

Declaration of Conformity

Certificate Identification: SC-09H46
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---------------------------------------|-----------|----------------------------------|----------------|
| 09H46-02 | 58236 | CELL-DYN Emerald CLEANER | Self-declared |
| 09H47-02 | 61165 | CELL-DYN Emerald CN-FREE LYSE | Self-declared |
| 09H48-02 | 58237 | CELL-DYN Emerald DILUENT | Self-declared |

| | |
|---|--|
| Authorized European Representative (Name and Address) | ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany |
| Storage site of technical documentation (Name and Address) | Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 |
| Harmonized Standards | Listed in the Technical Documentation |

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:



Signature:



Full Name:

Barry Simpson

Full Name:

Marcy Jaqua

Position:

Site Quality Manager

Position:

Director, Regulatory Affairs

Date of Approval:

02. Dec. 2015

Date of Approval:

01 DEC 2015

Date Issued:

DEC 02 2015

Place Issued:

Abbott Santa Clara

Supersedes:

IRIS V6
July 6, 2015

Effective (Date or Lot Number):

DEC 03 2015

Declaration of Conformity

Certificate Identification: SC-09H59
Legal Manufacturer's Name: Abbott Laboratories
Legal Manufacturer's Address: Diagnostics Division
Abbott Park, IL 60064 USA

| List Numbers and Size Code of Devices | GMDN Code | Names and Description of Devices | Classification |
|---------------------------------------|-----------|----------------------------------|----------------|
| 09H59-01 | 35476 | CELL-DYN Emerald 22 Instrument | Self-declared |

| | |
|---|---|
| Authorized European Representative (Name and Address) | ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany |
| Storage site of technical documentation (Name and Address) | Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 BIT Group France Parc Euromedecine II, Rue de la Valsiere 34 099 – Montpellier, Cedex 5 France |
| Harmonized Standards | Listed in the Technical Documentation |

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices and Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011, as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

| | |
|--|--|
| <p>Signature: <u></u></p> <p>Full Name: <u>Kevin Richardson</u></p> <p>Position: <u>Manager, Supplier Quality</u></p> <p>Date of Approval: <u>10 - July - 2017</u></p> <p>Date Issued: <u>JUL 10 2017</u></p> <p>Supersedes: <u>IRIS V1, April 15, 2016</u></p> | <p>Signature: <u></u></p> <p>Full Name: <u>Mirna DiPano</u></p> <p>Position: <u>Director of Regulatory Affairs</u></p> <p>Date of Approval: <u>10 - July - 2017</u></p> <p>Place Issued: <u>Abbott Santa Clara</u></p> <p>Effective (Date or Lot Number): <u>JUL 10 2017</u></p> |
|--|--|

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

MDSAP Facility Identifier: 079226220

has been audited by LRQA and found to conform to the following audit criteria:

ISO 13485:2016

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1
(Excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

RDC ANVISA n. 16/2013
RDC ANVISA n. 23/2012
RDC ANVISA n. 67/2009

Canada:

Medical Devices Regulations – Part 1- SOR 98/282

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68
PMD Act

United States:

21 CFR 820
21 CFR 803
21 CFR 806



Cliff Muckleroy - Area Operations Manager Americas
Issued By: Lloyd's Register Quality Assurance, Inc.

Certificate Approval Number: UQA 00000846

Effective Date: 2018 October 13

Expiry Date: 2021 October 12

Certificate Issue Number: 10155325

Original Approval:

MDSAP/ ISO 13485 – 2017 December 7



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

Certificate Schedule

Certificate Issue Number: 10155325

Approval Number: MDSAP – 0015682

The scope of this approval is applicable to:

Design and Manufacture of In Vitro Diagnostic Medical Devices, used in the Screening of Blood Donor Units for Transmissible Diseases. Design and Manufacture of In Vitro Diagnostic Medical Devices used in the Diagnosis, Management and Detection of Cancer, Autoimmune Status, Cardiac Markers, Endocrine Disorders, and for Therapeutic Drug Monitoring. Design, Development, Manufacture, Refurbishment, Distribution, and Post-Market Customer Service and Support of In Vitro Diagnostic Medical Devices for Immunoassay and Clinical Chemistry Systems. Manufacture, Design / Development of In Vitro Diagnostic Products including Instruments, Reagents, and Accessories for Hematology.



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

Certificate Schedule

Certificate Issue Number: 10155325

| Location | Activities |
|--|--|
| 100 Abbott Park Road, Abbott Park, IL, 60064, United States | MDSAP 2017 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments. |
| Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States MDSAP Facility Identifier: 079226220-002 | MDSAP 2017 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites. |
| K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States MDSAP Facility Identifier: 079226220-003 | MDSAP 2017 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments. |



Lloyd's Register Quality Assurance, Inc. is an MDSAP authorised auditing organization.

