MATERIAL SAFETY DATA SHEET

Boehringer Ingelheim Pharmaceuticals, Inc.

900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877
(203) 798-4081 9AM - 4PM EST

MICARDIS® HCT

ORIGINAL DATE ISSUED: 8/30/05
REVISION DATE: 2/10/2012

EMERGENCY TELEPHONE NUMBER
CHEMTREC - 24 hours
1-800-424-9300

1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME: Mixture of 4' [(1,4' -dimethyl-2' -propyl [2,6-bi-1H-benzimidazol]-1' -yl) methyl]-[1,1' -biphenyl]-2-carboxylic acid with 2H-1,2,4-benzothiadiazine-7-sulfonamide

GENERIC NAME: Telmisartan/Hydrochlorothiazide

MOLECULAR FORMULA: ($C_{33}H_{30}N_4O_2$) Telmisartan ($C_7H_8ClN_3O_4S_2$) Hydrochlorothiazide

TRADEMARK: MICARDIS®Hydrochlorothiazide Combination Tablets

MOLECULAR WEIGHT: 514.63[1] 297.74[2]

PRODUCT USE: Anti-hypertensive and diuretic

CAS NUMBER: 144701-48-4 [1] 58-93-5[2]

[1] Telmisartan
[2] Hydrochlorothiazide

SYNONYMS: Micardis® Hydrochlorothiazide 40/12.5 mg
Micardis® Hydrochlorothiazide 80/12.5 mg
Micardis® Hydrochlorothiazide 80/25 mg

2. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

Biconvex two layered tablets in three combinations. The Telmisartan layer is white in all three tablets, the hydrochlorothiazide layer is red in the 40/12.5 and 80/12.5 strength and yellow in the 80/25 strength.

Acrid, flammable fumes may develop in a fire. Use water spray, foam, CO_2, or dry chemical agents to extinguish fires.

ROUTES OF ENTRY: Inhalation, Ingestion, Skin contact

SIGNS AND SYMPTOMS OF EXPOSURE: Possible reaction to dust if inhaled (breathed), ingested (swallowed), or in contact with eyes. The most common adverse events reported were upper respiratory tract irritation/infection, back pain, sinusitis, diarrhea and pharyngitis. See Package Insert for further information.

The most likely manifestation of overdosage would be hypotension, dizziness, and tachycardia, diuresis, vomiting, digestive disorders, convulsions and coma; bradycardia could occur from vagal stimulation. Supportive treatment should be instituted. Telmisartan is not removed by hemodialysis.

CHRONIC EXPOSURE: May reduce blood pressure.

MEDICAL CONDITIONS POTENTIALLY AGGRAVATED BY EXPOSURE: Dust allergies, and pre-existing respiratory conditions and anyone who is hypersensitive to any component of this product. Persons with low blood volume, and hepatic insufficiency may be at additional risk.

Because of the hydrochlorothiazide component, this product is contraindicated in patients with anuria or hypersensitivity to other sulfonamide-derived drugs.

CARCINOGENICITY: Not listed as carcinogen/potential carcinogen by NTP, IARC Monographs or OSHA.

3. COMPONENTS PER UNIT DOSE

Active Ingredient:	**Exposure Limit**	**Active Ingredient**:	**Exposure Limit**
Telmisartan	100 ug/m3*	Hydrochlorothiazide	500 ug/m3*
Excipients:		**Excipients:**	
Sodium hydroxide	2 mg/m3 (Ceiling)**	Lactose monohydrate	Not established**
Meglumine	Not established*	Microcrystalline Cellulose	10 mg/m3** (total) 5mg/m3 (respirable)**
Povidone	Not established**	Corn Starch	Not established**
Sorbitol	Not established**	Red Iron Oxide (40/12.5 & 80/12.5 tablets	5 mg/m3**
Magnesium stearate	10 mg/m^3 (stearates)**	Yellow Iron Oxide(80/25 tablets)	5 mg/m3**
		Sodium starch glycolate	Not established**

* BIEL is the BI Exposure Control Level. When lower governmentally imposed occupational exposure limits exist, such limits should take precedence.
** TLV established by the American Conference of Governmental Industrial Hygienists (ACGIH) 2005

4. EMERGENCY FIRST AID PROCEDURES

Persons developing anaphylactic (life-threatening) reactions, such as difficulty in breathing or unconsciousness, must receive immediate medical attention.

