SAFETY DATA SHEET

VALIUM(R) Tablets (2 mg)

SECTION 1. IDENTIFICATION

Product name : VALIUM(R) Tablets (2 mg)
Product code : 00010039874

Manufacturer or supplier’s details
Company name of supplier : Genentech, Inc.
Address : 1 DNA Way
South San Francisco, CA 94080
USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone number : US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-</td>
<td>439-14-5</td>
<td>1.2</td>
</tr>
<tr>
<td>Lactose-monohydrate</td>
<td>10039-26-6</td>
<td>58.9</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>39.5</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>0.4</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice
Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled
Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact
If on skin, rinse well with water.

In case of eye contact
Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed
Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed
None known.

Notes to physician
The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media
High volume water jet

Specific hazards during firefighting
No information available.

Hazardous combustion products
Carbon oxides
In case of fire hazardous decomposition products may be produced such as:
Nitrogen oxides (NOx)
Gaseous hydrogen chloride (HCl).

Further information
Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment
Wear self-contained breathing apparatus for firefighting if
SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Avoid exposure
- Avoid dust formation.
- Avoid breathing dust.

Environmental precautions:
- Prevent further leakage or spillage if safe to do so.
- Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up:
- Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion:
- Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling:
- Avoid formation of respirable particles.
- Do not breathe vapors/dust.
- For personal protection see section 8.
- Smoking, eating and drinking should be prohibited in the application area.
- Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage:
- Keep container tightly closed in a dry and well-ventilated place.
- Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions:
- See label, package insert or internal guidelines

Storage temperature:
- Protect against light.
- Protect from moisture.

Further information on storage stability:
- No decomposition if stored and applied as directed.

Packaging material:
- Suitable material: Polyethylene bag in metal drum, Blister packages, glass bottles

SECTION 8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of)</th>
<th>Control parameters / Basis</th>
</tr>
</thead>
</table>


SAFETY DATA SHEET

VALIUM(R) Tablets (2 mg)

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazepam</td>
<td>Surface waters</td>
<td>27.3 µg/l</td>
</tr>
<tr>
<td></td>
<td>Remarks:</td>
<td>Based on chronic data</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC):

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-</td>
<td>IOEL</td>
<td>0.02 mg/m³</td>
</tr>
<tr>
<td>439-14-5</td>
<td></td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
</tbody>
</table>

Engineering measures : No data available

Personal protective equipment

Hand protection

In case of contact through splashing:

- Material : Nitrile rubber
- Break through time : > 30 min
- Glove thickness : > 0.11 mm

In case of full contact:

- Material : butyl-rubber
- Break through time : > 480 min
- Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water

Tightly fitting safety goggles

Skin and body protection : Dust impervious protective suit

Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : Instruction of employees recommended

Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet

Color : off-white

Odor : Not applicable

Odor Threshold : Not applicable

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : Not applicable

Relative density : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
  Viscosity, dynamic : Not applicable
  Viscosity, kinematic : Not applicable
SAFETY DATA SHEET

VALIUM(R) Tablets (2 mg)

Version: 1.5
Revision Date: 10-14-2021
Date of last issue: 11-01-2019
Date of first issue: 12-04-2015

Reactivity: No dangerous reaction known under conditions of normal use.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions: No decomposition if stored and applied as directed.

Conditions to avoid: Exposure to moisture. Exposure to light. Heat.

Incompatible materials: No data available

Hazardous decomposition products: No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
Lactose-monohydrate:
Acute oral toxicity: LD50 Oral (Rat): > 10,000 mg/kg

Starch:
Acute oral toxicity: Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

Acute inhalation toxicity: Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

Acute dermal toxicity: Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:
Acute oral toxicity: LD50 Oral (Rat): 249 mg/kg
LD50 Oral (Mouse): > 1,000 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Components:
2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:
Remarks: This information is not available.
Serious eye damage/eye irritation
Not classified based on available information.

Components:
2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:
Remarks: This information is not available.

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:
2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:
Genotoxicity in vitro: Remarks: In vitro tests did not show mutagenic effects

Carcinogenicity
Not classified based on available information.

Components:
Lactose-monohydrate:
Remarks: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:
2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:
Effects on fetal development: Remarks: No significant adverse effects were reported

STOT—single exposure
Not classified based on available information.
Components:

Starch:
Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:
Target Organs : Central nervous system
Assessment : May cause drowsiness or dizziness.

