Abbott

Release Date: 3/27/24

REF GTIN	Product Name
08P2821	***Alinity i HAVAb IgM Reagent Kit***

Components:

08P28G	**Alinity i HAVAb IgM Microparticles**
08P28H	**Alinity i HAVAb IgM Conjugate**
08P28J	**Alinity i HAVAb IgM Assay Diluent**

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

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

*

1 Identification

· **Product name:** Alinity i HAVAb IgM Microparticles

· **ADD List number:** 08P28G

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

· **Manufacturer / Supplier:**
Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

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

· **Emergency telephone number**
Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.
Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

2 Hazard(s) identification

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

Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Aquatic Acute 3	H402 Harmful to aquatic life.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Warning

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

· **Hazard statements:**
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements:**
P261 Avoid breathing mist / vapors / spray.

P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 If on skin: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents / container in accordance with local regulations.

· **Routes of Exposure:**
Skin

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)

· **Health:** 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: 145224-94-8	Morpholinoethanesulfonic acid, monohydrate	1.3954%
CAS: 55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	0.003%

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.

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Microparticles

· **Information for Medical Personnel**
This product contains human sourced and/or potentially infectious components. See package insert / instructions for use for details. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection.

· **Most important symptoms and effects, both acute and delayed:**
Allergic reactions
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.

· **Medical conditions aggravated by exposure:**
Pre-existing skin ailments
Skin allergies

5 Fire-fighting measures

· **Suitable extinguishing agents**
Dry chemical, carbon dioxide (CO_2), water spray or regular foam.
- Caution: CO_2 will displace air in confined spaces and may cause an oxygen-deficient atmosphere.
- For larger fires: There are no unique chemical or reactivity hazards that would impact firefighting decisions related to this product. Use firefighting measures that suit the environment.

· **Special hazards arising from the substance or mixture**
There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.
No further relevant information available.

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

6 Accidental release measures

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

· **Environmental precautions**
Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

· **Methods and material for containment and cleaning up**
Blot up small volumes of spilled or spattered product with paper towels or similar materials.
- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:
- warm water and detergent or similar cleansing agent

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.

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

· **Requirements to be met by storerooms and receptacles:** Store only in the original container.

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

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

8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**
The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

CAS: 7647-01-0 hydrochloric acid (0.0001 %)	
PEL	Ceiling limit value: 7 mg/m³, 5 ppm
REL	Ceiling limit value: 7 mg/m³, 5 ppm
TLV	Ceiling limit value: 2 ppm A4

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

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

Avoid contact with the skin.

Immediately remove all soiled and contaminated clothing.

· **Breathing equipment:**
Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate NIOSH-approved air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

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

· **Hand protection:**
Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· **Material of gloves and breakthrough time of the glove material:**
The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· **Eye protection:**
Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· **Body protection:**
Normal use: protect personal clothing from spatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution).
Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and chemical properties

· **General Information**	
· **Color:**	Red-brown
· **Odor:**	Odorless
· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Explosion limits**	
· **Lower:**	Not determined
· **Upper:**	Not determined
· **Flash point**	Not applicable
· **pH-value at 20 °C (68 °F)**	8.2
· **Dynamic:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Vapor pressure:**	
· **Density at 20 °C (68 °F)**	1.043 g/cm³ (8.7038 lbs/gal)

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Microparticles

· **Form:**	Liquid
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Water:**	88.8 %
· **Solids content:**	0.1 %
· **Evaporation rate:**	Not determined

10 Stability and reactivity

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

· **Possibility of hazardous reactions:** No dangerous reactions known.

· **Conditions to avoid:** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

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

· **Ingredients (100% pure substance/s):**		
CAS: 145224-94-8 Morpholinoethanesulfonic acid, monohydrate		
Oral	LD50	1,880 mg/kg (rat) By analogy to morpholinopropylchloride.

