

SYNTEX (U.S.A.) INC -- TORADOL IM INJECTABLE

=====

MSDS Safety Information

=====

FSC: 6505
NIIN: 01-319-8245
MSDS Date: 10/09/1992
MSDS Num: BSYPQ
Product ID: TORADOL IM INJECTABLE
MFN: 01
Responsible Party
Cage: 26282
Name: SYNTEX (U.S.A.) INC
Address: 3401 HILLVIEW AVENUE
City: PALO ALTO CA 94304
Info Phone Number: 415-796-5050
Emergency Phone Number: 415-796-5050
Review Ind: Y
Published: Y

=====

Contractor Summary

=====

Cage: 26282
Name: SYNTEX (U.S.A.) INC
Address: 3401 HILLVIEW AVENUE
City: PALO ALTO CA 94304
Phone: 415-796-5050

=====

Item Description Information

=====

Item Name: KETOROLAC TROMETHAMINE INJECTION,USP
Type of Container: PACKAGE

=====

Ingredients

=====

Cas: 74103-07-4
Name: KETOROLAC TROMETHAMINE
% Wt: 1.5 -3%
Other REC Limits: NONE RECOMMENDED
OSHA PEL: NOT ESTABLISHED
ACGIH TLV: NOT ESTABLISHED

Cas: 64-17-5
RTECS #: KQ6300000
Name: ETHYL ALCOHOL (ETHANOL) INGREDIENTS 2, 3 & 4 EQUAL 97-98.5%
% Wt: 97-98.5
Other REC Limits: NONE RECOMMENDED
OSHA PEL: 1000 PPM

ACGIH TLV: 1000 PPM; 9394

Cas: 7647-14-5

RTECS #: VZ4725000

Name: SODIUM CHLORIDE INGREDIENTS 2, 3 & 4 EQUAL 97-98.5 %

% Wt: 97-98.5

Other REC Limits: NONE RECOMMENDED

OSHA PEL: NOT ESTABLISHED

ACGIH TLV: NOT ESTABLISHED

Cas: 7732-18-5

RTECS #: ZC0110000

Name: WATER INGREDIENTS 2, 3 & 4 EQUAL 97 - 98.5 %

% Wt: 97-98.5

Other REC Limits: NONE RECOMMENDED

OSHA PEL: NOT ESTABLISHED

ACGIH TLV: NOT ESTABLISHED

Name: SODIUM HYDROXIDE AND/OR HYDROCHLORIC ACID ARE ADDED TO ADJUST PH OF PRODUCT.

Other REC Limits: NONE RECOMMENDED

Health Hazards Data

LD50 LC50 Mixture: ORAL LD50 = 200 TO 225 MG/KG (RATS)

Route Of Entry Inds - Inhalation: YES

Skin: YES

Ingestion: YES

Carcinogenicity Inds - NTP: NO

IARC: YES

OSHA: NO

Effects of Exposure: MAY IRRITATE EYES. REPEATED ORAL OR INTRAMUSCULAR DOSES MAY CAUSE GASTROINTESTINAL COMPLAINTS AND CENTRAL NERVOUS SYSTEM EFFECTS. DUE TO LOW CONCENTRATIONS IN PRODUCT, THESE ADVERSE EFFECTS WOULD BE EXPECTED ONLY IN CASES OF EXTREME MISUSE, E.G., INGESTION OF LARGE QUANTITIES OR REPEATED INGESTION.

Explanation Of Carcinogenicity: ETHANOL IS LISTED BY IARC AS A CARCINOGEN.

Signs And Symptions Of Overexposure: EYE IRRITATION, NAUSEA, VOMITING, DIARRHEA, DROWSINESS, INSOMNIA, HEADACHE, DIZZINESS.

Medical Cond Aggravated By Exposure: ALLERGY TO NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (E.G. ASPIRIN).

First Aid: INHALATION: REMOVE FROM EXPOSURE. RESTORE BREATHING. KEEP WARM AND QUIET. GET MEDICAL ATTENTION. SKIN: WASH AFFECTED AREA THOROUGHLY WITH SOAP AND WATER. IF IRRITATION PERSISTS, GET MEDICAL ATTENTION. EYES: FLUSH WITH LARGE AMOUNTS OF WATER FOR 15 MINUTES. GET MEDICAL ATTENTION. INGESTION: DRINK A MODERATE AMOUNT (8-12OZ) OF WATER AND NOTIFY MEDICAL PERSONNEL.

