**Release Date:** 5/31/18

| REF<br>GTIN | Product Name |
|---|---|
| **08P2020**<br>**08P2030** | ***Alinity c Alkaline Phosphatase Reagent Kit*** |

Components:

| | |
|---|---|
| **08P20/R1** | **Alinity c Alkaline Phosphatase Reagent 1** |
| **08P20/R2** | **Alinity c Alkaline Phosphatase Reagent 2** |

# Safety data sheet

according to 1907/2006/EC, Article 31

 Release date 31.05.2018 Version number 10 Last alteration on 29.05.2018

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## SECTION 1: Identification of the substance/mixture and of the company/ undertaking

### · 1.1 Product identifier

· **Trade name:** **Alinity c Alkaline Phosphatase Reagent 1**

· **Article number:** 08P20/R1

### · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

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

### · 1.3 Details of the supplier of the safety data sheet

· **Supplier:**
Abbott Diagnostics
Abbott House
Norden Road
MAIDENHEAD
SL6 4XF Berkshire
England UK
Tel. (+44)1628773413

MSDS-support@Abbott.com

### · 1.4 Emergency telephone number

Tel: +44 (0) 1628 773355

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.

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## SECTION 2: Hazards identification

### · 2.1 Classification of the substance or mixture

· **Classification according to Regulation (EC) No 1272/2008:**

| | | |
|---|---|---|
| Skin Irrit. 2 | H315 | Causes skin irritation. |
| Eye Irrit. 2 | H319 | Causes serious eye irritation. |
| Aquatic Chronic 3 | H412 | Harmful to aquatic life with long lasting effects. |

### · 2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008:**
The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms:**

· **Signal word:** Warning

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# Safety data sheet

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## Trade name: Alinity c Alkaline Phosphatase Reagent 1

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· **Hazard-determining components of labelling:**
2-Amino-2-methylpropanol
Zinc sulfate heptahydrate

· **Hazard statements:**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H412 Harmful to aquatic life with long lasting effects.

· **Precautionary statements:**

| | |
|---|---|
| P264 | Wash hands thoroughly after handling. |
| P273 | Avoid release to the environment. |
| P280 | Wear protective gloves/protective clothing/eye protection. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P332+P313 | If skin irritation occurs: Get medical advice/attention. |
| P337+P313 | If eye irritation persists: Get medical advice/attention. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |
| P501 | Dispose of contents / container in accordance with local regulations. |

· **Routes of Exposure:**
Skin
Eye

### · 2.3 Other hazards

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

* 

## SECTION 3: Composition/information on ingredients

### · 3.2 Mixtures

| · **Dangerous components according to EC criteria:** | | |
|---|---|---|
| CAS: 124-68-5<br>EINECS: 204-709-8<br>Reg.nr.: 01-2119475788-16-xxxx | 2-Amino-2-methylpropanol<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Aquatic Chronic 3, H412 | 13.80% |
| CAS: 7446-20-0<br>EINECS: 231-793-3 | Zinc sulfate heptahydrate<br>Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Acute Tox. 4, H302 | 0.12% |

· **Additional information:**
For the complete text of Hazard (H) codes displayed in this section, refer to Section 16.

## SECTION 4: First aid measures

### · 4.1 Description of first aid measures

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

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**Trade name: Alinity c Alkaline Phosphatase Reagent 1**

(Continued from page 2)

· **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.

· **4.2 Most important symptoms and effects, both acute and delayed:**
Skin irritation
Eye irritation

· **4.3 Indication of any immediate medical attention and special treatment needed:**
No additional relevant information available.

## SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

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

· **5.2 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.

· **5.3 Advice for firefighters**

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

## SECTION 6: Accidental release measures

· **6.1 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.

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

· **6.3 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.

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**Trade name: Alinity c Alkaline Phosphatase Reagent 1**

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· **6.4 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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## SECTION 7: Handling and storage

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

· **Information about protection against explosions and fires:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and containers:**
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.

· **7.3 Specific end use(s):** No additional relevant information available.

## SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Components with limit values that require monitoring at the workplace:**
The product does not contain any hazardous ingredients with occupational exposure limits.

· **8.2 Exposure controls**

· **Personal protective equipment:**

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

Avoid contact with the skin.
Avoid contact with the eyes.

· **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 air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection.

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Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

· **Protection of hands:**
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.

