

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078492776

N/A

**MATERIAL SAFETY DATA SHEET****SECTION 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

**Common Name:** OMEPRAZOLE

**Chemical Name:** 5-Methoxy-2-[[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole

**Synonym(s):** ---

**Trade Name:** Prilosec, Losec

**Manufacturer's Name:** Dr. Reddy's Laboratories Limited, 7-1-27, Ameerpet, Hyderabad  
**500016, INDIA**  
**and Address**

**Emergency Telephone:** +91 40 23731946, +91 40 291279485

**Date MSDS Prepared:** 24.02.04

**MSDS Prepared by:** Dr. Reddy's Laboratories Limited, R&D

**Phone Number:** +91 40 279485

**SECTION 2 - COMPOSITION / INFORMATION ON INGREDIENTS****Active Ingredient(s):**

**CAS #:** 73590-58-6

**MF:**  $C_{17}H_{19}N_3O_3S$

**EC NO:** Not available

**SECTION 3 - HAZARDS IDENTIFICATION****LABEL PRECAUTIONARY STATEMENTS****TOXIC**

TOXIC BY INHALATION, IN CONTACT WITH SKIN AND IF SWALLOWED.

POSSIBLE RISK OF IRREVERSIBLE EFFECTS.

Effected on respiratory tract, eyes and Skin

**TARGET ORGAN(S):**

IN CASE OF ACCIDENT OR IF YOU FEEL UNWELL, SEEK MEDICAL ADVICE

IMMEDIATELY (SHOW THE LABEL WHERE POSSIBLE).

WEAR SUITABLE PROTECTIVE CLOTHING, GLOVES AND EYE/FACE PROTECTION.

**SECTION 4 - FIRST AID MEASURES**

IN CASE OF CONTACT, IMMEDIATELY FLUSH EYES OR SKIN WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES WHILE REMOVING CONTAMINATED CLOTHING AND SHOES.

IF INHALED, REMOVE TO FRESH AIR. IF NOT BREATHING GIVE ARTIFICIAL RESPIRATION.

IF BREATHING IS DIFFICULT, GIVE OXYGEN.

IF SWALLOWED, WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS.

CALL A PHYSICIAN.

WASH CONTAMINATED CLOTHING BEFORE REUSE.

**SECTION 5 - FIRE FIGHTING MEASURES****EXTINGUISHING MEDIA**

WATER SPRAY.

CARBON DIOXIDE, DRY CHEMICAL POWDER OR APPROPRIATE FOAM.



**SPECIAL FIREFIGHTING PROCEDURES**

WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING TO PREVENT CONTACT WITH SKIN AND EYES.

**UNUSUAL FIRE AND EXPLOSIONS HAZARDS**

EMITS TOXIC FUMES UNDER FIRE CONDITIONS.

**SECTION 6 - ACCIDENTAL RELEASE MEASURES**

EVACUATE AREA.

WEAR SELF-CONTAINED BREATHING APPARATUS, RUBBER BOOTS AND HEAVY RUBBER GLOVES.

SWEEP UP, PLACE IN A BAG AND HOLD FOR WASTE DISPOSAL.

AVOID RAISING DUST.

VENTILATE AREA AND WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.

**SECTION 7 - HANDLING AND STORAGE**

REFER TO SECTION 8.

**SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION**

WEAR APPROPRIATE NIOSH/MSHA-APPROVED RESPIRATOR, CHEMICAL-RESISTANT GLOVES, SAFETY GOGGLES, OTHER PROTECTIVE CLOTHING.

USE ONLY IN A CHEMICAL FUME HOOD.

SAFETY SHOWER AND EYE BATH.

DO NOT BREATHE DUST.

DO NOT GET IN EYES, ON SKIN, ON CLOTHING.

WASH THOROUGHLY AFTER HANDLING.

POSSIBLE TERATOGEN.

TOXIC.

POSSIBLE SENSITIZER.

KEEP TIGHTLY CLOSED.

STORE IN A COOL DRY PLACE.

