

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories Release date 29.04.2023 Version number 15 (replaces version 14)

Last alteration on 29.04.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

· Trade name: **ARCHITECT Gentmamicin Calibrator B - F**

· Article number:

1P31B

1P31C

1P31D

1P31E

1P31F

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Product category PC0 Other

· Application of the substance / the preparation: For In Vitro Diagnostic Use

1.3 Details of the supplier of the safety data sheet

· Supplier:

Abbott GmbH

Max-Planck-Ring 2

65205 Wiesbaden

Tel.: (+49)-6122-58-0

MSDS-Support@Abbott.com

1.4 Emergency telephone number

(+49)-6122-58-0 (English only)

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

- Telephone 09 8010034 if you are calling from New Zealand.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The classification is in alignment with current European regulations. It incorporates information from technical literature and information provided by supplier companies.

· Classification according to Regulation (EC) No 1272/2008:

Skin Sens. 1 H317 May cause an allergic skin reaction.

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2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008:**

The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms:**



· **Signal word:** Warning

· **Hazard-determining components of labelling:**

2-Methyl-4-isothiazolin-3-one
Sodium azide

· **Hazard statements:**

H317 May cause an allergic skin reaction.

· **Precautionary statements:**

P261 Avoid breathing mist / vapours / spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves / protective clothing / eye protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents / container in accordance with local regulations.

· **Additional information:**

EUH032 Contact with acids liberates very toxic gas.

· **Routes of Exposure:**

Skin
Inhalation

For bloodborne pathogens and potentially infectious materials:

- non-intact skin
- mucous membranes (which includes, but is not limited to, the lining of the nose, mouth and throat)
- parenteral contact (e.g. by injection, puncture)

2.3 Other hazards

This product contains human-sourced components. No known test method can offer complete assurance that products derived from human sources will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious.

This product may cause skin sensitization (allergic reactions) in some people.

· **Results of PBT and vPvB assessment:**

- **PBT:** Not applicable

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· vPvB: Not applicable

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SECTION 3: Composition/information on ingredients

3.2 Mixtures

Dangerous components according to EC criteria:

CAS: 26628-22-8 EINECS: 247-852-1 Reg.nr.: 01-2119457019-37-xxxx	Sodium azide Acute Tox. 2, H300; Acute Tox. 1, H310; Aquatic Acute 1, H400; Aquatic Chronic 1, H410, EUH032	0.0974%
CAS: 2682-20-4 EINECS: 220-239-6 Reg.nr.: 01-2120764690-50-xxxx	2-Methyl-4-isothiazolin-3-one Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330; Skin Corr. 1B, H314; Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=1); Skin Sens. 1, H317 Specific concentration limit: Skin Sens. 1A; H317: C ≥ 0.0015 %	0.0148%

Additional information:

For the complete text of Hazard (H) codes displayed in this section, refer to Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:** Remove from source of exposure. Seek medical attention and appropriate follow-up.
- **After skin contact:**
Take off any clothing that the product touched. Wash affected area with soap and water. Seek medical attention and appropriate follow-up.
- **After eye contact:**
Rinse open eye(s) cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention and appropriate follow-up. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.
- **Information for Medical Personnel:**
This product contains human-sourced and/or potentially infectious material. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced material should be considered potentially infectious.

The human-sourced material used in this product has been tested and found to be:
 - Nonreactive for HBsAg (hepatitis B surface antigen)
 - Nonreactive for anti-HCV (antibodies to hepatitis C virus)
 - Nonreactive for HIV-1 Ag or HIV-1 RNA (human immunodeficiency virus type 1 antigen or human immunodeficiency virus type 1 ribonucleic acid)
 - Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)

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- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)

4.2 Most important symptoms and effects, both acute and delayed:

Allergic reactions
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.
Respiratory irritation

4.3 Indication of any immediate medical attention and special treatment needed:

No additional relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents:

- Dry chemical, carbon dioxide (CO₂), water spray or regular foam.
- Caution: CO₂ will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

5.2 Special hazards arising from the substance or mixture

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

No further relevant information available.

5.3 Advice for firefighters

Protective equipment:

For large fires, wear appropriate heat- and flame-resistant personal protective equipment and an approved positive-pressure, self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Handle as a potentially infectious material.

Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

6.2 Environmental precautions

Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

6.3 Methods and material for containment and cleaning up

Ensure adequate ventilation.

Blot up small volumes of spilled or spattered product with paper towels or similar materials.

- Contain larger spills by placing absorbents around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:

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- warm water and detergent or similar cleansing agent

Apply a suitable disinfectant. Select a disinfectant that is effective against bloodborne infectious agents, as well as other microbial agents that you might expect to be prevalent in your population. A disinfectant that is effective against Mycobacterium tuberculosis is generally effective against all known viruses and non-sporeforming bacteria, and is suitable for most clinical laboratory situations.