To validate certificate authenticity visit: <http://www.lrqausa.com/help-and-support/Request-for-certificate-verification>

Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 13485:2016



Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018

Expiry date: 12 October 2021

Certificate identity number: 10155326

Original approval(s):

ISO 13485 – 7 December 2017

Approval number(s): ISO 13485 – 0015680

The scope of this approval is applicable to:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



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Certificate Schedule

Certificate identity number: 10155326

| Location | Activities |
|--|--|
| 100 Abbott Park Road, Abbott Park, IL, 60064, United States | ISO 13485:2016 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments. |
| Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States | ISO 13485:2016 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites. |
| K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States | ISO 13485:2016 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments. |



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Certificate of Approval

This is to certify that the Management System of:

Abbott Laboratories Diagnostics Division

100 Abbott Park Road, Abbott Park, IL, 60064, United States

has been approved by LRQA to the following standards:

ISO 9001:2015



Cliff Muckleroy - Area Operations Manager Americas

Issued by: Lloyd's Register Quality Assurance, Inc.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 13 October 2018

Expiry date: 12 October 2021

Certificate identity number: 10155324

Original approval(s):

ISO 9001 – 3 December 2017

Approval number(s): ISO 9001 – 0015681

The scope of this approval is applicable to:

Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments.



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Certificate Schedule

Certificate identity number: 10155324

| Location | Activities |
|--|---|
| 100 Abbott Park Road, Abbott Park, IL, 60064, United States | ISO 9001:2015 Design, Manufacture, Development, Installation, Service and Support of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments. |
| Conway Park, 675 North Field Drive, Lake Forest, IL, 60045, United States | ISO 9001:2015 Oversight of the Quality Management System for the Abbott Diagnostics Division Sites. |
| K Complex - Distribution Center Route 41 & Martin Luther King Drive, North Chicago, IL, 60064, United States | ISO 9001:2015 Distribution of In Vitro Diagnostic Products including Test Kits, Reagents, Accessories and Instruments. |



001

Release Date: 3/24/16

| | |
|-------------|--------------|
| REF | Product Name |
| GTIN | |

| | |
|--|--|
| 09H60-01 00380740120764 | <i>CELL-DYN Emerald 22 Easy Cleaner</i> |
|--|--|

Components:

| | |
|--------------|---|
| 09H60 | CELL-DYN Emerald 22 Easy Cleaner |
|--------------|---|

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories Release date 24.03.2016

Version number 7

Last alteration on 14.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

- Trade name: **CELL-DYN Emerald 22 Easy Cleaner**

- Article number: 09H60

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 GmbH & Co.KG
Max-Planck-Ring 2
65205 Wiesbaden
Tel.: (+49)-6122-58-0

MSDS-Support@Abbott.com

1.4 Emergency telephone number:

(+49)-6122-58-0

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:**

This product has been evaluated per the classification criteria in Regulation (EC) No 1272/2008 (CLP) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This product does not meet the criteria for classification in accordance with either CLP or GHS.

2.2 Label elements

- Labelling according to Regulation (EC) No 1272/2008:** None

- Hazard pictograms:** None

- Signal word:** None

- Hazard-determining components of labelling:**
Sodium azide

- Hazard statements:** None

- Precautionary statements:**

- P501 Dispose of contents / container in accordance with local regulations.

- Additional information:**

EUH032 Contact with acids liberates very toxic gas.

- 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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- Inhalation: No adverse effects expected when used as directed.
- Ingestion: No adverse effects expected when used as directed.

2.3 Other hazards

Results of PBT and vPvB assessment:

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

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Dangerous components according to EC criteria:

| | | |
|-----------|---|-------|
| 9002-93-1 | polyethylene glycol octylphenyl ether Eye Dam. 1, H318; Aquatic Chronic 2, H411; Acute Tox. 4, H302; Skin Irrit. 2, H315 | 0,40% |
|-----------|---|-------|

SVHC

| | |
|-----------|---------------------------------------|
| 9002-93-1 | polyethylene glycol octylphenyl ether |
|-----------|---------------------------------------|

Additional information:

For the complete text of Risk (R) and/or 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.

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:

Changes in blood parameters

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.

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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 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

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.