**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

APPEARANCE AND ODOR

WHITE POWDER

PHYSICAL PROPERTIES

MELTING POINT: ~156°C

**SECTION 10 - STABILITY AND REACTIVITY****INCOMPATIBILITIES****STRONG OXIDIZING AGENTS****HAZARDOUS COMBUSTION OR DECOMPOSITION PRODUCTS****TOXIC FUMES OF:****CARBON MONOXIDE, CARBON DIOXIDE****SECTION 11 - TOXICOLOGICAL INFORMATION****ACUTE EFFECTS****HARMFUL IF SWALLOWED, INHALED, OR ABSORBED THROUGH SKIN.****MAY CAUSE IRRITATION.****PROLONGED OR REPEATED EXPOSURE MAY CAUSE ALLERGIC REACTIONS IN CERTAIN SENSITIVE INDIVIDUALS.****CHRONIC EFFECTS****OVEREXPOSURE MAY CAUSE REPRODUCTIVE DISORDER(S) BASED ON TESTS WITH LABORATORY ANIMALS.****TARGET ORGAN(S):****ADDITIONAL INFORMATION****CLINICAL TRIALS HAVE SHOWN THE FOLLOWING POSSIBLE ADVERSE REACTIONS: GASTROINTESTINAL DISTURBANCES INCLUDING NAUSEA, VOMITING, CRAMPS, DIARRHEA, CONSTIPATION, BLOATING, CENTRAL NERVOUS SYSTEM EFFECTS WHICH INCLUDE DIZZINESS, HEADACHE, DEPRESSION, INSOMNIA, ASEPTIC MENINGITIS, SOMNOLENCE, DERMATOLOGICAL EFFECTS OF MACULOPAPULAR AND VESICULOBULLOUS ERUPTIONS, URTICARIA, ALOPECIA, ERYTHEMA MULTIFORME, STEVENS-JOHNSON SYNDROME, HEMATOLOGIC EFFECTS OF NEUTROPENIA, APLASTIC AND HEMOLYTIC ANEMIA, THROMBOCYTOPENIA, DECREASES IN HEMOGLOBIN AND HEMATOCRIT.****RTECS #: MU6640000****HYDRATROPIC ACID, P-ISOBUTYL-****TOXICITY DATA****ORL-MAN LDLO:171 MG/KG****ORL-CHD LDLO:469 MG/KG****ORL-RAT LD50:636 MG/KG****IPR-RAT LD50:626 MG/KG****SCU-RAT LD50:740 MG/KG****BMJOAE 281,1458,80****AEMED3 15,1308,86****ARZNAD 34,280,84****ARZNAD 27,1006,77****OYYAA2 24,415,82**

REC-RAT LD50:530 MG/KG	OYYAA2 24,415,82
ORL-MUS LD50:740 MG/KG	PCJOAU 14,119,80
IPR-MUS LD50:320 MG/KG	TXAPA9 15,310,69
SCU-MUS LD50:395 MG/KG	OYYAA2 24,415,82
REC-MUS LD50:620 MG/KG	OYYAA2 24,415,82
ORL-GPG LD50:495 MG/KG	ATSUDG 7,365,84
ORL-HAM LD50:1690 MG/KG	ATSUDG 7,365,84
ORL-MAM LD50:1 GM/KG	APPHAX 42,545,85

