

HOFFMANN-LA ROCHE -- SULFAMETHOXAZOLE, BACTRIM PEDIATRIC SUSPENSION
MATERIAL SAFETY DATA SHEET
NSN: 650500N046348
Manufacturer's CAGE: 04493
Part No. Indicator: A
Part Number/Trade Name: SULFAMETHOXAZOLE, BACTRIM PEDIATRIC SUSPENSION
=====

General Information

=====

Company's Name: HOFFMANN-LA ROCHE
Company's Street: ENVIRONMENTAL & SAFETY AFFAIRS
Company's City: NUTLEY
Company's State: NJ
Company's Country: US
Company's Zip Code: 07110-1199
Company's Emerg Ph #: 201-235-3729
Company's Info Ph #: 201-235-3729
Record No. For Safety Entry: 001
Tot Safety Entries This Stk#: 001
Status: SMJ
Date MSDS Prepared: 07JUN89
Safety Data Review Date: 10DEC93
MSDS Serial Number: BTMQZ
Hazard Characteristic Code: NK
=====

Ingredients/Identity Information

=====

Proprietary: NO
Ingredient: SULFANILAMIDE, N'-(5-METHYL-3-ISOXAZOLYL)-; (SULFAMETHOXAZOLE)
Ingredient Sequence Number: 01
NIOSH (RTECS) Number: WP0700000
CAS Number: 723-46-6
OSHA PEL: N/K (FP N)
ACGIH TLV: N/K (FP N)

Proprietary: NO
Ingredient: SUPP DATA:THESE FINDINGS ARE CONSIDERED TO BE AN INDIRECT EFT
DUE TO HORMONAL IMBALANCE CAUSED BY THE GOITROGENIC(ING 3)
Ingredient Sequence Number: 02
NIOSH (RTECS) Number: 9999999ZZ
OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO
Ingredient: ING 2:EFT OF SOME SULFONAMIDES IN RODENTS. SULFAMETHOXAZOLE
HAS BEEN OBSERVED TO BE GOITROGENIC IN THE RAT & DOG (ING 4)
Ingredient Sequence Number: 03
NIOSH (RTECS) Number: 9999999ZZ
OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO
Ingredient: ING 3: BUT NOT IN THE MONKEY. THE SPECIES DIFFERENCES BETWEEN
RODENTS & PRIMATES ARE CONSIDERED TO BE DUE TO (ING 5)
Ingredient Sequence Number: 04
NIOSH (RTECS) Number: 9999999ZZ
OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO
Ingredient: ING 4: DIFFERENCES IN METABOLISM AND ENZYME INHIBITION RATES.
REPROD: STUDY W/RATS FED 5 & 50 MG/KG/DAY (ING 6)
Ingredient Sequence Number: 05

NIOSH (RTECS) Number: 9999999ZZ
OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: ING 5: BEFORE AND DURING TWO MATINGS & THROUGH WEANING EACH
TIME DID NOT SHOW A DELETERIOUS EFT ON REPROD OR (ING 7)

Ingredient Sequence Number: 06
NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: ING 6: CAUSE THE OCCURRENCE OF MALFORMED FETUSES.
TERATOGENICITY: STUDIES W/PREGNANT RATS GIVEN THIS MATL ON (ING 8)

Ingredient Sequence Number: 07
NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: ING 7: GESTATION DAYS 8-16 AT 307-512 MG/KG/DAY SHOWED NO
MALFORMED FETUSES & @ 533-1000 MG/KG/DAY BIRTH (ING 9)

Ingredient Sequence Number: 08
NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: ING 8: DEFECTS MANIFESTED MAINLY AS CLEFT PALATES WERE
OBSERVED.

Ingredient Sequence Number: 09
NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: OTHER PREC: DAYS AT 110C), LIGHT (GRADUALLY DECOMPOSES) AND
AIR. DO NOT MIX W/MINERAL ACIDS (HYDROLYSES TO (ING 11)

Ingredient Sequence Number: 10
NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: ING 10: SULFANILAMIDE) OR OXIDIZING AGENTS. ALL DUST HANDLING
EQUIP & MATL TRANSPORT SYSTEMS SHOULD USE EXPLO (ING 12)

Ingredient Sequence Number: 11
NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: ING 11: RELIEF VENTS OR OPERATE IN AN OXYGEN DEFICIENT
ATMOSPHERE. DUST COLLECTORS SHOULD BE PLACED ON THE ROOF (ING 13)

