



Release Date: 11/22/24

REF		Product Name
GTIN		

07P6220 07P6230	<i>Alinity i CEA Reagent Kit</i>
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Components:

07P62G	Alinity i CEA Microparticles
07P62H	Alinity i CEA Conjugate

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

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Last alteration on 11/21/2024

1 Identification

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

· **ADD List number:** 07P62G

· **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.

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:** none

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

polyethylene glycol octylphenyl ether

· **Hazard statements:**

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements:**

P273 Avoid release to the environment.

P391 Collect spillage.

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.

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Product name: Alinity i CEA Microparticles

- Inhalation: No adverse effects expected when used as directed.
- Ingestion: No adverse effects expected when used as directed.
- **Health:** No adverse effects expected if used as directed.
- **Fire:** Noncombustible
- **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

3 Composition/information on ingredients

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

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

CAS: 9002-93-1 polyethylene glycol octylphenyl ether	0.4377%
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4 First-aid measures

- **After inhalation:** Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.
- **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists, get medical advice/attention. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **Most important symptoms and effects, both acute and delayed:** None expected
- **Medical conditions aggravated by exposure:** None known

5 Fire-fighting measures

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Last alteration on 11/21/2024

Product name: Alinity i CEA Microparticles

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 direct contact with material. If handled, wash thoroughly. Practice general safety precautions.

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

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

· **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 remaining constituent has no known exposure limits.

CAS: 25322-68-3 Polyethylene glycol (0.0016 %)

WEEL	TWA: 10 mg/m ³ (H); MW>200
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Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 11/22/2024

Last alteration on 11/21/2024

Product name: Alinity i CEA Microparticles

CAS: 556-67-2 octamethylcyclotetrasiloxane (D4) (0.001 %)

WEEL TWA: 10* ppm
*OARS WEEL

CAS: 26628-22-8 Sodium azide (0.0003 %)

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

General protective and hygienic measures:

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

Breathing equipment:

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

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

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

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

Hand protection:

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

Material of gloves and breakthrough time of the glove material:

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

Eye protection:

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

Body protection:

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

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

9 Physical and chemical properties

General Information

Color: Brown
Odor: Odorless

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according to OSHA Hazard Communication standard 29CFR 1910.1200

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Last alteration on 11/21/2024

Product name: Alinity i CEA Microparticles

- **Melting point/Melting range:** Not determined
- **Boiling point/Boiling range:** Not determined
- **Flammability (solid, gaseous)** Not applicable
- **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)** 1.028 g/cm³ (8.5787 lbs/gal)
- **Form:** Suspension
- **Auto igniting** Product is not self-igniting.
- **Danger of explosion** Product does not present an explosion hazard.
- **Water:** <91.6 %
- **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.
- **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: 9002-93-1 polyethylene glycol octylphenyl ether

Oral LD50 1,800 mg/kg (rat)

- **Skin irritation:** Based on available data, the classification criteria are not met.
- **Eye irritation:** Based on available data, the classification criteria are not met.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.

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Product name: Alinity i CEA Microparticles

- **Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

- **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:** Unknown

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.
- **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 11/21/2024

Product name: Alinity i CEA 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 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 none
· Class 9 Miscellaneous dangerous substances and articles
· Class 9 Miscellaneous dangerous substances and articles
· IMDG, IATA



· Class 9 Miscellaneous dangerous substances and articles
· Label 9
· DOT none
· IMDG, IATA III

· Environmental hazards

· Marine pollutant: Symbol (fish and tree)
· Special marking (IATA): Symbol (fish and tree)
· 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.
· IMDG
· Remarks: Not restricted for transportation.
· IATA
· Remarks: Not restricted for transportation.

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Last alteration on 11/21/2024

Product name: Alinity i CEA Microparticles

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

· Hazardous Air Pollutants

None of the ingredients is 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

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Last alteration on 11/21/2024

Product name: Alinity i CEA Microparticles

Phone: 1-877-4 ABBOTT

· **Date of preparation / last revision 11/22/2024 / 22**

· **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

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.**

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Last alteration on 11/21/2024

1 Identification

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

· **ADD List number:** 07P62H

· **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.

