



MATERIAL SAFETY DATA SHEET
Acetaminophen-SL Enzyme Reagent (R1)

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Acetaminophen-SL Enzyme Reagent (R1)

Synonym(s): R1

Product Use: Component of Acetaminophen-SL Assay (Catalog # 505-10 & 505-30). For the in vitro quantitative measurement of acetaminophen in serum and plasma. For In Vitro Diagnostic Use Only.

Description: Aqueous solution containing trace amounts of buffer, enzyme (protein), surfactant and preservatives.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Distributor

Genzyme Diagnostics

50 Gibson Drive
Kings Hill, West Malling
Kent, ME19 4AF
UK

Phone: 44 (0) 1732 220022

Manufacturer/Distributor

Genzyme Diagnostics P.E.I. Inc.

70 Watts Ave.
Charlottetown, PE C1E 2B9
CANADA

Phone: 800-332-1042

Distributor

Genzyme Diagnostics

115 Summit Drive
Exton, PA 19341
USA

Phone: 800-999-6578

Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555

CHEMTREC (U.S.): 800-424-9300

CHEMTREC (Outside U.S.): +1 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, colorless liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	No data available.
Eye	No data available. Eye exposure may cause irritation.
Skin	No data available. Skin contact may cause irritation, redness and discomfort.
Ingestion	No data available.
Chronic Effects	No data available.
Target Organs	Unknown.

Regulatory Status:

This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.



MATERIAL SAFETY DATA SHEET

Acetaminophen-SL Enzyme Reagent (R1)

Potential Environmental Effects:

Unknown.

3. COMPOSITION / INFORMATION ON INGREDIENTS

No hazardous ingredients are present at or above the minimum concentration limits requiring disclosure per U.S. and international MSDS regulations.

4. FIRST AID MEASURES

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

Carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

Do not let preparation enter drains.

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.



MATERIAL SAFETY DATA SHEET

Acetaminophen-SL Enzyme Reagent (R1)

7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2 to 8°C (36 to 46°F). Do not store with incompatible substances. See Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory	A respirator is not required under normal conditions of use.
Eye/Face	Wear appropriate protective chemical safety glasses.
Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless liquid	pH:	8.6 at 25°C
Odor:	Not available	Solubility:	Water-soluble
Boiling Point:	Not available	Evaporation Rate:	Not available
Melting Point:	Not applicable	Density:	1.006 g/mL
Freezing Point:	Not available	Vapor Pressure:	Not available
Viscosity:	Not available	Partition Coefficient (n-octanol/water):	Not available
		Vapor Density:	Not available
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	Not available		



MATERIAL SAFETY DATA SHEET
Acetaminophen-SL Enzyme Reagent (R1)

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:

No data available.

Local Effects:

No data available.

Chronic Effects:

No data available.

Carcinogenicity:

No data available.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.



MATERIAL SAFETY DATA SHEET
Acetaminophen-SL Enzyme Reagent (R1)

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canadian Hazardous Products:

WHMIS Status Exempt

European Communities Dangerous Substances/Preparations:

EC Hazard Class None

Risk Phrases None

Safety Phrases None

16. OTHER INFORMATION

Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

MSDS Origination Date: April 17, 2008

Version #: 4

Revision Date: April 14, 2009



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Acetaminophen-SL Enzyme Reagent (R1)

Disclaimer:

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MATERIAL SAFETY DATA SHEET

Acetaminophen-SL Color Reagent (R2)

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Acetaminophen-SL Color Reagent (R2)

Synonym(s): R2

Product Use: Component of Acetaminophen-SL Assay (Catalog # 505-10 & 505-30). For the in vitro quantitative measurement of acetaminophen in serum and plasma. For In Vitro Diagnostic Use Only.

Description: Dilute, basic, aqueous solution containing sodium carbonate buffer and trace amounts of salts, surfactant and preservatives.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Distributor

Genzyme Diagnostics

50 Gibson Drive
Kings Hill, West Malling
Kent, ME19 4AF
UK

Phone: 44 (0) 1732 220022

Manufacturer/Distributor

Genzyme Diagnostics P.E.I. Inc.

70 Watts Ave.
Charlottetown, PE C1E 2B9
CANADA

Phone: 800-332-1042

Distributor

Genzyme Diagnostics

115 Summit Drive
Exton, PA 19341
USA

Phone: 800-999-6578

Emergency Telephone Numbers

Genzyme (U.S.): 617-562-4555

CHEMTREC (U.S.): 800-424-9300

CHEMTREC (Outside U.S.): +1 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

CAUTION! The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: pale yellow liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	No data available.
Eye	No data available. Eye exposure may cause irritation.
Skin	No data available. Skin contact may cause irritation, redness and discomfort.
Ingestion	No data available.
Chronic Effects	No data available.
Target Organs	Unknown.

Regulatory Status:

This preparation is classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIP 2002 No. 1689; and/or U.N. GHS ST/SG/AC 10/30. Refer to Sec. 15, Regulatory Information, for details regarding hazard classification.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.