Ingredient Sequence Number: 12
NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: ING 12: OF THE BUILDING OR OUTSIDE IN A REMOTE LOCATION.
Ingredient Sequence Number: 13

NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE
ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: SPILL PROC: PROT EQUIP & CLTHG AS SPECIFIED PREVIOUSLY. SHUT
OFF SOURCE OF SPILL OR LEAK IF SAFE TO DO SO. (ING 15)

Ingredient Sequence Number: 14

NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE

ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: ING 14: TRANSFER SPILLED MATL INTO A SUITABLE LABELED OPEN-
HEAD DRUM USING A STAINLESS STEEL SCOOP OR SHOVEL. (ING 14)

Ingredient Sequence Number: 15

NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE

ACGIH TLV: NOT APPLICABLE

Proprietary: NO

Ingredient: ING 15: SECURE DRUM COVER AND MOVE THE CONTAINER TO A SAFE
HOLDING AREA. MOP OR FLUSH WITH WATER.

Ingredient Sequence Number: 16

NIOSH (RTECS) Number: 9999999ZZ

OSHA PEL: NOT APPLICABLE

ACGIH TLV: NOT APPLICABLE

=====

Physical/Chemical Characteristics

=====

Appearance And Odor: WHITE TO OFF-WHITE FINE CRYSTALLINE POWDER,
PRACTICALLY ODORLESS.

Boiling Point: N/A

Melting Point: >334F, >168C

Vapor Pressure (MM Hg/70 F): N/A

Vapor Density (Air=1): N/A

Specific Gravity: N/A

Evaporation Rate And Ref: NOT APPLICABLE

Solubility In Water: INSOLUBLE

=====

Fire and Explosion Hazard Data

=====

Extinguishing Media: AS APPROPRIATE FOR FIRE IN SURROUNDING MATERIALS.

Special Fire Fighting Proc: WEAR NIOSH/MSHA APPROVED SCBA AND FULL
PROTECTIVE EQUIPMENT (FP N).

Unusual Fire And Expl Hazrds: VIOLENT THERMAL DECOMPOSITION HAZARD. SEVERE
DUST EXPLOSION HAZARD. SENSITIVE TO IGNITION BY ELECTROSTATIC CHARGE.

=====

Reactivity Data

=====

Stability: YES

Cond To Avoid (Stability): TEMPERATURES GREATER THAN 175C OR 155C FOR LONG
PERIODS (TO AVOID THERMAL RUNAWAY REACTION).

Materials To Avoid: UNKNOWN.

Hazardous Decomp Products: OXIDES OF NITROGEN, SULFUR DIOXIDE.

Hazardous Poly Occur: NO

Conditions To Avoid (Poly): NOT RELEVANT

=====

Health Hazard Data

=====

LD50-LC50 Mixture: LD50: (ORAL, RAT) 3000 MG/KG

Route Of Entry - Inhalation: YES

Route Of Entry - Skin: NO

Route Of Entry - Ingestion: YES

Health Haz Acute And Chronic: ACUTE/CHRONIC: GENERALIZED ALLERGIC RXNS

INCL SKIN RASH. DIRECT CONTACT MAY CAUSE EYE IRRIT. NOTE: SIGNS & SYMPS OF OVERDOSAGE OF SULFONAMIDES DURING MEDICAL TREATMENT INCLUDE NAUSEA, VOMIT, DIZZINESS, HDCH, DROWSINESS AND BLOOD CHANGES. EYE IRRIT: A STUDY W/ALBINO RABBITS PRODUCED SCORES OF 5.0/110, (EFTS OF OVEREXP)

Carcinogenicity - NTP: NO

Carcinogenicity - IARC: NO

Carcinogenicity - OSHA: NO

Explanation Carcinogenicity: NOT RELEVANT

Signs/Symptoms Of Overexp: HLTH HAZ: 3.7/110, 2.7/110, (CONJUNCTIVAL IRRIT ONLY) AT 1 HR, 1,2 & 3 DAYS POST-INSTILLATION, RESPECTIVELY, INDICATING THAT THIS MATL IS PRACTICALLY NON-IRRIT TO EYES UNDER THE STUDY CNDTNS UTILIZED. SKIN: A SCORE OF 0.00 (ALBINO RABBITS) INDICATES THAT THIS MATL IS NON-IRRIT TO SKIN UNDER STUDY CNDTNS (SUPP DATA)

Med Cond Aggravated By Exp: SEVERE ALLERGY, E.G., HYPERSENSITIVITY TO SULFONAMIDES OR BRONCHIAL ASTHMA HISTORY.