## SECTION 9: Physical and chemical properties

### · 9.1 Information on basic physical and chemical properties

· **General Information**

| | |
|---|---|
| · **Appearance:** | |
| · **Form:** | Solution |
| · **Colour:** | Colourless |
| · **Odour:** | Odourless |
| · **Odour threshold:** | Not determined |
| · **pH-value at 20 °C:** | 10.6 |
| · **Change in condition:** | |
| · **Melting point/freezing point:** | Not determined |
| · **Initial boiling point and boiling range:** | Not determined |
| · **Flash point:** | Not applicable |
| · **Inflammability (solid, gaseous):** | Not applicable |
| · **Auto igniting** | Product is not self-igniting. |
| · **Explosive properties:** | Product does not present an explosion hazard. |
| · **Explosion limits** | |
| · **Lower:** | Not determined |
| · **Upper:** | Not determined |
| · **Density at 20 °C** | 1.023 g/cm³ |
| · **Relative density:** | Not determined |
| · **Evaporation rate:** | Not determined |
| · **Solubility in / Miscibility with** | |
| · **Water:** | Fully miscible |
| · **Viscosity:** | |
| · **dynamic:** | Not determined |

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| | |
|---|---|
| · **Water:** | 80.6 % |
| · **Solids content:** | 0.0 % |
| · **9.2 Other information** | No further relevant information available. |

## SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.

· **10.2 Chemical stability:**

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

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

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

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

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

* 

## SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**

· **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values that are relevant for classification:**

| · **Ingredients (100% pure substance/s):** | | |
|---|---|---|
| **CAS: 124-68-5 2-Amino-2-methylpropanol** | | |
| Oral | LD50 | 2,150 mg/kg (mouse)<br>2,900 mg/kg (rat) |

· **Primary irritant effect:**

· **Skin corrosion/irritation**
Irritating to skin and mucous membranes.
Causes skin irritation.

· **Serious eye damage/irritation**
Irritating.
Causes serious eye irritation.

· **Sensitisation:** Based on available data, the classification criteria are not met.

· **Additional toxicological information:** None

· **Target organs/systems:**
Eye
Skin

· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**

· **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.

· **STOT-single exposure** Based on available data, the classification criteria are not met.

· **STOT-repeated exposure** Based on available data, the classification criteria are not met.

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

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## SECTION 12: Ecological information

· **12.1 Toxicity**

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

· **12.2 Persistence and degradability:** No further relevant information available.

· **12.3 Bioaccumulative potential:** No further relevant information available.

· **12.4 Mobility in soil:** 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 bodies or sewage system.

Refer to applicable local regulations for limit values of discharge into sewage system.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable

· **vPvB:** Not applicable

· **12.6 Other adverse effects:** No further relevant information available.

## SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

There are no uniform EU regulations for the disposal of laboratory waste. In general, laboratory waste is under special supervision of the authorities.

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

Dispose in accordance with national, state and local regulations.

· **European waste catalogue:**

Consult the responsible regulatory body for the assignment of disposal codes according to the European Waste Catalogue.

· **The following waste disposal key numbers are possible:**

18 01 06: chemicals consisting of or containing dangerous substances

· **Uncleaned packagings**

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

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

## SECTION 14: Transport information

· **14.1 UN-Number**

· **ADR, ADN, IMDG, IATA** None

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**Trade name: Alinity c Alkaline Phosphatase Reagent 1**

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· **14.2 UN proper shipping name**
· **ADR, ADN, IMDG, IATA** None

· **14.3 Transport hazard class(es)**
· **ADR, ADN, IMDG, IATA**
· **Class** None

· **14.4 Packing group**
· **ADR, IMDG, IATA** None

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

· **14.6 Special precautions for user** Not applicable

· **Transport/Additional information**
· **ADR**
· **Remarks:** Not restricted for transportation.
· **IMDG**
· **Remarks:** Not restricted for transportation.
· **IATA**
· **Remarks:** Not restricted for transportation.

* 
## SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **15.2 Chemical safety assessment** A Chemical Safety Assessment has not been carried out.

* 
## SECTION 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 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.

· **Complete text for H (Hazard) codes displayed in Section 3:**
Note: The respective H statements apply to the pure substances.
H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.

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## Trade name: Alinity c Alkaline Phosphatase Reagent 1

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H319 Causes serious eye irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H412 Harmful to aquatic life with long lasting effects.

