MATERIAL SAFETY DATA SHEET

Boehringer Ingelheim Pharmaceuticals, Inc.

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MICARDIS®

DATE ISSUED 4/99
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EMERGENCY TELEPHONE NUMBER
CHEMTREC - 24 hours
1-800-424-9300

1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME: (Telmisartan) 4'-[(1,4'-dimethyl-2'-propyl[2,6'-bi-1H-benzimdazol]-1'-yl)methyl]-[1,1'-biphenyl]-2-carboxylic acid.

CAS TYPE: 1

GENERIC NAME: Telmisartan

MOLECULAR FORMULA: $C_{33}H_{30}N_4O_2$

TRADEMARK: **MICARDIS®**

MOLECULAR WEIGHT: 514.63

PRODUCT USE: Angiotensin II Antagonist

CAS NUMBER: 144701-48-4

SYNONYMS:

2. COMPONENTS PER UNIT DOSE

MATERIAL	% by Weight	EXPOSURE LIMITS
Active Ingredient:		
Telmisartan	17%	0.1 mg/m^3 BIEL**
Excipients:		
Sodium hydroxide		C 2.0 mg/m3
Meglumine		Not established*
Povidone		Not established*
Sorbitol		Not established*
Magnesium stearate		10 mg/m^3 (stearates)
		* As per 2002 ACGIH

**BIEL is the BI Exposure Limit. Where governmentally imposed occupational exposure limits which are lower than the BIEL are in effect, such limits should take precedence.

3. HAZARD IDENTIFICATION

EMERGENCY OVERVIEW

White, oblong-shaped, uncoated tablets, with the BOEHRINGER INGELHEIM logo on one side and either 51H or 52H on the other.

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

CONTRAINDICATIONS: **MICARDIS®** should not be used by patients with clinically significant hypersensitivity to any of the components in this product.

WARNING:

When used in pregnancy during the second and third trimesters, drugs that act directly on the renin-angiotensin system can cause injury and even death to the developing fetus.

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 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; 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.

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

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		

FIRE EXTINGUISHING MEDIA: Water spray, foam, CO_2, or dry chemical.

SPECIAL FIREFIGHTING PROCEDURES: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.[2] Use water spray to keep fire-exposed containers cool.[6]

UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

6. SPILL AND ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN THE EVENT OF A SPILL: Wear approved respirator and chemically compatible gloves if containers have been compromised and dust is present. Vacuum or sweep up spillage. Avoid creating dust. Very fine particles can cause a fire or explosion; therefore, eliminate all sources of ignition. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before reuse. Ventilate area, wash down spill site and control wash water.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

HANDLING AND STORAGE PRECAUTIONS: Do not handle product without appropriate protective equipment. If dust is present it may form flammable dust-air mixtures. Avoid creating dusts. In situations where dusts will be unavoidably generated, ground all equipment and use explosion-proof apparatus.

Avoid breathing dusts if dust is present; avoid contact with skin or eyes. Wear appropriate protective equipment (See Section 8.) Wash thoroughly after handling.

STORAGE

Store in a cool, dry place [77°F (25°C)]. The bottles should be kept tightly closed.

8. CONTROL MEASURES

ENGINEERING CONTROLS: Minimize dust generation. Use closed equipment where possible. Use local exhaust ventilation to remove dust from the work area. If operations generate dusts, use explosion-proof ventilation equipment to control airborne levels. (See section 2 for exposure limits.) Use appropriate respiratory protection based on an industrial hygiene survey.)

RESPIRATORY PROTECTION: The need for respiratory protection should be determined by an industrial hygiene survey. (See Section 2 for exposure limits.) NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.[5]

VENTILATION: General ventilation should be adequate to maintain exposure levels below recommended established exposure limits. If general ventilation is not sufficient, local exhaust is recommended.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection: Safety glasses with side shields or goggles	Hand Protection: Durable rubber gloves
Protective Clothing: Long sleeve shirts, long pants. In extremely dusty areas, disposable coveralls should be worn.	Other: Eye wash

9. PHYSICAL/CHEMICAL CHARACTERISTICS

For MICARDIS®:

APPEARANCE AND ODOR: White, oblong-shaped, uncoated tablets, with the BOEHRINGER INGELHEIM logo on one side and either 51H or 52H on the other.

Boiling Point: N/D	Specific Gravity: N/A
Vapor Pressure (mmHg): N/D	Melting Point: 265°C.
Vapor Density: N/D	Evaporation Rate: N/A
Water Solubility:	pH: N/A

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 oxides of carbon and nitrogen.

HAZARDOUS POLYMERIZATION: Will not occur.

11. TOXICOLOGICAL INFORMATION

ACUTE TOXICITY OF ACTIVE INGREDIENT

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.

OCULAR
No Data Available

DERMAL
No Data Available

TARGET ORGANS
Rats & Dogs - the main target organs in rats and dogs were the heart, liver, kidneys and gastrointestinal tract.

Reproductive Toxicity of Active Ingredient
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. The doses applied (5-100 mg/kg) were pharmacologically active and produced slight toxicity (reduced body weight gain). The NOEL for fertility and early embryonic development was 100 mg/kg. Further more, no drug-induced histopathological changes were observed in the reproductive organs of male and female mice at doses up to 1000 mg/kg for 2 years, rats given doses up to 100 mg/kg for 2 years and dogs at doses up to 50 mg/kg for 1 year.

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

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

12. ECOLOGICAL INFORMATION

For Active Ingredient:

Daphnia EC50 – 18.0 mg/l 48 hours. The active ingredient is harmful to aquatic organisms. Not readily biodegradable. May cause long-term adverse effects in the aquatic environment.

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

This material is **not** listed on the US TSCA Inventory. 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 Prepared: 4/99
Date Revised: 11/02
Updated exposure limits in Section 2 Components Per Unit Dose, Section 12 Ecological Information and other minor editorial changes

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SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION