

Calibrator beta2-MicroglobulinVersion
3.5Revision Date:
10-11-2021Date of last issue: 02-08-2021
Date of first issue: 06-27-2017**SECTION 1. IDENTIFICATION**

Product name : Calibrator beta2-Microglobulin

Product code : 08047545190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

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Address : 9115 Hague Road
Indianapolis, IN 46250
USA

Telephone : 1-800-428-5074

Emergency telephone

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)**Recommended use of the chemical and restrictions on use**

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)**

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section GHS Label elements contains the resulting labelling for the kit

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H302 + H312 Harmful if swallowed or in contact with skin.
H373 May cause damage to organs through prolonged or repeated exposure.Precautionary Statements : **Prevention:**
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing.

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P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P302 + P352 + P312 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/ doctor if you feel unwell.
P314 Get medical advice/ attention if you feel unwell.
P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS***b-2-Microglobulin F3*****GHS Classification**

Acute toxicity (Oral) : Category 4
Acute toxicity (Dermal) : Category 4
Specific target organ toxicity : Category 2
- repeated exposure
Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sodium azide (Na(N ₃))	26628-22-8	>= 1 - < 5

Actual concentration is withheld as a trade secret

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.

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- 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 fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- 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 dust formation.
- 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 : Provide appropriate exhaust ventilation at places where dust

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
b-2-Microglobulin F3
Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sodium azide (Na(N ₃))	26628-22-8	C	0.1 ppm (HN ₃)	NIOSH REL
		C (Vapor)	0.11 ppm (Hydrazoic acid)	ACGIH
		C	0.3 mg/m ³ (Sodium azide)	NIOSH REL
		C	0.1 ppm (Ammonia)	OSHA P0
		C	0.3 mg/m ³ (Sodium azide)	OSHA P0
		C	0.29 mg/m ³ (Sodium azide)	ACGIH

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

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	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 concentration of the dangerous substance at the work place.
Hygiene measures	: Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES***b-2-Microglobulin F3***

Appearance	: solid
Color	: No data available
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

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Solubility(ies)	
Water solubility	: soluble
Solubility in other solvents	: 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
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

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.

SECTION 11. TOXICOLOGICAL INFORMATION***b-2-Microglobulin F3*****Acute toxicity**

Harmful if swallowed or in contact with skin.

Components:**Sodium azide (Na(N₃)):**

Acute oral toxicity	: LD50 Oral (Rat): 27 mg/kg
Acute inhalation toxicity	: LC50: 0.053 - 0.52 mg/l Test atmosphere: dust/mist Target Organs: Respiratory system Acute toxicity estimate: > 0.05 mg/l Test atmosphere: dust/mist Method: Expert judgment
Acute dermal toxicity	: LD50 Dermal (Rabbit): 20 mg/kg

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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Sodium azide (Na(N₃)):**

Assessment : Fatal if inhaled.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

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.

STOT-single exposure

Not classified based on available information.

Components:**Sodium azide (Na(N₃)):**

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

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:**Sodium azide (Na(N₃)):**

Assessment : May cause damage to organs through prolonged or repeated exposure.

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Assessment**Aspiration toxicity**

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION***b-2-Microglobulin F3*****Ecotoxicity****Components:****Sodium azide (Na(N3)):**Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 5.46 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203Toxicity to daphnia and other : EC50 (Daphnia pulex (Water flea)): 4.2 mg/l
aquatic invertebrates Exposure time: 96 hToxicity to algae/aquatic : EC50 (Pseudokirchneriella subcapitata (green algae)): 0.35
plants mg/l
Exposure time: 96 h
Test Type: static test
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): 43 - 66 mg/l

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Persistence and degradability

No data available

Bioaccumulative potential**Components:****Sodium azide (Na(N3)):**Partition coefficient: n- : log Pow: 0.3
octanol/water**Other adverse effects**

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration). 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

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CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide (Na(N ₃))	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide (Na(N ₃))	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
Sodium azide (Na(N3))	26628-22-8	500

SARA 311/312 Hazards : Acute toxicity (any route of exposure)
Specific target organ toxicity (single or repeated exposure)

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Sodium azide (Na(N3))	26628-22-8	>= 1 - < 5 %
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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 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

Sodium azide (Na(N3))	26628-22-8
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Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned
Sodium azide (Na(N3))	26628-22-8

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 List of Hazardous Substances

Sodium azide (Na(N3))	26628-22-8
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California Permissible Exposure Limits for Chemical Contaminants

Sodium azide (Na(N3))	26628-22-8
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The ingredients of this product are reported in the following inventories:

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AIIC	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Human serum /-plasma / -hemolysate, lyophilized Bovine Serum Albumin
NZIoC	: On the inventory, or 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
IECSC	: Not in compliance with the inventory
TCSI	: Not in compliance with the inventory
TSCA	: Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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GHS label elements

Hazard pictograms



Signal Word : Warning

Hazard Statements : H302 + H312 Harmful if swallowed or in contact with skin.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary Statements : **Prevention:**
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON

SAFETY DATA SHEET



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CENTER/ doctor if you feel unwell. Rinse mouth.
P302 + P352 + P312 IF ON SKIN: Wash with plenty of wa-
ter.Call a POISON CENTER/ doctor if you feel unwell.
P314 Get medical advice/ attention if you feel unwell.
P363 Wash contaminated clothing before reuse.

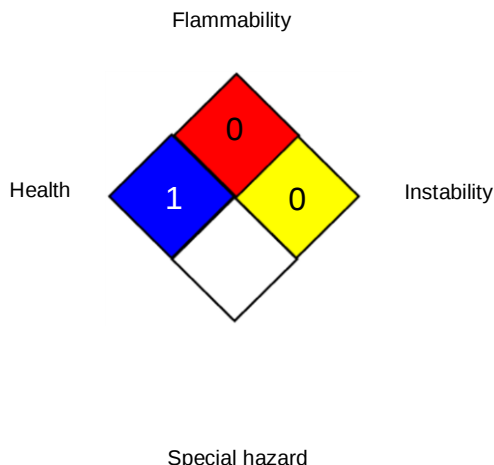
Disposal:

P501 Dispose of contents/ container to an approved waste dis-
posal plant.

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	2
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

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 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)

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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; TECL - 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

Revision Date : 10-11-2021

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