NOTE: Commercial disinfectants must be used according to manufacturer directions. Disinfectants are typically hazardous chemicals that react with many chemicals, materials and living tissues. Obtain and review the manufacturer's safety information before using the disinfectant.

This product contains sodium azide, which is toxic and reactive. See Sections 10 and 13 for additional information that could affect handling and disposal of contaminated spill materials.

NOTE FOR LARGE-VOLUME SPILL: This product contains sodium azide, which reacts with acid to liberate hydrazoic acid, a very toxic gas. Select a disinfectant with the following properties if disinfection of materials used to absorb a large volume of spilled product is required:

- Do not use any chemical or product with a pH below 6 to disinfect waste that contains sodium azide. Hydrazoic acid, a toxic gas, will be released when the pH is lower than 6.
- Do not use any chemical or product that contains mercury or any other metal to disinfect waste that contains sodium azide. This will create metal azide compounds, which can be highly explosive under pressure or shock (percussion).
- Select a disinfectant that does not bubble, effervesce or otherwise generate aerosols.
- Do not use excess disinfectant.
- Failure to follow manufacturer's directions may lead to unexpected reactions with the waste.
- Do not use a disinfectant if you do not have the proper facility, equipment and other appropriate protective measures available to work with it safely.

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling:

Handle as a potentially infectious material.
Ensure good ventilation in the workplace.
Prevent formation of aerosols or vapours.
Avoid contact with skin.

- **Information about protection against explosions and fires:** No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

- **Requirements to be met by storerooms and containers:** Store only in the original container.

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- **Information about storage in one common storage facility:** Store in original packaging.
- **Further information about storage conditions:**
Refer to the package insert or product label for additional information on storage conditions for product quality.

· **7.3 Specific end use(s):** No additional relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

· **Components with limit values that require monitoring at the workplace:**

CAS: 26628-22-8 Sodium azide (0.0974 %)

IOELV (European Union)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ Skin
WEL (Great Britain)	Short-term value: 0.3 mg/m ³ Long-term value: 0.1 mg/m ³ (as NaN ₃), Sk

8.2 Exposure controls

· **Individual protection measures, such as personal protective equipment**

· **General protective and hygienic measures:**

Always maintain good housekeeping and follow general precautionary measures. Do not eat, drink or store food and beverages in areas where chemicals or specimens are used. Wash hands before breaks, after handling reagents and specimens, and at the end of the workshift.

Observe universal precautions and other appropriate biosafety practices for handling potentially infectious material.

Avoid contact with the skin.

Immediately remove all soiled and contaminated clothing.

· **Breathing equipment:**

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection.

Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

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· Hand protection

Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· Material of gloves and breakthrough time of the glove material:

The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· Eye/face protection

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· Body protection:

Normal use: protect personal clothing from spatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution). Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Physical state	Liquid
· Colour:	Colourless
· Odour:	Odourless
· Odour threshold:	Not determined
· Melting point/freezing point:	Not determined
· Boiling point or initial boiling point and boiling range	Not determined
· Flammability	Not applicable
· Lower and upper explosion limit	
· Lower:	Not determined
· Upper:	Not determined
· Flash point:	Not applicable
· pH at 20 °C	7.3
· Viscosity:	
· dynamic:	Not determined
· Solubility	
· Water:	Fully miscible
· Vapour pressure:	Not determined
· Density and/or relative density	
· Density at 20 °C	1.025 g/cm ³
· Relative density:	Not determined

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9.2 Other information

· Appearance:	
· Form:	Solution
· Auto igniting	Product is not self-igniting.
· Explosive properties:	Product does not present an explosion hazard.
· Water:	1.2 %
· Solids content:	0.0 %
· Change in condition:	
· Evaporation rate:	Not determined
· Information with regard to physical hazard classes	
· Explosives	None
· Flammable gases	None
· Aerosols	None
· Oxidising gases	None
· Gases under pressure	None
· Flammable liquids	None
· Flammable solids	None
· Self-reactive substances and mixtures	None
· Pyrophoric liquids	None
· Pyrophoric solids	None
· Self-heating substances and mixtures	None
· Substances and mixtures, which emit flammable gases in contact with water	None
· Oxidising liquids	None
· Oxidising solids	None
· Organic peroxides	None
· Corrosive to metals	None
· Desensitised explosives	None

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

· 10.2 Chemical stability:

· **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.

· 10.3 Possibility of hazardous reactions:

This product contains sodium azide. Sodium azide solutions are reported to:

- react with acids to release hydrazoic acid, a very toxic gas. Higher quantities of hydrazoic acid are released as the solution becomes more acidic (i.e., as the pH of the solution gets lower). Low quantities of hydrazoic acid can be released from sodium azide in water.
- react with certain metals (copper, lead, silver, brass) to form explosive metal azide compounds. Violent explosions have been reported during plumbing work on drain systems containing accumulations of azide on copper, lead, brass, or solder.

