MATERIAL SAFETY DATA SHEET

MANUFACTURER: AMERICAN CYANAMID COMPANY
LEDERLE LABORATORIES
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PEARL RIVER, NY 10965

MSDS No.: 04465-01
Supersedes: (new)
DATE: 08/16/93

TELEPHONE: (914) 732-5000

I. PRODUCT IDENTIFICATION

PRODUCT NAME: DIAMOX\ acetazolamide SEQUELS\, 500 mg:
(Product Code: PR; 04465 & STZ; 0753)

CAN CAUSE EFFECTS ON BLOOD, KIDNEY, AND NERVOUS SYSTEM.

CHEMICAL/THERAPEUTIC FAMILY: Sulfonamide; carbonic anhydrase inhibitor; diuretic.

II. HAZARDOUS INGREDIENTS AND EXPOSURE LIMITS

CHEMICAL AND COMMON NAMES	CAS NO.	%	RECOMMENDED AIRBORNE LEVELS*	
		OSHA	TLV (1992-93)	ACGO-TWA
Acetazolamide USP 5 mg/m3 2-acetylamino-1,3,4-thiadiazole-5-sulfonamide; CI 6,063; DIAMOX	[59-66-5]	55.6	Not est.	Not est.
Product also contains:				
Glycerin USP 10 mg/m3	[56-81-5]	5.8	10 mg/m3	10 mg/m3
1,2,3-Propanetriol			(total) 5 mg/m3 (resp. fraction)	(total)

*Airborne limits have been established for Glycerin mist.

III. PHYSICAL PROPERTIES

MOLECULAR WEIGHT: 222.25] EMPIRICAL FORMULA: C4H6N4O3S2]
92.09] C3H8O3]

APPEARANCE AND ODOR: Clear orange, soft shell capsule, printed with the word "DIAMOX" over "D3", in blue ink.

BOILING POINT: Not available MELTING POINT: 258-259° C]

VAPOR PRESSURE: Not available SPECIFIC GRAVITY: Not available

VAPOR DENSITY: Not available PERCENT VOLATILE: Not available

]Property of Acetazolamide USP.
]Property of Glycerin USP.

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III. PHYSICAL PROPERTIES

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SOLUBILITY, ORGANIC SOLVENTS: ACETAZOLAMIDE is slightly soluble in alcohol, acetone; insoluble in chloroform, diethyl ether, carbon tetrachloride.

SOLUBILITY, AQUEOUS (WATER): ACETAZOLAMIDE is sparingly soluble in cold water.

pH: Not available (Acetazolamide is a weak acid)

SATURATION IN AIR (BY VOLUME): Not available

EVAPORATION RATE: Not available

IV. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT: GLYCERIN: 176° C FLAMMABLE LIMITS: Not available
(METHOD: Open cup) LOWER: N/A UPPER: N/A

AUTOIGNITION TEMP.: GLYCERIN autoignite at 400° C.

HAZARDOUS COMBUSTION PRODUCTS: Not determined; combustion products will vary with fire conditions and oxygen supply to the flame. As with other organic materials, combustion may produce carbon monoxide, carbon dioxide, nitrogen oxides, irritating aldehydes, ketones and organic acids and, possibly, hydrogen cyanide. Hydrogen chloride and sulfur oxides and other chlorine- and sulfur-containing compounds may also be generated.

EXPLOSION HAZARDS: Not available

V. REACTIVITY DATA

STABILITY: Stable CONDITIONS TO AVOID: N/A

POLYMERIZATION: Will not occur CONDITIONS TO AVOID: N/A

INCOMPATIBLE MATERIALS: GLYCERIN reacts violently with strong oxidants.

DECOMPOSITION TEMPERATURE: GLYCERIN decomposes when heated above 290° C.

HAZARDOUS DECOMPOSITION PRODUCTS: GLYCERIN will emit acrolein, a corrosive gas, when heated to decomposition.

VI. SUMMARY OF TOXICITY AND HEALTH HAZARD DATA

SIGNS AND SYMPTOMS OF OVEREXPOSURE IN THE WORKPLACE:

EYES: None known or expected.

SKIN: None known or expected.

INHALATION: Mists or aerosols of GLYCERIN may cause respiratory tract irritation.

INGESTION: None known or expected.

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VI. SUMMARY OF TOXICITY AND HEALTH HAZARD DATA

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MEDICAL CONDITIONS GENERALLY RECOGNIZED AS BEING AGGRAVATED BY EXPOSURE:

Exposure to DIAMOX\ acetazolamide SEQUELS\ may aggravate preexisting marked kidney and liver disease or dysfunction, and suprarenal gland failure. Clinically-observed side effects of exposure to ACETAZOLAMIDE include paresthesias (tingling in the extremities), hearing dysfunction (tinnitus; ringing in the ears), loss of appetite, altered taste, gastrointestinal disturbances (such as nausea, vomiting, diarrhea), polyuria (excessive urination), and occasional instances of drowsiness and confusion. Metabolic acidosis and electrolyte imbalances may also occur; transient myopia (nearsightedness) has also been reported.

Long-term clinical administration of DIAMOX\ acetazolamide SEQUELS\ is contraindicated in patients with certain types of glaucoma since it may hide the symptoms while the actual underlying problem worsens.

Clinically-observed adverse effects associated with the use of GLYCERIN are mainly due to its dehydrating effects.

