### Product Name

<table>
<thead>
<tr>
<th>REF</th>
<th>GTIN</th>
<th>Product Name</th>
</tr>
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<tbody>
<tr>
<td>3L52-25</td>
<td>00380740005863</td>
<td>ARCHITECT 25-OH Vitamin D Reagent Kit</td>
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#### Components:

<table>
<thead>
<tr>
<th>3L52G</th>
<th>ARCHITECT 25-OH Vitamin D Microparticles</th>
</tr>
</thead>
<tbody>
<tr>
<td>3L52H</td>
<td>ARCHITECT 25-OH Vitamin D Conjugate</td>
</tr>
<tr>
<td>3L52J</td>
<td>ARCHITECT 25-OH Vitamin D Assay Diluent</td>
</tr>
<tr>
<td>3L52X</td>
<td>ARCHITECT 25-OH Vitamin D Pretreatment 1</td>
</tr>
<tr>
<td>3L52Z</td>
<td>ARCHITECT 25-OH Vitamin D Pretreatment 2</td>
</tr>
</tbody>
</table>

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.
1 Identification

- **Product name:** ARCHITECT 25-OH Vitamin D Microparticles
- **ADD List number:** 3L52G
- **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.
  - 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.

2 Hazard(s) identification

- **Classification of the substance or mixture**
  Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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:**
  2-Methyl-4-isothiazolin-3-one
  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.

- **Precautionary statements:**
  P261 Avoid breathing mist / vapors / spray.
  P272 Contaminated work clothing should not be allowed out of the workplace.
  P302+P352 If on skin: Wash with plenty of water.
  P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
Product name: ARCHITECT 25-OH Vitamin D Microparticles

3 Composition/information on ingredients

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

<table>
<thead>
<tr>
<th>CAS</th>
<th>Ingredient</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>2682-20-4</td>
<td>2-Methyl-4-isothiazolin-3-one</td>
<td>0.014%</td>
</tr>
<tr>
<td>55965-84-9</td>
<td>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)</td>
<td>0.0034%</td>
</tr>
</tbody>
</table>

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.

Information for Medical Personnel

- 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

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.
Product name: ARCHITECT 25-OH Vitamin D Microparticles

- 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.

- 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 absorbants 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
  
  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.
  Refer to the package insert or product label for additional information on storage conditions for product quality.

- Information about storage in one common storage facility: Store in original packaging.

- Further information about storage conditions: Protect from heat and direct sunlight.
8 Exposure controls/personal protection

· Components with Occupational Exposure Limits
  The product does not contain any hazardous ingredients with occupational exposure limits established by OSHA, ACGIH, or NIOSH.

· 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
  · Form: Liquid
  · Color: Orange
Product name: ARCHITECT 25-OH Vitamin D Microparticles

- Odor: Odorless
- pH-value at 20 °C (68 °F): 8
  - Melting point/Melting range: Not determined
  - Boiling point/Boiling range: Not determined
- Flash point: Not applicable
- Flammability (solid, gaseous): Not applicable
- Auto igniting: Product is not self-igniting.
- Danger of explosion: Product does not present an explosion hazard.
- Explosion limits:
  - Lower: Not determined
  - Upper: Not determined
- Density at 20 °C (68 °F):
  - Evaporation rate: Not determined
- Solubility in / Miscibility with:
  - Water: Fully miscible
  - Dynamic: Not determined
  - Water: 85.7 %
  - Solids content: 0.0 %

* 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
  - LD50/LC50 values for hazardous ingredients per OSHA criteria:
    - Ingredients (100% pure substance/s):
      - CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one
        - Oral LD50 60 mg/kg (mouse)
          By analogy to methylchloroisothiazolinone.
Product name: ARCHITECT 25-OH Vitamin D Microparticles

53 mg/kg (rat)
By analogy to methylchloroisothiazolinone.

- Primary toxicological effects of the final product:
  - Skin irritation: No irritant effect.
  - Eye irritation: No irritant effect.
  - Sensitization: Sensitization possible through skin contact.

- Additional toxicological information: None

- 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:
  - CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one
  - LC50 96 h 0.19 mg/l (trout) (Flow through)
  - LC50 48 h (Static) 0.056 mg/l (other) (Crustacean - Acartia tonsa)

- Additional ecological information
  - General notes:
    Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system.