· **Sensitization:**
Sensitization possible through skin contact.
May cause an allergic skin reaction.
· **Aspiration hazard**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs/systems:**
Skin

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Microparticles

Immune system

12 Ecological information

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

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

· **Additional ecological information**
· **General notes:**
Do not allow product to reach ground water, water course, or sewage system.
Harmful to aquatic organisms.

13 Disposal considerations

· **Recommendation for disposal of unused product:**
Dispose in accordance with federal, state and local regulations and institutional requirements. 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.
· **Waste disposal key:**
· **Recommendation for disposal of packaging:**
Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.
For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

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

14 Transport information

· **DOT, ADN, IMDG, IATA** none

· **UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** none

· **Transport hazard class(es)**

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

· **Environmental hazards**
· **Marine pollutant:** No

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Microparticles

· **Additional information**

· **DOT**
· **Remarks:** Not restricted for transportation.
· **IMDG**
· **Remarks:** Not restricted for transportation.
· **IATA**
· **Remarks:** Not restricted for transportation.

15 Regulatory information

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

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

CAS: 7647-01-0	hydrochloric acid

· **Section 313 (40CFR372.65):**

CAS: 7647-01-0	hydrochloric acid

· **Hazardous Air Pollutants**

CAS: 7647-01-0	hydrochloric acid

· **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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Microparticles

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

· **Department issuing SDS**
- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

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

Phone: 1-877-4 ABBOTT

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

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Sensitization - Skin 1: Skin sensitisation – Category 1
Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

*

1 Identification

· **Product name:** Alinity i HAVAb IgM Conjugate

· **ADD List number:** 08P28H

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

· **Manufacturer / Supplier:**
Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

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

· **Emergency telephone number**
Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.
Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

2 Hazard(s) identification

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

Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Aquatic Acute 3	H402 Harmful to aquatic life.
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects.

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Warning

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

· **Hazard statements:**
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Conjugate

· **Precautionary statements:**
P261 Avoid breathing mist / vapors / spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection.
P302+P352 If on skin: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents / container in accordance with local regulations.

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

3 Composition/information on ingredients

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

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

CAS: 75621-03-3	3-[(3-Cholamidopropyl)dimethylammonio]-1-propanesulfonate	1.2886%
CAS: 55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	0.0034%

4 First-aid measures

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

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

· **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.

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

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

· **Most important symptoms and effects, both acute and delayed:**
Allergic reactions
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.
Skin irritation
Respiratory irritation

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Conjugate

· **Medical conditions aggravated by exposure:**
Pre-existing respiratory ailments
Pre-existing skin ailments
Skin allergies

5 Fire-fighting measures

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

· **Special hazards arising from the substance or mixture**
There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.
No further relevant information available.

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

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible. Keep unprotected persons away.

· **Environmental precautions**
Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

· **Methods and material for containment and cleaning up**
Blot up small volumes of spilled or spattered product with paper towels or similar materials.
- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:
- warm water and detergent or similar cleansing agent

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Conjugate

7 Handling and storage

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

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

· **Requirements to be met by storerooms and receptacles:** Store only in the original container.

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

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

8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

CAS: 68-12-2 N,N-dimethylformamide (0.0001 %)	
PEL	TWA: 30 mg/m³, 10 ppm Skin
REL	TWA: 30 mg/m³, 10 ppm Skin
TLV	TWA: 5 ppm Skin; BEI, A3
CAS: 7647-01-0 hydrochloric acid (0.0001 %)	
PEL	Ceiling limit value: 7 mg/m³, 5 ppm
REL	Ceiling limit value: 7 mg/m³, 5 ppm
TLV	Ceiling limit value: 2 ppm A4

· **Ingredients with biological limit values:**

CAS: 68-12-2 N,N-dimethylformamide (0.0001 %)	
BEI	30 mg/L Medium: urine Time: end of shift Parameter: Total N-Methylformamide (sum of N-Methylformamide and N-(Hydroxymethyl)-N-Methylformamide 30 mg/L Medium: urine Time: end of shift at end of workweek Parameter: N-Acetyl-S-(N-methylcarbamoyl) cysteine

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

Avoid contact with the skin.
Immediately remove all soiled and contaminated clothing.

