SAFETY DATA SHEET

VALIUM(R) Tablets (5 mg)

Version 1.4
Revision Date: 10-14-2021
Date of last issue: 11-04-2019
Date of first issue: 12-04-2015

SECTION 1. IDENTIFICATION

Product name : VALIUM(R) Tablets (5 mg)
Product code : 00010018402

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>2.9</td>
</tr>
<tr>
<td>Lactose-1-Hydrate</td>
<td>64044-51-5</td>
<td>58.8</td>
</tr>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>37.7</td>
</tr>
<tr>
<td>Octadecanoic acid, magnesium salt (2:1)</td>
<td>557-04-0</td>
<td>0.4</td>
</tr>
<tr>
<td>C.I. Pigment Yellow 42</td>
<td>51274-00-1</td>
<td>0.1</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: Flush eyes with water as a precaution.
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.

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 fire fighting: Do not allow run-off from fire fighting to enter drains or water courses.

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: Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must
be disposed of in accordance with local regulations.

Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions:
- Prevent product from entering drains
- 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
- Containers which are opened must be carefully resealed and kept upright to prevent leakage
- 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/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable fraction)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total dust)</td>
<td>15 mg/m³</td>
<td>OSHA P0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable dust fraction)</td>
<td>5 mg/m³</td>
<td>OSHA P0</td>
</tr>
<tr>
<td>2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-</td>
<td>439-14-5</td>
<td>IOEL</td>
<td>0.02 mg/m³</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC):

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

- Choose body protection according to the amount and
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 : solid
Color : light yellow
Odor : Not applicable
Odor Threshold : Not applicable
pH : 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
Solubility(ies)
  Water solubility : No data available
  Solubility in other solvents : No data available
Partition coefficient: n-octanol/water : No data available
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Autoignition temperature : No data available
Decomposition temperature : No data available

**Viscosity**
- Viscosity, dynamic : Not applicable
- Viscosity, kinematic : Not applicable

**SECTION 10. STABILITY AND REACTIVITY**

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-1-Hydrate:**
- Acute oral toxicity : LD50 Oral (Rat): > 10,000 mg/kg
- 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

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

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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-1-Hydrate:
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:

Lactose-1-Hydrate:
Assessment: The substance or mixture is not classified as specific target organ toxicant, single exposure.

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:

Lactose-1-Hydrate:
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

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

Aspiration toxicity
Not classified based on available information.
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Lactose-1-Hydrate:
Toxicity to fish:
- LC50: > 100 mg/l
- Exposure time: 96 h

Toxicity to fish (Chronic toxicity):
- > 1 mg/l

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

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

Bioaccumulative potential

**Components:**

**Lactose-1-Hydrate:**
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).

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

**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: The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company. Can be disposed as waste water, when in compliance with local regulations.

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-1-Hydrate 64044-51-5
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:
AIIC : Not in compliance with the inventory
DSL : This product contains the following components that are not on the Canadian DSL nor NDSL:
non hazardous compounds
NZIoC : Not in compliance with the inventory
ENCS : Not in compliance with the inventory
ISHL : Not in compliance with the inventory
KECI : Not in compliance with the inventory
PICCS : Not in compliance with the inventory
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IECSC : Not in compliance with the inventory
TCSI : Not in compliance with the inventory
TSCA : Product contains substance(s) not listed on 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:

Flammability

HEALTH / 0

FLAMMABILITY 0

PHYSICAL HAZARD 0

Instability

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

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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.