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

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- 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:

57-55-6 1,2-propylene glycol (9,90 %)

| | |
|---------------------|--|
| WEL (Great Britain) | Long-term value: 474* 10** mg/m ³ , 150* ppm *total vapour and particulates **particulates |
|---------------------|--|

9014-01-1 Subtilisin (0,0999 %)

| | |
|---------------------|---|
| WEL (Great Britain) | Long-term value: 0,00004 mg/m ³ Sen |
|---------------------|---|

26628-22-8 Sodium azide (0,05 %)

| | |
|------------------------|---|
| WEL (Great Britain) | Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³ (as NaN ₃), Sk |
| IOELV (European Union) | Short-term value: 0,3 mg/m ³ Long-term value: 0,1 mg/m ³ Skin |

64-17-5 Ethanol (0,01 %)

| | |
|---------------------|--|
| WEL (Great Britain) | Long-term value: 1920 mg/m ³ , 1000 ppm |
|---------------------|--|

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.

Breathing equipment:

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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: Liquid
· Colour: purple

· Odour: Odourless
· Odour threshold: Not determined

· pH-value at 20 °C: 8,8

· Change in condition:

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

· Flash point: Not applicable
· Inflammability (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

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- **Density at 20 °C** 1,02 g/cm³
- **Relative density:** Not determined
- **Evaporation rate:** Not determined

- **Solubility in / Miscibility with**
- **Water:** Fully miscible

- **Viscosity:**
- **dynamic:** Not determined

- **Water:** 87,0 %

- **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:

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.

- **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):** Not applicable.

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

- **Additional toxicological information:** None

- **Target organs/systems:** Blood

- **CMR effects (carcinogenicity, 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.

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Trade name: CELL-DYN Emerald 22 Easy Cleaner

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- **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.

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 and institutional requirements. Waste containing this product may be considered hazardous per 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).

· **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:**

180106: 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.

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

SECTION 14: Transport information

· **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.

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations:**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

9002-93-1 polyethylene glycol octylphenyl ether

· **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.

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Version number 7

Last alteration on 14.01.2016

Trade name: CELL-DYN Emerald 22 Easy Cleaner

(Continued from page 8)

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) and/or R (Risk) codes displayed in Section 3:**

Note: The respective H and/or R statements apply to the pure substances.

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H411 Toxic to aquatic life with long lasting effects.

• **Contact supplier**

Environmental Affairs & Product Safety

Tel.: +49 (0) 6122 58 0

• **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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

SVHC: Substance of Very High Concern (REACH)

Acute Tox. 4: Acute toxicity, Hazard Category 4

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2

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

ENG

Release Date: 3/24/16

| | |
|-------------|--------------|
| REF | Product Name |
| GTIN | |

| | |
|--|--|
| 09H72-01 00380740119829 09H72-02 00380740119836 | <i>CELL-DYN 22 Plus Control Kit</i> |
|--|--|

Components:

| | |
|---|---------------------------------------|
| 09H72L 09H72N 09H72H | CELL-DYN 22 Plus Control L,N,H |
|---|---------------------------------------|

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories Release date 24.03.2016

Version number 7

Last alteration on 24.03.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** CELL-DYN 22 Plus Control L,N,H**Article number:**

09H72L

09H72N

09H72H

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 GmbH & Co.KG

Max-Planck-Ring 2

65205 Wiesbaden

Tel.: (+49)-6122-58-0

MSDS-Support@Abbott.com

1.4 Emergency telephone number:

(+49)-6122-58-0

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:**

This product has been evaluated per the classification criteria in Regulation (EC) No 1272/2008 (CLP) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This product does not meet the criteria for classification in accordance with either CLP or GHS.

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008:** None**Hazard pictograms:** None**Signal word:** None**Hazard statements:** None**Routes of Exposure:**

For bloodborne pathogens and potentially infectious materials:

- non-intact skin

- mucous membranes (which includes, but is not limited to, the lining of the nose, mouth and throat)

- parenteral contact (e.g. by injection, puncture)

(Continued on page 2)

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Version number 7

Last alteration on 24.03.2016

Trade name: CELL-DYN 22 Plus Control L,N,H

(Continued from page 1)

2.3 Other hazards

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

Results of PBT and vPvB assessment:

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

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Dangerous components according to EC criteria:

| | |
|---|---------|
| Proprietary Ingredient - Cell Stabilizing Components (biological salts, anticoagulants, osmotic stabilizers) STOT SE 3, H335 | 2,9999% |
|---|---------|

Additional information:

For the complete text of Risk (R) and/or 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.

