



Abbott

Release Date: 3/27/24

REF	Product Name
GTIN	

1P30-24	<i>ARCHITECT iVancomycin Reagent Kit</i>
----------------	---

Components:

1P30G	ARCHITECT iVancomycin Microparticles
1P30H	ARCHITECT iVancomycin Conjugate

Abbott Customers:

For additional information, please contact your Abbott Customer Support Center Representative by calling 1-800-527-1869, 1-800-323-9100, or 1-800-235-5396.

Abbott employees:

For additional information relative to the content of the SDSs, please contact your local Safety Representative.



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

1 Identification

· **Product name:** ARCHITECT iVancomycin Microparticles

· **ADD List number:** 1P30G

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

· **Manufacturer / Supplier:**

Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Department issuing SDS:** Abbott Diagnostics Environmental Health and Safety

· **Emergency telephone number**

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.

2 Hazard(s) identification

· **Classification of the substance or mixture**

The classification was made according to U.S. OSHA 29 CFR 1910.1200 and 1910.1030 and applicable European regulations, and is expanded upon from supplier company and/or literature data.

Sensitization - Skin 1 H317 May cause an allergic skin reaction.

Aquatic Acute 3 H402 Harmful to aquatic life.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **Label elements**

· **GHS label elements:** The product is labelled according to the Globally Harmonized System (GHS).

· **Hazard pictograms:**



· **Signal word:** Warning

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

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

· **Hazard statements:**

H317 May cause an allergic skin reaction.

H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements:**

P261 Avoid breathing mist / vapors / spray.



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Microparticles

- P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
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.

- **Routes of Exposure:** Skin
- **Health:** Sensitizer in contact with skin
- **Fire:** Noncombustible
- **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

3 Composition/information on ingredients

- **Chemical characterization:** Mixture of chemical and/or biological substances for in vitro diagnostic use.

- **Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):**

CAS: 55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	0.0036%
-----------------	--	---------

4 First-aid measures

- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:** Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.
- **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists, get medical advice/attention. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **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.
- **Medical conditions aggravated by exposure:**
Pre-existing skin ailments
Skin allergies



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Microparticles

5 Fire-fighting measures

· 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.

· 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.

· Protective equipment

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

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

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

· Environmental precautions

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

· Methods and material for containment and cleaning up

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:

- warm water and detergent or similar cleansing agent

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.



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Microparticles

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.

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.

7 Handling and storage

- Precautions for safe handling:** Avoid contact with skin.
- Information about protection against explosions and fires:** The product is not flammable.
- Requirements to be met by storerooms and receptacles:** Store only in the original container.
- 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.

8 Exposure controls/personal protection

Components with Occupational Exposure Limits

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the remaining constituent has no known exposure limits.

CAS: 26628-22-8 Sodium azide (0.005 %)

REL	Ceiling limit value: 0.3** mg/m ³ , 0.1* ppm *as HN ₃ ; **as NaN ₃ ; Skin
TLV	Ceiling limit value: 0.29** mg/m ³ , 0.11* ppm *as HN ₃ vapor **as NaN ₃ , A4

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.

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 NIOSH-approved air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Microparticles

Hazardous Materials Emergencies or Firefighting - use NIOSH/NFPA-approved respiratory protection.

· **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 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.

9 Physical and chemical properties

· **General Information**

· Color:	Brown
· Odor:	Odorless
· Melting point/Melting range:	Not determined
· Boiling point/Boiling range:	Not determined
· Flammability (solid, gaseous)	Not applicable
· Explosion limits	
· Lower:	Not determined
· Upper:	Not determined
· Flash point	Not applicable
· pH-value at 20 °C (68 °F)	8
· Dynamic:	Not determined
· Solubility in / Miscibility with	
· Water:	Fully miscible
· Vapor pressure:	
· Density at 20 °C (68 °F)	1.007 g/cm ³ (8.4034 lbs/gal)
· Form:	Liquid
· Auto igniting	Product is not self-igniting.
· Danger of explosion	Product does not present an explosion hazard.
· Water:	98.1 %
· Solids content:	0.0 %
· Evaporation rate:	Not determined



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Microparticles

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided**
No decomposition if used and stored according to specifications.
- **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.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD50/LC50 values for hazardous ingredients per OSHA criteria:**
- **Ingredients (100% pure substance/s):** Not applicable.
- **Sensitization:**
Sensitization possible through skin contact.
May cause an allergic skin reaction.
- **Aspiration hazard**
- **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)
None of the ingredients is listed.
· NTP (National Toxicology Program)
None of the ingredients is listed.
· OSHA-Ca (Occupational Safety & Health Administration)
None of the ingredients is listed.
- **Target organs/systems:**
Skin
Immune system

12 Ecological information

- **Aquatic toxicity:** No further relevant information available.