I**NGESTION:** Give 3-4 glasses of water, but **DO NOT** induce vomiting. If vomiting occurs, give fluids again. Get medical attention to determine whether vomiting or evacuation of stomach is necessary. Do not give anything by mouth to an unconscious or convulsing person.

INHALATION: Remove from area to fresh air. Seek medical attention if respiratory irritation develops or if breathing becomes difficult.

EYE CONTACT:
Remove contact lenses if necessary. Flush eyes with large amounts of running water for at least 15 minutes. Seek medical attention if irritation develops or persists.

SKIN CONTACT: Wash affected areas with plenty of water, and soap if available, for several minutes. Seek medical attention if irritation develops or persists.

NOTE TO PHYSICIAN: **MICARDIS®** is not removed by hemodialysis

5. FIRE AND EXPLOSION HAZARD DATA

	Flammable Limits	
Flash Point	**Upper**	**Lower**
N/A		

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

SPECIAL FIRE FIGHTING PROCEDURES: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to keep fire-exposed containers cool and protect against all exposures.

UNUSUAL FIRE AND EXPLOSION HAZARDS: As with all organic powders, this material presents a dust explosion hazard. It can burn in a fire, producing acrid flammable fumes including acid gases and oxides of carbon, nitrogen and sulfur.

6. SPILL AND ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF TABLETS ARE BROKEN: Wear an approved respirator, eye protection, personal protective coverings and gloves. Use HEPA filtered vacuum or wet sweeping to clean up spillage. Avoid dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before use.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

HANDLING AND STORAGE PRECAUTIONS: Store in tight container. Store away from foodstuffs.

HANDLING SIGNIFICANT QUANTITIES OF BROKEN TABLETS: Avoid contact with eyes, skin or clothing. Avoid generating dust. Wash hands thoroughly after handling.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls: Not generally required when handling containers or tablets. (See Section 3 for exposure limits). Good ventilation (typically 10 air changes per hour should be used. Ventilation rates should be matched to conditions.

If operations involve crushing or other processes that may release powder, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Respiratory Protection: Not generally required when handling containers or tablets. The need for respiratory protection should be determined by an industrial hygiene survey. (See Section 3 exposure limits). NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

PERSONAL PROTECTIVE EQUIPMENT: Not generally required when handling containers. If containers are compromised or exposure to the active ingredient or mixture is likely wear:

Eye Protection: Safety goggles w/ side shields or goggles

Hand Protection: Neoprene or nitrile gloves

Protective Clothing: Laboratory coats

Other: Eye wash

WORK/HYGIENIC PRACTICES: Keep away from foodstuffs, beverages and feed. Immediately remove all soiled contaminated clothing. Wash hands before breaks and at the end of work.

9. PHYSICAL/CHEMICAL CHARACTERISTICS

APPEARANCE AND ODOR: Biconvex two layered tablets in three combinations. The Telmisartan layer is white in all three tablets, the hydrochlorothiazide layer is red in the 40/12.5 and 80/12.5 strength and yellow in the 80/25 strength.

For Telmisartan		**For Hydrochlorothiazide**	
Vapor Pressure (mmHg):	N/A	Vapor Pressure (mmHg):	N/A
Vapor Density:	N/A	Vapor Density:	N/A
Water Solubility:	Practically insoluble	Water Solubility:	Slightly Soluble
Specific Gravity:	N/A	Specific Gravity:	N/K
Melting Point:	265°C.	Melting Point:	N/K
Evaporation Rate:	N/A	Evaporation Rate:	N/A
pH:	N/A	pH:	

10. REACTIVITY DATA

STABILITY: Stable.

CONDITIONS TO AVOID: None known

INCOMPATIBLE MATERIALS: None known

HAZARDOUS DECOMPOSITION OR BY-PRODUCTS: When heated to decomposition or under fire conditions, material emits acid gases and oxides of carbon, nitrogen and sulfur.

HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

TOXICITY FOR ACTIVE INGREDIENT 1: Telmisartan

INGESTION:

Rats & Dogs – Acute oral toxicity was low. No deaths and no changes occurred in rats or dogs at 2000 mg/kg, the highest dose tested.

