



Release Date: 7/19/18

REF	Product Name
GTIN	
07P5020 07P5030	<i>Alinity i Estradiol Reagent Kit</i>

Components:

07P50G	Alinity i Estradiol Microparticles
07P50H	Alinity i Estradiol Conjugate
07P50J	Alinity i Estradiol Assay Diluent
07P50U	Alinity i Estradiol Specimen 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

1 Identification

· **Product name:** Alinity i Estradiol Microparticles

· **ADD List number:** 07P50G

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

· **Manufacturer / Supplier:**

Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

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

· **Emergency telephone number**

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

2 Hazard(s) identification

· **Classification of the substance or mixture**

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

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Warning

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

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

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

· **Hazard statements:**

H317 May cause an allergic skin reaction.

· **Precautionary statements:**

P261 Avoid breathing mist / vapors / spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

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.



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Last alteration on 07/19/2018

Product name: Alinity i Estradiol Microparticles

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

3 Composition/information on ingredients

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

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

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)	0.0031%
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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. If irritation or signs of toxicity occur, seek medical attention.
- **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **Information for Medical Personnel**
 - **Most important symptoms and effects, both acute and delayed:**
Allergic reactions
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.
 - **Medical conditions aggravated by exposure:**
Pre-existing skin ailments
Skin allergies

5 Fire-fighting measures

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



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Product name: Alinity i Estradiol Microparticles

to this product. Use firefighting measures that suit the environment.

- **Special hazards arising from the substance or mixture**

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

- **Protective equipment**

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

6 Accidental release measures

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

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

- **Environmental precautions**

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

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

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

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

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

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

- **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

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

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

- **Requirements to be met by storerooms and receptacles:**

Store only in the original container.

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

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

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



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Last alteration on 07/19/2018

Product name: Alinity i Estradiol Microparticles

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 remaining constituent has no known exposure limits.

CAS: 25322-68-3 Polyethylene glycol (0.0061 %)

WEEL TWA: 10 mg/m³
(H); MW>200

CAS: 556-67-2 octamethylcyclotetrasiloxane (0.0025 %)

WEEL TWA: 10* ppm
*OARS WEEL

· 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.



Product name: Alinity i Estradiol Microparticles

· **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:** Brown

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 6.5
· **Melting point/Melting range:** Not determined
· **Boiling point/Boiling range:** Not determined

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

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

· **Density at 20 °C (68 °F)** 1.069 g/cm³ (8.9208 lbs/gal)
· **Evaporation rate:** Not determined

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

· **Water:** 86.5 %
· **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.



Product name: Alinity i Estradiol Microparticles

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

11 Toxicological information

· **Acute toxicity**

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

· **Additional toxicological information:** None

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Target organs/systems:**

Skin
Immune system

12 Ecological information

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

· **Additional ecological information**

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

· **Results of PBT and vPvB assessment**

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

13 Disposal considerations

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

Dispose in accordance with federal, state and local regulations.

· **Recommendation for disposal of packaging:**

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.



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Product name: Alinity i Estradiol Microparticles

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

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

14 Transport information

- **DOT, ADN, IMDG, IATA** none

- **UN proper shipping name**

- **DOT, ADR, ADN, IMDG, IATA** none

- **Transport hazard class(es)**

- **DOT, ADR, ADN, IMDG, IATA**

- **Class** none

- **DOT, IMDG, IATA** none

- **Environmental hazards**

- **Marine pollutant:** No

- **Additional information**

- **DOT**

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

- **ADR**

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

- **IMDG**

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

- **IATA**

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

15 Regulatory information

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

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

The product does not contain listed substances.

- **Section 313 (40CFR372.65):**

The product does not contain listed substances.

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

CAS: 55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)
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- **California Proposition 65 (USA):**

- **Chemicals known to cause cancer:**

The product does not contain listed substances.

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Product name: Alinity i Estradiol Microparticles**Chemicals known to cause female reproductive toxicity:**

None of the ingredients is listed.

Chemicals known to cause male reproductive toxicity:

None of the ingredients is listed.

Chemicals known to cause developmental reproductive toxicity:

None of the ingredients is listed.

