



Release Date: 5/31/18

REF	
GTIN	Product Name

08P9871	<i>Alinity c-series Maintenance Solutions Kit</i>
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Components:

08P98	c-series Water Bath Additive
08P98 POWDER	Alinity c-series Lyophilized Cleaning Solution (as sold)
08P98 SOLUTION	Alinity c-series Cleaning Solution (as sold)
08P98 RECONST	Alinity c-series Working Cleaning Solution (as used)

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.



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Safety Data Sheet

Last alteration on 05/08/2018

1 Identification

· **Product name:** **C-series Water Bath Additive**

· **ADD List number:** 08P98

· **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**

Acute Tox. 4 H302 Harmful if swallowed.
Acute Tox. 4 H332 Harmful if inhaled.
Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2A H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **Additional information:** Testing has been done on a similar material to determine the hazards.

· **Label elements**

· **GHS label elements:**

This product is subject to FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) requirements and therefore it is labelled accordingly. See Section 15 for FIFRA labeling requirements. The classification and labeling requirements per GHS are only present in the SDS.

The product is labelled according to the Globally Harmonized System (GHS).

· **Hazard pictograms:**



· **Signal word:** Warning

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

5-Chloro-2-methyl-4-isothiazolin-3-one



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Last alteration on 05/08/2018

Product name: c-series Water Bath Additive

2-Methyl-4-isothiazolin-3-one

· **Hazard statements:**

- H302+H332 Harmful if swallowed or if inhaled.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H317 May cause an allergic skin reaction.
- H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements:**

- P261 Avoid breathing mist / vapors / spray.
- P264 Wash hands thoroughly after handling.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection.
- P301+P312 If swallowed: Call a poison center/doctor if you feel unwell.
- P302+P352 If on skin: Wash with plenty of water.
- P304+P312 IF INHALED: Call a POISON CENTER/doctor if you feel unwell.
- 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/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P501 Dispose of contents / container in accordance with local regulations.

· **Additional information:**

This product is subject to FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) requirements and therefore it is labelled accordingly. Refer to Section 15 for FIFRA labeling requirements.

· **Routes of Exposure:**

- Skin
- Eye
- Inhalation

· **Hazard Overview**

· **Health:**

- Sensitizer in contact with skin
- Causes skin irritation
- Causes eye irritation
- Harmful if swallowed

· **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: 13446-18-9	Magnesium Nitrate Hexahydrate	1.60%
CAS: 26172-55-4	5-Chloro-2-methyl-4-isothiazolin-3-one	0.22%



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Product name: c-series Water Bath Additive

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

0.078%

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
Skin irritation
Eye irritation
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 eye ailments
Pre-existing skin ailments
Skin allergies

5 Fire-fighting measures

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

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Product name: c-series Water Bath Additive

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.

7 Handling and storage

· **Precautions for safe handling:**

Avoid contact with skin.

Avoid contact with eyes.

Avoid inhalation.

· **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.



Product name: c-series Water Bath Additive

· **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.

Avoid contact with the eyes.

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:** Colorless

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 3.9

· **Melting point/Melting range:** Not determined

· **Boiling point/Boiling range:** Not determined



Product name: c-series Water Bath Additive

· 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)	1.001 g/cm ³ (8.3533 lbs/gal)
· Evaporation rate:	Not determined
· Solubility in / Miscibility with	
· Water:	Fully miscible
· Dynamic:	Not determined
· Water:	97.6 %
· 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:** 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: 13446-18-9 Magnesium Nitrate Hexahydrate		
	Target Organ Effects	(human) By analogy to other magnesium salts, a mild irritant to eyes and nasal mucosa.
CAS: 26172-55-4 5-Chloro-2-methyl-4-isothiazolin-3-one		
Oral	LD50	60 mg/kg (mouse) 53 mg/kg (rat)
Dermal	LD50	>1,008 mg/kg (rat) (IUCLID Dataset)



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Product name: c-series Water Bath Additive

Inhalation	LC50 4 h	1.23 mg/l (rat) (IUCLID Dataset)
	Mutagenicity	(Ames Assay) (IUCLID Dataset)
	Target Organ Effects	(rabbit) (IUCLID Dataset)

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

Oral	LD50	60 mg/kg (mouse) By analogy to methylchloroisothiazolinone. 53 mg/kg (rat) By analogy to methylchloroisothiazolinone.
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- **Primary toxicological effects of the final product:**
 - **Skin irritation:** Irritating to skin and mucous membranes.
 - **Eye irritation:** Irritating.
- **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:**

Eye
Skin
Immune system

12 Ecological information

· **Aquatic toxicity:**

CAS: 26172-55-4 5-Chloro-2-methyl-4-isothiazolin-3-one

LC50 96 h	1.5 mg/l (other) (IUCLID Dataset) Species = Oncorhynchus mykiss (a freshwater fish)
LC50 48 h	4.71 mg/l (daphnia) (IUCLID Dataset) Value is actually an EC50, but variable is not available in database at this time.

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)



Product name: c-series Water Bath Additive

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

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.