- Results of PBT and vPvB assessment
  - PBT: Not applicable
  - vPvB: Not applicable

13 Disposal considerations

- Recommendation for disposal of unused product:
  Dispose in accordance with federal, state and local regulations.

- 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.
Product name: ARCHITECT 25-OH Vitamin D Microparticles

- 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.
  - ADR
    - 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):
    The product does not contain listed substances.

- TSCA new (21st Century Act) (Substances not listed)
  - 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)

- California Proposition 65 (USA):
  - Chemicals known to cause cancer:
    The product does not contain listed substances.
Product name: ARCHITECT 25-OH Vitamin D Microparticles

- **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.

- **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** 10/04/2018 / 3

- **Abbreviations and acronyms:**
  - 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
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<tr>
<th>Safety Data Sheet</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product name:</strong> ARCHITECT 25-OH Vitamin D Microparticles</td>
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<tr>
<td>Skin Sens. 1: Skin sensitisation – Category 1</td>
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<tr>
<td>* Sections marked with an asterisk (*) have been altered since the previous version.</td>
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</table>
1 Identification

- **Product name:** ARCHITECT 25-OH Vitamin D Conjugate
- **ADD List number:** 3L52H
- **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.
  - 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.

2 Hazard(s) identification

- **Classification of the substance or mixture**
  This product has been evaluated per the classification criteria in the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This product does not meet the criteria for classification in accordance with the GHS.

- **Label elements**
  - **GHS label elements:** none
  - **Hazard pictograms:** none
  - **Signal word:** none
  - **Hazard-determining components of labeling:** Sodium azide
  - **Hazard statements:** none

- **Routes of Exposure:**
  - Skin: No adverse effects expected when used as directed.
  - Eye: No adverse effects expected when used as directed.
  - Inhalation: No adverse effects expected when used as directed.
  - Ingestion: No adverse effects expected when used as directed.

- **Hazard Overview**
  - **Health:** No adverse effects expected if used as directed.
  - **Fire:** Noncombustible
  - **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.
Product name: ARCHITECT 25-OH Vitamin D Conjugate

3 Composition/information on ingredients

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


<table>
<thead>
<tr>
<th>CAS</th>
<th>Ingredient</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>26628-22-8</td>
<td>Sodium azide</td>
<td>0.099%</td>
</tr>
</tbody>
</table>

4 First-aid measures

- **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.

Information for Medical Personnel

- **Most important symptoms and effects, both acute and delayed:** None expected
- **Medical conditions aggravated by exposure:** None known

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.

- **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 absorbants 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.

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.

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**7 Handling and storage**

**Precautions for safe handling:**
Avoid direct contact with material. If handled, wash thoroughly. Practice general safety precautions.

**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.
Refer to the package insert or product label for additional information on storage conditions for product quality.

**Information about storage in one common storage facility:** Store in original packaging.

**Further information about storage conditions:** Protect from heat and direct sunlight.
8 Exposure controls/personal protection

- **Components with Occupational Exposure Limits**
  - **CAS: 26628-22-8 Sodium azide (0.099 %)**
    - REL Ceiling limit value: 0.3** mg/m³, 0.1* ppm
      - *as HN3; **as NaN3; Skin
    - TLV Ceiling limit value: 0.29** mg/m³, 0.11* ppm
      - *as HN3 vapor; **as NaN3

- **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.

- **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**
  - **Form:** Liquid
  - **Color:** Colorless
Product name: ARCHITECT 25-OH Vitamin D Conjugate

- Odor: Odorless

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH-value at 20 °C (68 °F)</td>
<td>6.8</td>
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<tr>
<td>Melting point/Melting range:</td>
<td>Not determined</td>
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<td>Boiling point/Boiling range:</td>
<td>Not determined</td>
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<tr>
<td>Flash point</td>
<td>Not applicable</td>
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<tr>
<td>Flammability (solid, gaseous)</td>
<td>Not applicable</td>
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<tr>
<td>Auto igniting</td>
<td>Product is not self-igniting.</td>
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<tr>
<td>Danger of explosion</td>
<td>Product does not present an explosion hazard.</td>
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<tr>
<td>Explosion limits</td>
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<tr>
<td>Lower:</td>
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<tr>
<td>Upper:</td>
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<tr>
<td>Density at 20 °C (68 °F)</td>
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<tr>
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<td>Solids content:</td>
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</table>

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
  · LD50/LC50 values for hazardous ingredients per OSHA criteria:
    · Ingredients (100% pure substance/s): Not applicable.
  · Primary toxicological effects of the final product:
    · Skin irritation: No irritant effect.
    · Eye irritation: No irritant effect.
  · Sensitization: No sensitizing effects known.