16 Other information

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Department issuing SDS

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

Contact

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

Phone: 1-877-4 ABBOTT

• **Date of preparation / last revision** 07/19/2018 / 31

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value



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Product name: Alinity i Estradiol Microparticles

PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Sens. 1: Skin sensitisation – Category 1

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

USA

Safety Data Sheet

1 Identification

· **Product name:** Alinity i Estradiol Conjugate

· **ADD List number:** 07P50H

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

· **Manufacturer / Supplier:**

Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

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

· **Emergency telephone number**

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

2 Hazard(s) identification

· **Classification of the substance or mixture**

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

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Warning

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

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

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

· **Hazard statements:**

H317 May cause an allergic skin reaction.

· **Precautionary statements:**

P261 Avoid breathing mist / vapors / spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

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.



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Last alteration on 07/19/2018

Product name: Alinity i Estradiol Conjugate

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

3 Composition/information on ingredients

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

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

CAS: 8047-15-2	Saponin	2.26%
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)	0.0029%

4 First-aid measures

- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:** Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.
- **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **Information for Medical Personnel**
 - **Most important symptoms and effects, both acute and delayed:**
Allergic reactions
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.
Skin irritation
Respiratory irritation
 - **Medical conditions aggravated by exposure:**
Pre-existing respiratory ailments
Pre-existing eye ailments
Pre-existing skin ailments



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Safety Data Sheet

Last alteration on 07/19/2018

Product name: Alinity i Estradiol Conjugate

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

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

· Environmental precautions

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

· Methods and material for containment and cleaning up

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

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

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

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

· Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

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

- **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.



Product name: Alinity i Estradiol Conjugate

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 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 (0.0063 %)

PEL	TWA: 30 mg/m ³ , 10 ppm Skin
REL	TWA: 30 mg/m ³ , 10 ppm Skin
TLV	TWA: (30) NIC-15 mg/m ³ , (10) NIC-5 ppm NIC-A3; Skin; BEI

CAS: 25322-68-3 Polyethylene glycol (0.0026 %)

WEEL	TWA: 10 mg/m ³ (H); MW>200
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CAS: 556-67-2 octamethylcyclotetrasiloxane (0.001 %)

WEEL	TWA: 10* ppm *OARS WEEL
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· Ingredients with biological limit values:

CAS: 68-12-2 N,N-dimethylformamide (0.0063 %)

BEI	15 mg/L Medium: urine Time: end of shift Parameter: N-Methylformamide
	40 mg/L Medium: urine Time: prior to last shift of workweek Parameter: N-Acetyl-S-(N-methylcarbamoyl) cysteine (semi-quantitative)

· 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.



Safety Data Sheet

Product name: Alinity i Estradiol Conjugate

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

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

· **Hand protection:**

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

· **Material of gloves and breakthrough time of the glove material:**

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

· **Eye protection:**

Wear safety glasses or other protective eyewear. If splash potential exists, wear full face shield or goggles.

· **Body protection:**

Normal use: protect personal clothing from spatters and small spills. Wear a laboratory coat (or other protective clothing required by your institution).

Larger spills (e.g. that can saturate cloth): wear appropriate water-repellant covering over clothing.

9 Physical and chemical properties

· **General Information**

· **Form:** Liquid
· **Color:** Colorless

· **Odor:** Odorless

· **pH-value at 20 °C (68 °F)** 5

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

· **Flash point** Not applicable

· **Flammability (solid, gaseous)** Not applicable

· **Auto igniting** Product is not self-igniting.

· **Danger of explosion** Product does not present an explosion hazard.

· **Explosion limits**

· **Lower:** Not determined
· **Upper:** Not determined

· **Density at 20 °C (68 °F)** 1.131 g/cm³ (9.4382 lbs/gal)

· **Evaporation rate:** Not determined

· **Solubility in / Miscibility with**

· **Water:** Fully miscible



Product name: Alinity i Estradiol Conjugate

· Dynamic:	Not determined
· Water:	81.1 %
· Solids content:	0.0 %

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided**
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions:** 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: 8047-15-2 Saponin		
Oral	LDLo	3,000 mg/kg (mouse)
Dermal	LDLo	900 mg/kg (mouse)
	Target Organ Effects	Subcutaneous. Glycosides are powerful hemolytics when injected into the bloodstream, causing destruction of red blood cells. (mammal) Causes severe destruction to tissues of the mucous membranes and upper respiratory tract. Symptoms include a burning sensation, coughing, wheezing, laryngitis, shortness of breath, headache, nausea and vomiting. Severe cases may be fatal as a result of spasms, inflammation and edema of the larynx and bronchi, chemical pneumonitis and pulmonary edema.