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Microparticles

Results of PBT and vPvB assessment

- **PBT:** Not applicable
- **vPvB:** Not applicable

Additional ecological information

General notes:

Do not allow product to reach ground water, water course, or sewage system.
Harmful to aquatic organisms.

13 Disposal considerations

Recommendation for disposal of unused product:

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

- 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).

Waste disposal key:

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 cleansing agent:** Water with cleansing agents, if necessary.

14 Transport information

- **DOT, ADN, IMDG, IATA** none

UN proper shipping name

- **DOT, ADR, ADN, IMDG, IATA** none

Transport hazard class(es)

- **DOT, ADR, ADN, IMDG, IATA**
- **Class** none
- **DOT, IMDG, IATA** none

Environmental hazards

- **Marine pollutant:** No

Additional information

- **DOT**
- **Remarks:** Not restricted for transportation.
- **IMDG**
- **Remarks:** Not restricted for transportation.



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Microparticles

- IATA
- Remarks: Not restricted for transportation.

15 Regulatory information

· **SARA (Superfund Amendments and Reauthorization Act of 1986 - USA):**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

CAS: 26628-22-8 Sodium azide

· **Section 313 (40CFR372.65):**

CAS: 26628-22-8 Sodium azide

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **California Proposition 65 (USA):**

· **Chemicals known to cause cancer:**

The product does not contain listed substances.

· **Chemicals known to cause female reproductive toxicity:**

None of the ingredients is listed.

· **Chemicals known to cause male reproductive toxicity:**

None of the ingredients is listed.

· **Chemicals known to cause developmental reproductive toxicity:**

None of the ingredients is listed.

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.

This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any particular course of treatment. It is not intended to supplement, modify or supersede any information (e.g. labeling and package inserts) provided with respect to the medical use of the product. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

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

· **Department issuing SDS**

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Microparticles

· **Contact**

- General information about this product:

Abbott Diagnostics
Technical Support
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision 03/27/2024**

· **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 européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Sensitization - Skin 1: Skin sensitisation – Category 1

Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· *** Sections marked with an asterisk (*) have been altered since the previous version.**



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

1 Identification

- **Product name:** ARCHITECT iVancomycin Conjugate
- **ADD List number:** 1P30H
- **Application of the substance / mixture:** For In Vitro Diagnostic Use
- **Manufacturer / Supplier:**
Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT
- **Department issuing SDS:** Abbott Diagnostics Environmental Health and Safety
- **Emergency telephone number**
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.

2 Hazard(s) identification

- **Classification of the substance or mixture**
The classification was made according to U.S. OSHA 29 CFR 1910.1200 and 1910.1030 and applicable European regulations, and is expanded upon from supplier company and/or literature data.
Sensitization - Skin 1 H317 May cause an allergic skin reaction.
Aquatic Acute 2 H401 Toxic to aquatic life.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.
- **Additional information:** Testing has been done on a similar material to determine the hazards.
- **Label elements**
- **GHS label elements:** The product is labelled according to the Globally Harmonized System (GHS).
- **Hazard pictograms:**

- **Signal word:** Warning
- **Hazard-determining components of labeling:**
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)
5-sulfosalicylic acid dihydrate
polyethylene glycol octylphenyl ether
Copper sulphate



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Conjugate

· Hazard statements:

- H317 May cause an allergic skin reaction.
- H401 Toxic to aquatic life.
- H412 Harmful to aquatic life with long lasting effects.

· Precautionary statements:

- P261 Avoid breathing mist / vapors / spray.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- 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.

· Routes of Exposure: Skin

· Health: Sensitizer in contact with skin

· Fire: Noncombustible

· Reactivity: Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

3 Composition/information on ingredients

· Chemical characterization: Mixture of chemical and/or biological substances for in vitro diagnostic use.