· Additional toxicological information: None

· 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: Unknown

12 Ecological information

· Aquatic toxicity: No further relevant information available.

· Additional ecological information
  · General notes: Not known to be a water pollutant.

· Results of PBT and vPvB assessment
  · PBT: Not applicable
  · vPvB: Not applicable

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).

USA
### Product name: ARCHITECT 25-OH Vitamin D Conjugate

- **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.
  - ADR 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):**
    - CAS: 26628-22-8 Sodium azide
  - **Section 313 (40CFR372.65):**
    - CAS: 26628-22-8 Sodium azide

- **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.
Product name: ARCHITECT 25-OH Vitamin D Conjugate

- **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.

- **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** 10/04/2018 / 10

- **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

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

- **Product name:** ARCHITECT 25-OH Vitamin D Assay Diluent
  - **ADD List number:** 3L52J
  - **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.
  - 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.

2 Hazard(s) identification

- **Classification of the substance or mixture**
  Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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:**
  2-Methyl-4-isothiazolin-3-one
  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.

- **Precautionary statements:**
  P261 Avoid breathing mist / vapors / spray.
  P272 Contaminated work clothing should not be allowed out of the workplace.
  P302+P352 If on skin: Wash with plenty of water.
  P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
Product name: ARCHITECT 25-OH Vitamin D Assay Diluent

- P363 Wash contaminated clothing before reuse.

- Routes of Exposure: Skin

- Hazard Overview
  - 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.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Ingredient</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>6381-92-6</td>
<td>EDTA disodium salt, dihydrate</td>
<td>2.93%</td>
</tr>
<tr>
<td>2682-20-4</td>
<td>2-Methyl-4-isothiazolin-3-one</td>
<td>0.015%</td>
</tr>
<tr>
<td>55965-84-9</td>
<td>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)</td>
<td>0.0035%</td>
</tr>
</tbody>
</table>

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.

- Information for Medical Personnel
  - Most important symptoms and effects, both acute and delayed:
    - Cramps
    - Gastric or intestinal disorders
    - Nausea
    - Kidney effects
    - 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:
    - Pregnancy
    - Pre-existing respiratory ailments
    - Pre-existing eye ailments
### 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.

- **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 absorbants 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

  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.
Product name: ARCHITECT 25-OH Vitamin D Assay Diluent

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

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.

<table>
<thead>
<tr>
<th>CAS: 64-19-7 Acetic acid (0.24 %)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PEL</strong></td>
</tr>
<tr>
<td><strong>REL</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>TLV</strong></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

- **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.
Product name: ARCHITECT 25-OH Vitamin D Assay Diluent

· **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

<table>
<thead>
<tr>
<th>General Information</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>· Form:</td>
<td>Liquid</td>
</tr>
<tr>
<td>· Color:</td>
<td>Colorless</td>
</tr>
<tr>
<td>· Odor:</td>
<td>Odorless</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>pH-value at 20 °C (68 °F)</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Melting point/Melting range:</td>
<td>Not determined</td>
</tr>
<tr>
<td>· Boiling point/Boiling range:</td>
<td>Not determined</td>
</tr>
</tbody>
</table>

| Flash point | Not applicable |
| Flammability (solid, gaseous) | Not applicable |
| Auto igniting | Product is not self-igniting. |

| Danger of explosion | Product does not present an explosion hazard. |
| Explosion limits |   |
| · Lower: | Not determined |
| · Upper: | Not determined |

| Density at 20 °C (68 °F) | 1.017 g/cm³ (8.4869 lbs/gal) |
| Evaporation rate: | Not determined |

| Solubility in / Miscibility with |   |
| · Water: | Fully miscible |
| · Dynamic: | Not determined |

| Water: | 95.9 % |
| Solids content: | 0.8 % |
**Product name:** ARCHITECT 25-OH Vitamin D Assay Diluent

### 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**
  - **LD50/LC50 values for hazardous ingredients per OSHA criteria:**

<table>
<thead>
<tr>
<th>CAS: 6381-92-6 EDTA disodium salt, dihydrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

Possible adverse effects from pharmacological use include fever and effects on the: kidneys, gastro intestinal system, CNS, cardiovascular system, skin, blood, metabolism.

