

MATERIAL SAFETY DATA SHEET
 KETOROLAC TROMETHAMINE INJECTION, USP

PAGE 1
 ISSUED 09/01/99

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

45834
 45833

MATERIAL NAME: KETOROLAC TROMETHAMINE INJECTION, USP
 LIST NUMBER: 2023, 2036, 2039, 2287, 2288, 3793, 3795,
 3796
 CODE NUMBERS: K952,
 K953, K954, KB96, KB96V, KB98, KB98V, KB99, KB99V, K196,
 K198, KL96, KL96V, KL98, KL98V, KL99, KL99V, K096V,
 K098, K098V, K099

MANUFACTURER: HOSPITAL PRODUCTS DIVISION
 ABBOTT LABORATORIES
 ABBOTT PARK, ILLINOIS 60064

EMERGENCY TELEPHONE NUMBER: 1-847-937-7970
 CHEMTREC TELEPHONE NUMBER: 1-800-424-9300

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME: KETOROLAC TROMETHAMINE *
 CAS/RTECS NUMBERS: 74103-07-4 / N/A
 OSHA-PEL 8HR TWA: N/L
 STEL: N/L
 CEILING: N/L
 ACGIH-TLV 8HR TWA: N/L
 STEL: N/L
 CEILING: N/L
 OTHER 8HR TWA: 0.04 MG/M3 (ABBOTT LABORATORIES)
 LIMITS STEL: N/A
 CEILING: N/A

* HAZARDOUS PER OSHA CRITERIA

INGREDIENT NAME: ETHYL ALCOHOL *
 CAS/RTECS NUMBERS: 64-17-5 / KQ6300000
 OSHA-PEL 8HR TWA: 1000 PPM (1900 MG/M3)
 STEL: N/L
 CEILING: N/L
 ACGIH-TLV 8HR TWA: 1000 PPM (1900 MG/M3)
 STEL: N/L
 CEILING: N/L
 OTHER 8HR TWA: N/A
 LIMITS STEL: N/A
 CEILING: N/A

* HAZARDOUS PER OSHA CRITERIA

MATERIAL SAFETY DATA SHEET
 KETOROLAC TROMETHAMINE INJECTION, USP

PAGE 2
 ISSUED 09/01/99

3. HAZARDS INFORMATION

EMERGENCY OVERVIEW: IN CLINICAL USE, THIS MATERIAL IS USED FOR THE
 MANAGEMENT OF PAIN. THE ACTIVE INGREDIENT IS A POTENT DRUG AND IS
 TOXIC BY INGESTION. TARGET ORGANS INCLUDE THE GASTROINTESTINAL

TRACT, HEMATOPOIETIC SYSTEM, NERVOUS SYSTEM, REPRODUCTIVE SYSTEM,
LIVER, KIDNEYS, SKIN AND POSSIBLY-THE EYES.

ROUTE(S) OF ENTRY: SKIN: UNLIKELY
INHALATION: UNLIKELY
INGESTION: UNLIKELY

INGESTION RATING: N/D

SKIN ABSORPTION RATING: N/D

INHALATION RATING: N/D

CORROSIVENESS RATING: N/D

SKIN CONTACT RATING: N/D

SKIN SENSITIZATION RATING: N/D

EYE CONTACT RATING: POSSIBLE IRRITANT

TARGET ORGANS: GASTROINTESTINAL TRACT, BLOOD AND HEMATOPOETIC SYSTEM,
REPRODUCTIVE SYSTEM, LIVER, NERVOUS SYSTEM, KIDNEYS, SKIN, POSSIBLY
EYES

CARCINOGENICITY RATING: NTP: N/L IARC: N/L OSHA: N/L
ACGIH: N/L

ALCOHOLIC BEVERAGES ARE CLASSIFIED BY IARC AS GROUP 1 HUMAN
CARCINOGENS.

SIGNS AND SYMPTOMS: N/D. IN CLINICAL USE, COMMON SIDE EFFECTS INCLUDE
NAUSEA, INSOMNIA, CONSTIPATION, DIZZINESS, SLEEPINESS, DRY MOUTH,
HEARTBURN, GASTROINTESTINAL PAIN AND HEADACHE. MORE SEVERE
REACTIONS INCLUDE GASTROINTESTINAL ULCERATION, ALTERED RENAL
FUNCTION PARAMETERS, BLEEDING AND ALTERED PLATELET FUNCTION. DIRECT
CONTACT WITH THE EYES COULD BE IRRITATING.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: N/D. DATA SUGGEST
PRE-EXISTING GASTROINTESTINAL ULCERATION, RENAL OR LIVER DISEASE,
EYE AILMENTS, CARDIAC DECOMPENSATION, HYPERTENSION, BLEEDING
TENDENCIES, AND HYPERSENSITIVITY TO KETOROLAC TROMETHAMINE.
CONCURRENT USE OF ACETYL SALICYCLIC ACID OR OTHER NON-STEROIDAL
ANTI-INFLAMMATORY DRUGS.