Emergency/First Aid Proc: EYE: FLUSH W/PLENTY OF WATER FOR AT LEAST 15 MIN. IF EYES ARE IRRIT, CNTCT MD. SKIN: FLUSH W/PLENTY OF WATER AND WASH CNTCT AREA W/SOAP AND WATER. IF SKIN IS IRRIT, CNTCT MD. REMOVE CONTAM CLTHG & SHOES & WASH BEFORE REUSE. INHAL: REMOVE TO FRESH AIR. IF DISCOMFORT OCCURS OR PERSISTS, CONTACT MD. INGEST: GET MD IMMEDIATELY (FP N).

Precautions for Safe Handling and Use

Steps If Matl Released/Spill: SPILLS/RELEASES OF THIS MATL NEED NOT TO BE REPORTED TO ENVIRONMENTAL REGULATORY AGENCIES UNLESS THE SPILL ENDANGERS PUBLIC HEALTH OR THE ENVIRONMENT OR UNLESS APPLIC STATE OR LOCAL REGS REQUIRE REPORTING. SPILL CONTROL: USE PERSONAL (ING 14)

Neutralizing Agent: NONE SPECIFIED BY MANUFACTURER.

Waste Disposal Method: TRANSPORT CONTAINED WASTE TO AN INCINERATOR OR LANDFILL APPROVED FOR INDUSTRIAL WASTE. DISPOSAL MUST BE IN ACCORDANCE WITH FEDERAL, STATE AND LOCAL REGULATIONS (FP N).

Precautions-Handling/Storing: DO NOT HEAT >175C. DO NOT GENERATE DUST/ EXPOSE TO IGNIT SOURCES. GROUND & BOND ALL TRANSFER EQUIP. AVOID CNTCT W/ EYES. AVOID PRLNG/RPTD SKIN CNTCT.

Other Precautions: AVOID BRTHG DUST. USE W/ADEQ VENT. WHEN HNDLG, USE PROPER PESONAL EQUIP AS NEEDED. KEEP CNTNR CLOSED WHEN NOT IN USE. STORE AT MODERATE TEMPS OUT OF DIRECT SUNLIGHT. CLOSELY MONITOR TEMPS. PROT FROM HEAT (TEMPS >110C-STABLE FOR 5 (ING 10)

Control Measures

Respiratory Protection: NIOSH/MSHA APPROVED AIR-PURIFYING RESP WITH DUST FILTERS FOR DUSTY OPERATIONS.

RECOMMENDED.

Protective Gloves: NEOPRENE OR RUBBER AS NEEDED.

Eye Protection: ANSI APPRVD CHEM WORKER GOGGLES (FP N).

Other Protective Equipment: LONG SLEEVES OR OTHER ARM COVERING TO PREVENT SKIN CONTACT AS NEEDED.

Work Hygienic Practices: WASH THOROUGHLY AFTER HANDLING.

Suppl. Safety & Health Data: EFTS OF OVEREXP: UTILIZED. DERMAL: NO SIGNS OF SKIN IRRIT OR SKIN SENSIT (ALBINO GUINEA PIGS) WERE OBSERVED UNDER THE STUDY CNDTNS UTILIZED. CARCIN: IARC CONCLUDED THAT THERE IS "LIMITED EVIDENCE" FOR THE CARCIN OF THIS MATL IN EXPERIMENTAL ANIMALS. THYROID FOLLICULAR CELL CARCINOMA HAS BEEN PRODUCED IN THE RAT.(ING 2)

Transportation Data

Disposal Data

Label Data

Label Required: YES
Technical Review Date: 10DEC93
Label Date: 10DEC93
Label Status: G
Common Name: SULFAMETHOXAZOLE, BACTRIM PEDIACTRIC SUSPENSION
Chronic Hazard: NO
Signal Word: CAUTION!
Acute Health Hazard-Slight: X
Contact Hazard-Slight: X
Fire Hazard-None: X
Reactivity Hazard-None: X
Special Hazard Precautions: ACUTE: MAY IRRITATE EYES, CAUSES SKIN RASH.
CHRONIC: NONE SPECIFIED BY MANUFACTURER.
Protect Eye: Y
Protect Skin: Y
Protect Respiratory: Y
Label Name: HOFFMANN-LA ROCHE
Label Street: ENVIRONMENTAL & SAFETY AFFAIRS
Label City: NUTLEY
Label State: NJ
Label Zip Code: 07110-1199
Label Country: US
Label Emergency Number: 201-235-3729