

1. Product and Company Identification

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| Material name | ACETAMINOPHEN L3K® Color Reagent (R2) |
| Version # | 01 |
| Issue date | 02-04-2013 |
| Revision date | - |
| Supersedes date | - |
| CAS # | Mixture |
| Kit number | 506-10; 506-30 |
| Product use | For the quantitative measurement of acetaminophen in serum and plasma. For In Vitro Diagnostic use only. |
| Manufacturer information | |
| Corporate Headquarters | Sekisui Diagnostics, LLC 31 New York Avenue, Framingham, MA 01701 USA www.sekisuidiagnostics.com Phone: 800-332-1042 |
| Emergency Telephone Numbers | Americas 1-760-476-3962 Europe, Middle East & Africa +1-760-476-3961 Asia Pacific +1-760-476-3960 Access code 333512 |

2. Hazards Identification

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| Physical state | Liquid. |
| Appearance | Slight yellow liquid. |
| Emergency overview | DANGER Causes skin and eye burns. Prolonged exposure may cause chronic effects. |
| OSHA regulatory status | This product is considered hazardous under 29 CFR 1910.1200 (Hazard Communication). |
| Potential health effects | |
| Routes of exposure | Inhalation. Ingestion. Skin contact. Eye contact. |
| Eyes | This product causes eye burns. |
| Skin | Causes skin burns. |
| Inhalation | In high concentrations, mists/vapors may irritate throat and respiratory system and cause coughing. |
| Ingestion | Can burn mouth, throat, and stomach. |
| Target organs | Eyes. Respiratory system. Skin. Gastro-intestinal tract |
| Chronic effects | Prolonged skin contact may defat the skin and produce dermatitis. |
| Signs and symptoms | May cause burns in mucous membranes, throat, esophagus and stomach. |
| Potential environmental effects | The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. |

3. Composition / Information on Ingredients

| Components | CAS # | Percent |
|----------------------------------|-----------|---------|
| Sodium carbonate | 497-19-8 | 1 - 2.5 |
| Tris-(hydroxymethyl)aminomethane | 77-86-1 | 1 - 2.5 |
| Sodium hydroxide | 1310-73-2 | < 0.5 |

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| Composition comments | Contains a small amount of 2,5 Dimethylphenol. All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume. |
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4. First Aid Measures

First aid procedures

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| Eye contact | Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if irritation develops and persists. |
| Skin contact | Immediately flush thoroughly with water for at least 15 minutes. Get medical attention if irritation develops and persists. |
| Inhalation | If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Get medical attention immediately. |
| Ingestion | Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. |
| Notes to physician | Symptoms may be delayed. |
| General advice | Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. |

5. Fire Fighting Measures

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| Flammable properties | This product is not flammable. |
| Extinguishing media | |
| Suitable extinguishing media | Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire. |
| Unsuitable extinguishing media | None known. |
| Protection of firefighters | |
| Specific hazards arising from the chemical | None known. |
| Protective equipment and precautions for firefighters | Self-contained breathing apparatus and full protective clothing must be worn in case of fire. |
| Fire fighting equipment/instructions | Use standard firefighting procedures and consider the hazards of other involved materials. |
| Hazardous combustion products | No data available. |

6. Accidental Release Measures

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| Personal precautions | Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. |
| Environmental precautions | Do not allow to enter drains, sewers or watercourses. |
| Methods for containment | Absorb spillage with non-combustible, absorbent material. |
| Methods for cleaning up | Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13. |
| Other information | Absorb small leaks or spills with sponge, mop up large spills with plenty of soap and water. Clean up in accordance with all applicable regulations. |

7. Handling and Storage

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| Handling | Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care. |
| Storage | Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials. |

8. Exposure Controls / Personal Protection

Occupational exposure limits

US. ACGIH Threshold Limit Values

| Components | Type | Value |
|----------------------------------|---------|---------|
| Sodium hydroxide (CAS 1310-73-2) | Ceiling | 2 mg/m3 |

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

| Components | Type | Value |
|----------------------------------|------|---------|
| Sodium hydroxide (CAS 1310-73-2) | PEL | 2 mg/m3 |

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

| Components | Type | Value |
|----------------------------------|---------|---------|
| Sodium hydroxide (CAS 1310-73-2) | Ceiling | 2 mg/m3 |