- **CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one**

<table>
<thead>
<tr>
<th>Oral</th>
<th>LD50</th>
<th>60 mg/kg (mouse)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>By analogy to methylchloroisothiazolinone.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>53 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>By analogy to methylchloroisothiazolinone.</td>
</tr>
</tbody>
</table>

- **Primary toxicological effects of the final product:**
  - **Skin irritation:** No irritant effect.
  - **Eye irritation:** No irritant effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:** None

- **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.
12 Ecological information

· Aquatic toxicity:
  
  CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one
  
  LC50 96 h 0.19 mg/l (trout) (Flow through)
  LC50 48 h (Static) 0.056 mg/l (other) (Crustacean - Acartia tonsa)

· Additional ecological information
  
  · General notes:
    Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system.

· Results of PBT and vPvB assessment
  
  · PBT: Not applicable
  · vPvB: Not applicable

13 Disposal considerations

· Recommendation for disposal of unused product:
  Dispose in accordance with federal, state and local regulations.

· 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
Product name: ARCHITECT 25-OH Vitamin D Assay Diluent

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.
- ADR
  - 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):
    The product does not contain listed substances.
- TSCA new (21st Century Act) (Substances not listed)
  - EDTA disodium salt, dihydrate
  - 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)
- 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.
Product name: ARCHITECT 25-OH Vitamin D Assay Diluent

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.

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 10/04/2018 / 10

Abbreviations and acronyms:
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- 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
- Skin Sens. 1: Skin sensitisation – Category 1

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

- **Product name:** ARCHITECT 25-OH Vitamin D Pretreatment 1
- **ADD List number:** 3L52X
- **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.
  - 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.

2 Hazard(s) identification

- **Classification of the substance or mixture**
  Flam. Liq. 3 H226 Flammable liquid and vapor.
  Acute Tox. 4 H302 Harmful if swallowed.
  Acute Tox. 4 H312 Harmful in contact with skin.
  Acute Tox. 4 H332 Harmful if inhaled.
  STOT SE 1 H370 Causes damage to organs.

- **Label elements**
  - **GHS label elements:** The product is labelled according to the Globally Harmonized System (GHS).
  - **Hazard pictograms:**

  ![Hazard pictograms]

  - **Signal word:** Danger
  - **Hazard-determining components of labeling:** Methanol
  - **Hazard statements:**
    H226 Flammable liquid and vapor.
    H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled.
    H370 Causes damage to organs.
  - **Precautionary statements:**
    P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Product name: ARCHITECT 25-OH Vitamin D Pretreatment 1

P233 Keep container tightly closed.
P260 Do not breathe mist / vapors / spray.
P280 Wear protective gloves/protective clothing/eye protection.
P301+P330+P312 IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor / physician if you feel unwell.
P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P307+P311 IF exposed: Call a POISON CENTER or doctor/physician.
P370+P378 In case of fire: Use CO2, dry chemical, dry sand, alcohol resistant foam to extinguish.
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents / container in accordance with local regulations.

· Additional information:
  Combustible.
  May cause blindness.

· Routes of Exposure:
  Skin
  Inhalation

· Hazard Overview
  · Health:
    Harmful if swallowed
    May cause blindness.
  · Fire: Flammable
  · Reactivity: Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.
  · Special Hazards: See section 11 for details.

· IARC (International Agency for Research on Cancer) Group 3
  · Interpretation of the IARC listing
    Group 3: The substance or mixture listed above is not classifiable as to carcinogenicity in humans. Evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals.

* 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: 67-56-1 Methanol                          | 16.63%   |

* 4 First-aid measures
  · 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.
Safety Data Sheet

Product name: ARCHITECT 25-OH Vitamin D Pretreatment 1

· 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.

· Information for Medical Personnel
  · Most important symptoms and effects, both acute and delayed:
    Liver effects
    Kidney effects
    Cramps
    Gastric or intestinal disorders
    Nausea
    Headache
    Disorientation
    Dizziness
  · Medical conditions aggravated by exposure:
    Pre-existing respiratory ailments
    Pre-existing cardiovascular ailments
    Pre-existing liver condition
    Pre-existing kidney ailments
    Pre-existing gastrointestinal tract ailments
    Pre-existing nervous system ailments

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.

· 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

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.