STOT-repeated exposure
Not classified based on available information.

Components:

Starch:
Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity
Not classified based on available information.

Components:

Starch:
No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Starch:
Toxicity to fish : LC50: > 100 mg/l
Exposure time: 96 h

Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.
Toxicity Data on Soil : Not expected to adsorb on soil.
Other organisms relevant to the environment : No data available

2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:
Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 84 mg/l
Exposure time: 96 h
NOEC (Oncorhynchus mykiss (rainbow trout)): 50 mg/l
Exposure time: 96 h

NOEC (Danio rerio (zebra fish)): 0.273 mg/l
Exposure time: 35 d
GLP: yes

Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 4.3 mg/l
Exposure time: 24 h

Toxicity to algae/aquatic plants

ErC50 (Desmodesmus subspicatus (green algae)): 3.11 mg/l
Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 0.035 mg/l
Exposure time: 72 h

NOEC (Desmodesmus subspicatus (green algae)): 2.56 mg/l
Exposure time: 336 h

ErC50 (Synechococcus leopoliensis (blue-green algae)): > 11.9 mg/l
Exposure time: 72 h

NOEC (Synechococcus leopoliensis (blue-green algae)): 0.667 mg/l
Exposure time: 72 h

EC50 (Synechococcus leopoliensis (blue-green algae)): > 100 mg/l
Exposure time: 168 h

NOEC (Synechococcus leopoliensis (blue-green algae)): 16 mg/l
Exposure time: 168 h

Toxicity to daphnia and other aquatic invertebrates
(Chronic toxicity)

NOEC (Daphnia magna (Water flea)): 0.91 mg/l
Exposure time: 21 d
Remarks: nominal concentration

Ecotoxicology Assessment

Acute aquatic toxicity: Toxic to aquatic life.

Chronic aquatic toxicity: Toxic to aquatic life with long lasting effects.

Other organisms relevant to the environment: No data available

Persistence and degradability

Components:

2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:

Biodegradability: Biodegradation: 0 %
Exposure time: 21 d
SAFETY DATA SHEET

VALIUM(R) Tablets (2 mg)

Biochemical Oxygen Demand (BOD)/Theoretical oxygen demand (ThOD): < 5 %

Bioaccumulative potential

Components:

Lactose-monohydrate:
Bioaccumulation: Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water: log Pow: -5.03

Starch:
Partition coefficient: n-octanol/water: Remarks: No data available

Diazepam:
Partition coefficient: n-octanol/water: log Pow: 2.58
pH: 7.2

Mobility in soil
No data available

Other adverse effects

Product:
Ozone-Depletion Potential: Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:
2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-:

Additional ecological information: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Toxic to aquatic life with long lasting effects.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Do not contaminate ponds, waterways or ditches with chemical or used container. Send to a licensed waste management company.
Contaminated packaging: Empty remaining contents. Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: No SARA Hazards

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B). This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61). This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F). This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).
Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307.
This product does not contain any priority pollutants related to the U.S. Clean Water Act.

US State Regulations

Massachusetts Right To Know
Starch 9005-25-8
2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl- 439-14-5

Pennsylvania Right To Know
Lactose-monohydrate 10039-26-6
Starch 9005-25-8

Maine Chemicals of High Concern
Product does not contain any listed chemicals

Vermont Chemicals of High Concern
Product does not contain any listed chemicals

Washington Chemicals of High Concern
Product does not contain any listed chemicals

California Prop. 65
WARNING: This product can expose you to chemicals including 2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants
Starch 9005-25-8

The ingredients of this product are reported in the following inventories:
AIIIC : Not in compliance with the inventory
DSL : All components of this product are on the Canadian DSL
NZIoC : Not in compliance with the inventory
ENCS : Not in compliance with the inventory
ISHL : Not in compliance with the inventory
KECI : On the inventory, or in compliance with the inventory
PICCS : Not in compliance with the inventory
IECSC : Not in compliance with the inventory
TCSI : On the inventory, or in compliance with the inventory
TSCA : All substances listed as active on the TSCA inventory
TECI : Not in compliance with the inventory

TSCA list
No substances are subject to a Significant New Use Rule.
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA 704:

HMIS® IV:

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits
OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA : 8-hour, time-weighted average
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA : 8-hour time weighted average
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2010