IN CASE OF EMERGENCY
Emergency Phone: (614) 276-4000

Boehringer Ingelheim
Roxane Laboratories

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Common/Trade Name: Zidovudine Tablets USP
Chemical Name: 3′-azido-3′-deoxythymidine
Synonyms: None
Molecular Formula: $C_{10}H_{13}N_5O_4$
Molecular Weight: 267.24
CAS No: 30516-87-1
Chemical Family: Pyrimidine nucleoside analogue
Product Use: Treatment and prevention of HIV infection

Manufacturer's Name: Boehringer Ingelheim Roxane Inc.
Address: 1809 Wilson Road
Columbus, Ohio 43228

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition	CAS#	Exposure Limit
Zidovudine (active ingredient)	30516-87-1	None established

REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%

3. HAZARDS IDENTIFICATION

Emergency Overview	Physical State: Round, biconvex, film-coated tablets The 300 mg tablets are white with "54 777" embossed on one side and blank on the other. Odor: None WARNING! May be harmful if swallowed. Accidental ingestion of large amounts may be harmful.
Primary Route(s) of Entry	Ingestion
Potential Health Effects:	Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form. Eye Contact: Not expected to be a hazard to the eye in final pharmaceutical form. Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. Ingestion: May be harmful if ingested. Ingestion may cause headache, nausea, vomiting, abdominal pain and insomnia.
Toxicity Data:	See Section 11
Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure by ingestion may cause fatigue, headache, vomiting and occasional reports of hematological disturbances.
Target Organs:	Blood, Immune System

4. FIRST AID MEASURES

Eye Exposure	Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.
Skin Exposure	Wash with soap and water. Get medical attention if symptoms occur.

Ingestion	Call a physician or poison control center immediately.
Inhalation	Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.

5. FIRE AND EXPLOSION HAZARDS

Flammability	Lower: N/A Upper: N/A
Flash Point	Not Applicable
Extinguishing Media	Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus.
Unusual Fire/Explosion Hazards	Not Applicable
Hazardous Combustion Products	Carbon dioxide, carbon monoxide, oxides of nitrogen

6. ACCIDENTAL RELEASE INFORMATION

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED:
Use appropriate personal protective equipment (see Section 8). Sweep up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.

7. PRECAUTIONS FOR SAFE HANDLING AND USE

Precautions Handling Significant Quantities of Product:	Observe good industrial hygiene practices.
Storage	Store at 20° to 25°C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.

8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Exposure Limits	None
Engineering Controls	Not required when handling tablets or containers. Ventilation should be matched to conditions.
Respiratory Protection	Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.
Personal Protection	Not required when handling tablets. If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves
Recommended Facilities	Eye wash, washing facilities

9. PHYSICAL / CHEMICAL CHARACTERISTICS

Appearance	White, round, biconvex, film-coated tablets	Melting point	Not available	Solubility in water	Good (active)
Odor	None	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available

10. STABILITY AND REACTIVITY DATA

Stability	Stable
Incompatibility	None known
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen
Conditions to	

Avoid	**Excessive heat, light**
Hazardous Polymerization	**Will not occur.**

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Active Ingredient:
Oral LD50 (rat): 3084 mg/kg
Oral LD50 (mouse): 1920 mg/kg

Carcinogenicity: Not listed as a carcinogen by NTP, IARC Monographs or OSHA.

12. ENVIRONMENTAL IMPACT INFORMATION

No information is currently available on the environmental impact of this product.

13. DISPOSAL INFORMATION

Waste Disposal Considerations: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended.
At home: Discard away from children's reach.

14. TRANSPORTATION INFORMATION

This product is not subject to the regulations for the safe transport of hazardous chemicals.
DOT: Not regulated
TDG: Not regulated
IATA: Not regulated
IMDG: Not regulated

15. REGULATORY INFORMATION

DEA: Zidovudine is not a controlled substance.

FDA: Zidovudine is an approved prescription medication.

Inventory Status: 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.
This material is not listed on the DSL Inventory but is exempt.

16. OTHER DATA

ABBEVIATIONS:
N/A – not applicable

Prepared by: Boehringer Ingelheim Roxane, Inc.

References:

1. **Zidovudine Tablets USP, Package Insert, Boehringer Ingelheim Roxane, Inc., Columbus, Ohio**
2. **RTECS No. XP2072000 – Thymidine, 3'-azido-3'-deoxy-**
3. **Ariel Webinsight. Regulatory and ChemExpert Database.**
4. **PDR – Physicians Desk Reference**

Date: New MSDS: 09/15/2005 **Revised: 10/16/2008**

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated, it may pose hazards not mentioned in this MSDS. It is the users' responsibility to use the information according to the application. Boehringer Ingelheim Roxane, Inc. assumes no responsibility or liability resulting from the use of this information.