

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078042446

N/A



## SAFETY DATA SHEET

05778865

Bayer Healthcare LLC  
Diabetes Care  
555 White Plains Road, 5th Floor  
Tarrytown, NY 10591; USA

Emergency Telephone  
1-800-424-9300 (Chemtrec)  
Technical Information  
1-800-348-8100

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Product Name: KETOSTIX

Product Number: 05778865, 2881

Date Prepared: 8/10/2008

Revision Number: 5

Recommended Use: In vitro diagnostic reagent

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Pursuant to United States OSHA Regulations 29 CFR Part 1910.1200, This Product Is Not Considered To Contain Hazardous Materials.

EU Classification (1999/45/EC): Not applicable

EU Risk and Safety Phrases: None

### 3. HAZARDS IDENTIFICATION

This product is not considered to be a critical hazard to man or the environment.

### 4. FIRST AID MEASURES

Inhalation, Skin Contact and Eye Contact: Not considered health risks.

Ingestion: Have patient drink 2-8 oz. glasses of water or milk to dilute. Contact Physician for further care.

### 5. FIRE-FIGHTING MEASURES

Extinguishing Media: Use whatever is required for the surrounding area.

Special Fire Fighting Procedures: It is always best to wear a self-contained breathing apparatus.

Unusual Fire and Explosion Hazards: None determined.



## 6. ACCIDENTAL RELEASE MEASURES

Steps to be taken in case material is released or spilled: Pick up and place in a disposal container.

## 7. HANDLING AND STORAGE

Store at temperatures and conditions as indicated on the product label. See product label or Package Insert for instructions on handling product during test use.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Ventilation:** Use general room ventilation, there is no special respiratory protection required.

**Protective Gloves and Other Protective Equipment:** Not required

**Eye Protection:** Not needed or required to use this product.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance and odor:** Plastic strips with 1 pads/strip.

**pH:** Not applicable

**Solubility in Water:** Not soluble

**Physical Characteristics:** not significant

**Flash Point (Method Used):** None

**Flammable Limits:** LEL: Not Applicable UEL: Not Applicable

## 10. STABILITY AND REACTIVITY

**Stability:** This product is stable as sold if used as directed. There are no specific conditions to avoid.

## 11. TOXICOLOGICAL INFORMATION

**Chronic Effects of Overexposure:** None currently known. None of the components are listed as a carcinogen or suspected carcinogen.

**Acute Toxicity:**

**Inhalation, Skin Contact and Eye Contact:** Not considered health risks.

**Ingestion:** If ingestion should occur the patient may feel uncomfortable. Treat as indicated.



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Acute Toxicity Values: Not applicable

## **12. ECOLOGICAL INFORMATION**

Ecological effects of the product strips have not been determined.

## **13. DISPOSAL CONSIDERATIONS**

**Primary Container Type:** The product container is HD polyethylene. Plastic strips are polystyrene with chemically impregnated paper affixed.

**Waste Disposal Method:** Each disposal facility must determine proper disposal methods to comply with Local, State and Federal Environmental Regulations. Incineration of the product could produce trace amounts of toxic gasses. Check your local regulations before incineration

## **14. TRANSPORT INFORMATION**

**Proper Shipping Name:** Not regulated

**Technical Name:**

**UN Number:** N/A

**Hazard Class and Packaging Group:** Not regulated

**Label(s):** N/A

**Packing Instruction (Passenger Aircraft):** N/A

**Packing Instruction (Cargo Aircraft):** N/A

**Unit Volume:** 100 strips/bottle

**Primary Container Type:** Plastic, HD polyethylene

**Sales Unit:** 1 bottle

## **15. REGULATORY INFORMATION**

**SARA 311/312: Hazard categories for SARA Section 311/312 Reporting:** Not Hazardous

**Canadian WHMIS Classification:** Not a controlled product.

**EU Classification (1999/45/EC):** Not applicable





**EU Risk and Safety Phrases:** None



## SAFETY DATA SHEET

05778865

### 16. OTHER INFORMATION

HMIS Hazard Rating		
 Health:	0	4 Severe Hazard
 Fire:	0	3 Serious Hazard
 Reactivity:	0	2 Moderate Hazard
 Personal	0	1 Slight Hazard
Protection:	0	0 Minimal Hazard
		* An asterisk indicates significant chronic health effects

**Reason for Revision:** Revisions to section(s) 1,2,3,8,9,16

**Prepared by:** HES Department

The opinions expressed herein are those of qualified experts within Bayer Corporation. We believe that the information contained herein is current as of the date of this Material Safety Data Sheet. Since the use of this information and these opinions and the conditions of use of the product are not within the control of Bayer Corporation, it is the users' obligation to assure safe use of the product.