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Product name: c-series Water Bath Additive

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: 13446-18-9 Magnesium Nitrate Hexahydrate

CAS: 10031-43-3 Copper (II) Nitrate Trihydrate

· **TSCA new (21st Century Act) (Substances not listed)**

CAS: 13446-18-9 Magnesium Nitrate Hexahydrate

· **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.

· **EPA (Environmental Protection Agency - USA):**

This product is subject to FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act) requirements. EPA registration number: 275-3

This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets, and for workplace labels of non-pesticide chemicals. Following is the hazard information as required on the pesticide label:

CAUTION

Causes moderate eye and skin irritation.

Harmful if swallowed or inhaled.

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

This chemical is toxic to terrestrial and aquatic plants, fish and aquatic invertebrates.

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



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Product name: c-series Water Bath Additive

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** 05/31/2018 / 13

· 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
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
Skin Sens. 1: Skin sensitisation – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

Safety Data Sheet

1 Identification

· **Product name:** **Alinity c-series Lyophilized Cleaning Solution (as sold)**

· **ADD List number:** 08P98 POWDER

· **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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2A H319 Causes serious eye irritation.

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

STOT SE 3 H335 May cause respiratory irritation.

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Danger

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

Protease enzyme from Aspergillus

· **Hazard statements:**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

· **Precautionary statements:**

P261 Avoid breathing dust.



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Product name: Alinity c-series Lyophilized Cleaning Solution (as sold)

- P264 Wash hands thoroughly after handling.
- P271 Use only outdoors or in a well-ventilated area.
- P280 Wear protective gloves/protective clothing/eye protection.
- P284 In case of inadequate ventilation wear respiratory protection.
- P302+P352 If on skin: Wash with plenty of water.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- 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/attention.
- P337+P313 If eye irritation persists: Get medical advice/attention.
- P342+P311 If experiencing respiratory symptoms: Call a poison center/doctor.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P501 Dispose of contents / container in accordance with local regulations.

· **Routes of Exposure:**

- Skin
- Eye
- Inhalation

· **Hazard Overview**

· **Health:**

- Causes skin irritation
- 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: 9074-07-1	Protease enzyme from Aspergillus	100.00%
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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:**

- Skin irritation



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Product name: Alinity c-series Lyophilized Cleaning Solution (as sold)

- Eye irritation
- Possibly immune response
- Respiratory irritation
- **Medical conditions aggravated by exposure:**
 - Pre-existing eye ailments
 - Pre-existing respiratory ailments
 - Pre-existing skin 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

Avoid formation of dust.

If material is released or spilled, minimize exposure by using appropriate personal protective equipment as listed in Section 8. Keep unprotected persons away.

· Environmental precautions

Prevent from entering sewage system, storm drains, surface waters, or soil.

· Methods and material for containment and cleaning up

Damp down dust with water spray.

Sweep up material and place into a suitable disposal container.

Vacuum (HEPA filter or equivalent recommended) or wet sweep products that are powders to avoid dust dispersal.

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.



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Product name: Alinity c-series Lyophilized Cleaning Solution (as sold)

7 Handling and storage

- **Precautions for safe handling:**
Ensure good ventilation in the workplace.
Avoid contact with skin.
Avoid contact with eyes.
Avoid inhalation.
Prevent formation of dust.
- **Information about protection against explosions and fires:**
The product is not flammable.
Combustible - finely divided dust may be explosive.
- **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.
Avoid contact with the eyes.
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.



Safety Data Sheet

Product name: Alinity c-series Lyophilized Cleaning Solution (as sold)

· **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 splatters 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:** Solid
- **Color:** Beige

- **Odor:** Odorless

- **pH-value:** Not applicable.
- **Melting point/Melting range:** Not determined
- **Boiling point/Boiling range:** Not determined

- **Flash point:** Not applicable
- **Flammability (solid, gaseous):** Not determined.
- **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:** Not determined
- **Evaporation rate:** Not applicable.

- **Solubility in / Miscibility with**
- **Water:** Soluble
- **Dynamic:** Not applicable.
- **Solids content:** 100,0 %

10 Stability and reactivity

· **Thermal decomposition / conditions to be avoided**

No decomposition if used and stored according to specifications.



Product name: Alinity c-series Lyophilized Cleaning Solution (as sold)

- **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: 9074-07-1 Protease enzyme from Aspergillus		
Oral	LD50	15,900 mg/kg (mouse) 14,400 mg/kg (rat)
	Target Organ Effects	(human) Protease compounds are known to be primary dermal and respiratory irritants. Proteases have been shown to cause bronchioconstriction and respiratory allergies in workers. Proteases have also been shown to cause dermal sensitization in hypersuseptible populations.
	Supplier Information	(guinea pig) LC50 6hr in guinea pigs pre-treated with four injections of 0.25 mg proteolytic enzyme derived from Bacillus subtilis (Subtilisin; 12% powder in Freund's adjuvant) 2 weeks prior to challenge by inhalation: 22.75 mg/m ³ , calculated as 12% crystalline active pure enzyme.

- **Primary toxicological effects of the final product:**
 - **Skin irritation:** Irritating to skin and mucous membranes.
 - **Eye irritation:** Irritating.
- **Sensitization:** Sensitization possible through inhalation.