· Hazardous chemical ingredients per U.S. OSHA criteria (29 CFR 1910.1200 Hazard Communication):

CAS: 5965-83-3	5-sulfosalicylic acid dihydrate	3.33%
CAS: 7758-98-7	Copper sulphate	0.18%
CAS: 9002-93-1	polyethylene glycol octylphenyl ether	0.10%
CAS: 55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	0.0036%

4 First-aid measures

· General information: Immediately remove any clothing soiled by the product.

· After inhalation: Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.

· After skin contact:

Take off any clothing that the product touched.

Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.

· After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.

· After swallowing: Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Conjugate

· **Most important symptoms and effects, both acute and delayed:**

Cramps
Gastric or intestinal disorders
Nausea
Allergic reactions
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.

· **Medical conditions aggravated by exposure:**

Pre-existing gastrointestinal tract ailments
Pre-existing eye ailments
Pre-existing skin ailments
Skin allergies

5 Fire-fighting measures

· **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.

· **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.

· **Protective equipment**

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

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**

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

· **Environmental precautions**

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

· **Methods and material for containment and cleaning up**

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:

- warm water and detergent or similar cleansing agent



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Conjugate

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.

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.

7 Handling and storage

- Precautions for safe handling:** Avoid contact with skin.
- Information about protection against explosions and fires:** The product is not flammable.
- Requirements to be met by storerooms and receptacles:** Store only in the original container.
- 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.

8 Exposure controls/personal protection

Components with Occupational Exposure Limits

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

CAS: 68-12-2 N,N-dimethylformamide (0.0005 %)

PEL TWA: 30 mg/m³, 10 ppm
Skin

REL TWA: 30 mg/m³, 10 ppm
Skin

TLV TWA: 5 ppm
Skin; BEI, A3

Ingredients with biological limit values:

CAS: 68-12-2 N,N-dimethylformamide (0.0005 %)

BEI 30 mg/L
Medium: urine
Time: end of shift
Parameter: Total N-Methylformamide (sum of N-Methylformamide and N-(Hydroxymethyl)-N-Methylformamide

30 mg/L
Medium: urine
Time: end of shift at end of workweek
Parameter: N-Acetyl-S-(N-methylcarbamoyl) cysteine



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Conjugate

· 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.

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 NIOSH-approved air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use NIOSH/NFPA-approved respiratory protection.

· 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 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.

9 Physical and chemical properties

· General Information

- | | |
|---------------------------------|----------------|
| · Color: | Green |
| · Odor: | Odorless |
| · Melting point/Melting range: | Not determined |
| · Boiling point/Boiling range: | Not determined |
| · Flammability (solid, gaseous) | Not applicable |
| · Explosion limits | |
| · Lower: | Not determined |
| · Upper: | Not determined |



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Conjugate

· Flash point	Not applicable
· pH-value at 20 °C (68 °F)	6
· Dynamic:	Not determined
· Solubility in / Miscibility with	
· Water:	Fully miscible
· Vapor pressure:	
· Density at 20 °C (68 °F)	1.029 g/cm ³ (8.587 lbs/gal)
· Form:	Liquid
· Auto igniting	Product is not self-igniting.
· Danger of explosion	Product does not present an explosion hazard.
· Water:	94.4 %
· Solids content:	0.0 %
· Evaporation rate:	Not determined

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided**
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD50/LC50 values for hazardous ingredients per OSHA criteria:**

Ingredients (100% pure substance/s):

CAS: 5965-83-3 5-sulfosalicylic acid dihydrate

Oral	LD50	608-2,450 mg/kg (rat) By analogy to sulfosalicylic acid (anhydrous). Gastric bleeding produced in animals.
	LDLo	1,300 mg/kg (rabbit) By analogy to sulfosalicylic acid (anhydrous).

- **Sensitization:**
Sensitization possible through skin contact.
May cause an allergic skin reaction.
- **Additional toxicological information:**
Endocrine disrupting effects caused by this substance have been observed in the environment. No adverse human health effects are known. See Section 12 for more information.



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Conjugate

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Target organs/systems:

Gastrointestinal tract

Skin

Immune system

12 Ecological information

· **Aquatic toxicity:** No further relevant information available.