Handling and storage

- Precautions for safe handling: Avoid inhalation.
- Information about protection against explosions and fires:
  Use explosion-proof electrical/ventilating/lighting/equipment.
  Ground/bond container and receiving equipment.
  Use only non-sparking tools.
  Take precautionary measures against static discharge.
- Requirements to be met by storerooms and receptacles:
  Store only in the original container.
  Refer to the package insert or product label for additional information on storage conditions for product quality.
- Information about storage in one common storage facility: Store in original packaging.
- Further information about storage conditions: Protect from heat and direct sunlight.

Exposure controls/personal protection

- Components with Occupational Exposure Limits

| CAS: 67-56-1 Methanol (16.63 %) |  |
| PEL | TWA: 260 mg/m³, 200 ppm |
| REL | STEL/C: 325 mg/m³, 250 ppm |
| | TWA: 260 mg/m³, 200 ppm |
| | Skin |
| TLV | STEL/C: 328 mg/m³, 250 ppm |
| | TWA: 262 mg/m³, 200 ppm |
| | Skin; BEI |

| CAS: 7646-85-7 Zinc chloride (0.0014 %) |  |
| PEL | TWA: 1 mg/m³ |
| Fume |  |
Product name: ARCHITECT 25-OH Vitamin D Pretreatment 1

REL
- STEL/C: 2 mg/m³
- TWA: 1 mg/m³

TLV
- STEL/C: 2 mg/m³
- TWA: 1 mg/m³

Ingredients with biological limit values:

CAS: 67-56-1 Methanol (16.63 %)

BEI 15 mg/L
- Medium: urine
- Time: end of shift
- Parameter: Methanol (background, nonspecific)

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.

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.
# Safety Data Sheet

**Product Name:** ARCHITECT 25-OH Vitamin D Pretreatment 1

## 9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Form</strong></td>
<td>Liquid</td>
</tr>
<tr>
<td><strong>Color</strong></td>
<td>Light yellow</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>Odorless</td>
</tr>
<tr>
<td><strong>pH-value at 20 °C (68 °F)</strong></td>
<td>7.7</td>
</tr>
<tr>
<td><strong>Melting point/Melting range</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Boiling point/Boiling range</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>49 °C (120.2 °F)</td>
</tr>
<tr>
<td><strong>Flammability (solid, gaseous)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Ignition temperature</strong></td>
<td>0 °C (32 °F)</td>
</tr>
<tr>
<td><strong>Auto igniting</strong></td>
<td>Product is not self-igniting.</td>
</tr>
<tr>
<td><strong>Danger of explosion</strong></td>
<td>Product is not explosive. However, formation of explosive air/vapor mixtures is possible.</td>
</tr>
<tr>
<td><strong>Lower</strong></td>
<td>0.0 Vol %</td>
</tr>
<tr>
<td><strong>Upper</strong></td>
<td>0.0 Vol %</td>
</tr>
<tr>
<td><strong>Density at 20 °C (68 °F)</strong></td>
<td>0.98 g/cm³ (8.1781 lbs/gal)</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Solubility in / Miscibility with</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Water</strong></td>
<td>Fully miscible</td>
</tr>
<tr>
<td><strong>Dynamic</strong></td>
<td>Not determined</td>
</tr>
<tr>
<td><strong>Water</strong></td>
<td>80.6 %</td>
</tr>
<tr>
<td><strong>Solids content</strong></td>
<td>0.0 %</td>
</tr>
</tbody>
</table>

## 10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions:** Reacts with acids, alkalis and oxidizing agents.
- **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
  - LD50/LC50 values for hazardous ingredients per OSHA criteria:

<table>
<thead>
<tr>
<th>CAS: 67-56-1 Methanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
</tr>
<tr>
<td>LD50</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>LDLo</td>
</tr>
<tr>
<td>Dermal</td>
</tr>
<tr>
<td>LD50</td>
</tr>
<tr>
<td>Inhalation</td>
</tr>
<tr>
<td>LC50 4 h</td>
</tr>
</tbody>
</table>

- Primary toxicological effects of the final product:
  - Skin irritation: No irritant effect.
  - Eye irritation: No irritant effect.
  - Sensitization: No sensitizing effects known.

- Additional toxicological information: None

- Carcinogenic categories
  - IARC (International Agency for Research on Cancer)
    - CAS: 102-71-6 Triethanolamine
      - 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:
  - Liver
  - Kidneys
  - Gastrointestinal tract
  - Nervous system
  - Cardiovascular system
  - Pancreas

12 Ecological information

- Aquatic toxicity: No further relevant information available.

