

Release Date: 11/24/15

REF	Product Name
GTIN	

5J08-016	<i>VYSIS CEP 16 (D16Z3) SpectrumOrange Probe</i>
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Components:

5J08-016 PROBE	VYSIS CEP 16 (D16Z3) SpectrumOrange Probe
30-804828 GHS	VYSIS CEP Hybridization Buffer

Safety Data Sheet

according to 1907/2006/EC, Article 31

© Abbott Laboratories Release date 24.11.2015

Version number 1

Last alteration on 24.11.2015

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

1.1 Product identifier

· Trade name: **VYSIS CEP 16 (D16Z3) SpectrumOrange Probe**

· Article number: 5J08-016 PROBE

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 Molecular
1300 E. Touhy Ave
Des Plaines, IL 60018-3315 USA
Tel. Abbott Molecular Customer Service: 1-800-553-7042

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 675834.

- 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)

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.

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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. Seek medical attention and appropriate follow-up.
- **After skin contact:**
Take off any clothing that the product touched. Wash affected area with soap and water. Seek medical attention and appropriate follow-up.
- **After eye contact:**
Rinse open eye(s) cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek medical attention and appropriate follow-up. Wash hands after handling.
- **After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

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 components. See package insert / instructions for use for details. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection.

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**

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 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

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.

See Section 13 for disposal information.

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.

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- **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.

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

- **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 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.

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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:	7,5
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· Change in condition:

· Melting point/Melting range:	Not determined
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· Boiling point/Boiling range:	Not determined
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· 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
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· Upper:	Not determined
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· Density at 20 °C

 1 g/cm³

· Relative density:	Not determined
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· Evaporation rate:	Not determined
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· Solubility in / Miscibility with

· Water:	Fully miscible
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· Viscosity:

· dynamic:	Not determined
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· Water:	99,2 %
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· 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.
- **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.**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 federal, state and local regulations and institutional requirements. The following may be particularly important when identifying appropriate disposal:

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- 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

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.

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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

Tel. Abbott Molecular Customer Service: 1-800-553-7042

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

1.1 Product identifier

· Trade name: **VYSIS CEP Hybridization Buffer**

· Article number: 30-804828 GHS

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 Molecular
1300 E. Touhy Ave
Des Plaines, IL 60018-3315 USA
Tel. Abbott Molecular Customer Service: 1-800-553-7042

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 675834.

- 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:

Repr. 1B H360 May damage fertility or the unborn child.

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: Danger

· Hazard-determining components of labelling:

Formamide

· Hazard statements:

H360 May damage fertility or the unborn child.

· Precautionary statements:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/protective clothing/eye protection.

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P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

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

Additional information:

Refer to section 15 for labelling per Directives 67/548/EEC or 1999/45/EC.

Restricted to professional users.

Routes of Exposure: 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 Chemical characterisation: Mixtures

Dangerous components according to EC criteria:

CAS: 75-12-7	Formamide	Repr. 1B, H360D	68,5868%
EINECS: 200-842-0			

SVHC

75-12-7	Formamide
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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 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. Symptoms (such as pain) may be delayed and lead to underestimating the possible damage. Provide medical observation for at least 48 hours after exposure.

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:

Liver effects

Kidney effects

Irreversible eye damage

4.3 Indication of any immediate medical attention and special treatment needed:

No additional relevant information available.

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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**

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:**

Prevent formation of aerosols or vapours.

Avoid contact with eyes.

- **Information about protection against explosions and fires:** Keep breathing equipment ready.

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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:

75-12-7 Formamide (68,5868 %)

WEL (Great Britain)	Short-term value: 56 mg/m ³ , 30 ppm
	Long-term value: 37 mg/m ³ , 20 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.

Immediately remove all soiled and contaminated clothing.

Store protective clothing separately.

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.

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- **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: Colourless

- Odour: Odourless
- Odour threshold: Not determined

- pH-value at 20 °C: 7,5

· Change in condition:

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

- Flash point: Not applicable

- Inflammability (solid, gaseous): Not applicable

- Ignition temperature: 0 °C
- Auto igniting: Product is not self-igniting.

- Danger of explosion: Product does not present an explosion hazard.

- Lower: 0,0 Vol %
- Upper: 0,0 Vol %

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

· Solubility in / Miscibility with

- Water: Not miscible or difficult to mix

- Viscosity:
- dynamic: Not determined

- Water: 14,1 %

- **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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- **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):**

75-12-7 Formamide

Oral	LD50	3150 mg/kg (mouse) 5577 mg/kg (rat)
	Mutagenicity	Negative (Ames Assay)
	Target Organ Effects	(other) Formamide is highly embryotoxic and teratogenic in animals receiving oral, interperitoneal and dermal dosages that did not cause maternal toxicity (LOAEL= 0.19 ml/kg). Formamide also caused testicular atrophy at near lethal dosages.

- **Primary irritant effect:**
 - **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
 - **Serious eye damage/irritation** Strong irritant, with the danger of severe eye injury.
- **Sensitisation:** Based on available data, the classification criteria are not met.
- **Additional toxicological information:** Product is suspected to cause birth defects.
- **Target organs/systems:**
 - Eye
 - Liver
 - Kidneys
 - Reproductive system
- **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**
 - May damage fertility or the unborn child.
- **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.

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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

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

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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

Labelling according to Directives 67/548/EEC or 1999/45/EC

Code letter and hazard designation of product:



T Toxic

Hazard-determining components of labelling:

Formamide

Risk phrases:

61 May cause harm to the unborn child.

41 Risk of serious damage to eyes.

Safety phrases:

53 Avoid exposure - obtain special instructions before use.

45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

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

75-12-7 Formamide

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

SECTION 16: Other information

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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.

H360D May damage the unborn child.

· **Contact supplier**

Tel. Abbott Molecular Customer Service: 1-800-553-7042

Environmental Affairs & Product Safety

Tel.: +49 (0) 6122 58 0

· **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

SVHC: Substance of Very High Concern (REACH)

Repr. 1B: Reproductive toxicity, Hazard Category 1B

Repr. 1B: Reproductive toxicity, Hazard Category 1B

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

ENG