Material Safety Data Sheet

VALIUM(R) Tablets (2 mg)

1. Product and Company Identification

Product name	VALIUM(R) Tablets (2 mg)
Product code	CSE-1313
Use	- Valium is an anti-anxiety (sedative) agent.
Company information	Enquiries: Local representation: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America Phone 001-973/235 50 00 E-Mail info.sds@roche.com US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300
Roche Nutley Inventory Code	78901

2. Hazards identification

Emergency Overview

Form	tablets
Color	white
Hazard Overview	- Causes central nervous system depression.

Potential Health Effects	- Exposure: Ingestion - Target Organs: skin, kidneys, liver, respiratory tract, Central nervous system - Acute Effects: May cause allergic reactions., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., Causes central nervous system depression., May cause hepatic (liver) system effects., Signs and symptoms may include elevation of liver enzyme levels and jaundice (yellowing of the skin and eyes)., May cause renal (kidney) system effects., Signs and symptoms may include urine retention, increase or decrease in urine production, painful urination and presence of blood in urine., May cause respiratory effects., Signs and symptoms may include difficulty in breathing, coughing, wheezing, irritation (inflammation) and respiratory arrest. - Chronic Effects: May cause confusion and disorientation., May cause hallucinations. - Carcinogenicity: formulation not listed by NTP, IARC or OSHA
Additional Health Information	- Conditions Aggravated: Hypersensitivity to this material and other materials in its chemical class. Acute narrow angle glaucoma. Respiratory system conditions. - This material may cause impairment of mental and/or physical abilities which are required to perform hazardous tasks, such as operating machinery or driving a motor vehicle. - Reproductive Toxicity: An increased risk of congenital malformations associated with the use of minor tranquilizers, such as diazepam and chlordiazepoxide, during the first trimester of pregnancy has been suggested. *1 - The placental transfer of this material in humans has been documented. *1 - Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure. *1 - It is also advisable for nursing mothers to exercise caution regarding exposure. *1
*1 referring to:	Diazepam

3. Composition/Information on ingredients

Characterization: final product

Ingredients	**Concentration**
Corn starch CAS: 9005-25-8	~ 31 %
Diazepam CAS: 439-14-5	1 - 6 %

4. First-aid measures

Eye contact	- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	- remove immediately contaminated clothes, wash affected skin with plenty of water
Inhalation	- in case of inhalation remove to fresh air and seek medical aid
Ingestion	- consult physician

5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	not applicable
Specific hazards	- Toxic emissions may be given off in a fire
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

6. Accidental release measures

Personal precautions	- ensure adequate ventilation
Environmental protection	- avoid release to the environment
Methods for cleaning up	- Scoop or shovel spilled material into a suitable labeled open head drum - Secure the drum cover and move the container to a safe holding area - Clean spill area thoroughly - Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal. - Check area for residual material and repeat clean up if detected

7. Handling and storage

Handling

Technical measures	- local exhaust ventilation necessary - avoid dust formation; consider dust explosion hazard

Storage

Storage conditions	- keep containers tightly closed - room temperature - store in a dry place

8. Exposure controls/Personal protection

Engineering Measures	- see 7.	
Threshold value (USA) air	- ACGIH-TLV: 10 mg/m3 (not classifiable as a human carcinogen)	*2
	- OSHA-PEL: 5 mg/m3 (respirable fraction)	*2
	- OSHA-PEL: 15 mg/m3 (total dust)	*2
	- NIOSH-REL: 5 mg/m3 (respirable fraction)	*2
	- NIOSH-REL: 10 mg/m3 (total dust)	*2
Threshold value (Roche) air	- IOEL (Internal Occupational Exposure Limit): 0.02 mg/m3 (defined as 8-hour time-weighted average)	*1

Personal protective equipment

Respiratory protection	- Respiratory protection is recommended as a precaution to minimze exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.	
	- respiratory protection not necessary during normal operations	
	- in case of very high dust concentrations: particle mask or respirator with independent air supply	
Hand protection	- protective gloves	
Eye protection	- safety glasses	
Body protection	- protective clothing	

*1 referring to: Diazepam
*2 referring to: Corn starch

9. Physical and chemical properties

Color	white
Form	tablets

10. Stability and reactivity

Stability	- stable under normal conditions
Conditions to avoid	- None known
Materials to avoid	- None known