After skin contact:

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

After eye contact:

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

After swallowing:

Rinse mouth with water. If irritation or signs of toxicity occur, seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed: None expected

Information for Medical Personnel:

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

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

- Nonreactive for HBsAg (hepatitis B surface antigen)
- Nonreactive for anti-HCV (antibodies to hepatitis C virus)
- Nonreactive for HIV-1 Ag or HIV-1 RNA (human immunodeficiency virus type 1 antigen or human immunodeficiency virus type 1 ribonucleic acid)
- Nonreactive for anti-HIV-1 (antibodies to human immunodeficiency virus type 1)
- Nonreactive for anti-HIV-2 (antibodies to human immunodeficiency virus type 2)
- Nonreactive for syphilis bacteria (*Treponema pallidum pallidum*)

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Last alteration on 24.03.2016

Trade name: CELL-DYN 22 Plus Control L,N,H

(Continued from page 2)

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.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Handle as a potentially infectious material.

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

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 splattered product with paper towels or similar materials.

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

Clean the affected area. Suitable cleaners are:

- warm water and detergent or similar cleansing agent

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

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

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

6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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Version number 7

Last alteration on 24.03.2016

Trade name: CELL-DYN 22 Plus Control L,N,H

See Section 13 for disposal information.

(Continued from page 3)

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling:** Handle as a potentially infectious material.
 - **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.
 - **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

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© Abbott Laboratories Release date 24.03.2016

Version number 7

Last alteration on 24.03.2016

Trade name: CELL-DYN 22 Plus Control L,N,H

(Continued from page 4)

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.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

- **Form:** Liquid
 - **Colour:** Red

- **Odour:** Odourless
 - **Odour threshold:** Not determined

- **pH-value at 20 °C:** 6,8

- **Change in condition:**

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

- **Flash point:** Not applicable
 - **Inflammability (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** Not determined
 - **Relative density:** Not determined
 - **Evaporation rate:** Not determined

- **Solubility in / Miscibility with**
 - **Water:** Not miscible or difficult to mix

- **Viscosity:**
 - **dynamic:** Not determined

- **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.

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Trade name: CELL-DYN 22 Plus Control L,N,H

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- **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):** Not applicable.
 - **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:** Based on available data, the classification criteria are not met.
 - **Additional toxicological information:** None
 - **Target organs/systems:** Unknown
 - **CMR effects (carcinogenicity, 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.

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.

ENG

(Continued on page 7)

Trade name: CELL-DYN 22 Plus Control L,N,H

(Continued from page 6)

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:

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

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 07: chemicals other than those mentioned in 18 01 06

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

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.

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Last alteration on 24.03.2016

Trade name: CELL-DYN 22 Plus Control L,N,H

(Continued from page 7)

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.
- **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) and/or R (Risk) codes displayed in Section 3:**

Note: The respective H and/or R statements apply to the pure substances.

H335 May cause respiratory irritation.

- **Contact supplier**

Environmental Affairs & Product Safety

Tel.: +49 (0) 6122 58 0

- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

ENG

Release Date: 3/24/16

| | |
|-------------|--------------|
| REF | Product Name |
| GTIN | |

| | |
|--|---|
| 09H62-01 00380740120788 | <i>CELL-DYN Emerald 22 Diluent</i> |
|--|---|

Components:

| | |
|--------------|------------------------------------|
| 09H62 | CELL-DYN Emerald 22 Diluent |
|--------------|------------------------------------|

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories Release date 24.03.2016

Version number 4

Last alteration on 14.01.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

- Trade name: **CELL-DYN Emerald 22 Diluent**

- Article number: 09H62

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 GmbH & Co.KG
Max-Planck-Ring 2
65205 Wiesbaden
Tel.: (+49)-6122-58-0

MSDS-Support@Abbott.com

1.4 Emergency telephone number:

(+49)-6122-58-0

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:**

This product has been evaluated per the classification criteria in Regulation (EC) No 1272/2008 (CLP) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This product does not meet the criteria for classification in accordance with either CLP or GHS.

2.2 Label elements

- Labelling according to Regulation (EC) No 1272/2008:** None

- Hazard pictograms:** None

- Signal word:** None

- Hazard statements:** None

- Routes of Exposure:**

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

2.3 Other hazards

- Results of PBT and vPvB assessment:**

- PBT:** Not applicable

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Version number 4

Last alteration on 14.01.2016

Trade name: CELL-DYN Emerald 22 Diluent· **vPvB:** Not applicable

(Continued from page 1)

SECTION 3: Composition/information on ingredients· **3.2 Chemical characterisation: Mixtures**· **Dangerous components according to EC criteria:** None· **Additional information:**

For the complete text of Risk (R) and/or 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.

· **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:** None expected· **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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Trade name: CELL-DYN Emerald 22 Diluent

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

- **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.