MATERIAL SAFETY DATA SHEET
KETOROLAC TROMETHAMINE INJECTION, USP

PAGE 3
ISSUED 09/01/99

4. FIRST AID MEASURES

EYES: REMOVE FROM SOURCE OF EXPOSURE. FLUSH WITH COPIOUS AMOUNTS OF
WATER. IF IRRITATION PERSISTS OR SIGNS OF TOXICITY OCCUR, SEEK
MEDICAL ATTENTION. NO KNOWN ANTIDOTE. PROVIDE SYMPTOMATIC/SUPPORTIVE
CARE, MONITORING GASTROINTESTINAL, PLATELET AND KIDNEY FUNCTION, AS
NECESSARY.

SKIN: REMOVE FROM SOURCE OF EXPOSURE. FLUSH WITH COPIOUS AMOUNTS OF
WATER. IF IRRITATION PERSISTS OR SIGNS OF TOXICITY OCCUR, SEEK
MEDICAL ATTENTION. NO KNOWN ANTIDOTE. PROVIDE SYMPTOMATIC/SUPPORTIVE
CARE, MONITORING GASTROINTESTINAL, PLATELET AND KIDNEY FUNCTION, AS
NECESSARY.

INGESTION: REMOVE FROM SOURCE OF EXPOSURE. IF SIGNS OF TOXICITY OCCUR, SEEK MEDICAL ATTENTION. NO KNOWN ANTIDOTE. PROVIDE SYMPTOMATIC/SUPPORTIVE CARE, MONITORING GASTROINTESTINAL, PLATELET AND KIDNEY FUNCTION, AS NECESSARY.

INHALATION: REMOVE FROM SOURCE OF EXPOSURE. IF SIGNS OF TOXICITY OCCUR, SEEK MEDICAL ATTENTION. NO KNOWN ANTIDOTE. PROVIDE SYMPTOMATIC/SUPPORTIVE CARE, MONITORING GASTROINTESTINAL, PLATELET AND KIDNEY FUNCTION, AS NECESSARY.

5. FIRE FIGHTING PROCEDURES

FLASH POINT: 43 C

FLASH POINT METHOD: TAGLIABUE CLOSED TESTER/TAG CLOSED TESTED

LOWER EXPLOSIVE LIMIT(%): N/D

UPPER EXPLOSIVE LIMIT(%): N/D

AUTOIGNITION TEMPERATURE: N/A

FIRE & EXPLOSION HAZARDS: N/D

EXTINGUISHING MEDIA: USE MEDIA APPROPRIATE FOR PRIMARY CAUSE OF FIRE.

FIRE FIGHTING INSTRUCTIONS: WEAR PROTECTING CLOTHING AND SELF CONTAINED BREATHING APPARATUS.

NOTE: FLASH POINT OF ETHYL ALCOHOL IS 55.6 DEG. F, TESTED BY THE CLOSED CUP METHOD.

6. ACCIDENTAL RELEASE MEASURES

SPILL OR RELEASE PROCEDURES: ABSORB WITH SUITABLE MATERIAL AND PLACE INTO APPROPRIATE CONTAINER FOR DISPOSAL ACCORDING TO SECTION 13.

MATERIAL SAFETY DATA SHEET

PAGE 4

KETOROLAC TROMETHAMINE INJECTION, USP

ISSUED 09/01/99

7. HANDLING AND STORAGE

HANDLING: PROTECT FROM LIGHT, RETAIN IN CARTON UNTIL TIME OF USE.

STORAGE: STORE AT CONTROLLED ROOM TEMPERATURE OF 15-30 DEGREES C (59-86 DEGREES F).

SPECIAL PRECAUTIONS: PROTECT FROM LIGHT, RETAIN IN CARTON UNTIL TIME OF USE.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: NO SPECIAL PROVISIONS ARE REQUIRED UNDER NORMAL USE CONDITIONS.

RESPIRATORY PROTECTION: RESPIRATORY PROTECTION IS NOT NEEDED DURING NORMAL PRODUCT USE.

SKIN PROTECTION: IF SKIN CONTACT IS LIKELY, IMPERVIOUS GLOVES ARE RECOMMENDED.

EYE PROTECTION: EYE PROTECTION IS NOT REQUIRED DURING TYPICAL PRODUCT USE CONDITIONS. EYE PROTECTION IS RECOMMENDED IF CONTACT IS LIKELY.

OTHER PROTECTION: N/D

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: CLEAR, SLIGHTLY YELLOW SOLUTION.

ODOR: N/D

BOILING POINT: 91 DEG. C

MELTING/FREEZING POINT: N/D

VAPOR PRESSURE (MM HG): N/D

VAPOR DENSITY (AIR=1): N/D

EVAPORATION RATE: N/D

BULK DENSITY: 0.991 G/ML

SPECIFIC GRAVITY: N/D

SOLUBILITY: WATER, ETHYL ALCOHOL.

PH: 6.9 - 7.9

VISCOSITY: 1.29 CPS.

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: N/D

INCOMPATIBILITIES: N/D

MATERIAL SAFETY DATA SHEET
KETOROLAC TROMETHAMINE INJECTION, USP

PAGE 5
ISSUED 09/01/99

10. STABILITY AND REACTIVITY, CONTINUED

HAZARDOUS DECOMPOSITION PRODUCTS: WHEN HEATED TO DECOMPOSITION IT EMITS CO AND CO₂.

