SAFETY DATA SHEETS

This SDS packet was issued with item:

078930580

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078930581

Diltiazem Hydrochloride Raw Material Material Safety Data Sheet

1090 Horsham Road
North Wales, PA 19454
Effective: 3/25/2010 12:13:00 PM

Telephone Calls: (201) 930-3411
Emergency Contact: Chemtrac
1-800-424-9300 24 Hours

SECTION 1 - IDENTIFICATION

PRODUCT NAME	Diltiazem Hydrochloride Raw Material	***SYNONYMS***	Cardizem, Tiazac, Dilacor
CHEMICAL FAMILY	Benzothizaepine	***THERAPEUTIC CATEGORY***	Coronary Vasodilator (calcium channel blocker).

SECTION 2 – HEALTH HAZARD INFORMATION

EMERGENCY OVERVIEW

WARNING – EFFECTS CARDIOVASCULAR SYSTEM; THIS MATERIAL IS A TEVA OHC 3 NON SMMA PRODUCT.

ECB

Toxic
R22 – Harmful if swallowed.
R24 – Toxic in contact with skin.
R36/38 - Irritating to eyes/skin.
R48 – Danger of serious damage to health by prolonged exposure.
R61 – May cause harm to the unborn child (Category 2).
S36/37 – Wear suitable protective clothing/gloves.
S45 – In case of accident or if you feel unwell, seek medical advice immediately.
S53 – Avoid exposure – obtain special instructions before use.

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GHS	Danger, Warning Acute Toxicity – Category 3 – Toxic if swallowed. Acute Dermal toxicity – Category 3 – Toxic in contact with skin. Skin Irritation – Category 2 – Causes skin irritation. Target Organ Toxicity – Category 1 – Causes damage to organs through repeated or prolonged exposure. Reproductive Toxicity – Category 1B – May cause damage to fertility or the unborn child.

EYE	Contact may cause irritation.
SKIN	Contact may cause moderate irritation.
INGESTION	Ingestion may cause irritation.
INHALATION	Breathing of dust may cause irritation to the respiratory tract.
ADVERSE SYSTEMIC EFFECTS	Peripheral edema, headache, pain, dizziness, asthenia, dyspepsia, increased frequency of coughing, and dyspnea.
CHRONIC (CANCER) INFORMATION	NTP – Not Listed IARC – Not Listed OSHA – Not listed
REPRODUCTION INFO	No adequate human studies have been conducted. This material is an FDA Pregnancy Category C material.
MEDICAL	Individuals with hypersensitivity to material and individuals with sick sinus

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CONDITIONS/MEDS AGGRAVATED BY EXPOSURE syndrome or 2nd or 3rd degree AV block (except those with pacemakers).

TARGET ORGANS Cardiovascular System.

APPEARANCE White to off white crystalline powder.

ODOR Odorless with a bitter taste.

SECTION 3 – INGREDIENT INFORMATION

COMPONENT	*CAS NUMBER*	*% BY WEIGHT*
Diltiazem Hydrochloride	33286-22-5	100

SECTION 4 – FIRST AID MEASURES

EYES Flush with large quantities of water for 15 minutes.

SKIN Powders: Brush off material, remove contaminated clothing, flush with large quantities of water for 15 minutes.

INGESTION Flush mouth with water – obtain medical attention.

INHALATION Remove to fresh air.

NOTE TO PHYSICIANS N/A

SECTION 5 – FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES Material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material in order to dissipate static charges.

HAZARDOUS COMBUSTION PRODUCTS Emits toxic fumes under fire conditions.

EXTINGUISHING MEDIA Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

FIRE FIGHTING INSTRUCTION	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

SMALL SPILL	Wear recommended PPE. Scoop up slowly without generating dust. (NO DRY SWEEPING). Wet wipe surfaces.
LARGE SPILL	Wear recommended PPE. Scoop up slowly without generating dust. (NO DRY SWEEPING). Wet wipe surfaces.

SECTION 7 – HANDLING AND STORAGE

HANDLING	Keep container closed, minimize dust generation during transfer. Also for more handling information, contact EHS, see Teva Global EHS "Guidelines for Safe Handling of APIs & Drugs" or "Containment Guidelines for Handling Different Quantities of Active Ingredients".
STORAGE	Store in a tight container and keep away from light and heat.