- **Primary toxicological effects of the final product:**
 - **Skin irritation:** No irritant effect.
 - **Eye irritation:** No irritant effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** None
- **Carcinogenic categories**

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



Product name: Alinity i Estradiol Conjugate

· **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
- Hematopoietic system
- Eye
- Skin
- Immune system

12 Ecological information

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

· **Additional ecological information**

· **General notes:**

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

· **Results of PBT and vPvB assessment**

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

13 Disposal considerations

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

Dispose in accordance with federal, state and local regulations.

· **Recommendation for disposal of packaging:**

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

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

14 Transport information

· **DOT, ADN, IMDG, IATA** none

· **UN proper shipping name**

· **DOT, ADR, ADN, IMDG, IATA** none

· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**

· **Class** none



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Last alteration on 07/19/2018

Product name: Alinity i Estradiol Conjugate

· 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):

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

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

CAS: 8047-15-2 | Saponin

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

· California Proposition 65 (USA):

· Chemicals known to cause cancer:

The product does not contain listed substances.

· 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,



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Product name: Alinity i Estradiol Conjugate

OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE.

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

· Department issuing SDS

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

· Contact

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

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision 07/19/2018 / 32**

· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
BEI: Biological Exposure Limit
Skin Sens. 1: Skin sensitisation – Category 1

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

Safety Data Sheet

1 Identification

· **Product name:** Alinity i Estradiol Assay Diluent

· **ADD List number:** 07P50J

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

· **Manufacturer / Supplier:**

Abbott Diagnostics
100 Abbott Park Road
Abbott Park, IL 60064-3500

Phone: 1-877-4 ABBOTT

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

· **Emergency telephone number**

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to Abbott customer number 675805.

- Telephone (800) 424-9300 (toll-free) if you are calling from within the United States, Canada, Puerto Rico and the Virgin Islands.

- Telephone +1 (703) 527-3887, the international and maritime number (collect calls accepted), if you are calling from outside the United States or from a ship at sea.

2 Hazard(s) identification

· **Classification of the substance or mixture**

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

· **Label elements**

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

· **Hazard pictograms:**



· **Signal word:** Warning

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

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

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

· **Hazard statements:**

H317 May cause an allergic skin reaction.

· **Precautionary statements:**

P261 Avoid breathing mist / vapors / spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

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.



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Last alteration on 07/19/2018

Product name: Alinity i Estradiol Assay Diluent

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

3 Composition/information on ingredients

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

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

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%
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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. If irritation or signs of toxicity occur, seek medical attention.
- **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **Information for Medical Personnel**
 - **Most important symptoms and effects, both acute and delayed:**
Allergic reactions
Possibly immune response
This product may cause skin sensitization reactions in some people. See Section 11 for additional information.
 - **Medical conditions aggravated by exposure:**
Pre-existing skin ailments
Skin allergies

5 Fire-fighting measures

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



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Safety Data Sheet

Last alteration on 07/19/2018

Product name: Alinity i Estradiol Assay Diluent

to this product. Use firefighting measures that suit the environment.

- **Special hazards arising from the substance or mixture**

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

- **Protective equipment**

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

6 Accidental release measures

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

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

- **Environmental precautions**

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

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

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

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

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

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

- **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7 Handling and storage

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

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

- **Requirements to be met by storerooms and receptacles:**

Store only in the original container.

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

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

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



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Last alteration on 07/19/2018

Product name: Alinity i Estradiol Assay Diluent

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 remaining constituent has no known exposure limits.

CAS: 64-17-5 Ethanol (0.093 %)

PEL	TWA: 1900 mg/m ³ , 1000 ppm
REL	TWA: 1900 mg/m ³ , 1000 ppm
TLV	STEL/C: 1880 mg/m ³ , 1000 ppm

CAS: 25322-68-3 Polyethylene glycol (0.0012 %)

WEEL	TWA: 10 mg/m ³ (H); MW>200
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CAS: 556-67-2 octamethylcyclotetrasiloxane (0.00047 %)

WEEL	TWA: 10* ppm *OARS WEEL
------	----------------------------

· 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.