Handling and Disposal

=====
Spill Release Procedures: TAKE PROPER PRECAUTIONS TO MINIMIZE EXPOSURE BY USING PROPER PERSONAL PROTECTIVE EQUIPMENT. RETAIN SPILL. SOAK UP WITH ABSORBENT MATERIAL, E.G. PAPER TOWELS. WASH SPILL AREA THOROUGHLY WITH SOAP AND WATER. COLLECT FOR DISPOSAL.

Neutralizing Agent: NONE SPECIFIED BY MANUFACTURER.

Waste Disposal Methods: PREVENT WASTE FROM CONTAMINATING SURROUNDING ENVIRONMENT. DISCARD ANY PRODUCT, RESIDUE, DISPOSAL CONTAINER OR LINER IN ACCORDANCE WITH ALL FEDERAL, STATE AND LOCAL REGULATIONS.

Handling And Storage Precautions: AVOID EXCESSIVE CONTACT WITH SKIN, EYES OR CLOTHING. USE ADEQUATE VENTILATION TO MINIMIZE EXPOSURE. WASH THOROUGHLY AFTER HANDLING. STORE IN COOL AREA

Other Precautions: MAY CAUSE GASTROINTESTINAL TOXICITY, EG, ULCERATION, BLEEDING, PERFORATION, IF IMPORPERLY HANDLED AND EXCESSIVE EXPOSURE OCCURS. MATERIAL INTENDED FOR HUMAN PHARMACEUTICAL USE BY INTRAMUSCULAR INJECTI ON AS PRESCRIBED BY PHYSICIAN.

=====
Fire and Explosion Hazard Information
=====

Flash Point Text: 120F,49C

Lower Limits: 3.3% ETHANOL

Upper Limits: 19% ETHANOL

Extinguishing Media: WATER, MULTIPURPOSE DRY CHEMICAL OR HALON FIRE EXTINGUISHER

Fire Fighting Procedures: WEAR FULL PROTECTIVE CLOTHING AND NIOSH/MSHA APPROVED POSITIVE PRESSURE, SELF-CONTAINED BREATHING APPARATUS. WASH ALL EQUIPMKENT THOROUGHLY AFTER USE.

Unusual Fire/Explosion Hazard: NONE SPECIFIED BY MANUFACTURER.

=====
Control Measures
=====

Respiratory Protection: SHOULD NOT BE NEEDED DURING NORMAL HANDLING OF MATERIAL.

Ventilation: NORMAL ROOM VENTILATION SHOULD BE ADEQUATE. KEEP AWAY FOR SPARKS OR OTHER SOURCES OF IGNITION.

Protective Gloves: SHOULD NOT BE NEEDED

Eye Protection: SHOULD NOT BE NEEDED

Other Protective Equipment: NONE SPECIFIED BY MANUFACTURER.

Work Hygienic Practices: WASH WITH SOAP AND WATER AFTER HANDLING PRODUCT AND BEFORE EATING DRINKING OR SMOKING.

Supplemental Safety and Health: WEAR SAFETY GLASSES WITH SIDE SHIELDS, GLOVES, LAB COAT OR OTHER PROTECTIVE OVERGARMENT AND NIOSH/MSHA-APPROVED HALF-FACE AIR PURIFYING RESPIRATOR FOR CLEAN UP OF LARGE SPILL.

=====
Physical/Chemical Properties
=====

HCC: F4

B.P. Text: NOT GIVEN

M.P/F.P Text: NOT GIVEN
Decomp Text: UNKNOWN
Vapor Pres: NOT GIVEN
Vapor Density: NOT GIVEN
Spec Gravity: NOT GIVEN
PH: 7.6
Evaporation Rate & Reference: NOT GIVEN
Solubility in Water: NOT GIVEN
Appearance and Odor: CLEAR TO SLIGHTLY YELLOW LIQUID
Corrosion Rate: UNKNOWN

=====
Reactivity Data
=====

Stability Indicator: YES
Stability Condition To Avoid: SPARKS AND OTHER SOURCES OF IGNITION
Materials To Avoid: STRONG OXIDIZING AGENTS (E.G. PERMANGANATES, NITRIC ACID)
Hazardous Decomposition Products: EMITS CARBON MONOXIDE AND CARBON DIOXIDE WHEN HEATED TO DECOMPOSITION.
Hazardous Polymerization Indicator: NO
Conditions To Avoid Polymerization: NONE. WILL NOT OCCUR.

