

Bayer HealthCare



**SAFETY DATA SHEET**  
**Clinifast Reagent tablets**

Version 1.1

Revision Date 06/29/2010

122000003380

**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**Product Information**

Product Name: Clinifast Reagent tablets/SDS Number: 122000003380  
Use : In Vitro diagnostic reagent.

**Company**

BAYER HEALTHCARE LLC  
Diabetes Care  
555 White Plains Road  
Tarrytown, NY 10591  
UNITED STATES  
(800) 348-8100

In case of emergency: Call Chemtrec  
Chemtrec: (800) 424-9300  
BAYER INFORMATION PHONE: (800) 348-8100

**2. HAZARDS IDENTIFICATION**

**Emergency Overview**

Colour: blue Form: solid tablet Odour: odourless.  
Corrosive, when wet or dissolved can cause burns to the eyes and skin. Tablets are highly sensitive to moisture from air or water. Moisture may cause a chemical reaction and the glass bottle could explode.

**Hazard Communication (29CFR 1910.1200)**

No Carcinogenic substances as defined by IARC, NTP and/or OSHA

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Weight Percent	Components	CAS-No.
1 - 5%	Copper sulphate anhydrous	7758-98-7
30 - 60%	Sodium hydroxide	1310-73-2

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**4. FIRST AID MEASURES**

General advice: Call a physician immediately. Arrange for transport to nearest emergency room.  
If inhaled: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

In case of skin contact: After contact with skin, wash immediately with plenty of soap and water. Take off contaminated clothing and shoes immediately. Wash contaminated clothing before re-use.

In case of eye contact: In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed: If swallowed, seek medical advice immediately and show this container or label. Do NOT induce vomiting. Give two glasses of water or milk for dilution.

Contact Number: Use the Bayer Emergency Number in Section 1

**5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media: Any

Specific hazards during fire fighting: Fire may cause evolution of Carbon monoxide Carbon dioxide (CO2)

Special protective equipment for fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Further information: Prevent fire extinguishing water from contaminating surface water or the ground water system.

**6. ACCIDENTAL RELEASE MEASURES**

Personal precautions: Use personal protective equipment

Methods for cleaning up: Place in closed containers. Label for proper disposal.

**7. HANDLING AND STORAGE**

Handling: Avoid contact with skin, eyes and clothing.

Store at temperatures and conditions as indicated on the product label. Keep container tightly closed. Avoid contact with moisture/water. Moisture may cause a chemical reaction and the glass

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bottle could explode.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Sodium hydroxide (1310-73-2)

U.S. ACGIH Threshold Limit Values  
Ceiling Limit Value: 2 mg/m<sup>3</sup>  
U.S. NIOSH Pocket Guide to Chemical Hazards  
Ceiling Limit Value and Time Period (if specified): 2 mg/m<sup>3</sup>  
U.S. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)  
PEL: 2 mg/m<sup>3</sup>

Copper sulphate anhydrous (7758-98-7)

U.S. NIOSH Pocket Guide to Chemical Hazards  
Recommended exposure limit (REL): 1 mg/m<sup>3</sup> as Cu (Dust and mist.)

**Respiratory protection:**  
not required

**Hand protection:**  
Chemically resistant gloves.

**Eye protection:**  
Chemical safety goggles or glasses.

**Other protective measures:**  
Wear suitable protective equipment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form: tablet  
Colour: blue  
Odour: odourless  
Density: no data available  
Bulk density: no data available  
Vapour pressure: not applicable  
Water solubility: soluble  
pH: Wet tablets are corrosive - prevent contact.  
Partition coefficient (n-octanol/water): no data available  
Solubility in organic solvents: no data available  
Flash point: not applicable  
Ignition temperature: not applicable

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Ignition temperature: no data available

10. STABILITY AND REACTIVITY

Conditions to avoid: Exposure to moisture

Materials to avoid: Strong acids, Metals, halogens  
Action of humidity leads to formation of heat and overpressure. Protect from moisture.

Hazardous reactions: Decomposes in contact with water. Corrosive in contact with metals

**Thermal decomposition:**  
no data available

**Hazardous decomposition products:**  
Carbon monoxide, Carbon dioxide (CO<sub>2</sub>)

11. TOXICOLOGICAL INFORMATION

**Other information on toxicity:**

If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach.

**Acute oral toxicity:**

Copper sulphate anhydrous  
LD50 rat: 300 mg/kg

LDL0 human: 50 mg/kg

**Acute inhalation toxicity:**

Inhalation of mist or dried residue causes irritation of respiratory system.

**Skin irritation:**

Acute dermal irritator/corrosion

**Eye irritation:**

May cause eye and skin irritation. Risk of blindness!

**Genotoxicity in vitro:**

Bacterial mutagenicity Escherichia coli  
Result: negative

Copper sulphate anhydrous

Micronucleus test

Result: negative. No indication of mutagenic effects.