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Last alteration on 07/19/2018

Product name: Alinity i Estradiol Assay Diluent

· **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)** 4.5
· **Melting point/Melting range:** Not determined
· **Boiling point/Boiling range:** Not determined

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

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

· **Density at 20 °C (68 °F)** 1.035 g/cm³ (8.6371 lbs/gal)
· **Evaporation rate:** Not determined

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

· **Water:** 93.7 %
· **Solids content:** 0.0 %

10 Stability and reactivity

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



Product name: Alinity i Estradiol Assay Diluent

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

11 Toxicological information

· **Acute toxicity**

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

· **Additional toxicological information:** None

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

· **Target organs/systems:**

- Skin
- Immune system

12 Ecological information

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

· **Additional ecological information**

· **General notes:**

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

· **Results of PBT and vPvB assessment**

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

13 Disposal considerations

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

Dispose in accordance with federal, state and local regulations.

· **Recommendation for disposal of packaging:**

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.



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Last alteration on 07/19/2018

Product name: Alinity i Estradiol Assay Diluent

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

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

14 Transport information

- **DOT, ADN, IMDG, IATA** none

- **UN proper shipping name**

- **DOT, ADR, ADN, IMDG, IATA** none

- **Transport hazard class(es)**

- **DOT, ADR, ADN, IMDG, IATA**

- **Class** none

- **DOT, IMDG, IATA** none

- **Environmental hazards**

- **Marine pollutant:** No

- **Additional information**

- **DOT**

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

- **ADR**

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

- **IMDG**

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

- **IATA**

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

15 Regulatory information

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

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

The product does not contain listed substances.

- **Section 313 (40CFR372.65):**

The product does not contain listed substances.

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

CAS: 55965-84-9	Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1); reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)
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- **California Proposition 65 (USA):**

- **Chemicals known to cause cancer:**

The product does not contain listed substances.

Safety Data Sheet

Product name: Alinity i Estradiol Assay Diluent**· Chemicals known to cause female reproductive toxicity:**

None of the ingredients is listed.

· Chemicals known to cause male reproductive toxicity:

None of the ingredients is listed.

· Chemicals known to cause developmental reproductive toxicity:

None of the ingredients is listed.

16 Other information

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

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

· Department issuing SDS

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

· Contact

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

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision** 07/19/2018 / 28

· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value



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Last alteration on 07/19/2018

Product name: Alinity i Estradiol Assay Diluent

PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Skin Sens. 1: Skin sensitisation – Category 1

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

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Safety Data Sheet

Last alteration on 07/19/2018

1 Identification

· **Product name:** Alinity i Estradiol Specimen Diluent

· **ADD List number:** 07P50U

· **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**

Repr. 2 H361 Suspected of damaging fertility or the unborn child.

· **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:**

Diethylenetriamine-pentaacetic acid
Sodium azide

· **Hazard statements:**

H361 Suspected of damaging fertility or the unborn child.

· **Precautionary statements:**

P201 Obtain special instructions before use.
P280 Wear protective gloves/protective clothing/eye protection.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P501 Dispose of contents / container in accordance with local regulations.

· **Routes of Exposure:**

- Skin: No adverse effects expected when used as directed.
- Eye: No adverse effects expected when used as directed.



Product name: Alinity i Estradiol Specimen Diluent

- Inhalation: No adverse effects expected when used as directed.
- Ingestion: No adverse effects expected when used as directed.
- **Hazard Overview**
 - **Health:** Possible risk of harm to the unborn child
 - **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: 77-86-1	Tris hydroxymethyl aminomethane	1.11%
CAS: 67-43-6	Diethylenetriamine-pentaacetic acid	0.72%
CAS: 26628-22-8	Sodium azide	0.18%

4 First-aid measures

- **After inhalation:** Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.
- **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/attention. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **Information for Medical Personnel**
 - **Most important symptoms and effects, both acute and delayed:** Kidney effects
 - **Medical conditions aggravated by exposure:**
 - Pre-existing respiratory ailments
 - Pre-existing kidney ailments
 - Pregnancy

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.



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Safety Data Sheet

Last alteration on 07/19/2018

Product name: Alinity i Estradiol Specimen Diluent

· **Special hazards arising from the substance or mixture**

There are no unique chemical or reactivity hazards that would impact firefighting decisions due to the chemicals in this product.

· **Protective equipment**

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

6 Accidental release measures

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

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

· **Environmental precautions**

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

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

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

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

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

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

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

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

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

· **Reference to other sections**

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.



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Safety Data Sheet

Last alteration on 07/19/2018

Product name: Alinity i Estradiol Specimen Diluent

7 Handling and storage

- **Precautions for safe handling:** Provide local exhaust ventilation if dust or vapor is formed.
- **Information about protection against explosions and fires:** The product is not flammable.
- **Requirements to be met by storerooms and receptacles:**
Store only in the original container.
Refer to the package insert or product label for additional information on storage conditions for product quality.
- **Information about storage in one common storage facility:** Store in original packaging.
- **Further information about storage conditions:** Protect from heat and direct sunlight.