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:** none

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

polyethylene glycol octylphenyl ether

· **Hazard statements:**

H411 Toxic to aquatic life with long lasting effects.

· **Precautionary statements:**

P273 Avoid release to the environment.

P391 Collect spillage.

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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Last alteration on 11/21/2024

Product name: Alinity i CEA Conjugate

- Inhalation: No adverse effects expected when used as directed.
- Ingestion: No adverse effects expected when used as directed.
- **Health:** No adverse effects expected if used as directed.
- **Fire:** Noncombustible
- **Reactivity:** Minimal hazard - Stable, even in a fire. Not reactive with water. Not an oxidizer.

3 Composition/information on ingredients

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

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

CAS: 9002-93-1 polyethylene glycol octylphenyl ether	0.9723%
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4 First-aid measures

- **After inhalation:** Remove from source of exposure. If irritation or signs of toxicity occur, seek medical attention.
- **After skin contact:**
Take off any clothing that the product touched.
Rinse skin with running water for 15 to 20 minutes. Seek medical attention if irritation or signs of toxicity occur.
- **After eye contact:**
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists, get medical advice/attention. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.
- **Most important symptoms and effects, both acute and delayed:** None expected
- **Medical conditions aggravated by exposure:** None known

5 Fire-fighting measures

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

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

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Last alteration on 11/21/2024

Product name: Alinity i CEA Conjugate

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 direct contact with material. If handled, wash thoroughly. Practice general safety precautions.

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

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

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 remaining constituent has no known exposure limits.

CAS: 25322-68-3 Polyethylene glycol (0.0016 %)

WEEL	TWA: 10 mg/m ³ (H); MW>200
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Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 11/22/2024

Last alteration on 11/21/2024

Product name: Alinity i CEA Conjugate

CAS: 556-67-2 octamethylcyclotetrasiloxane (D4) (0.001 %)

WEEL TWA: 10* ppm
*OARS WEEL

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

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.

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.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 11/22/2024

Last alteration on 11/21/2024

Product name: Alinity i CEA Conjugate

• 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
- **Flammability (solid, gaseous)** Not applicable
- **Explosion limits**
- **Lower:** Not determined
- **Upper:** Not determined
- **Flash point** Not applicable
- **pH-value at 20 °C (68 °F)** 6.3
- **Dynamic:** Not determined
- **Solubility in / Miscibility with**
- **Water:** Fully miscible
- **Vapor pressure:**
- **Density at 20 °C (68 °F)** 1.015 g/cm³ (8.4702 lbs/gal)
- **Form:** Solution
- **Auto igniting** Product is not self-igniting.
- **Danger of explosion** Product does not present an explosion hazard.
- **Water:** <96.3 %
- **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.

• Hazardous decomposition products: No dangerous decomposition products known.

Safety Data Sheet

according to OSHA Hazard Communication standard 29CFR 1910.1200

© Abbott Laboratories Release date 11/22/2024

Last alteration on 11/21/2024

Product name: Alinity i CEA Conjugate

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)

- **Skin irritation:** Based on available data, the classification criteria are not met.
- **Eye irritation:** Based on available data, the classification criteria are not met.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - single exposure** Based on available data, the classification criteria are not met.
- **Specific target organ toxicity - repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

· **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:** Unknown

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

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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.
- **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
- **Label** 9
- **DOT** none
- **IMDG, IATA** III
- **Environmental hazards**
- **Marine pollutant:** Symbol (fish and tree)

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Product name: Alinity i CEA Conjugate

- **Special marking (IATA):** Symbol (fish and tree)
- **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.
- **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

- **Hazardous Air Pollutants**

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

- **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.

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Product name: Alinity i CEA Conjugate

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 11/22/2024 / 22**· 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
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.