- Additional ecological information
  - General notes:
    - Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system.

- Results of PBT and vPvB assessment
  - PBT: Not applicable
### Product name: ARCHITECT 25-OH Vitamin D Pretreatment 1

- vPvB: Not applicable

### 13 Disposal considerations

- **Recommendation for disposal of unused product:**
  Dispose in accordance with federal, state and local regulations.

- **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, IMDG, IATA** UN1992

- **UN proper shipping name**
  - DOT, ADR Flammable liquids, toxic, n.o.s. (Methanol)
  - IMDG, IATA FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL)

- **Transport hazard class(es)**
  - **DOT**
    - Class 3 Flammable liquids
    - Label 3
    - Class 3 Flammable liquids
    - Label 3+6.1

  - **IMDG**
    - Class 3 Flammable liquids
    - Label 3/6.1

  - **IATA**
    - Class 3 Flammable liquids
    - Label 3.6.1
# Safety Data Sheet

**Product Name:** ARCHITECT 25-OH Vitamin D Pretreatment 1

## Environmental Hazards
- **Marine pollutant:** No
- **EMS Number:** F-E,S-D
- **Stowage Category:** A

## Additional Information
The information in this section reflects the actual chemical name and transport information for the material. Due to legal exceptions that are permitted by transport regulations, the proper shipping name and transport information included on the actual shipping document may differ. When this product is shipped as a component of an in vitro diagnostic medical device, exceptions that may be used include, but are not limited to, the following:
- Chemical Kit
- Excepted Quantity
- Consumer Commodity

**ADR**
- **Excepted quantities (EQ)**
  - Code: E1
  - Maximum net quantity per inner packaging: 30 ml
  - Maximum net quantity per outer packaging: 1000 ml

**IMDG**
- **Limited quantities (LQ)**: 5L
- **Excepted quantities (EQ)**
  - Code: E1
  - Maximum net quantity per inner packaging: 30 ml
  - Maximum net quantity per outer packaging: 1000 ml

## 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: 67-56-1** Methanol
- **CAS: 7646-85-7** Zinc chloride

**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.
Product name: ARCHITECT 25-OH Vitamin D Pretreatment 1

Chemicals known to cause developmental reproductive toxicity:
CAS: 67-56-1 Methanol

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.

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 10/04/2018 / 5

Abbreviations and acronyms:
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
BEI: Biological Exposure Limit
Flam. Liq. 3: Flammable liquids – Category 3
Acute Tox. 4: Acute toxicity – Category 4
STOT SE 1: Specific target organ toxicity (single exposure) – Category 1

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

- Product name: ARCHITECT 25-OH Vitamin D Pretreatment 2
  - ADD List number: 3L52Z
  - 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.
  - 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.

2 Hazard(s) identification

- Classification of the substance or mixture
  Flam. Liq. 3  H226  Flammable liquid and vapor.
  Acute Tox. 4  H302  Harmful if swallowed.
  Acute Tox. 4  H312  Harmful in contact with skin.
  Acute Tox. 4  H332  Harmful if inhaled.
  STOT SE 1  H370  Causes damage to organs.

- Label elements
  - GHS label elements: The product is labelled according to the Globally Harmonized System (GHS).
    - Hazard pictograms:

    ![Hazard Pictograms]

  - Signal word: Danger

  - Hazard-determining components of labeling:
    Methanol

  - Hazard statements:
    H226  Flammable liquid and vapor.
    H302+H312+H332  Harmful if swallowed, in contact with skin or if inhaled.
    H370  Causes damage to organs.

  - Precautionary statements:
    P210  Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Product name: ARCHITECT 25-OH Vitamin D Pretreatment 2

P233 Keep container tightly closed.
P260 Do not breathe mist / vapors / spray.
P280 Wear protective gloves/protective clothing/eye protection.
P301+P330+P312 IF SWALLOWED: Rinse mouth. Call a POISON CENTER or doctor / physician if you feel unwell.
P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P307+P311 IF exposed: Call a POISON CENTER or doctor/physician.
P370+P378 In case of fire: Use CO2, dry chemical, dry sand, alcohol resistant foam to extinguish.
P403+P235 Store in a well-ventilated place. Keep cool.
P501 Dispose of contents / container in accordance with local regulations.

· Additional information: Combustible. May cause blindness.