· **Breathing equipment:**
Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

Small-volume spills (e.g. small enough to clean up with a paper towel or small sorbent pad) - respiratory protection should not be necessary if room is well ventilated.

Other unusual conditions (e.g. volume spilled too big to clean up with materials in arm's reach) - Use appropriate NIOSH-approved air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

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

· **Hand protection:**
Wear impervious gloves if hand contact with the material is anticipated. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.

· **Material of gloves and breakthrough time of the glove material:**
The glove material must be suitable for use in a microbiological laboratory and have a measured breakthrough time of at least 30 minutes, such as those with a Class 2 protection index per EN374 (or equivalent standard applicable in your region). NOTE: This recommendation applies only to the product stated in this Safety Data Sheet. When dissolving in or mixing with other substances, contact the supplier of approved gloves.

· **Eye protection:**
Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· **Body protection:**
Normal use: protect personal clothing from spatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution).
Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and chemical properties

· **General Information**	
· **Color:**	Colorless
· **Odor:**	Odorless
· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Explosion limits**	
· **Lower:**	Not determined
· **Upper:**	Not determined
· **Flash point**	Not applicable
· **pH-value at 20 °C (68 °F)**	6.6
· **Dynamic:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Conjugate

· **Vapor pressure:**	
· **Density at 20 °C (68 °F)**	1.027 g/cm³ (8.5703 lbs/gal)
· **Form:**	Liquid
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Water:**	93.0 %
· **Solids content:**	0.0 %
· **Evaporation rate:**	Not determined

10 Stability and reactivity

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

· **Possibility of hazardous reactions:** No dangerous reactions known.

· **Conditions to avoid:** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** No dangerous decomposition products known.

*

11 Toxicological information

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

· **Ingredients (100% pure substance/s):**		
CAS: 75621-03-3 3-[(3-Cholamidopropyl)dimethylammonio]-1-propanesulfonate		
Oral	LD50	380 mg/kg (rat)

· **Sensitization:**
Sensitization possible through skin contact.
May cause an allergic skin reaction.
· **Aspiration hazard**

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.

· **NTP (National Toxicology Program)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Target organs/systems:**
Skin
Respiratory tract

Skin
Immune system

12 Ecological information

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

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

· **Additional ecological information**
· **General notes:**
Do not allow product to reach ground water, water course, or sewage system.
Harmful to aquatic organisms.

13 Disposal considerations

· **Recommendation for disposal of unused product:** Dispose in accordance with federal, state and local regulations.
· **Waste disposal key:**
· **Recommendation for disposal of packaging:**
Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.
For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

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

14 Transport information

· **DOT, ADN, IMDG, IATA**	none

· **UN proper shipping name**
· **DOT, ADR, ADN, IMDG, IATA** none

· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**

· **Class**	none
· **DOT, IMDG, IATA**	none

· **Environmental hazards**
· **Marine pollutant:** No

· **Additional information**

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Conjugate

· **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: 7647-01-0	hydrochloric acid

· **Section 313 (40CFR372.65):**

CAS: 68-12-2	N,N-dimethylformamide
CAS: 7647-01-0	hydrochloric acid

· **Hazardous Air Pollutants**

CAS: 68-12-2	N,N-dimethylformamide
CAS: 7647-01-0	hydrochloric acid

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

· **Chemicals known to cause cancer:**

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

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

16 Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

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

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Conjugate

· **Department issuing SDS**
- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

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

Phone: 1-877-4 ABBOTT

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

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
BEI: Biological Exposure Limit
Sensitization - Skin 1: Skin sensitisation – Category 1
Aquatic Acute 3: Hazardous to the aquatic environment - acute aquatic hazard – Category 3
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

*

1 Identification

· **Product name:** Alinity i HAVAb IgM Assay Diluent

· **ADD List number:** 08P28J

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

· **Manufacturer / Supplier:**
Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

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

· **Emergency telephone number**
Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.
Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

2 Hazard(s) identification

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

Eye Irritation 2A	H319 Causes serious eye irritation.
Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Aquatic Acute 2	H401 Toxic to aquatic life.
Aquatic Chronic 2	H411 Toxic to aquatic life with long lasting effects.