(Continued on page 4)

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Version number 4

Last alteration on 14.01.2016

Trade name: CELL-DYN Emerald 22 Diluent

(Continued from page 3)

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.

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: Liquid
 Colour: Colourless

Odour: Odourless
 Odour threshold: Not determined

pH-value at 20 °C: 7,4

Change in condition:

Melting point/Melting range: Not determined

(Continued on page 5)

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Safety Data Sheet

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| | |
|---|---|
| · Boiling point/Boiling range: | Not determined |
| · Flash point: | Not applicable |
| · Inflammability (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 | 1 g/cm ³ |
| · Relative density: | Not determined |
| · Evaporation rate: | Not determined |
| · Solubility in / Miscibility with | |
| · Water: | Fully miscible |
| · Viscosity: | |
| · dynamic: | Not determined |
| · Water: | 98,2 % |
| · 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.

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):** Not applicable.
 - **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:** Based on available data, the classification criteria are not met.
 - **Additional toxicological information:** None
 - **Target organs/systems:** Unknown
 - **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
 - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

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- **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.

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:** Generally not hazardous for water.
- **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 07: chemicals other than those mentioned in 18 01 06
 - **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

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

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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.

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

SECTION 16: Other information

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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) and/or R (Risk) codes displayed in Section 3:

Note: The respective H and/or R statements apply to the pure substances.

· Contact supplier

Environmental Affairs & Product Safety

Tel.: +49 (0) 6122 58 0

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Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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

ENG

Release Date: 7/28/16

| | |
|-------------|--------------|
| REF | Product Name |
| GTIN | |

| | |
|--|--|
| 09H61-01 00380740120771 | <i>CELL-DYN Emerald 22 Lyse</i> |
|--|--|

Components:

| | |
|--------------|---------------------------------|
| 09H61 | CELL-DYN Emerald 22 Lyse |
|--------------|---------------------------------|

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Release date 28.07.2016

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Last alteration on 28.07.2016

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

- Trade name: **CELL-DYN Emerald 22 Lyse**

- Article number: 09H61

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 GmbH & Co.KG
Max-Planck-Ring 2
65205 Wiesbaden
Tel.: (+49)-6122-58-0

MSDS-Support@Abbott.com

1.4 Emergency telephone number:

(+49)-6122-58-0

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:**

This product has been evaluated per the classification criteria in Regulation (EC) No 1272/2008 (CLP) and the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This product does not meet the criteria for classification in accordance with either CLP or GHS.

2.2 Label elements

- Labelling according to Regulation (EC) No 1272/2008:** None

- Hazard pictograms:** None

- Signal word:** None

- Hazard statements:** None

- Additional information:**

Contains 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). May produce an allergic reaction.

- Routes of Exposure:**

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

2.3 Other hazards

Results of PBT and vPvB assessment:

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

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

- **Dangerous components according to EC criteria:** None
- **Additional information:**
For the complete text of Risk (R) and/or 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.
- **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: None expected

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.

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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 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.

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

- **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.

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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.

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: Liquid
Colour: Light yellow

Odour: Odourless

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| | |
|------------------------------------|---|
| · Odour threshold: | Not determined |
| · pH-value at 20 °C: | 6,5 |
| · Change in condition: | |
| · Melting point/Melting range: | Not determined |
| · Boiling point/Boiling range: | Not determined |
| · Flash point: | Not applicable |
| · Inflammability (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 | 1,015 g/cm ³ |
| · Relative density: | Not determined |
| · Evaporation rate: | Not determined |
| · Solubility in / Miscibility with | |
| · Water: | Not miscible or difficult to mix |
| · Viscosity: | |
| · dynamic: | Not determined |
| · Water: | 96,2 % |
| · 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.

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):** Not applicable.
 - **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.

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- **Sensitisation:**
Sensitization is possible with prolonged exposure, based on the reported properties of methylisothiazolones.
- **Additional toxicological information:** None
- **Target organs/systems:** Unknown
 - **CMR effects (carcinogenicity, 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.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

| | |
|-----------|--------------------|
| LC50 96 h | >750 mg/l (minnow) |
|-----------|--------------------|

- **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 07: chemicals other than those mentioned in 18 01 06
- **Uncleaned packagings**
For disposal of contaminated packaging, refer to applicable local regulations and institutional policies.

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- **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

· 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.

· 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.

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· Complete text for H (Hazard) and/or R (Risk) codes displayed in Section 3:

Note: The respective H and/or R statements apply to the pure substances.

· Contact supplier

Environmental Affairs & Product Safety

Tel.: +49 (0) 6122 58 0

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

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

· * Data compared to the previous version altered.

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