11. Toxicological information

Acute toxicity	- LD_{50}	> 1'000	mg/kg	(oral, mouse)	*1
	- LD_{50}	352	mg/kg	(oral, rat)	*1
	- LD_{50}	249	mg/kg	(oral, rat)	*1
Chronic toxicity	- liver enzyme induction after high doses				*1

Mutagenicity	- not mutagenic (various test systems)	*1
Carcinogenicity	- rat; no evidence of carcinogenicity	*1
Reproduction toxicity	- not teratogenic	*1

*1 referring to: Diazepam

12. Ecological information

Inherent biodegradability	- not inherently biodegradable 0 %, 21 days (MITI Test II, OECD No. 302 C)	*1
	- not inherently biodegradable partial primary degradation evidenced by HPLC < 5 % BOD/ThOD, 28 d < 5 % BOD/ThOD, 84 d (MITI Test II, OECD No. 302 C)	*1
	- inhibits anaerobic biodegradability at high concentrations (toxic to bacteria) 30 %, 13 d -7 %, 62 d (Ultimate anaerobic biodegradability, ISO 11734)	*1
Abiotic degradation	- notable degradation, photodegradation, no hydrolysis (36.3 mg/l, water; HPLC) 100 %, 0 h, ~ 22 °C, start of test 98 %, 120 h, ~ 22 °C, dark 75 %, 120 h, ~ 22 °C, under illumination	*1
Ecotoxicity	- barely toxic for microorganisms (activated sludge) NOEC > 100 mg/l	*1
	- moderately toxic for fish (rainbow trout) LC_{50} (96 h) 84 mg/l NOEC (96 h) 50 mg/l	*1
	- moderately toxic for planktonic crustaceans (Daphnia magna) EC_{50} (24 h) 14 mg/l (OECD No. 202)	*1
	- strongly toxic for planktonic crustaceans (Daphnia magna) EC_{50} (24 h) 4.3 mg/l	*1
	- strongly toxic for algae (Scenedesmus (=Desmodesmus) subspicatus) ErC_{50} (72 h) 3.11 mg/l (average measured concentration) NOEC (72 h) 0.035 mg/l (average measured concentration) (OECD No. 201)	*1
	- adaptation/recovery of organisms upon prolongation of test duration (Scenedesmus (=Desmodesmus) subspicatus) NOEC (14 d) 2.56 mg/l (nominal concentration) LOEC (14 d) 16 mg/l (nominal concentration) (OECD No. 201)	*1
	- moderately toxic for bluegreen algae (Synechococcus leopoliensis, Cyanobacteria) ErC_{50} (72 h) > 11.9 mg/l (average measured concentration) NOEC (72 h) 0.667 mg/l (average measured concentration) (OECD No. 201)	*1

	- adaptation/recovery of organisms upon prolongation of test duration (Synechococcus leopoliensis, Cyanobacteria) NOEC (7 d) 16 mg/l (nominal concentration) LOEC (7 d) 40 mg/l (nominal concentration) EC_{50} (7 d) > 100 mg/l (nominal concentration) (OECD No. 201)	*1
	- no adverse influence on substrate biodegradation (activated sludge) concentration (28 d) 30 mg/l (MITI Test II, OECD No. 302C)	*1
Mobility	- medium adsorption (, 72 h)	*1
	- strong adsorption (water-activated sludge, 24 h, ~22 °C) K_d = 52000 to 57000 l/kg (activated sludge)	*1
Air pollution	- observe local/national regulations	*1
*1 referring to:	Diazepam	

13. Disposal considerations

Waste from residues	- incinerate in qualified installation with flue gas scrubbing - observe local/national regulations regarding waste disposal - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.
Contaminated packaging	- Empty containers must be triple rinsed prior to disposal, recycling or reuse.
RCRA waste	- not regulated under RCRA

14. Transport information

Note	- not classified by transport regulations, proper shipping name non-regulated

15. Regulatory information

TSCA Status	- FDA Exemption - not on inventory
Reporting Requirements	- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. - In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials. - State and local regulations vary and may impose additional reporting requirements.

16. Other information

Edition documentation	-	changes from previous version in sections 13

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.