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Warning

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

· **Hazard statements:**
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

H411 Toxic 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.
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.
P391	Collect spillage.
P501	Dispose of contents / container in accordance with local regulations.

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

3 Composition/information on ingredients

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

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

CAS: 9002-93-1	polyethylene glycol octylphenyl ether	1.0669%
CAS: 26628-22-8	Sodium azide	0.0191%
CAS: 55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)	0.0027%

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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Assay Diluent

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

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

· **Most important symptoms and effects, both acute and delayed:**
Allergic reactions
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.
No further relevant information available.

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

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Minimize exposure by using appropriate personal protective equipment as listed in Section 8. Stop leak if possible.
Keep unprotected persons away.

· **Environmental precautions**
Prevent liquid and vapor from entering sewage system, storm drains, surface waters, and soil.

· **Methods and material for containment and cleaning up**
Blot up small volumes of spilled or spattered product with paper towels or similar materials.
- Contain larger spills by placing absorbants around the outside edges of the spill. Absorb with any material suitable for water-based liquids - e.g. paper towels, universal sorbents, sand, diatomite, sawdust, etc.

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

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

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

Dispose of spilled and contaminated material in accordance with Federal, State, and Local regulations. See Section 13 for information that may impact disposal of materials contaminated with this product.

· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

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

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

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

8 Exposure controls/personal protection

· **Components with Occupational Exposure Limits**
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
At this time, the other constituents have no known exposure limits.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Assay Diluent

CAS: 26628-22-8 Sodium azide (0.0191 %)	
REL	Ceiling limit value: 0.3** mg/m³, 0.1* ppm *as HN3; **as NaN3; Skin
TLV	Ceiling limit value: 0.29** mg/m³, 0.11* ppm *as HN3 vapor **as NaN3, A4
CAS: 7647-01-0 hydrochloric acid (0.0001 %)	
PEL	Ceiling limit value: 7 mg/m³, 5 ppm
REL	Ceiling limit value: 7 mg/m³, 5 ppm
TLV	Ceiling limit value: 2 ppm A4

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

Avoid contact with the skin.
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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Assay Diluent

9 Physical and chemical properties

· **General Information**	
· **Color:**	Colorless
· **Odor:**	Odorless
· **Melting point/Melting range:**	Not determined
· **Boiling point/Boiling range:**	Not determined
· **Explosion limits**	
· **Lower:**	Not determined
· **Upper:**	Not determined
· **Flash point**	Not applicable
· **pH-value at 20 °C (68 °F)**	8
· **Dynamic:**	Not determined
· **Solubility in / Miscibility with**	
· **Water:**	Fully miscible
· **Vapor pressure:**	
· **Density at 20 °C (68 °F)**	1.02 g/cm³ (8.5119 lbs/gal)
· **Form:**	Liquid
· **Auto igniting**	Product is not self-igniting.
· **Danger of explosion**	Product does not present an explosion hazard.
· **Water:**	<95.9 %
· **Solids content:**	0.0 %
· **Evaporation rate:**	Not determined

10 Stability and reactivity

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

· **Possibility of hazardous reactions:**
This product contains sodium azide. Sodium azide solutions are reported to:
- react with acids to release hydrazoic acid, a very toxic gas. Higher quantities of hydrazoic acid are released as the solution becomes more acidic (i.e., as the pH of the solution gets lower). Low quantities of hydrazoic acid can be released from sodium azide in water.
- react with certain metals (copper, lead, silver, brass) to form explosive metal azide compounds. Violent explosions have been reported during plumbing work on drain systems containing accumulations of azide on copper, lead, brass, or solder.