· **Contact supplier**
Abbott Diagnostics, Quality & Regulatory Manager
Abbott Diagnostics, Customer Service Manager

· **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
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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
Acute Tox. 4: Acute toxicity – Category 4
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

· *** Data compared to the previous version altered.**

# Safety data sheet

according to 1907/2006/EC, Article 31

 Release date 31.05.2018 Version number 5 Last alteration on 29.05.2018

* 

## SECTION 1: Identification of the substance/mixture and of the company/ undertaking

### · 1.1 Product identifier

· **Trade name:** **Alinity c Alkaline Phosphatase Reagent 2**

· **Article number:** 08P20/R2

### · 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

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

### · 1.3 Details of the supplier of the safety data sheet

· **Supplier:**
Abbott Diagnostics
Abbott House
Norden Road
MAIDENHEAD
SL6 4XF Berkshire
England UK
Tel. (+44)1628773413

MSDS-support@Abbott.com

### · 1.4 Emergency telephone number

Tel: +44 (0) 1628 773355

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.

* 

## SECTION 2: Hazards identification

### · 2.1 Classification of the substance or mixture

· **Classification according to Regulation (EC) No 1272/2008:**
Skin Sens. 1 H317 May cause an allergic skin reaction.

### · 2.2 Label elements

· **Labelling according to Regulation (EC) No 1272/2008:**
The product is classified and labelled according to the CLP regulation.

· **Hazard pictograms:**

· **Signal word:** Warning

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# Safety data sheet

according to 1907/2006/EC, Article 31

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## Trade name: Alinity c Alkaline Phosphatase Reagent 2

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· **Hazard-determining components of labelling:**
2-Methyl-4-isothiazolin-3-one
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 / vapours / 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.
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

### · 2.3 Other hazards

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

* 

## SECTION 3: Composition/information on ingredients

### · 3.2 Mixtures

| · **Dangerous components according to EC criteria:** | | |
|---|---|---|
| CAS: 114-63-6 | 4-Hydroxybenzoic acid, sodium salt<br>Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319 | 5.60% |
| CAS: 77-86-1<br>EINECS: 201-064-4<br>Reg.nr.: 01-2119957659-16-xxxx | Tris hydroxymethyl aminomethane<br>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | 1.12% |
| CAS: 2682-20-4<br>EINECS: 220-239-6 | 2-Methyl-4-isothiazolin-3-one<br>Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1, H317 | 0.0099% |
| 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);<br>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)<br>Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; Skin Corr. 1B, H314; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1, H317 | 0.0018% |

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**Trade name: Alinity c Alkaline Phosphatase Reagent 2**

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· **Additional information:**
For the complete text of Hazard (H) codes displayed in this section, refer to Section 16.

## SECTION 4: First aid measures

### · 4.1 Description of 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.

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

### · 4.3 Indication of any immediate medical attention and special treatment needed:
No additional relevant information available.

## SECTION 5: Firefighting measures

### · 5.1 Extinguishing media

· **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.

### · 5.2 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.

### · 5.3 Advice for firefighters

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



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# Safety data sheet

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**Trade name: Alinity c Alkaline Phosphatase Reagent 2**

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## SECTION 6: Accidental release measures

· **6.1 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.

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

· **6.3 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.

· **6.4 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.

* 

## SECTION 7: Handling and storage

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

· **Information about protection against explosions and fires:** No special measures required.

· **7.2 Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and containers:**
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.

· **7.3 Specific end use(s):** No additional relevant information available.

* 

## SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Components with limit values that require monitoring at the workplace:**
The product does not contain any hazardous ingredients with occupational exposure limits.

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## · 8.2 Exposure controls

· **Personal protective equipment:**

· **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 air-purifying respirator if airborne chemical concentrations may exceed the exposure limit (if any) listed above.

Hazardous Materials Emergencies or Firefighting - use approved respiratory protection.
Take precautions if chemical concentrations exceed the exposure limits (if any) listed above.

· **Protection of hands:**
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.

# SECTION 9: Physical and chemical properties

## · 9.1 Information on basic physical and chemical properties

· **General Information**

| | |
|---|---|
| · **Appearance:** | |
| · **Form:** | Solution |
| · **Colour:** | Yellow |
| · **Odour:** | Odourless |
| · **Odour threshold:** | Not determined |

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| | |
|---|---|
| · **pH-value at 20 °C:** | 8.4 |
| · **Change in condition:** | |
| · **Melting point/freezing point:** | Not determined |
| · **Initial boiling point and boiling range:** | Not determined |
| · **Flash point:** | Not applicable |
| · **Inflammability (solid, gaseous):** | Not applicable |
| · **Auto igniting** | Product is not self-igniting. |
| · **Explosive properties:** | Product does not present an explosion hazard. |
| · **Explosion limits** | |
| · **Lower:** | Not determined |
| · **Upper:** | Not determined |
| · **Density at 20 °C** | 1.062 g/cm³ |
| · **Relative density:** | Not determined |
| · **Evaporation rate:** | Not determined |
| · **Solubility in / Miscibility with** | |
| · **Water:** | Fully miscible |
| · **Viscosity:** | |
| · **dynamic:** | Not determined |
| · **Water:** | 86.3 % |
| · **Solids content:** | 0.0 % |
| · **9.2 Other information** | No further relevant information available. |

## SECTION 10: Stability and reactivity

· **10.1 Reactivity**

· **10.2 Chemical stability:**

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

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

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

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

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

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## SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**

· **Acute toxicity** Based on available data, the classification criteria are not met.