=====
Toxicological Information
=====

=====
Ecological Information
=====

=====
MSDS Transport Information
=====

=====
Regulatory Information
=====

=====
Other Information
=====

=====
Transportation Information
=====

Responsible Party Code: 26282
Trans ID NO: 125135
Product ID: TORADOL IM INJECTABLE
MSDS Prepared Date: 10/09/1992
Review Date: 03/31/1994
MFN: 1
Tech Entry NOS Shipping Nm: CONTAINS ETHYL ALCOHOL
Multiple KIT Number: 0
Review IND: Y
Type Of Container: PACKAGE

=====

Detail DOT Information

=====

DOT PSN Code: GJL
Symbols: G
DOT Proper Shipping Name: FLAMMABLE LIQUIDS, N.O.S.
Hazard Class: 3
UN ID Num: UN1993
DOT Packaging Group: III
Label: FLAMMABLE LIQUID
Special Provision: B1,B52,T7,T30
Packaging Exception: 150
Non Bulk Pack: 203
Bulk Pack: 242
Max Qty Pass: 60 L
Max Qty Cargo: 220 L
Vessel Stow Req: A

=====

Detail IMO Information

=====

IMO PSN Code: HIA
IMO Proper Shipping Name: FLAMMABLE LIQUID, N.O.S. o
IMDG Page Number: 3345
UN Number: 1993
UN Hazard Class: 3.3
IMO Packaging Group: III
Subsidiary Risk Label: -
EMS Number: 3-07
MED First Aid Guide NUM: T

=====

Detail IATA Information

=====

IATA PSN CA
IATA UN ID Num: 1993
IATA Proper Shipping Name: FLAMMABLE LIQUID, N.O.S. *
IATA UN Class: 3
IATA Label: FLAMMABLE LIQUID
UN Packing Group: III
Packing Note Passenger: 309
Max Quant Pass: 60L
Max Quant Cargo: 220L
Packaging Note Cargo: 310

=====

Detail AFI Information

=====

AFI PSN CA
AFI Symbols: *
AFI Proper Shipping Name: FLAMMABLE LIQUIDS, N.O.S.

AFI Hazard Class: 3
AFI UN ID NUM: UN1993
AFI Packing Group: III
Special Provisions: P5
Back Pack Reference: A7.3

=====
HAZCOM Label
=====

Product ID: TORADOL IM INJECTABLE
Cage: 26282
Company Name: SYNTEX (U.S.A.) INC
Street: 3401 HILLVIEW AVENUE
City: PALO ALTO CA
Zipcode: 94304
Health Emergency Phone: 415-796-5050
Label Required IND: Y
Date Of Label Review: 03/31/1994
Status Code: C
MFG Label NO: NONE
Label Date: 03/31/1994
Origination Code: G
Chronic Hazard IND: Y
Eye Protection IND: YES
Skin Protection IND: YES
Signal Word: WARNING
Health Hazard: Moderate
Contact Hazard: Slight
Fire Hazard: Moderate
Reactivity Hazard: None

Hazard And Precautions: MAY IRRITATE EYES. REPEATED ORAL OR INTRAMUSCULAR DOSES MAY CAUSE GASTROINTESTINAL COMPLAINTS AND CENTRAL NERVOUS SYSTEM EFFECTS. DUE TO LOW CONCENTRATIONS IN PRODUCT, THESE ADVERSE EFFECTS WOULD BE EXPECTED ONLY IN CASES OF EXTREME MISUSE, E.G., INGESTION OF LARGE QUANTITIES OR REPEATED INGESTION. AVOID EXCESSIVE CONTACT WITH SKIN, EYES OR CLOTHING. USE ADEQUATE VENTILATION TO MINIMIZE EXPOSURE. WASH THOROUGHLY AFTER HANDLING. STORE IN COOL AREA FIRST AID: INHALATION: REMOVE FROM EXPOSURE. RESTORE BREATHING. KEEP WARM AND QUIET. GET MEDICAL ATTENTION. SKIN: WASH AFFECTED AREA THOROUGHLY WITH SOAP AND WATER. IF IRRITATION PERSISTS, GET MEDICA

=====
Disclaimer (provided with this information by the compiling agencies): This information is formulated for use by elements of the Department of Defense. The United States of America in no manner whatsoever expressly or implied warrants, states, or intends said information to have any application, use or viability by or to any person or persons outside the Department of Defense nor any person or persons contracting with any instrumentality of the United States of America and disclaims all liability for such use. Any person utilizing this instruction who is not a military or civilian employee of the United States of America should seek competent professional advice to verify

and assume responsibility for the suitability of this information to their particular situation regardless of similarity to a corresponding Department of Defense or other government situation.