

<u>SAFETY DATA SHEET – TELMISARTAN TABLETS USP</u>

1. IDENTIFICATION

Material Identification : TELMISARTAN TABLETS USP 20mg, 40mg and 80mg

.

Active Ingredient : Telmisartan

Molecular Formula : C₃₃H₃₀N₄O₂ Molecular Weight : 514.62 g/mol

CAS Number : 144701-48-4

Product Use : Telmisartan Tablets is indicated for treatment of hypertension, to lower blood

pressure.

Manufactured by : Micro Labs Limited Manufactured for : Micro Labs USAInc

Plot No. S-155 to S-159 and N1 Phase III and

Phase IV.

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Verna - 403722, Goa, India.

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+91 8554983380

2. HAZARDS IDENTIFICATION

Labeling according to GHS / : Acute Toxicity: Oral, Category 2 1272/2008 (CLP) Toxic To Reproduction, Category 2

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Classification according to EU Directives 67/548/EEC or 1999/45/EC

Harmful if swallowed.

Adverse Human Health Effects and

Symptoms

Material may be irritating to the mucous membranes and upper

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USA

respiratory tract.

May be harmful by inhalation, ingestion, or skin absorption.

May cause eye, skin, or respiratory system irritation. Suspected of damaging fertility or the unborn child.

Toxic to aquatic life with long lasting effects.



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3. COMPOSITION/INFORMATION ON INGREDIENTS

Material %

Telmisartan : 17.02

Mannitol (Pearlitol SD 200) : *

Meglumine : *

Sodium Hydroxide : *

Povidone K-30 : *

Crospovidone Type A / Kollidon CL : *

Magnesium Stearate :

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eye contact : Bathe the eye with running water for 15 minutes. Consult a doctor.

Skin contact: Wash immediately with plenty of soap and water. Remove all

contaminated clothes and footwear immediately unless stuck to

skin.

Inhalation : Consult a doctor. Remove casualty from exposure ensuring one's

own safety whilst doing so.

Ingestion: Wash out mouth with water. Do not induce vomiting. If conscious,

give half a litre of water to drink immediately. Consult a doctor.

Transfer to hospital as soon as possible.

5. FIRE FIGHTING MEASURES

Suitable Extinguishing

media

: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical

spray.

Special protective equipment and

precautions

Protective equipment and precautions for fire fighters as in any fire

wear self-contained breathing apparatus pressure-Demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

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6. ACCIDENTAL RELEASE MEASURES

Personal Protections	:	Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).
Emergency Procedures	:	Operate and process as per standard operating process. Don't encourage wrong Operating practices. Follow and act as per factory emergency prepared ness plan.
Environmental Precautions	:	Prevent entry into waterways, sewers, basements or confined areas. Do not flush into Surface water or sanitary sewer system. Do not discharge into drains or rivers.

7. HANDLING AND STORAGE

Precautions for safe

handling

: Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid

prolonged or repeated exposure.

Storage Conditions : Keep container tightly closed. Store in accordance with

information listed on the product insert.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure control/ Personal protection

This product, as supplied, does not contain any hazardous materials with occupational Exposure limits established by the

region specific regulatory bodies.

If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must

be provided in accordance with current local regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State : Tablet

Color : White to off white

Appearance : 20 mg:White to off- white, circular, flat face bevel edged,

uncoated tablets, engraved with 'T' on one face and '20' on other

face.

40 mg:White to off- white, oval shaped, biconvex, uncoated tablets, engraved with 'T40' on one face and plain on other face. **80 mg:**White to off- white, capsule shaped, biconvex, uncoated tablets, engraved with '**T80**' on one face and plainon other face.

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10. STABILITY AND REACTIVITY

Reactivity : NA

Chemical Stability:Stable under recommended storage conditionsConditions to avoid:Extremes of temperature and direct sunlight.

11. TOXICOLOGICAL INFORMATION

PDE (mg/day) : 0.05

Genotoxicant : No

Reproductive/ developmental toxicant : Yes

Carcinogen : No

Highly sensitising Potential : No

12. ECOLOGICAL INFORMATION

Ecological information: Avoid release into the environment. Runoff from fire control or

dilution water may cause pollution

13. DISPOSAL CONSIDERATIONS

Disposal of wastes : Dispose in accordance with local, state, and federal regulations.

14. TRANSPORTATION INFORMATION

Dispose in accordance with local, state, and federal regulations.

15. REGULATORY / STATUTORY INFORMATION

Regulatory information: General health, safety and environmental precautions to be

followed.



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16. OTHER INFORMATION

Date of preparation:

21/03/20

The information contained in this Material Safety Data Sheet is believed to be accurate and represents the best information available at the time of preparation. However, no warranty, express or implied, with respect to such information, is made. The data in this Material Safety Data Sheet relate only to the specific material designated herein and does not relate to use in combination with any other material. The data in this Material Safety Data Sheet are subject to revision as additional knowledge and experience are gained.

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End of Safety Data Sheet