· Results of PBT and vPvB assessment

· **PBT:** Not applicable

· **vPvB:** Not applicable

· Ecotoxicological effects:

Copper Sulfate:

Fish Toxicity: 140 ug/L 96 hours L50 (Mortality) Australian Redtail Rainbowfish (*Melanotaenia nigra*)

Invertebrate Toxicity: 17.3 ug/L 48 hours EC50 (Immobilization) Water flea (*Daphnia magna*)

Other Toxicity: 39 ug/L 96 hours L50 (Mortality) Frog (*Rana hexadactyla*)

· Additional ecological information

4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [4-tert-octylphenol ethoxylates; 4-tert-OPnEO] degrade to 4-(1,1,3,3-tetramethylbutyl)phenol, either already in wastewater treatment plants, or via further degradation processes in sediments (e.g. of aquatic bodies receiving the wastewater effluents) and soils (e.g. receiving sewage sludge). Available information for 4-tert-OPnEO and its close analogues 4-nonylphenol ethoxylates [4-NPnEO] indicate that 4-tert-OPnEO contribute to the 4-tert-OP concentration in the environment. A significant amount is either degraded to 4-tert-OP itself in waste water treatment plants or is released to rivers in a form which may undergo further degradation to 4-tert-OP. Available information for 4-NPnEO and 4-nonylphenol indicate that 4-tert-OP formed from degradation of 4-tert-OPnEO may be responsible for an increase of the 4-tert-OP load to the environment (soil, sediment and water) by 54 to 758%. Sediment organisms may be exposed to the 4-tert-OP, which results from the degradation of 4-tert-OPnEO, either directly, downstream of the effluent, or in the longer term after its adsorption to sediment and soil. Similar holds true for pelagic organisms such as fish which may be exposed via remobilisation of 4-tert-OP from sediment to the water body.

· General notes:

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Toxic for aquatic organisms

Harmful to aquatic organisms.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Conjugate

13 Disposal considerations

- **Recommendation for disposal of unused product:** Dispose in accordance with federal, state and local regulations.
- **Waste disposal key:**
- **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 cleansing agent:** Water with cleansing agents, if necessary.

14 Transport information

· DOT, ADN, IMDG, IATA none

· **UN proper shipping name**

· DOT, ADR, ADN, IMDG, IATA none

· **Transport hazard class(es)**

· DOT, ADR, ADN, IMDG, IATA

· Class none

· DOT, IMDG, IATA none

· **Environmental hazards**

· Marine pollutant: No

· **Additional information**

· DOT

· Remarks: Not restricted for transportation.

· IMDG

· Remarks: Not restricted for transportation.

· IATA

· Remarks: Not restricted for transportation.

15 Regulatory information

· **SARA (Superfund Amendments and Reauthorization Act of 1986 - USA):**

· **Section 302/304 (40CFR355.30 / 40CFR355.40):**

The product does not contain listed substances.

· **Section 313 (40CFR372.65):**

CAS: 7758-98-7 Copper sulphate

CAS: 68-12-2 N,N-dimethylformamide

· **Hazardous Air Pollutants**

CAS: 68-12-2 N,N-dimethylformamide



Abbott

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Conjugate

· California Proposition 65 (USA):

· Chemicals known to cause cancer:

CAS: 68-12-2 N,N-dimethylformamide

· Chemicals known to cause female reproductive toxicity:

None of the ingredients is listed.

· Chemicals known to cause male reproductive toxicity:

None of the ingredients is listed.

· Chemicals known to cause developmental reproductive toxicity:

None of the ingredients is listed.

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.

This information is not a substitute for the advice of a health care professional, nor is it a recommendation for any particular course of treatment. It is not intended to supplement, modify or supersede any information (e.g. labeling and package inserts) provided with respect to the medical use of the product. Abbott Laboratories assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.

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

· Department issuing SDS

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

· Contact

- General information about this product:

Abbott Diagnostics
Technical Support
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· Date of preparation / last revision 03/27/2024

· 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 européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024

Last alteration on 03/20/2024

Product name: ARCHITECT iVancomycin Conjugate

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

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

BEI: Biological Exposure Limit

Sensitization - Skin 1: Skin sensitisation – Category 1

Aquatic Acute 2: Hazardous to the aquatic environment - acute aquatic hazard – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· * Sections marked with an asterisk (*) have been altered since the previous version.