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

| Components | Type | Value |
|----------------------------------|---------|---------|
| Sodium hydroxide (CAS 1310-73-2) | Ceiling | 2 mg/m3 |

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

| Components | Type | Value |
|----------------------------------|---------|---------|
| Sodium hydroxide (CAS 1310-73-2) | Ceiling | 2 mg/m3 |

Canada. Quebec OELs. (Ministry of Labor - Regulation Respecting the Quality of the Work Environment)

| Components | Type | Value |
|----------------------------------|---------|---------|
| Sodium hydroxide (CAS 1310-73-2) | Ceiling | 2 mg/m3 |

Mexico. Occupational Exposure Limit Values

| Components | Type | Value |
|----------------------------------|---------|---------|
| Sodium hydroxide (CAS 1310-73-2) | Ceiling | 2 mg/m3 |

Exposure guidelines

Follow standard monitoring procedures.

Engineering controls

Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Personal protective equipment**Eye / face protection**

Wear approved safety glasses or goggles.

Skin protection

Wear lab coat or other protective garments. Remove contaminated clothing promptly.

Respiratory protection

Under normal conditions, respirator is not normally required.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical & Chemical Properties

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|-------------------------------------|-----------------------|
| Appearance | Slight yellow liquid. |
| Physical state | Liquid. |
| Form | Liquid. |
| Color | Slight yellow. |
| Odor | Phenolic. |
| Odor threshold | Not available. |
| pH | 11.5 @ 25 °C |
| Vapor pressure | Not available. |
| Vapor density | Not available. |
| Boiling point | Not available. |
| Melting point/Freezing point | Not available. |
| Solubility (water) | Soluble. |
| Specific gravity | 1.024 |
| Flash point | Not available. |

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| Flammability limits in air, upper, % by volume | Not available. |
| Flammability limits in air, lower, % by volume | Not available. |
| Auto-ignition temperature | Not available. |

10. Chemical Stability & Reactivity Information

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|------------------------------------|--|
| Chemical stability | Stable under normal storage and handling conditions. |
| Conditions to avoid | None under normal conditions. |
| Incompatible materials | Strong bases. |
| Hazardous decomposition products | No data available. |
| Possibility of hazardous reactions | Hazardous polymerization does not occur. |

11. Toxicological Information

Toxicological data

| Components | Species | Test Results |
|--|---|-------------------|
| Sodium carbonate (CAS 497-19-8) | | |
| Acute | | |
| <i>Inhalation</i> | | |
| LC50 | Rat | 2.3 mg/l, 2 Hours |
| <i>Oral</i> | | |
| LD50 | Rat | 4090 mg/kg |
| Tris-(hydroxymethyl)aminomethane (CAS 77-86-1) | | |
| Acute | | |
| <i>Oral</i> | | |
| LD50 | Rat | 5900 mg/kg |
| Sensitization | Not a skin sensitizer. | |
| Acute effects | Causes skin and eye burns. | |
| Local effects | Irritating to respiratory system. | |
| Chronic effects | Prolonged skin contact may defat the skin and produce dermatitis. | |
| Carcinogenicity | Not classified. | |
| Epidemiology | Not available. | |
| Mutagenicity | No data available. | |
| Neurological effects | Not available. | |
| Reproductive effects | No data available. | |
| Teratogenicity | Not available. | |
| Symptoms and target organs | May cause burns in mucous membranes, throat, esophagus and stomach. | |
| Further information | No other specific acute or chronic health impact noted. | |

12. Ecological Information

Ecotoxicological data

| Components | | Species | Test Results |
|----------------------------------|------|---|------------------------------|
| Sodium carbonate (CAS 497-19-8) | | | |
| Aquatic | | | |
| Crustacea | EC50 | Water flea (Ceriodaphnia dubia) | 156.6 - 298.9 mg/l, 48 hours |
| Fish | LC50 | Bluegill (Lepomis macrochirus) | 300 mg/l, 96 hours |
| Sodium hydroxide (CAS 1310-73-2) | | | |
| Aquatic | | | |
| Crustacea | EC50 | Water flea (Ceriodaphnia dubia) | 34.59 - 47.13 mg/l, 48 hours |
| Fish | LC50 | Western mosquitofish (Gambusia affinis) | 125 mg/l, 96 hours |

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| Ecotoxicity | The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. |
| Environmental effects | An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. |
| Aquatic toxicity | Not classified. |
| Persistence and degradability | No data is available on the degradability of this product. |
| Bioaccumulation / Accumulation | Not available. |

Partition coefficient

Tris-(hydroxymethyl)aminomethane (CAS 77-86-1) -2.31 (20°C)

Mobility in environmental media The product is soluble in water.

