**Release Date:** 10/11/18

| REF<br>GTIN | Product Name |
|---|---|
| **08P3121**<br>**08P3131**<br>**08P3132** | ***Alinity i Intact PTH Reagent Kit*** |

Components:

| | |
|---|---|
| **08P31G** | **Alinity i Intact PTH Microparticles** |
| **08P31H** | **Alinity i Intact PTH Conjugate** |
| **08P31J** | **Alinity i Intact PTH Assay Diluent** |

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.

# Safety Data Sheet

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## 1 Identification

· **Product name:** **Alinity i Intact PTH Microparticles**

· **ADD List number:** 08P31G

· **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

· **Precautionary statements:**
P501 Dispose of contents / container in accordance with local regulations.

· **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

# Safety Data Sheet

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**Product name: Alinity i Intact PTH Microparticles**

· **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: 26628-22-8 | Sodium azide | 0.10% |

## 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 ($CO_2$), water spray or regular foam.
- Caution: $CO_2$ 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.

*

## 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.

**Product name: Alinity i Intact PTH Microparticles**

· **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 (0.10 %)**

| | |
|---|---|
| REL | Ceiling limit value: 0.3** mg/m³, 0.1* ppm<br>*as HN3; **as NaN3; Skin |
| TLV | Ceiling limit value: 0.29** mg/m³, 0.11* ppm<br>*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.

# Safety Data Sheet

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**Product name: Alinity i Intact PTH Microparticles**

## 9 Physical and chemical properties

· **General Information**
· **Form:** Liquid
· **Color:** Orange

· **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)** 1.058 g/cm³ (8.829 lbs/gal)
· **Evaporation rate:** Not determined

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

· **Water:** 84.9 %
· **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:**
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.

**Product name: Alinity i Intact PTH Microparticles**

· **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:**
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 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).

**Product name: Alinity i Intact PTH Microparticles**

· **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.

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**Product name: Alinity i Intact PTH Microparticles**

| · **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** 10/11/2018 / 4

· **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.**

# Safety Data Sheet

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## 1 Identification

· **Product name:** **Alinity i Intact PTH Conjugate**

· **ADD List number:** 08P31H

· **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**

Eye Irrit. 2A H319 Causes serious eye irritation.

· **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:**
polyethylene glycol octylphenyl ether
Sodium azide

· **Hazard statements:**
H319 Causes serious eye irritation.

· **Precautionary statements:**

| | |
|---|---|
| P264 | Wash hands thoroughly after handling. |
| P280 | Wear protective gloves/protective clothing/eye protection. |
| P305+P351+P338 | If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P332+P313 | If skin irritation occurs: Get medical advice. |
| P337+P313 | If eye irritation persists: Get medical advice/attention. |

**Product name: Alinity i Intact PTH Conjugate**

P501 Dispose of contents / container in accordance with local regulations.

· **Routes of Exposure:** Eye
· **Hazard Overview**
· **Health:** Causes eye irritation
· **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: 9002-93-1 | polyethylene glycol octylphenyl ether | 1.00% |
| CAS: 26628-22-8 | Sodium azide | 0.10% |

## 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:** Eye irritation
· **Medical conditions aggravated by exposure:** 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.

**Product name: Alinity i Intact PTH Conjugate**

· **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.

## 7 Handling and storage

· **Precautions for safe handling:** Avoid contact with eyes.

· **Information about protection against explosions and fires:** The product is not flammable.

# Safety Data Sheet

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**Product name: Alinity i Intact PTH Conjugate**

· **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 remaining constituent has no known exposure limits.

| CAS: 26628-22-8 Sodium azide (0.10 %) | |
|---|---|
| REL | Ceiling limit value: 0.3** mg/m³, 0.1* ppm<br>*as HN3; **as NaN3; Skin |
| TLV | Ceiling limit value: 0.29** mg/m³, 0.11* ppm<br>*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.
Avoid contact with the eyes.

· **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.

**Product name: Alinity i Intact PTH Conjugate**

· **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 |
| · **Odor:** | Odorless |
| · **pH-value at 20 °C (68 °F)** | 6 |
| · **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)** | 1.013 g/cm³ (8.4535 lbs/gal) |
| · **Evaporation rate:** | Not determined |
| · **Solubility in / Miscibility with** | |
| · **Water:** | Fully miscible |
| · **Dynamic:** | Not determined |
| · **Water:** | 95.9 % |
| · **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:**
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.

**Product name: Alinity i Intact PTH Conjugate**

· **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: 9002-93-1 polyethylene glycol octylphenyl ether** | | |
| Oral | LD50 | 1,800 mg/kg (rat) |

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

· **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:** Eye

## 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
· **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).

· **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.

# Safety Data Sheet

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**Product name: Alinity i Intact PTH Conjugate**

## 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.

· **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** 10/11/2018 / 4

# Safety Data Sheet

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**Product name: Alinity i Intact PTH Conjugate**

· **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
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A

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

# Safety Data Sheet

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## 1 Identification

· **Product name:** **Alinity i Intact PTH Assay Diluent**

· **ADD List number:** 08P31J

· **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

· **Precautionary statements:**
P501 Dispose of contents / container in accordance with local regulations.

· **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

# Safety Data Sheet

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**Product name: Alinity i Intact PTH Assay Diluent**

· **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: 26628-22-8 | Sodium azide | 0.10% |

## 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.

*

## 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.

# Safety Data Sheet

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**Product name: Alinity i Intact PTH Assay Diluent**

· **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 (0.10 %)**

| | |
|---|---|
| REL | Ceiling limit value: 0.3** mg/m³, 0.1* ppm<br>*as HN3; **as NaN3; Skin |
| TLV | Ceiling limit value: 0.29** mg/m³, 0.11* ppm<br>*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.

# Safety Data Sheet

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**Product name: Alinity i Intact PTH Assay Diluent**

## 9 Physical and chemical properties

· **General Information**
· **Form:** Solution
· **Color:** Colorless

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 7.4
· **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)** 1.01 g/cm³ (8.4285 lbs/gal)
· **Evaporation rate:** Not determined

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

· **Water:** 98.1 %
· **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:**
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.

**Product name: Alinity i Intact PTH Assay Diluent**

· **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:**
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 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).

**Product name: Alinity i Intact PTH Assay Diluent**

· **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: Alinity i Intact PTH Assay Diluent**

| · **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.

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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** 10/11/2018 / 3

· **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)
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DOT: US Department of Transportation
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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.**