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Bacterial mutagenicity: Escherichia coli  
Result: negative. No indication of mutagenic effects.

**12. ECOLOGICAL INFORMATION**

**General advice:**  
Do not allow to enter surface waters or groundwater.

**Toxicity to fish:**

Acute Fish toxicity: LC50 45.4 mg/l

Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

Acute Fish toxicity: LC50 99 mg/l

Test species: Lepomis macrochirus (Bluegill) Duration of test: 48 h

Copper sulphate anhydrous

LC50 0.11 mg/l

Test species: Oncorhynchus mykiss (rainbow trout) Duration of test: 96 h

**Toxicity to daphnia and other aquatic invertebrates:**

EC50 76 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 24 h

Copper sulphate anhydrous

EC50 0.024 mg/l

Test species: Daphnia magna (Water flea) Duration of test: 48 h

**Toxicity to algae:**

Copper sulphate anhydrous

EC50 0.1 mg/l

tested on: Scenedesmus quadricauda (Green algae) Duration of test: 4 h

**Biodegradability:**

The methods for determining biodegradability are not applicable to inorganic substances.

Copper sulphate anhydrous

The methods for determining biodegradability are not applicable to inorganic substances.

**13. DISPOSAL CONSIDERATIONS**

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

Waste disposal should be in accordance with existing federal, state and local environmental control laws.

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**14. TRANSPORT INFORMATION**

**Land transport (DOT)**

Proper shipping name: Sodium hydroxide, solid

Hazard Class or Division: 8

UN/NA Number: UN1823

Packaging group: II

Hazard Label(s): Corrosive

**Inland waterway transport**

Proper shipping name: Sodium hydroxide, solid

Hazard Class or Division: 8

UN/NA Number: UN1823

Packaging group: II

Hazard Label(s): Corrosive

**Railway transport**

Proper shipping name: Sodium hydroxide, solid

Hazard Class or Division: 8

UN/NA Number: UN1823

Packaging group: II

Hazard Label(s): Corrosive

**Sea transport (IMDG)**

Proper shipping name: SODIUM HYDROXIDE, SOLID

Hazard Class or Division: 8

UN-Number: UN1823

Packaging group: II

Hazard Label(s): CORROSIVE

Packaging group: II

Hazard Label(s): CORROSIVE

**Air transport (ICAO/IATA cargo aircraft only)**

Proper shipping name: Sodium hydroxide, solid

Hazard Class or Division: 8

UN-Number: UN1823

Packaging group: II

Hazard Label(s): CORROSIVE

**Air transport (ICAO/IATA passenger and cargo aircraft)**

Proper shipping name: Sodium hydroxide, solid

Hazard Class or Division: 8

UN-Number: UN1823

Packaging group: II

Hazard Label(s): CORROSIVE

**15. REGULATORY INFORMATION**

US: EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A) Components

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None

US EPA Emergency Planning and Community Right-To-Know Act (EPCRA) SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) - Supplier Notification Required  
Components  
Copper sulphate anhydrous

US EPA CERCLA Hazardous Substances (40 CFR 302) Components  
Copper sulphate anhydrous Reportable quantity: 10 lbs  
Sodium hydroxide Reportable quantity: 1000 lbs

Marine Pollutant Components

Copper sulphate anhydrous Sewer marine pollutant

Massachusetts, New Jersey or Pennsylvania Right to Know Substance Lists

Weight Percent Components CAS-No.  
1 - 5% Copper sulphate anhydrous 7738-98-7  
30 - 60% Sodium hydroxide 1310-73-2

New Jersey Environmental Hazardous Substances List and/or New Jersey RTK Special Hazardous Substances Lists

Weight Percent Components CAS-No.  
1 - 5% Copper sulphate anhydrous 7738-98-7

California Prop. 65

To the best of our knowledge, this product does not contain any of the listed chemicals, which the state of California has found to cause cancer, birth defects or other reproductive harm.

OSHA Hazcom Standard Rating Hazardous

16. OTHER INFORMATION

HMIS Rating	
Health	2
Flammability	0
Physical Hazard	2
Personal protective equipment	B

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe  
\* = Chronic Health Hazard  
A = Safety Glasses  
B = Safety Glasses, Gloves  
C = Safety Glasses, Gloves, Apron

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D = Face Shield, Gloves, Apron  
E = Safety Glasses, Gloves, Dust Respirator  
F = Safety Glasses, Gloves, Apron, Dust Respirator  
G = Safety Glasses, Gloves, Apron, Vapor Respirator  
H = Splash Goggles, Gloves, Apron, Vapor Respirator  
J = Splash Goggles, Gloves, Apron, Dust and Vapor Respirator  
K = Air Line Hood or Mask, Gloves, Full Suit, Boots  
L = Situation Requiring Special Handling

Further Information

The information provided in this Safety Data Sheet is correct to the best of our knowledge. Information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.