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- **10.4 Conditions to avoid:** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
 - **Acute toxicity** Based on available data, the classification criteria are not met.
 - **LD/LC50 values that are relevant for classification:**
 - **Ingredients (100% pure substance/s):** Not applicable.
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
 - **Sensitisation:**
 - Sensitization possible through skin contact.
 - May cause an allergic skin reaction.
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
 - **Carcinogenicity** Based on available data, the classification criteria are not met.
 - **Reproductive toxicity** Based on available data, the classification criteria are not met.
 - **STOT-single exposure** Based on available data, the classification criteria are not met.
 - **STOT-repeated exposure** Based on available data, the classification criteria are not met.
 - **Aspiration hazard** Based on available data, the classification criteria are not met.
 - **Target organs/systems:**
 - Skin
 - Immune system
 - Respiratory tract
- **11.2 Information on other hazards**
 - **Endocrine disrupting properties**
 - The product does not contain substances with endocrine disrupting properties.

SECTION 12: Ecological information

- **12.1 Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability:** No further relevant information available.
- **12.3 Bioaccumulative potential:** No further relevant information available.
- **12.4 Mobility in soil:** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
 - **PBT:** Not applicable
 - **vPvB:** Not applicable

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12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

12.7 Other adverse effects:

General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water bodies or sewage system.

Refer to applicable local regulations for limit values of discharge into sewage system.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

There are no uniform EU regulations for the disposal of laboratory waste. In general, laboratory waste is under special supervision of the authorities.

Recommendation for disposal of unused product:

Dispose in accordance with national, state and local regulations and institutional requirements. Waste containing this product may be considered hazardous per state or local regulations. The following may be particularly important when identifying appropriate disposal:

- Potentially infectious. See Section 4, Information for Medical Personnel, for more information.
- See Section 6, Measures for cleaning/collecting for information when institutional or regulatory requirements include any sort of treatment of potentially infectious waste.
- Contains sodium azide. See Section 10 when considering how to appropriately dispose of unused product.

For drain systems with pipes or solder containing copper, lead, brass and/or silver, flush drains thoroughly with copious amounts of water to prevent the formation of potentially explosive metal azides in plumbing. Detailed information about azides in drains is available from the U.S. NIOSH Current Intelligence Bulletin No. 13 (August 16, 1976).

European waste catalogue:

HP12	Release of an acute toxic gas
------	-------------------------------

The following waste disposal key numbers are possible:

18 01 06: chemicals consisting of or containing dangerous substances

Uncleaned packagings

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

Recommendation for disposal of packaging:

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

Recommended cleaning agent: Water with cleansing agents, if necessary.

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SECTION 14: Transport information

· **14.1 UN number or ID number**

· ADR, ADN, IMDG, IATA None

· **14.2 UN proper shipping name**

· ADR, ADN, IMDG, IATA None

· **14.3 Transport hazard class(es)**

· ADR, ADN, IMDG, IATA
· Class None

· **14.4 Packing group**

· ADR, IMDG, IATA None

· **14.5 Environmental hazards**

· Marine pollutant: No

· **14.6 Special precautions for user** Not applicable

· **14.7 Maritime transport in bulk according to IMO instruments**

· **Transport/Additional information**

· ADR
· Remarks: Not restricted for transportation.
· IMDG
· Remarks: Not restricted for transportation.
· IATA
· Remarks: Not restricted for transportation.

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Hazard-determining components of labelling:**

2-Methyl-4-isothiazolin-3-one

· **Risk phrases:**

32 Contact with acids liberates very toxic gas.
43 May cause sensitisation by skin contact.

· **Safety phrases:**

23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
24 Avoid contact with skin.
37 Wear suitable gloves.
60 This material and its container must be disposed of as hazardous waste.

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- **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients is listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

· **Regulation (EC) No 273/2004 on drug precursors**

None of the ingredients is listed.

· **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

None of the ingredients is listed.

- **15.2 Chemical safety assessment** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

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The information in this Safety Data Sheet (SDS) reflects the most current hazard information for this product.

· **Complete text for H (Hazard) codes displayed in Section 3:**

Note: The respective H statements apply to the pure substances.

- H300 Fatal if swallowed.
- H301 Toxic if swallowed.
- H310 Fatal in contact with skin.
- H311 Toxic in contact with skin.
- H314 Causes severe skin burns and eye damage.
- H317 May cause an allergic skin reaction.

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H330 Fatal if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
EUH032 Contact with acids liberates very toxic gas.

· Contact supplier

Environmental Affairs & Product Safety

Tel.: +49 (0) 6122 58 0

· Date of previous version: 14.04.2023**· Version number of previous version: 14****· Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (Division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: persistent, bioaccumulative and toxic

vPvB: very persistent and very bioaccumulative

Acute Tox. 2: Acute toxicity – Category 2

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 1: Acute toxicity – Category 1

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Sens. 1: Skin sensitisation – Category 1

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

· * Data compared to the previous version altered.

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