· **Conditions to avoid:** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** No dangerous decomposition products known.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Assay Diluent

11 Toxicological information

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

· **Ingredients (100% pure substance/s):**		
CAS: 9002-93-1 polyethylene glycol octylphenyl ether		
Oral	LD50	1,800 mg/kg (rat)

· **Eye irritation:** Causes serious eye irritation.

· **Sensitization:**
Sensitization possible through skin contact.
May cause an allergic skin reaction.

· **Additional toxicological information:**
Endocrine disrupting effects caused by this substance have been observed in the environment. No adverse human health effects are known. See Section 12 for more information.

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

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

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

OPnEO, either directly, downstream of the effluent, or in the longer term after its adsorption to sediment and soil. Similar holds true for pelagic organisms such as fish which may be exposed via remobilisation of 4-tert-OP from sediment to the water body.

· **General notes:**
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Toxic for aquatic organisms

13 Disposal considerations

· **Recommendation for disposal of unused product:**
Dispose in accordance with federal, state and local regulations and institutional requirements. Waste containing this product may be considered hazardous per U.S. EPA, state or local regulations. The following may be particularly important when identifying appropriate disposal:
- Contains sodium azide. See Section 10 when considering how to appropriately dispose of unused product. For drain systems with pipes or solder containing copper, lead, brass and/or silver, flush drains thoroughly with copious amounts of water to prevent the formation of potentially explosive metal azides in plumbing. Detailed information about azides in drains is available from the U.S. NIOSH Current Intelligence Bulletin No. 13 (August 16, 1976).

· **Waste disposal key:**

· **Recommendation for disposal of packaging:**
Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies. For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

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

14 Transport information

· **DOT**	none
· **IMDG, IATA**	UN3082

· UN proper shipping name

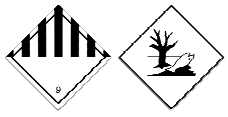
· **DOT**	none
· **ADR, IATA**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (polyethylene glycol octylphenyl ether)
· **IMDG**	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (polyethylene glycol octylphenyl ether), MARINE POLLUTANT

· Transport hazard class(es)

· **DOT**

· **Class**	none
· **Class**	9 Miscellaneous dangerous substances and articles

· **IMDG, IATA**



· **Class**	9 Miscellaneous dangerous substances and articles

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Assay Diluent

· **Label**	9
· **DOT**	none
· **IMDG, IATA**	III

· **Environmental hazards**

· **Marine pollutant:**	Symbol (fish and tree)
· **Special marking (IATA):**	Symbol (fish and tree)
· **EMS Number:**	F-A,S-F
· **Segregation groups**	(SGG17) Azides
· **Stowage Category**	A

· **Additional information** Packages smaller than or equal to 5 kg / 5L; not dangerous goods of Class 9.

· **DOT**	
· **Remarks:**	Not restricted for transportation.
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **IMDG**	
· **Limited quantities (LQ)**	5L
· **Excepted quantities (EQ)**	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
· **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
CAS: 7647-01-0	hydrochloric acid

· **Section 313 (40CFR372.65):**

CAS: 26628-22-8	Sodium azide
CAS: 7647-01-0	hydrochloric acid

· **Hazardous Air Pollutants**

CAS: 7647-01-0	hydrochloric acid

· **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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Assay Diluent

· **Chemicals known to cause male reproductive toxicity:**
None of the ingredients is listed.

· **Chemicals known to cause developmental reproductive toxicity:**
None of the ingredients is listed.

16 Other information

The information and recommendations contained herein are based upon information or tests believed to be reliable. Abbott Laboratories does not guarantee the accuracy or completeness of this information or recommendations contained herein, NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

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

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

· **Department issuing SDS**
- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

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

Phone: 1-877-4 ABBOTT

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

· **Abbreviations and acronyms:**
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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 03/27/2024 Last alteration on 03/27/2024

Product name: Alinity i HAVAb IgM Assay Diluent

Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Sensitization - Skin 1: Skin sensitisation – Category 1
Aquatic Acute 2: Hazardous to the aquatic environment - acute aquatic hazard – Category 2
Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

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