MATERIAL SAFETY DATA SHEET

Acetaminophen-SL Color Reagent (R2)

Potential Environmental Effects:

Unknown.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Sodium carbonate	497-19-8	207-838-8	1 - 2
EC R-Phrases: R36	EC Hazard Class: Xi		

4. FIRST AID MEASURES

Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.

Eye Contact:

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

Skin Contact:

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Ingestion:

In case of ingestion, contact a poison control center or physician for instructions.

5. FIRE FIGHTING MEASURES

Flammable Properties:

Dilute aqueous solution not considered a fire hazard.

Suitable Extinguishing Media:

Carbon dioxide, chemical foam, dry chemical or water spray.

Unsuitable Extinguishing Media:

Unknown.

Specific Hazards Arising from the Chemical:

None expected.

Standard Protective Equipment and Precautions for Firefighters:

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Precautions:

No information available.



MATERIAL SAFETY DATA SHEET

Acetaminophen-SL Color Reagent (R2)

Methods and Materials for Containment and Clean-Up:

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

7. HANDLING AND STORAGE

Handling:

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2 to 8°C (36 to 46°F). Do not store with incompatible substances. See Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

There are no ACGIH, NIOSH, OSHA or country-specific occupational exposure limits currently established for components present in this preparation at concentrations equal to or greater than 1% (0.1% if carcinogen).

Engineering Controls:

This preparation is aqueous and non-volatile and is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

Personal Protective Equipment (PPE):

Respiratory	A respirator is not required under normal conditions of use.
Eye/Face	Wear appropriate protective chemical safety glasses.
Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Pale yellow liquid	pH:	12.2 at 25°C
Odor:	Not available	Solubility:	Water-soluble
Boiling Point:	Not available	Evaporation Rate:	Not available
Melting Point:	Not applicable	Density:	1.016 g/mL
Freezing Point:	Not available	Vapor Pressure:	Not available
Viscosity:	Not available	Partition Coefficient (n-octanol/water):	Not available
		Vapor Density:	Not available
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	Not available		



MATERIAL SAFETY DATA SHEET

Acetaminophen-SL Color Reagent (R2)

10. STABILITY AND REACTIVITY

Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

Hazardous Decomposition Products:

None expected under normal conditions of use.

Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Effects:**Toxicology Data - Selected LD50s and LC50s**

Sodium carbonate	497-19-8	Oral LD50 Rat: 4090 mg/kg
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Local Effects:

No data available.

Chronic Effects:

No data available.

Carcinogenicity:

No data available.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:**Ecotoxicity - Freshwater Algae Data**

Sodium carbonate	497-19-8	120 Hr EC50 Nitzschia: 242 mg/L
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Ecotoxicity - Freshwater Fish Species Data

Sodium carbonate	497-19-8	96 Hr LC50 Lepomis macrochirus: 300 mg/L [static]
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Ecotoxicity - Water Flea Data

Sodium carbonate	497-19-8	48 Hr EC50 Daphnia magna: 265 mg/L
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Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.



MATERIAL SAFETY DATA SHEET

Acetaminophen-SL Color Reagent (R2)

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

Waste Classification:

U.S. - California - 22 CCR - Presumed Hazardous Wastes

Sodium carbonate	497-19-8	Corrosive
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14. TRANSPORT INFORMATION

Basic Shipping Description:

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

15. REGULATORY INFORMATION

US Federal Regulations:

This preparation is a component of an FDA-regulated in vitro diagnostic device.

Inventory - United States - Section 8(b) Inventory (TSCA)

Sodium carbonate	497-19-8	Present
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International Regulations:

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

Canada - WHMIS - Classifications of Substances

Sodium carbonate	497-19-8	D2B, E
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Canada - WHMIS - Ingredient Disclosure List

Sodium carbonate	497-19-8	1 %
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EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Classification

Sodium carbonate	497-19-8	Xi;R36
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EU - Dangerous Substances Directive (67/548/EEC) - Annex I - Safety Phrases

Sodium carbonate	497-19-8	S:2-22-26
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Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium carbonate	497-19-8	ID Number 222, hazard class 1 - low hazard to waters (footnote 8)
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Inventory - Australia - Inventory of Chemical Substances (AICS)

Sodium carbonate	497-19-8	Present
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Inventory - Canada - Domestic Substances List (DSL)

Sodium carbonate	497-19-8	Present
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Inventory - China

Sodium carbonate	497-19-8	Present
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Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Sodium carbonate	497-19-8	207-838-8
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Inventory - Japan Existing and New Chemical Substances (ENCS)

Sodium carbonate	497-19-8	1-164
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Inventory - Korea - Existing and Evaluated Chemical Substances

Sodium carbonate	497-19-8	KE-31380
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Canadian Hazardous Products:

WHMIS Status	Exempt
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MATERIAL SAFETY DATA SHEET

Acetaminophen-SL Color Reagent (R2)

European Communities Dangerous Substances/Preparations:

EC Hazard Class None

Risk Phrases None

Safety Phrases None

16. OTHER INFORMATION

Further Information:

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

MSDS Origination Date: April 17, 2008

Version #: 4

Revision Date: April 14, 2009

Disclaimer:

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