13. Disposal Considerations

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| Disposal instructions | Dispose in accordance with all applicable regulations. Contract with a licensed chemical disposal agency. |
| Waste from residues / unused products | Dispose in accordance with all applicable regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). |
| Contaminated packaging | Empty containers should be taken to an approved waste handling site for recycling or disposal. |

14. Transport Information

DOT

Basic shipping requirements:

| | |
|------------------------------|---------------------------|
| UN number | UN1824 |
| Proper shipping name | Sodium hydroxide solution |
| Hazard class | 8 |
| Packing group | III |
| Environmental hazards | |
| Marine pollutant | No |

Additional information:

| | |
|-----------------------------|-------------------|
| Special provisions | IB3, N34, T4, TP1 |
| Packaging exceptions | 154 |
| Packaging non bulk | 203 |
| Packaging bulk | 241 |

DOT

BULK

Basic shipping requirements:

| | |
|--------------------------------|---------------------------|
| UN number | UN1824 |
| Proper shipping name | Sodium hydroxide solution |
| Hazard class | 8 |
| Packing group | III |
| Additional information: | |

| | |
|-----------------------------|-------------------|
| Special provisions | IB3, N34, T4, TP1 |
| Packaging exceptions | 154 |
| Packaging non bulk | 203 |
| Packaging bulk | 241 |

IATA

| | |
|-----------------------------------|---------------------------|
| UN number | UN1824 |
| UN proper shipping name | Sodium hydroxide solution |
| Transport hazard class(es) | 8 |
| Subsidiary class(es) | - |
| Packing group | III |
| Environmental hazards | No |
| Labels required | 8 |
| ERG code | 8L |

IMDG

| | |
|-----------------------------------|---------------------------|
| UN number | UN1824 |
| UN proper shipping name | SODIUM HYDROXIDE SOLUTION |
| Transport hazard class(es) | 8 |

| | |
|-----------------------|----------|
| Subsidiary class(es) | - |
| Packing group | III |
| Environmental hazards | |
| Marine pollutant | No |
| Labels required | 8 |
| EmS | F-A, S-B |

TDG

| | |
|----------------------|---------------------------|
| UN number | UN1824 |
| Proper shipping name | SODIUM HYDROXIDE SOLUTION |
| Hazard class | 8 |
| Packing group | III |
| Marine pollutant | No |
| Labels required | 8 |

15. Regulatory Information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

CERCLA (Superfund) reportable quantity (lbs) (40 CFR 302.4)

Sodium hydroxide: 1000

Superfund Amendments and Reauthorization Act of 1986 (SARA)

| | |
|--------------------------|------------------------|
| Hazard categories | Immediate Hazard - Yes |
| | Delayed Hazard - Yes |
| | Fire Hazard - No |
| | Pressure Hazard - No |
| | Reactivity Hazard - No |

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| Section 302 extremely hazardous substance (40 CFR 355, Appendix A) | No |
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|-------------------------------------|-----|
| Section 311/312 (40 CFR 370) | Yes |
|-------------------------------------|-----|

| | |
|--|----------------|
| Drug Enforcement Administration (DEA) (21 CFR 1308.11-15) | Not controlled |
|--|----------------|

Canadian regulations This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

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|---------------------|------------|
| WHMIS status | Controlled |
|---------------------|------------|

| | |
|-----------------------------|---------------|
| WHMIS classification | E - Corrosive |
|-----------------------------|---------------|

WHMIS labeling



Inventory status

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|---|------------------------|
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | Yes |

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Hazardous Substances (Director's): Listed substance

| | |
|----------------------------------|---------|
| Sodium hydroxide (CAS 1310-73-2) | Listed. |
|----------------------------------|---------|

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US - New Jersey RTK - Substances: Listed substance

Sodium hydroxide (CAS 1310-73-2) Listed.

US. Massachusetts RTK - Substance List

Sodium hydroxide (CAS 1310-73-2) Listed.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Sodium hydroxide (CAS 1310-73-2) Listed.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

16. Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings Health: 3*
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 3
Flammability: 0
Instability: 0

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