· Routes of Exposure: Skin Inhalation

· Hazard Overview
  · Health: Harmful if swallowed. May cause blindness.
  · Fire: Flammable
  · Reactivity: Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.
  · Special Hazards: See section 11 for details.

· IARC (International Agency for Research on Cancer) Group 3
  · Interpretation of the IARC listing Group 3: The substance or mixture listed above is not classifiable as to carcinogenicity in humans. Evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals.

3 Composition/information on ingredients

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

<table>
<thead>
<tr>
<th>CAS</th>
<th>Methanol</th>
<th>16.63%</th>
</tr>
</thead>
</table>

4 First-aid measures

· 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.
Safety Data Sheet

Product name: ARCHITECT 25-OH Vitamin D Pretreatment 2

· 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.

Information for Medical Personnel

· Most important symptoms and effects, both acute and delayed:
  Cramps
  Gastric or intestinal disorders
  Nausea
  Headache
  Disorientation
  Liver effects
  Kidney effects
  Dizziness

· Medical conditions aggravated by exposure:
  Pre-existing respiratory ailments
  Pre-existing pancreas ailments
  Pre-existing cardiovascular ailments
  Pre-existing liver condition
  Pre-existing kidney ailments
  Pre-existing gastrointestinal tract ailments
  Pre-existing nervous system ailments

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.

· 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.
Product name: ARCHITECT 25-OH Vitamin D Pretreatment 2

· 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 absorbants 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
  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 inhalation.

· Information about protection against explosions and fires:
  Use explosion-proof electrical/ventilating/lighting/equipment.
  Ground/bond container and receiving equipment.
  Use only non-sparking tools.
  Take precautionary measures against static discharge.

· Requirements to be met by storerooms and receptacles:
  Store only in the original container.
  Refer to the package insert or product label for additional information on storage conditions for product quality.

· Information about storage in one common storage facility: Store in original packaging.

· Further information about storage conditions: Protect from heat and direct sunlight.

8 Exposure controls/personal protection

· Components with Occupational Exposure Limits

| CAS: 67-56-1 Methanol (16.63 %) |
|---|---|
| PEL | TWA: 260 mg/m³, 200 ppm |
| REL | STEL/C: 325 mg/m³, 250 ppm |
|     | TWA: 260 mg/m³, 200 ppm |
|     | Skin |
| TLV  | STEL/C: 328 mg/m³, 250 ppm |
|     | TWA: 262 mg/m³, 200 ppm |
|     | Skin; BEI |
Product name: ARCHITECT 25-OH Vitamin D Pretreatment 2

<table>
<thead>
<tr>
<th>CAS: 7646-85-7 Zinc chloride (0.0014 %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PEL TWA: 1 mg/m³</td>
</tr>
<tr>
<td>Fume</td>
</tr>
<tr>
<td>REL STEL/C: 2 mg/m³</td>
</tr>
<tr>
<td>TWA: 1 mg/m³</td>
</tr>
<tr>
<td>TLV STEL/C: 2 mg/m³</td>
</tr>
<tr>
<td>TWA: 1 mg/m³</td>
</tr>
<tr>
<td>fume</td>
</tr>
</tbody>
</table>

Ingredients with biological limit values:

<table>
<thead>
<tr>
<th>CAS: 67-56-1 Methanol (16.63 %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BEI 15 mg/L</td>
</tr>
<tr>
<td>Medium: urine</td>
</tr>
<tr>
<td>Time: end of shift</td>
</tr>
<tr>
<td>Parameter: Methanol (background, nonspecific)</td>
</tr>
</tbody>
</table>

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.

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**
  - **Form:** Liquid
  - **Color:** Light yellow
  - **Odor:** Odorless

- **pH-value at 20 °C (68 °F)**: 7.7
  - **Melting point/Melting range:** Not determined
  - **Boiling point/Boiling range:** Not determined

- **Flash point**: 49 °C (120.2 °F)
- **Flammability (solid, gaseous)**: Not applicable

- **Igntion temperature**: 0 °C (32 °F)
- **Auto igniting**: Product is not self-igniting.