#### TARGET ORGAN DATA

SENSE ORGANS AND SPECIAL SENSES (DIPLOPIA)  
 SENSE ORGANS AND SPECIAL SENSES (OTHER EYE EFFECTS)  
 BEHAVIORAL (GENERAL ANESTHETIC)  
 BEHAVIORAL (ALTERED SLEEP TIME)  
 BEHAVIORAL (CONVULSIONS OR EFFECT ON SEIZURE THRESHOLD)  
 BEHAVIORAL (CHANGE IN MOTOR ACTIVITY)  
 BEHAVIORAL (HEADACHE)  
 BEHAVIORAL (ANALGESIA)  
 VASCULAR (BP LOWERING NOT CHARACTERIZED IN AUTONOMIC SECTION)  
 LUNGS, THORAX OR RESPIRATION (RESPIRATORY OBSTRUCTION)  
 LUNGS, THORAX OR RESPIRATION (DYSPPNAE)  
 GASTROINTESTINAL (ULCERATION OR BLEEDING FROM STOMACH)  
 GASTROINTESTINAL (HYPERMOTILITY, DIARRHEA)  
 LIVER (HEPATITIS: HEPATOCELLULAR NECROSIS, DIFFUSE)  
 KIDNEY, URETER, BLADDER (CHANGES IN TUBULES)  
 BLOOD (THROMBOCYTOPENIA)  
 SKIN AND APPENDAGES (AFTER SYSTEMIC EXPOSURE: DERMATITIS, OTHER)  
 IMMUNOLOGICAL INCLUDING ALLERGIC (UNCHARACTERIZED)  
 MATERNAL EFFECTS (MENSTRUAL CYCLE CHANGES OR DISORDERS)  
 MATERNAL EFFECTS (PARTURITION)  
 EFFECTS ON FERTILITY (PRE-IMPLANTATION MORTALITY)  
 EFFECTS ON FERTILITY (LITTER SIZE)  
 EFFECTS ON EMBRYO OR FETUS (FETOTOXICITY)  
 EFFECTS ON EMBRYO OR FETUS (FETAL DEATH)  
 EFFECTS ON NEWBORN (LIVE BIRTH INDEX)  
 EFFECTS ON NEWBORN (VIABILITY INDEX)  
 EFFECTS ON NEWBORN (WEANING OR LACTATION INDEX)  
 EFFECTS ON NEWBORN (GROWTH STATISTICS)  
 NUTRITIONAL AND GROSS METABOLIC (CHANGES IN: METABOLIC ACIDOSIS)  
 NUTRITIONAL AND GROSS METABOLIC (BODY TEMPERATURE INCREASE)  
 NUTRITIONAL AND GROSS METABOLIC (BODY TEMPERATURE DECREASE)  
 BIOCHEMICAL EFFECTS (EFFECT ON INFLAMMATION OR MEDIATION OF INFLAMMATION)  
 ONLY SELECTED REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES  
 (RTECS) DATA IS PRESENTED HERE. SEE ACTUAL ENTRY IN RTECS FOR  
 COMPLETE INFORMATION.

**SECTION 12 - ECOLOGICAL INFORMATION**

DATA NOT AVAILABLE

**SECTION 13 - DISPOSAL CONSIDERATIONS**

DISSOLVE OR MIX THE MATERIAL WITH A COMBUSTIBLE SOLVENT AND BURN IN A CHEMICAL INCINERATOR EQUIPPED WITH AN AFTERBURNER AND SCRUBBER. OBSERVE ALL FEDERAL, STATE AND LOCAL ENVIRONMENTAL REGULATIONS.

**SECTION 14 - TRANSPORT INFORMATION**

CONTACT THE MANUFACTURER FOR TRANSPORTATION INFORMATION

**SECTION 15 - REGULATORY INFORMATION****EUROPEAN INFORMATION****TOXIC**

R 23/24/25

TOXIC BY INHALATION, IN CONTACT WITH SKIN AND IF SWALLOWED.

**R 40**

POSSIBLE RISK OF IRREVERSIBLE EFFECTS.

**S 45**

IN CASE OF ACCIDENT OR IF YOU FEEL UNWELL, SEEK MEDICAL ADVICE IMMEDIATELY (SHOW THE LABEL WHERE POSSIBLE).

**S 36/37/39**

WEAR SUITABLE PROTECTIVE CLOTHING, GLOVES AND EYE/FACE PROTECTION.

REVIEWS, STANDARDS, AND REGULATIONS

OEL=MAK

NOES 1983: HZD X4905; NIS 1; TNF 82; NOS 1; TNE 2249; TFE 1246

EPA TSCA SECTION 8(B) CHEMICAL INVENTORY

**SECTION 16 - OTHER INFORMATION**

The information provided in this Material Safety Data Sheet (MSDS) has been compiled from our experience and the data presented in various technical publications. It is the users responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the MSDS from time to time as new information becomes available. It is recommended that the user contact the company to make sure the MSDS in use is the latest one issued.