- **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
Skin
Immune system



Product name: Alinity c-series Lyophilized Cleaning Solution (as sold)

Respiratory tract

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.
- **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.



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Safety Data Sheet

Last alteration on 05/08/2018

Product name: Alinity c-series Lyophilized Cleaning Solution (as sold)

· **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: 9074-07-1 | Protease enzyme from Aspergillus

· **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



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Safety Data Sheet

Last alteration on 05/08/2018

Product name: Alinity c-series Lyophilized Cleaning Solution (as sold)

Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 05/31/2018 / 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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

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

Resp. Sens. 1: Respiratory sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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



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Safety Data Sheet

Last alteration on 05/08/2018

1 Identification

· **Product name:** Alinity c-series Cleaning Solution (as sold)

· **ADD List number:** 08P98 SOLUTION

· **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



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Safety Data Sheet

Last alteration on 05/08/2018

Product name: Alinity c-series Cleaning Solution (as sold)

· **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%
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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.



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Safety Data Sheet

Last alteration on 05/08/2018

Product name: Alinity c-series Cleaning Solution (as sold)

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

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

· Environmental precautions

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

· Methods and material for containment and cleaning up

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

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

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

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

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

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

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.



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Safety Data Sheet

Last alteration on 05/08/2018

Product name: Alinity c-series Cleaning Solution (as sold)

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

· **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: Alinity c-series Cleaning Solution (as sold)

9 Physical and chemical properties

· General Information

· Form:	Solution
· Color:	Colorless

· Odor:	Odorless
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· pH-value at 20 °C (68 °F)	6.9
· 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 g/cm ³ (8.345 lbs/gal)
· Evaporation rate:	Not determined

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

· Water:	99.0 %
· 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.



Safety Data Sheet

Product name: Alinity c-series Cleaning Solution (as sold)

· **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).



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Safety Data Sheet

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Last alteration on 05/08/2018

Product name: Alinity c-series Cleaning Solution (as sold)

- **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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Safety Data Sheet

Last alteration on 05/08/2018

Product name: Alinity c-series Cleaning Solution (as sold)

· **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

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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 05/31/2018 / 4**

· **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

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


Safety Data Sheet

1 Identification

- **Product name:** Alinity c-series Working Cleaning Solution (as used)
- **ADD List number:** 08P98 RECONST
- **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**
Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- **Label elements**
 - **GHS label elements:** The product is labelled according to the Globally Harmonized System (GHS).
 - **Hazard pictograms:**

 - **Signal word:** Danger
 - **Hazard-determining components of labeling:**
Protease enzyme from Aspergillus
Sodium azide
 - **Hazard statements:**
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 - **Precautionary statements:**
P261 Avoid breathing mist / vapors / spray.
P284 In case of inadequate ventilation wear respiratory protection.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342+P311 If experiencing respiratory symptoms: Call a poison center/doctor.
P501 Dispose of contents / container in accordance with local regulations.
 - **Routes of Exposure:** Inhalation



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Safety Data Sheet

Last alteration on 05/08/2018

Product name: Alinity c-series Working Cleaning Solution (as used)

· **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.

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: 9074-07-1	Protease enzyme from Aspergillus	1.03%
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:**
Possibly immune response
Respiratory irritation
 - **Medical conditions aggravated by exposure:** Pre-existing respiratory 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.



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Safety Data Sheet

Last alteration on 05/08/2018

Product name: Alinity c-series Working Cleaning Solution (as used)

· **Protective equipment**

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

6 Accidental release measures

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

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

· **Environmental precautions**

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

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

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

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

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

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

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

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

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:**

Ensure good ventilation in the workplace.

Avoid inhalation.



Product name: Alinity c-series Working Cleaning Solution (as used)

- **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 remaining constituent has no known exposure limits.

CAS: 26628-22-8 Sodium azide (0.10 %)

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

- **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.
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.



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- **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 splatters 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)** 6.9
- **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:** 98.0 %
- **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



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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):		
CAS: 9074-07-1 Protease enzyme from Aspergillus		
Oral	LD50	15,900 mg/kg (mouse) 14,400 mg/kg (rat)
	Target Organ Effects	(human) Protease compounds are known to be primary dermal and respiratory irritants. Proteases have been shown to cause bronchioconstriction and respiratory allergies in workers. Proteases have also been shown to cause dermal sensitization in hypersuseptible populations.
	Supplier Information	(guinea pig) LC50 6hr in guinea pigs pre-treated with four injections of 0.25 mg proteolytic enzyme derived from Bacillus subtilis (Subtilisin; 12% powder in Freund's adjuvant) 2 weeks prior to challenge by inhalation: 22.75 mg/m ³ , calculated as 12% crystalline active pure enzyme.

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

· **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:**

Immune system



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Respiratory tract

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).
- **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



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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

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

CAS: 9074-07-1 Protease enzyme from Aspergillus

· 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



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· Department issuing SDS

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

· Contact

- General information about this product:
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Technical Support
100 Abbott Park Road
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Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 05/31/2018 / 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
Resp. Sens. 1: Respiratory sensitisation – Category 1

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