDEN RELEASE: No

SARA TITLE III SECTION 313 (40 CFR 372.65): Not regulated.

OSHA PROCESS SAFETY (29CFR1910.119): Not regulated.

STATE REGULATIONS:

California Proposition 65: Not regulated.

CANADIAN REGULATIONS:

WHMIS CLASSIFICATION: Not determined.

EUROPEAN REGULATIONS:

EC CLASSIFICATION (CALCULATED): Not determined.

NATIONAL INVENTORY STATUS:

U.S. INVENTORY (TSCA): This product is exempt.

TSCA 12(b) EXPORT NOTIFICATION: Not listed.

16. OTHER INFORMATION

MSDS SUMMARY OF CHANGES

11. TOXICOLOGICAL INFORMATION

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