## SAFETY DATA SHEET

122000007043

**Ketostix® Reagent Strips for Urine-analysis**

Version 3.1

Revision Date 05/15/2015

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

**Product Name:** Ketostix® Reagent Strips for Urine-analysis  
**SDS Number:** 122000007043

**Use** : In Vitro diagnostic reagent.

**Company**

BAYER HEALTHCARE LLC  
Diabetes Care  
100 Bayer Boulevard PO Box 915  
Whippany, NY 07981-0915  
USA  
(800) 348-8100

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

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**2. HAZARDS IDENTIFICATION****Emergency Overview**

<b>Form:</b> solid, Test strips <b>Odour:</b> odourless.
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**GHS Classification:**

Not a dangerous substance / mixture according to GHS.

**GHS Label element:**

Not a dangerous substance / mixture according to GHS.

**Other hazards which do not result in classification:**

None known.

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**Ketostix® Reagent Strips for Urine-analysis**

Version 3.1

Revision Date 05/15/2015

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**3. COMPOSITION/INFORMATION ON INGREDIENTS**

This material is not hazardous under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

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**4. FIRST AID MEASURES**

**General advice:** No hazards which require special first aid measures.

**If inhaled:** Not an expected entry route.

**In case of skin contact:** Not considered a health risk.

**In case of eye contact:** Not considered a health risk.

**If swallowed:** Give two glasses of water or milk for dilution. Obtain medical attention.

**Contact Number:** Use the Bayer Emergency Number in Section 1

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**5. FIREFIGHTING MEASURES**

**Suitable extinguishing media:** Any

**Specific hazards during firefighting:** Fire may cause evolution of: Carbon monoxide (CO)  
Carbon dioxide (CO<sub>2</sub>)

**Special protective equipment for firefighters:** In the event of fire, wear self-contained breathing apparatus.

**Further information:** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions:** Use personal protective equipment.

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

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**Ketostix® Reagent Strips for Urine-analysis**

Version 3.1

Revision Date 05/15/2015

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**7. HANDLING AND STORAGE****Handling:**

No special precautions required.

**Storage:**Store at temperatures and conditions as indicated on the product label.

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**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Respiratory protection:**

not required

**Hand protection:**

not required

**Other protective measures:**Please consult label for end-user requirements.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

Form:	solid, Test strips
Colour:	No applicable information is available
Odour:	odourless
Odour Threshold:	No applicable information is available
Melting point:	No data available
Boiling point/boiling range:	No applicable information is available
Density:	No applicable information is available
Bulk density:	No applicable information is available
Vapour pressure:	No applicable information is available
Viscosity, dynamic:	No applicable information is available
Viscosity, kinematic:	No applicable information is available
Flow time:	No applicable information is available
Surface tension:	No applicable information is available
Miscibility with water:	No applicable information is available
Water solubility:	insoluble
pH:	Not applicable
Relative density:	No applicable information is available
Partition coefficient:	No applicable information is available
Solubility(ies):	No applicable information is available
Flash point:	Not applicable
Flammability (solid, gas):	No applicable information is available
Ignition temperature:	Not applicable
Explosion limits:	No applicable information is available

**Ketostix® Reagent Strips for Urine-analysis**

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**10. STABILITY AND REACTIVITY**

**Conditions to avoid:** The enclosed instructions for use should be consulted prior to use.

**Materials to avoid:** Oxidizing agents

**Hazardous reactions:** None known.

**Thermal decomposition:**

No data available

**Hazardous decomposition products:**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

**Oxidizing properties:**

No statements available.

**Impact sensitivity:**

No data available

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**11. TOXICOLOGICAL INFORMATION**

**Other information on toxicity:**

Further details are not available.

According to our experience and information the product has no harmful effects on health if properly handled.

**Acute oral toxicity:**

Acute toxicity estimate (ATE) > 5,000 mg/kg

**Pharmaceutic effects:**

active ingredient of a diagnostic

**Carcinogenicity:**

**STOT - single exposure:**

No data available

**STOT - repeated exposure:**

No data available

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**12. ECOLOGICAL INFORMATION**

**General advice:**

**Ketostix® Reagent Strips for Urine-analysis**

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No information on ecology is available.

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**13. DISPOSAL CONSIDERATIONS**

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

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**14. TRANSPORT INFORMATION****Land transport (CFR)**

non-regulated

**US Sea transport (IMDG)**

non-regulated

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

non-regulated

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

non-regulated

**International IATA**

IMDG

non-regulated

non-regulated

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**15. REGULATORY INFORMATION**

**Other regulations:** No statements available.

**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**

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**

None

**US. EPA CERCLA Hazardous Substances (40 CFR 302) Components**

None

**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**

Non-Hazardous

**Ketostix® Reagent Strips for Urine-analysis**

Version 3.1

Revision Date 05/15/2015

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**16. OTHER INFORMATION****HMIS Rating**

<b>Health</b>	0
<b>Flammability</b>	0
<b>Physical Hazard</b>	0

0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

\* = Chronic Health Hazard

**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.