- **Danger of explosion**: Product is not explosive. However, formation of explosive air/vapor mixtures is possible.
  - **Lower:** 0.0 Vol %
  - **Upper:** 0.0 Vol %

- **Density at 20 °C (68 °F)**: 0.98 g/cm³ (8.1781 lbs/gal)
  - **Evaporation rate:** Not determined

- **Solubility in / Miscibility with**
  - **Water:** Fully miscible
  - **Dynamic:** Not determined
  - **Water:** 80.6 %
  - **Solids content:** 0.0 %

10 Stability and reactivity

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

- **Possibility of hazardous reactions**: Reacts with acids, alkalis and oxidizing agents.

- **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
  · LD50/LC50 values for hazardous ingredients per OSHA criteria:

<table>
<thead>
<tr>
<th>CAS: 67-56-1 Methanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
</tr>
<tr>
<td>5,000-7,300 mg/kg (mammal)</td>
</tr>
<tr>
<td>5,628 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal LDLo</td>
</tr>
<tr>
<td>143 mg/kg (human)</td>
</tr>
<tr>
<td>Inhalation LC50 4 h</td>
</tr>
<tr>
<td>15,800 mg/kg (rabbit)</td>
</tr>
<tr>
<td>64,000 ppm (rat)</td>
</tr>
</tbody>
</table>

· Primary toxicological effects of the final product:
  · Skin irritation: No irritant effect.
  · Eye irritation: No irritant effect.
  · Sensitization: No sensitizing effects known.

· Additional toxicological information: None

· Carcinogenic categories
  · IARC (International Agency for Research on Cancer)
    CAS: 102-71-6 Triethanolamine 3
  · 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:
  Liver
  Kidneys
  Gastrointestinal tract
  Nervous system
  Cardiovascular system
  Pancreas

12 Ecological information

· Aquatic toxicity: No further relevant information available.

· Additional ecological information
  · General notes:
    Do not allow undiluted product or large quantities of it to reach ground water, water course, or sewage system.

· Results of PBT and vPvB assessment
  · PBT: Not applicable
**Product name:** ARCHITECT 25-OH Vitamin D Pretreatment 2

- vPvB: Not applicable

### 13 Disposal considerations

- **Recommendation for disposal of unused product:**
  Dispose in accordance with federal, state and local regulations.

- **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, IMDG, IATA**
  UN1992

- **UN proper shipping name**
  - **DOT, ADR**
    Flammable liquids, toxic, n.o.s. (Methanol)
  - **IMDG, IATA**
    FLAMMABLE LIQUID, TOXIC, N.O.S. (METHANOL)

- **Transport hazard class(es)**
  - **DOT**
    - **Class** 3 Flammable liquids
    - **Label** 3
    - **Class** 3 Flammable liquids
    - **Label** 3+6.1
  - **IMDG**
    - **Class** 3 Flammable liquids
    - **Label** 3/6.1
  - **IATA**
    - **Class** 3 Flammable liquids
    - **Label** 3,6.1
Product name: ARCHITECT 25-OH Vitamin D Pretreatment 2

- **DOT, IMDG, IATA** III

- **Environmental hazards**
  - Marine pollutant: No
  - EMS Number: F-E,S-D
  - Stowage Category A

- **Additional information**
  The information in this section reflects the actual chemical name and transport information for the material. Due to legal exceptions that are permitted by transport regulations, the proper shipping name and transport information included on the actual shipping document may differ. When this product is shipped as a component of an in vitro diagnostic medical device, exceptions that may be used include, but are not limited to, the following:
  - Chemical Kit
  - Excepted Quantity
  - Consumer Commodity

- **ADR**
  - **Excepted quantities (EQ)** Code: E1
    Maximum net quantity per inner packaging: 30 ml
    Maximum net quantity per outer packaging: 1000 ml

- **IMDG**
  - **Limited quantities (LQ)** 5L
  - **Excepted quantities (EQ)** Code: E1
    Maximum net quantity per inner packaging: 30 ml
    Maximum net quantity per outer packaging: 1000 ml

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**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: 67-56-1 Methanol
  - CAS: 7646-85-7 Zinc chloride

- **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.
Product name: ARCHITECT 25-OH Vitamin D Pretreatment 2

- Chemicals known to cause developmental reproductive toxicity:
  - CAS: 67-56-1 Methanol

16 Other information

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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 10/04/2018 / 12

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
- BEI: Biological Exposure Limit
- Flam. Liq. 3: Flammable liquids – Category 3
- Acute Tox. 4: Acute toxicity – Category 4
## Product name: ARCHITECT 25-OH Vitamin D Pretreatment 2

STOT SE 1: Specific target organ toxicity (single exposure) – Category 1

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

USA