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· **LD/LC50 values that are relevant for classification:**

| · **Ingredients (100% pure substance/s):** | | |
|---|---|---|
| **CAS: 114-63-6 4-Hydroxybenzoic acid, sodium salt** | | |
| Oral | LD50 | 480 mg/kg (mouse)<br>For salicylic acid<br>1,300 mg/kg (rabbit)<br>For salicylic acid<br>891 mg/kg (rat)<br>For salicylic acid |
| | Mutagenicity | (Ames Assay)<br>Positive in the S. cerevisiae gene reversion assay. |
| | Target Organ Effects | (mammal)<br>Clinical use of 8-20 grams of sodium salicylate produced tinnitus, temporary blindness and deafness, headache and stupor, and occasionally coma. In reproductive studies, oral dosages of 100 mg/kg/day in rats and 50 mg/kg/day in mice produced maternal and fetal toxicity and skeletal abnormalities in the offspring. Also reported to be teratogenic in rabbits. |
| **CAS: 77-86-1 Tris hydroxymethyl aminomethane** | | |
| Oral | LD50 | 5,900 mg/kg (rat) |
| | LDLo | 1,000 mg/kg (rabbit) |
| **CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one** | | |
| Oral | LD50 | 60 mg/kg (mouse)<br>By analogy to methylchloroisothiazolinone.<br>53 mg/kg (rat)<br>By analogy to methylchloroisothiazolinone. |

· **Primary irritant effect:**
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

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

· **Additional toxicological information:** None
· **Target organs/systems:**
Kidneys
Nervous system
Reproductive system
Ear
Skin
Immune system
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **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.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.



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## SECTION 12: Ecological information

· **12.1 Toxicity**

| · **Aquatic toxicity:** | |
|---|---|
| **CAS: 2682-20-4 2-Methyl-4-isothiazolin-3-one** | |
| LC50 96 h | 0.19 mg/l (trout) (Flow through) |
| LC50 48 h (Static) | 0.056 mg/l (other) (Crustacean - Acartia tonsa) |

· **12.2 Persistence and degradability:** No further relevant information available.

· **12.3 Bioaccumulative potential:** No further relevant information available.

· **12.4 Mobility in soil:** 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 bodies or sewage system.
Refer to applicable local regulations for limit values of discharge into sewage system.

· **12.5 Results of PBT and vPvB assessment**

· **PBT:** Not applicable

· **vPvB:** Not applicable

· **12.6 Other adverse effects:** No further relevant information available.

## SECTION 13: Disposal considerations

· **13.1 Waste treatment methods**

There are no uniform EU regulations for the disposal of laboratory waste. In general, laboratory waste is under special supervision of the authorities.

· **Recommendation for disposal of unused product:**
Dispose in accordance with national, state and local regulations.

· **European waste catalogue:**
Consult the responsible regulatory body for the assignment of disposal codes according to the European Waste Catalogue.

· **The following waste disposal key numbers are possible:**
18 01 06: chemicals consisting of or containing dangerous substances

· **Uncleaned packagings**
For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

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



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## SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, ADN, IMDG, IATA** None

· **14.2 UN proper shipping name**
· **ADR, ADN, IMDG, IATA** None

· **14.3 Transport hazard class(es)**
· **ADR, ADN, IMDG, IATA**
· **Class** None

· **14.4 Packing group**
· **ADR, IMDG, IATA** None

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

· **14.6 Special precautions for user** Not applicable

· **Transport/Additional information**
· **ADR**
· **Remarks:** Not restricted for transportation.
· **IMDG**
· **Remarks:** Not restricted for transportation.
· **IATA**
· **Remarks:** Not restricted for transportation.

* 

## SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **15.2 Chemical safety assessment** A Chemical Safety Assessment has not been carried out.

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## SECTION 16: Other information

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· **Complete text for H (Hazard) codes displayed in Section 3:**
Note: The respective H statements apply to the pure substances.
H301 Toxic if swallowed.
H302 Harmful if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

· **Contact supplier**
Abbott Diagnostics, Quality & Regulatory Manager
Abbott Diagnostics, Customer Service Manager

· **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
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
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
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

· *** Data compared to the previous version altered.**