SECTION 8 – EXPOSURE CONTROL AND PPE

ENGINEERING CONTROLS	Operations involving handling/transferring of dry powder must be performed using containment measures (i.e. enclosures, etc.) and local exhaust ventilation.
RESPIRATORY PROTECTION	Manufacturing operations (weighing out active material, compounding, compression/encap, coating) require PAPR equipped with HEPA cartridges. Packaging and lab operations require NIOSH approved and properly fitted respirator.
SKIN PROTECTION	Manufacturing operations (weighing active material, compounding, compression/encap/coating) require one layer of work uniform or disposable coveralls, and appropriate gloves. Packaging operations require work uniform and gloves. Lab operations require lab coat and appropriate gloves.
EYE PROTECTION	Manufacturing operations (weighing active material & compounding,

compression/coating) require PAPR hood. Packaging and lab operations require Safety Glasses with Side Shields.

COMPONENT	***EXPOSURE LIMIT***
Diltiazem Hydrochloride	PIEL 40 ug/m3.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT	No information found.	***MELTING POINT***	207- 212 and also reported as 187-188 ºC	***pH***	4.3-5.3 (1% Aqueous Solution).
VAPOR PRESSURE	No information found.	***VAPOR DENSITY***	No information found.		
SOLUBILITY IN WATER	Freely Soluble.	***ODOR***	Odorless with a bitter taste.		
APPEARANCE	White to off white crystalline powder.	***SPECIFIC GRAVITY***	No information found.		
AUTOIGNITION TEMPERATURE	No information found.	***FLAMMABLE LIMITS***	No information found.		
MOLECULAR WEIGHT	450.98	***FLASHPOINT***	N/A		
OCTANOL/WATER COEFFICIENT	2.7	***EVAPORATION RATE***	N/A		

SECTION 10 – STABILITY AND REACTIVITY

CHEMICAL STABILITY (CONDITIONS TO AVOID)	This material is considered stable from a safety point of view. Avoid exposure to light.
INCOMPATIBILITY	Strong Oxidizers.
HAZARDOUS	When heated to decomposition, material emits toxic fumes of NOx, SOx

DECOMPOSITION PRODUCTS	and HCl.
HAZARDOUS POLYMERIZATION	Will not occur.

SECTION 11 – TOXICOLOGICAL INFORMATION

EYE	No information found.
SKIN	No information found.
INGESTION	No information found.
INHALATION	No information found.
ACUTE/SUBCHRONIC	LD50 (560 mg/kg oral-rat, 271 mg/kg skin- rat).
MUTAGENICITY/ CARCINOGENICITY	Mutagenicity test battery (in vitro and in vivo) produced negative results. Animal carcinogenicity studies in mice have not shown carcinogenicity.
REPRODUCTION	Animal studies in rats, rabbits and mice have shown embryotoxicity/lethality at high doses, and teratogenicity in one species or another (skeletal, heart, retina, and tongue abnormalities). Male and female rat studies have not shown fertility impairment.

SECTION 12 – ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION	No information found.
CHEMICAL FATE INFORMATION	No information found.

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose of in appropriate container, keep container closed. If possible, ensure that liquids/powders are in a sealed inner container. Label with appropriate Non-Hazardous waste label. Move full drums to

designated waste storage area.

SECTION 14 – TRANSPORTATION INFORMATION

NON DOT REGULATED MATERIAL.

SECTION 15 – REGULATORY INFORMATION

OSHA	N/A
CERCLA	N/A
SECTION 313 (SARA TITLE III)	N/A
OTHER REGULATIONS	Subject to California Proposition 65 (known to the state to cause developmental toxicity) warning and release requirements April 1, 1990 and the California Safe Drinking Water and Toxic Enforcement Act of 1986 to keep out of water supplies and sewers.

SECTION 16 – OTHER INFORMATION

PREPARED BY	Rob Mc Cafferty & Nevada Venhorst.
REVISIONS	Updated to Teva's OHC from Barr's & Updated Section 8 with PIEL.

DISCLAIMER:

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