8 Exposure controls/personal protection

Components with Occupational Exposure Limits

The following 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: 26628-22-8 Sodium azide (0.18 %)

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

CAS: 25322-68-3 Polyethylene glycol (0.00076 %)

WEEL TWA: 10 mg/m³
(H); MW>200

CAS: 556-67-2 octamethylcyclotetrasiloxane (0.0003 %)

WEEL TWA: 10* ppm
*OARS WEEL

General protective and hygienic measures:

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

Breathing equipment:

Normal use and storage of product - respiratory protection is not necessary if room is well ventilated.

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

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

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



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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:** Yellow

· **Odor:** Odorless

pH-value at 20 °C (68 °F)

8

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

· **Flash point** Not applicable

· **Flammability (solid, gaseous)** Not applicable

· **Auto igniting** Product is not self-igniting.

· **Danger of explosion** Product does not present an explosion hazard.

Explosion limits

· **Lower:** Not determined
· **Upper:** Not determined

Density at 20 °C (68 °F)

1.026 g/cm³ (8.562 lbs/gal)

· **Evaporation rate:** Not determined

Solubility in / Miscibility with

· **Water:** Fully miscible
· **Dynamic:** Not determined

· **Water:** 91.6 %

· **Solids content:** 0.0 %



Product name: Alinity i Estradiol Specimen Diluent

10 Stability and reactivity

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

No decomposition if used and stored according to specifications.

· **Possibility of hazardous reactions:**

This product contains sodium azide. Sodium azide solutions are reported to:

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

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

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

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

11 Toxicological information

· **Acute toxicity**

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

· Ingredients (100% pure substance/s):		
CAS: 77-86-1 Tris hydroxymethyl aminomethane		
Oral	LD50	5,900 mg/kg (rat)
	LDLo	1,000 mg/kg (rabbit)
CAS: 67-43-6 Diethylenetriamine-pentaacetic acid		
Oral	LD50	>2,000 mg/kg (rat)

· **Primary toxicological effects of the final product:**

- **Skin irritation:** No irritant effect.
- **Eye irritation:** No irritant effect.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:** Product is suspected to cause birth defects.

· **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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· **Target organs/systems:**

Kidneys
Reproductive system

12 Ecological information

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

· **Additional ecological information**

· **General notes:**

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

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable

· **vPvB:** Not applicable

13 Disposal considerations

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

Dispose in accordance with federal, state and local regulations and institutional requirements. Waste containing this product may be considered hazardous per U.S. EPA, state or local regulations. The following may be particularly important when identifying appropriate disposal:

- Contains sodium azide. See Section 10 when considering how to appropriately dispose of unused product. For drain systems with pipes or solder containing copper, lead, brass and/or silver, flush drains thoroughly with copious amounts of water to prevent the formation of potentially explosive metal azides in plumbing. Detailed information about azides in drains is available from the U.S. NIOSH Current Intelligence Bulletin No. 13 (August 16, 1976).

· **Recommendation for disposal of packaging:**

Non-contaminated packaging may be used for recycling. Refer to applicable local regulations and institutional policies.

For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

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

14 Transport information

· **DOT, ADN, IMDG, IATA** none

· **UN proper shipping name**

· **DOT, ADR, ADN, IMDG, IATA** none

· **Transport hazard class(es)**

· **DOT, ADR, ADN, IMDG, IATA**

· **Class** none

· **DOT, IMDG, IATA** none



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· Environmental hazards

· **Marine pollutant:** No

· Additional information

· DOT

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

· ADR

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

· IMDG

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

· IATA

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

15 Regulatory information

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

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

CAS: 26628-22-8 | Sodium azide

· Section 313 (40CFR372.65):

CAS: 26628-22-8 | Sodium azide

· 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.

· Chemicals known to cause developmental reproductive toxicity:

None of the ingredients is listed.

16 Other information



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Department issuing SDS

- Abbott Diagnostics Safety, Health and Environmental Assurance
Department 0571

Contact

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- **Date of preparation / last revision** 07/19/2018 / 29

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (Division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative
OSHA: Occupational Safety & Health
TLV: Threshold Limit Value
PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Repr. 2: Reproductive toxicity – Category 2

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