INTRAVENOUS

Rats - The I.V. LD_{50} in rats was 150-200 mg/kg in males and 200 to 250 mg/kg in females.

REPRODUCTIVE TOXICITY: There is a clinical experience with ACE-inhibitors which have shown to cause fetal and neonatal morbidity and mortality when administered to pregnant women.

In studies on fertility and reproductive performance in male and female rats no effect on mating performance or fertility in either sex or on litter parameters in females was observed (5-100 mg/kg). The NOEL for fertility and early embryonic development was 100 mg/kg.

CARCINOGENESIS/MUTAGENISIS:
There was no evidence of carcinogenicity when Telmisartan was administered in the diet at 1000 mg/kg/day to mice and 100 mg/kg/day to rats for up to 2 years. Genotoxicity assays did not reveal any Telmisartan-related effects at either the gene or chromosome level.

TOXICITY FOR ACTIVE INGREDIENT 2: Hydrochlorothiazide

INGESTION:

Moderately toxic by ingestion. 500 ug/kg oral-woman TDLo; 2500 ug/kg/5 day(s) intermittent oral-woman LDLo; 12857 ug/kg/9 day(s) intermittent oral-man TDLo; 2 mg/kg/12 hour(s) intermittent oral-woman TDLo; 2750 mg/kg oral-rat LD50; 1175 mg/kg oral-mouse LD50;; 1100 mg/kg unreported-mouse LD50; 30 gm/kg/30 day(s) continuous oral-rat TDLo; 4550 mg/kg/13 week(s) intermittent oral-rat TDLo; 273 gm/kg/13 week(s) intermittent oral-mouse

INTRAVENOUS

Rats LD50 - 990 mg/kg. Mouse LD50 - 590 mg/kg. Dog LD50 - 250 mg/kgLD50. Rabbit LD50 461 mg/kg.

TARGET ORGANS

The main target organs are the heart, liver, kidneys and gastrointestinal tract.

CARCINOGENESIS/MUTAGENISIS:
Some evidence of carcinogenic activity was reported in male mice based on an increased incidence of hepatocellular neoplasms. Equivocal evidence of carcinogenic activity was reported in male rats based on a marginal increase in the incidence of neoplasms of the Zymbal gland. No evidence of carcinogenic activity was found in female rats or mice (NTP TR-357).

DNA-adduct-Escherichia coli 5mg/L; sex chromosome loss and non disjunction – Aspergillus nidulans 1gm/L; mutation in mammalian somatic cells – mouse lymphocyte 500 mg/L; cytogenetic analysis – hamster lung 500 mg/L 48 hours; sister chromatid exchange – hamster ovary 43 mg/L.

TUMORGENIC DATA:
309 gm/kg oral – mouse TDLo/2 years continuous.

12. ECOLOGICAL INFORMATION

NOEC: 5.4 mg/L (Daphnia)
Microbial growth inhibition: Generally greater than 1,000 mg/L

13. DISPOSAL CONSIDERATIONS

RCRA classification .....Not regulated

WASTE DISPOSAL CONSIDERATIONS: Dispose of in accordance with local, state and federal regulations. Recommended method is incineration or landfill. Preferred disposal is in an approved hazardous waste incinerator.

14. TRANSPORT INFORMATION

This product is not subject to the regulations for the safe transport of hazardous materials

DOT Proper Shipping Name:	N/A
Hazard Class:	Not regulated.
Identification Number:	N/A
Packing Group	N/A
Label	N/A

Emergency Response Guidebook - N/D

15. REGULATORY INFORMATION

Hydrochlorothiazide is listed on the TSCA Inventory. However, other active ingredients are not. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

16. OTHER INFORMATION

ABBREVIATIONS:

N/A - Not applicable
N/D - Not determined
N/E - Not established
N/K - Not known

PREPARATION INFORMATION

Prepared by: Environmental Affairs & Safety

Date Revised: 08/05

Replaces: 12/99

Reorganized and updated Sections 2& 3, and updated exposure limits in Section 3 Components Per Unit Dose, and Sections 6, 7 and 8 to reflect drug product handling information and other editorial changes.

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References:

BIPI MSDS, 12/99
Physician's Desk Reference, 2005.

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION