



Release Date: 7/19/18

REF	Product Name
GTIN	

09P1403	<i>Alinity c Lipid Multiconstituent Calibrator</i>
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Components:

09P14 AS SOLD	Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)
09P14 AS USED	Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

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

1 Identification

· **Product name:** **Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)**

· **ADD List number:** 09P14 AS SOLD

· **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 Corr. 1B H314 Causes severe skin burns and eye damage.

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

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

Aquatic Acute 3 H402 Harmful to aquatic life.

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

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Danger

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

2-Methyl-4-isothiazolin-3-one
Gentamicin sulfate

· **Hazard statements:**

H314 Causes severe skin burns and eye damage.

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

H317 May cause an allergic skin reaction.

H402 Harmful to aquatic life.



Product name: Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

- P260 Do not breathe dust.
- 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.
- P284 [In case of inadequate ventilation] wear respiratory protection.
- P301+P330+P331 If swallowed: Rinse mouth. Do NOT induce vomiting.
- P303+P361+P353 If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P310 Immediately call a poison center/doctor.
- P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
- P362+P364 Take off contaminated clothing and wash it before reuse.
- P391 Collect spillage.
- P501 Dispose of contents / container in accordance with local regulations.

Routes of Exposure:

- Skin
- Eye
- Inhalation

For bloodborne pathogens and potentially infectious materials:

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

Hazard Overview

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

Other hazards

This product contains potentially infectious material. Refer to the US OSHA Bloodborne pathogens standard (29 CFR 1910.1030) for additional relevant information.

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: 2682-20-4	2-Methyl-4-isothiazolin-3-one	0.69%
CAS: 1405-41-0	Gentamicin sulfate	0.17%



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Last alteration on 03/21/2018

Product name: Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)

4 First-aid measures

- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air or oxygen; seek immediate medical attention.
Remove from source of exposure. Seek medical attention and appropriate follow-up.
Symptoms (such as breathing difficulty) may be delayed and lead to underestimating the possible damage. Provide medical observation for at least 48 hours after exposure.
- **After skin contact:**
Take off any clothing that the product touched. Wash affected area with soap and water. Seek medical attention and appropriate follow-up.
Symptoms (such as pain) may be delayed and lead to underestimating the possible damage. Provide medical observation for at least 24 hours after exposure.
- **After eye contact:**
Rinse open eye(s) cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention and appropriate follow-up. Wash hands after handling.
Symptoms (such as pain) may be delayed and lead to underestimating the possible damage. Provide medical observation for at least 48 hours after exposure.
- **After swallowing:**
Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER or doctor/physician.
- **Information for Medical Personnel**
This product contains human-sourced and/or potentially infectious material. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced material should be considered potentially infectious.

The human-sourced material used in this product has been tested and found to be:

- Nonreactive for HBsAg (hepatitis B surface antigen)
- Nonreactive for HCV RNA (hepatitis C virus ribonucleic acid)
- Nonreactive for anti-HCV (antibodies to hepatitis C virus)
- Nonreactive for HIV-1 RNA (human immunodeficiency virus type 1 ribonucleic acid)
- Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)
- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)

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

- Allergic reactions
- Possible chemical burns to the skin and to the eyes
- Possibly immune response
- This product may cause skin sensitization reactions in some people. See Section 11 for additional information.
- Respiratory irritation

- **Medical conditions aggravated by exposure:**

- Pre-existing eye ailments
- Pre-existing respiratory ailments
- Pre-existing skin ailments
- Skin allergies



Safety Data Sheet

Product name: Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)

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

Handle as a potentially infectious material.

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

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

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

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.



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Product name: Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)

See Section 13 for disposal information.

7 Handling and storage

- **Precautions for safe handling:**
Handle as a potentially infectious material.
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 following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

CAS: 57-50-1 Sucrose, pure (55.17 %)

PEL	TWA: 15* 5** mg/m ³ *total dust **respirable fraction
REL	TWA: 10* 5** mg/m ³ *total dust **respirable fraction
TLV	TWA: 10 mg/m 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.

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

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.



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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:** Solid material.
- **Color:** White

- **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.



Product name: Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)

Solubility in / Miscibility with

- **Water:** Not miscible or difficult to mix
- **Dynamic:** Not applicable.

10 Stability and reactivity

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

11 Toxicological information

Acute toxicity

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

· Ingredients (100% pure substance/s):		
CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one		
Oral	LD50	60 mg/kg (mouse) By analogy to methylchloroisothiazolinone. 53 mg/kg (rat) By analogy to methylchloroisothiazolinone.

- **Primary toxicological effects of the final product:**
 - **Skin irritation:** Causes severe burns on skin and mucous membranes.
 - **Eye irritation:** Causes severe burns. Effects may be delayed.
- **Sensitization:**
Sensitization possible through inhalation.
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.



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Product name: Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)

· **Target organs/systems:**

- Eye
- Skin
- Immune system
- Respiratory tract

12 Ecological information

· **Aquatic toxicity:**

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

LC50 96 h	0.19 mg/l (trout) (Flow through)
LC50 48 h (Static)	0.056 mg/l (other) (Crustacean - Acartia tonsa)

· **Additional ecological information**

- **General notes:** Do not allow product 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. The following may be particularly important when identifying appropriate disposal:

- Potentially infectious. See Section 4, Information for Medical Personnel, for more information.
- See Section 6 for information when institutional or regulatory requirements include any sort of treatment of potentially infectious waste.

· **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



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Product name: Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)

· Environmental hazards

· Marine pollutant: No

· Additional information

· DOT

· Remarks: Not restricted for transportation.

· ADR

· Remarks: Not restricted for transportation.

· IMDG

· Remarks: Not restricted for transportation.

· IATA

· Remarks: Not restricted for transportation.

15 Regulatory information

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

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

The product does not contain listed substances.

· Section 313 (40CFR372.65):

The product does not contain listed substances.

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

CAS: 1405-41-0 | Gentamicin sulfate

· 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:

CAS: 1405-41-0 | Gentamicin sulfate

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: Alinity c Lipid Multiconstituent Calibrator (As Sold - Lyophilized)

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** 07/19/2018 / 8

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

Resp. Sens. 1: Respiratory sensitisation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

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

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

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



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Safety Data Sheet

Last alteration on 03/21/2018

1 Identification

· **Product name:** Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

· **ADD List number:** 09P14 AS USED

· **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.

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

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Warning

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

2-Methyl-4-isothiazolin-3-one

· **Hazard statements:**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

· **Precautionary statements:**

P261 Avoid breathing mist / vapors / spray.

P264 Wash hands thoroughly after handling.



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Last alteration on 03/21/2018

Product name: Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves/protective clothing/eye protection.
- P302+P352 If on skin: Wash with plenty of water.
- P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P333+P313 If skin irritation or rash 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.

· **Routes of Exposure:**

- Skin
- Eye

For bloodborne pathogens and potentially infectious materials:

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

· **Hazard Overview**

· **Health:**

- Sensitizer in contact with skin
- Causes skin irritation
- Causes eye irritation

· **Fire:** Noncombustible

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

· **Other hazards**

This product contains potentially infectious material. Refer to the US OSHA Bloodborne pathogens standard (29 CFR 1910.1030) for additional relevant information.

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: 2682-20-4	2-Methyl-4-isothiazolin-3-one	0.10%
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4 First-aid measures

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

· **After inhalation:** Remove from source of exposure. Seek medical attention and appropriate follow-up.

· **After skin contact:**

Take off any clothing that the product touched. Wash affected area with soap and water. Seek medical attention and appropriate follow-up.

· **After eye contact:**

Rinse open eye(s) cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention and appropriate follow-up. Wash hands after handling.



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Last alteration on 03/21/2018

Product name: Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

· **After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

· **Information for Medical Personnel**

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

The human-sourced material used in this product has been tested and found to be:

- Nonreactive for HBsAg (hepatitis B surface antigen)
- Nonreactive for HCV RNA (hepatitis C virus ribonucleic acid)
- Nonreactive for anti-HCV (antibodies to hepatitis C virus)
- Nonreactive for HIV-1 RNA (human immunodeficiency virus type 1 ribonucleic acid)
- Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)
- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)

· **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.

6 Accidental release measures

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

Handle as a potentially infectious material.

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



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Safety Data Sheet

Last alteration on 03/21/2018

Product name: Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

· 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

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

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

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:

Handle as a potentially infectious material.

Avoid contact with skin.

Avoid contact with eyes.

· **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.



Safety Data Sheet

Product name: Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

· **General protective and hygienic measures:**

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

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

Avoid contact with the skin.

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 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)** 7.4

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



Product name: Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

· 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)	1.033 g/cm ³ (8.6204 lbs/gal)
· Evaporation rate:	Not determined
· Solubility in / Miscibility with	
· Water:	Not miscible or difficult to mix
· Dynamic:	Not determined
· Solids content:	0.0 %

10 Stability and reactivity

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

11 Toxicological information

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

· Ingredients (100% pure substance/s):		
CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one		
Oral	LD50	60 mg/kg (mouse) By analogy to methylchloroisothiazolinone. 53 mg/kg (rat) By analogy to methylchloroisothiazolinone.

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



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Product name: Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

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

LC50 96 h	0.19 mg/l (trout) (Flow through)
LC50 48 h (Static)	0.056 mg/l (other) (Crustacean - Acartia tonsa)

· **Additional ecological information**

· **General notes:**

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

· **Results of PBT and vPvB assessment**

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

13 Disposal considerations

· **Recommendation for disposal of unused product:**

Dispose in accordance with federal, state and local regulations and institutional requirements. The following may be particularly important when identifying appropriate disposal:

- Potentially infectious. See Section 4, Information for Medical Personnel, for more information.
- See Section 6 for information when institutional or regulatory requirements include any sort of treatment of potentially infectious waste.

· **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.



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Product name: Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

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

14 Transport information

· **DOT, ADN, IMDG, IATA** none

· **UN proper shipping name**

· **DOT, ADR, ADN, IMDG, IATA** none

· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**

· **Class** none

· **DOT, IMDG, IATA** none

· **Environmental hazards**

· **Marine pollutant:** No

· **Additional information**

· **DOT**

· **Remarks:** Not restricted for transportation.

· **ADR**

· **Remarks:** Not restricted for transportation.

· **IMDG**

· **Remarks:** Not restricted for transportation.

· **IATA**

· **Remarks:** Not restricted for transportation.

15 Regulatory information

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

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

The product does not contain listed substances.

· **Section 313 (40CFR372.65):**

The product does not contain listed substances.

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

· **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.



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Safety Data Sheet

Last alteration on 03/21/2018

Product name: Alinity c Lipid Multiconstituent Calibrator (As Used - Reconstituted)

Chemicals known to cause developmental reproductive toxicity:

CAS: 1405-41-0 | Gentamicin sulfate

16 Other information

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Department issuing SDS

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

Contact

- General information about this product:
Abbott Diagnostics
Technical Support
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

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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
- Skin Sens. 1: Skin sensitisation – Category 1

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