

GLAXO INC -- ZOFRAN ONDANSETRON HYDROCHLORIDE TABLETS --

=====
Product Identification
=====

Product ID:ZOFRAN ONDANSETRON HYDROCHLORIDE TABLETS
MSDS Date:12/19/1994
FSC:NIIN:Submitter:F BT
Status Code:A
MSDS Number: CJGGK
=== Responsible Party ===
Company Name:GLAXO INC
Address:5 MOORE DR
City:RESEARCH TRIANGLE PARK
State:NC
ZIP:27709
Country:US
Info Phone Num:919-248-2100/2700
Emergency Phone Num:919-248-2100
CAGE:34006

=====
Contractor Identification
=====

Company Name:GLAXO WELLCOME INC.
Address:5 MOORE DR
Box:13398
City:DURHAM
State:NC
ZIP:27709
Country:US
Phone:919-248-2100
CAGE:34006

=====
Composition/Information on Ingredients
=====

Ingred Name:ONDANSETRON HYDROCHLORIDE
CAS:103639-04-9

=====
Hazards Identification
=====

Routes of Entry: Inhalation:YES Skin:NO Ingestion:YES
Health Hazards Acute and Chronic:INHALATION: MAY CAUSE ALLERGIC
SENSITIZATION. EYES: SEVERE IRRITANT. INGESTION: MAY RESULT IN A
VARIETY OF ADVERSE EFFECTS. ZOFRAN TABLETS ARE INTENDED FOR MEDICAL
USE TO PREVENT NAUSEA & VOMITING ASSOCIATED W/INITIAL & REPEATED
COURSES OF CANCER CHEMOTHERAPY & ALSO WHEN ACCOMPANYING
RADIOTHERAPY FOR CANCER.
Effects of Overexposure:IRRITATION, HEADACHE, SKIN RASH, CONSTIPATION,
ABDOMINAL PAIN, WEAKNESS, CHANGES IN HEART RATE, ELECTROCARDIOGRAM,
CHEST PAIN, DRY MOUTH, RARE BRONCHOSPASM, WHEEZING, ANAPHYLAXIS,
SHORTNESS OF BREATH, UNCONSCIOUSNESS, CONVULSIONS, SHOCK.
Medical Cond Aggravated by Exposure:INDIVIDUALS KNOWN TO BE
HYPERSENSITIVE TO ONDANSETRON HYDROCHLORIDE. PERSONS W/LIVER
DISEASE.

=====
First Aid Measures
=====

First Aid:EYES: FLUSH W/LARGE AMOUNTS OF COOL WATER FOR 15 MINS. SKIN:

WASH W/SOAP & WATER. INHALATION: IF NOT BREATHING, GIVE CPR/OXYGEN IF NECESSARY. INGESTION: IF AWAKE & ABLE TO SWALLOW, RINSE MOUTH W/WATER . NEVER GIVE ANYTHING BY MOUTH IF UNCONSCIOUS/HAVING CONVULSIONS. OBTAIN MEDICAL ATTENTION IN ALL CASES.

=====
Fire Fighting Measures
=====

Extinguishing Media:WATER SPRAY, MULTI-PURPOSE DRY CHEMICAL
Fire Fighting Procedures:WEAR FULL PROTECTIVE CLOTHING & USE SELF CONTAINED BREATHING APPARATUS.
Unusual Fire/Explosion Hazard:BREAKAGE OF TABLETS, IN BULK OPERATIONS, COULD CONTRIBUTE TO DUST FORMATION. AS W/ANY ORGANIC DUST, THERE IS POTENTIAL FOR EXPLOSION WHEN HIGH CONCENTRATIONS ARE SUSPENDED IN AIR.

=====
Accidental Release Measures
=====

Spill Release Procedures:PROTECTIVE EQUIPMENT MAY BE NECESSARY. FOR SMALL QUANTITIES, COLLECT LEAK & TRANSFER TO A WASTE CONTAINER FOR DISPOSAL. LARGE/BULK QUANTITIES, COLLECT BY CAREFULLY SWEEPING/WIPING & PLACE IN A LABEL LED, SEALED CONTAINER FOR DISPOSAL. WASH AREA (FLOOR & OTHER CONTACT SURFACES) THOROUGHLY W/SOAP & WATER.

=====
Handling and Storage
=====

Handling and Storage Precautions:STORE BETWEEN 36 & 86F. PROTECT FROM EXCESSIVE MOISTURE.

=====
Exposure Controls/Personal Protection
=====

Respiratory Protection:RESPIRATORY PROTECTIVE EQUIPMENT SHOULD BE WORN WHEN WORKERS ARE EXPOSED TO HIGH DUST LEVELS. RECOMMENDATIONS FOR RESPIRATOR SELECTIONS IS NIOSH (ANSI Z88.2.
Ventilation:PROVIDE GOOD GENERAL EXHAUST VENTILATION.
Protective Gloves:IMPERMEABLE/LATEX
Eye Protection:REQUIRED
Other Protective Equipment:PROTECTIVE CLOTHING
Work Hygienic Practices:REMOVE/LAUNDER CONTAMINATED CLOTHING & SHOES BEFORE REUSE. WORK SURFACES SHOULD BE PROPERLY CLEANED/DISPOSED OF AFTER USE. A SUITABLE SOLVENT SUCH AS SOAP & WATER SHOULD BE USED FOR CLEANING.
Supplemental Safety and Health
WASH HANDS & OTHER AREAS OF SKIN CONTACT THOROUGHLY AFTER HANDLING THIS MATERIAL.

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

Appearance and Odor:4 MG WHITE/8MG YELLOW, OVAL TABLET ENGRAVED W/"4" / "8" & GLAXO; ODORLESS

=====
Stability and Reactivity Data
=====

Stability Indicator/Materials to Avoid:YES
Hazardous Decomposition Products:THERMAL DECOMPOSITION OF ONDANSETRON HYDROCHLORIDE: OXIDES OF NITROGEN & HYDROCHLORIC ACID.

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

Toxicological Information:SOME PATIENTS (5%) TREATED INTRAVENOUSLY W/ZOFRAN WHILE ALSO TAKING ANTI-CANCER MEDICATION HAD BRIEF & REVERSIBLE ELEVATIONS IN THE CIRCULATING LEVEL OF TWO ENZYMES. THERE ARE REPORTS OF LIVER FAILURE & DEATH IN CANCER PATIENTS RECEIVING ONDANSETRON IN COMBINATION W/TOXIC ANTICANCER DRUGS. WHETHER ZOFRAN CONTRIBUTED TO THIS PROBLEM IS UNCLEAR. THERE IS NO INDICATION THAT ONDANSETRON CAUSES CANCER/ MUTATION/BIRTH DEFECTS/OTHER REPRODUCTIVE HEALTH EFFECTS IN STANDARD TESTS. IN THE OCCUPATIONAL SETTING, EXPOSURE TO ZOFRAN TABLETS SHOULD BE MEDICALLY EVALUATED DURING PREGNANCY/NURSING.

===== Disposal Considerations =====

Waste Disposal Methods:UNUSED PRODUCT SHOULD BE DISPOSED OF AT AN APPROVED FACILITY/DISPOSE OF IN ACCORDANCE W/LOCAL, STATE & FEDERAL REGULATIONS.

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

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 this information to be accurate and disclaims all liability for its use. Any person utilizing this document should seek competent professional advice to verify and assume responsibility for the suitability of this information to their particular situation.