Clinical use of GLYCERIN is contraindicated in cases of preexisting diabetes, kidney dysfunction, and patients at risk of dehydration.

PRIMARY ROUTE(S) OF EXPOSURE/ENTRY:

Inhalation of mists; eye or skin contact. The potential for absorption through intact or broken skin has not been evaluated.

CANCER INFORMATION:

None of the components of this formulation are listed by the National Toxicology Program (NTP) as carcinogens. None have been evaluated for carcinogenic potential by the International Agency for Research on Cancer (IARC). None are regulated as carcinogens by the Occupational Safety and Health Administration (OSHA).

No studies of the carcinogenic potential of ACETAZOLAMIDE have been conducted or reported.

REPORTED HUMAN EFFECTS:

Pharmacologic (drug-related) effects noted during clinical use of DIAMOX acetazolamide SEQUELS\ are discussed above under "MEDICAL CONDITIONS ...".

Very large oral doses of GLYCERIN can exert systemic effects including

headache, thirst, diarrhea, nausea, hyperglycemia, and vomiting; central nervous system disturbances such as confusion, euphoria, and drowsiness; and metabolic disturbances, particularly in diabetic subjects and subjects with glaucoma. Injection of large doses may induce convulsions, paralysis, hemolysis, and kidney failure. GLYCERIN dropped on the human eye causes a strong stinging and burning sensation, with tearing and dilation of the conjunctival vessels, but no obvious injury.

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VI. SUMMARY OF TOXICITY AND HEALTH HAZARD DATA

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REPORTED ANIMAL EFFECTS:

The oral LD50 of ACETAZOLAMIDE in rats is reported to be in excess of 1000 mg/kg (all animals survived). When administered intravenously, deaths occurred in mice receiving > 3000 mg/kg. No eye or skin irritation data are available. Short-term administration of ACETAZOLAMIDE at dose of 500 mg/kg/day for 4 days, followed by 1000 mg/kg/day for 6 days, to one male dog caused weakness, anorexia and vomiting. Administration of 33 mg/kg/day for 7 days to two female dogs caused lethargy, ataxia, and labored breathing indicative of changes in blood pH (metabolic acidosis).

In a repeat-dose study in rats, administration of ACETAZOLAMIDE at 50, 150, or 300 mg/kg/day for two weeks followed by increased doses of 100, 300, or 900 mg/kg/day for the balance of 6-months, caused changes in blood pH (acidosis) and electrolyte balance, as well as reversible effects on body weight gain and skeletal length; no hematologic or gross postmortem findings were attributed to treatment.

ACETAZOLAMIDE has been reported to be teratogenic in rats, mice, hamsters, and rabbits, producing a rare but compound-specific type of forelimb defect. However, this drug has been widely used as a diuretic in pregnant humans since its introduction in the early 1950's and there is no evidence of teratogenicity in humans.

No adverse effects were seen in offspring of lactating, ACETAZOLAMIDE-treated dogs. Although the average weight of acetazolamide-treated rat pups (0.1% ACETAZOLAMIDE in the diet) was less than controls, no effect was seen on reproduction or fertility. This effect on pup weight was not seen when the parental generation was mated for a second time.

LD50s in mice for GLYCERIN are reported to be 31.5 g/kg orally and 7.5 g/kg intravenously. Application of full strength GLYCERIN to rabbit eyes has produced no significant injury.

Dogs and rats fed 35-40% GLYCERIN diets for 40-50 weeks showed normal growth and reproduction. When administered orally in relatively high concentration (40%) and large doses, GLYCERIN can be irritating to the stomach lining of animals.

OTHER:

ACETAZOLAMIDE was negative in the Ames test for bacterial mutagenicity, with or without metabolic activation.

VII. EMERGENCY AND FIRST AID PROCEDURES

EYES: Immediately flush eyes with plenty of cool, low-pressure water for at least 20 minutes. Contact a physician if irritation occurs.

SKIN: Promptly wash with soap and cool running water. Remove contaminated clothing. Contaminated clothing should be washed before reuse. Contact a physician if irritation occurs.

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

INGESTION: Do not induce vomiting except as directed by medical personnel. Never give anything by mouth to an unconscious person. Never induce vomiting in an unconscious person. Call a physician.

VIII. EXPOSURE CONTROL METHODS

ENGINEERING CONTROLS:
Use closed-system handling, laboratory bench hood or local exhaust ventilation to control dust or mist.

WORK PRACTICE CONTROLS:
Minimize excess handling. Keep container closed when not in use. Wash hands, face and exposed body parts at lunch and breaks, and at end of shift.

PERSONAL PROTECTION EQUIPMENT:
If the PEL is exceeded, wear an approved air-purifying respirator with high-efficiency cartridges adequate to control exposure.

Rubber gloves should be worn to prevent contact with the skin. Eye protection should be worn.

IX. SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

Wearing disposable coveralls, rubber gloves and an approved, full-faced, air-purifying respirator with high-efficiency cartridges or a full-face self-contained or supplied-air respirator, contain and collect spilled materials.

WASTE DISPOSAL:

Dispose of in accordance with all Federal, State, and local regulations. This is not a RCRA-regulated hazardous waste.

X. STORAGE AND HANDLING

Maintain good housekeeping and personal hygiene procedures.

Store at controlled room temperature, 15-30° C (59-86° F).

XI. SARA SECTION 313 INFORMATION

Not applicable.

XII. APPENDIX