

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

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

Chemical name	CAS-No.	Concentration (% w/w)
2H-1,4-Benzodiazepin-2-one, 7-chloro-1,3-dihydro-1-methyl-5-phenyl-	439-14-5	2.9
Lactose-1-Hydrate	64044-51-5	58.8
Starch	9005-25-8	37.7
Octadecanoic acid, magnesium salt (2:1)	557-04-0	0.4
C.I. Pigment Yellow 42	51274-00-1	0.1

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non hazardous compounds	Not Assigned	0.1
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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

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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

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

Predicted No Effect Concentration (PNEC):

Substance name	Environmental Compartment	Value
Diazepam	Surface waters	27.3 µg/l
	Remarks: Based on chronic data	

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

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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 : 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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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.

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- 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.

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No data available

Starch:

No data available

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

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Exposure time: 96 hNOEC (Danio rerio (zebra fish)): 0.273 mg/l
Exposure time: 35 d
GLP: yesToxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 4.3 mg/l
aquatic invertebrates Exposure time: 24 hToxicity to algae/aquatic : ErC50 (Desmodesmus subspicatus (green algae)): 3.11 mg/l
plants Exposure time: 72 hNOEC (Desmodesmus subspicatus (green algae)): 0.035 mg/l
Exposure time: 72 hNOEC (Desmodesmus subspicatus (green algae)): 2.56 mg/l
Exposure time: 336 hErC50 (Synechococcus leopoliensis (blue-green algae)): >
11.9 mg/l
Exposure time: 72 hNOEC (Synechococcus leopoliensis (blue-green algae)):
0.667 mg/l
Exposure time: 72 hEC50 (Synechococcus leopoliensis (blue-green algae)): > 100
mg/l
Exposure time: 168 hNOEC (Synechococcus leopoliensis (blue-green algae)): 16
mg/l
Exposure time: 168 hToxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 0.91 mg/l
aquatic invertebrates Exposure time: 21 d
(Chronic toxicity) 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 : No data available
the environment**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

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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.

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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).

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This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM 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
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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

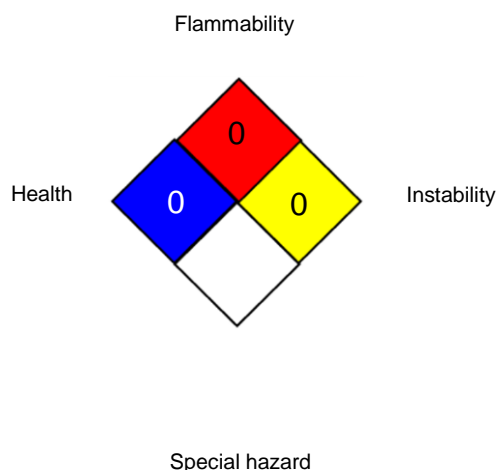
TSCA list

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:

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

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

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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 System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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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.

US / Z8 / 2010