HAZARDOUS POLYMERIZATION: N/D

11. TOXICOLOGICAL INFORMATION

ORAL TOXICITY: N/D. LD₅₀ > 202 MG/KG BUT < 505 MG/KG IN RATS, LD₅₀ = 200 MG/KG IN MICE FOR KETOROLAC TROMETHAMINE. LD₅₀ = 5560-13,700 MG/KG IN GUINEA PIGS, RATS, MICE AND RABBITS FOR ETHYL ALCOHOL.

DERMAL TOXICITY: N/D. LD₅₀ = 20,000 MG/KG IN RABBITS FOR ETHYL ALCOHOL.

INHALATION TOXICITY: N/D.

CORROSIVENESS: N/D.

DERMAL IRRITATION: N/D. KETOROLAC TROMETHAMINE WAS NON-IRRITATING IN A SKIN IRRITATION TEST IN RABBITS. ETHYL ALCOHOL A MILD TO SEVERE IRRITANT IN RABBITS BUT PRACTICALLY HARMLESS TO HUMAN SKIN.

OCULAR IRRITATION: N/D. KETOROLAC TROMETHAMINE WAS NON-IRRITATING IN

EYE IRRITATION TEST IN RABBITS. DILUTE AQUEOUS FORMULATIONS (0.5%) CAN PRODUCE TRANSIENT STINGING AND/OR BURNING-SENSATION TO THE EYES. ETHYL ALCOHOL A SEVERE EYE IRRITANT IN RABBITS AND CAUSES PAIN AND DULLING OF THE CORNEA THAT IS TRANSIENT IN MAN.

DERMAL SENSITIZATION: N/D. KETOROLAC TROMETHAMINE DID NOT PRODUCE A SKIN SENSITIZATION RESPONSE IN THE MAXIMIZATION ASSAY IN GUINEA PIGS AT A CHALLENGE CONCENTRATION OF 25% W/V IN PETROLATUM.

SPECIAL TARGET ORGAN EFFECTS: N/D. IN CLINICAL USE, KETOROLAC TROMETHAMINE IS AN ANTI-INFLAMMATORY DRUG THAT REDUCES PAIN. CHRONIC ETHYL ALCOHOL CONSUMPTION CAN LEAD TO PERIPHERAL NEUROPATHY, PHYSICAL DEPENDENCE, FATTY CHANGE AND CIRRHOSIS OF THE LIVER. USE DURING PREGNANCY CAN LEAD TO RETARDED GROWTH, DEVELOPMENT DELAYS AND ABNORMALITIES (FETAL ALCOHOL SYNDROME).

CARCINOGENICITY INFORMATION: N/D.

12. ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/D

MATERIAL SAFETY DATA SHEET
KETOROLAC TROMETHAMINE INJECTION, USP

PAGE 6
ISSUED 09/01/99

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHODS: DISPOSE OF IN ACCORDANCE WITH LOCAL, STATE AND FEDERAL REGULATIONS.

14. TRANSPORTATION INFORMATION

DOT STATUS: NOT REGULATED
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
UN NUMBER: N/A
PACKING GROUP: N/A
REPORTABLE QUANTITY: N/A

IATA/ICAO STATUS: NOT REGULATED
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
UN NUMBER: N/A
PACKING GROUP: N/A
REPORTABLE QUANTITY: N/A

IMO STATUS: NOT REGULATED
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
UN NUMBER: N/A
PACKING GROUP: N/A
REPORTABLE QUANTITY: N/A
FLASH POINT: 43 C

15. REGULATORY INFORMATION

NTSCA STATUS: N/D

CERCLA STATUS: N/D

SARA STATUS: N/D

RCRA STATUS: EPA HAZARDOUS WASTE (DOO1)

PROP 65 (CA): N/D

MATERIAL SAFETY DATA SHEET
KETOROLAC TROMETHAMINE INJECTION, USP

PAGE 7
ISSUED 09/01/99

16. OTHER INFORMATION

LEGEND: N/A = NOT APPLICABLE
N/D = NOT DETERMINED
N/L = NOT LISTED
L = LISTED
C = CEILING
S = SHORT-TERM
(R) = REGISTERED TRADEMARK OF ABBOTT LABORATORIES
(TM) = REGISTERED TRADEMARK OF ABBOTT LABORATORIES

THE INFORMATION AND RECOMMENDATIONS CONTAINED HEREIN ARE BASED UPON TESTS BELIEVED TO BE RELIABLE. HOWEVER, ABBOTT LABORATORIES DOES NOT GUARANTEE THEIR ACCURACY OR COMPLETENESS NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. ADJUSTMENT TO CONFORM WITH ACTUAL CONDITIONS OF USAGE MAY BE REQUIRED. ABBOTT LABORATORIES ASSUMES NO RESPONSIBILITY FOR RESULTS OBTAINED OR FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING FROM THE USE OF THESE DATA. NO FREEDOM FROM INFRINGEMENT OF ANY PATENT, COPYRIGHT OR TRADEMARK IS TO BE INFERRED.