SAFETY DATA SHEET
According to Regulation (EC) 1907/2006 (REACH) and Regulation (EC) 453/2010

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier
Product Name: Salicylate Enzyme Assay Kit
Product Code: K9001

1.2 Relevant identified uses of the substance or mixture and uses advised against
Components of a kit for the quantitative measurement of salicylate concentration in serum and plasma. In Vitro Medical Diagnostic Device according to Directive (EC) 98/79/EC.

Kit content (name and label reference)
Salicylate Enzyme Reagent K7106
NADH Reagent K7105
Salicylate Calibrator K7107

1.3 Details of the supplier of the safety data sheet
Cambridge Life Sciences Ltd.
14 St. Thomas’ Place, Ely, Cambridgeshire, CB7 4EX, UK
T: +44 (0)1353 645200
F: +44 (0)1353 645250
E: support@clsdiagnostics.com

1.4 Emergency telephone number:
Cambridge Life Sciences Ltd. (only office hours): +44 (0) 1353 645200

2. Hazards Identification

2.1 Classification of the substance or mixture

2.2 Label Elements
The labelling for these products is not classified as hazardous according to Regulation (EC) 1272/2008 (CLP).

2.3 Other Hazards
This product is intended for laboratory use by professional users only. Use appropriate personal protective equipment while working with the reagents provided.

3. Composition/information on ingredients

3.1 Substances
Not applicable

3.2 Mixtures

Salicylate Enzyme Reagent K7106
The manufacturer lists no ingredients as hazardous according to Regulation (EC) 1272/2008 (CLP).

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>EC No.</th>
<th>CAS No.</th>
<th>Conc (w/v)</th>
<th>Reg. 1272/2008</th>
<th>Dir. 67/548/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disodium EDTA dihydrate</td>
<td>205-358-3</td>
<td>6381-92-6</td>
<td>&lt;2.0%</td>
<td>na</td>
<td>na</td>
</tr>
<tr>
<td>Tris-(hydroxymethyl)aminomethane</td>
<td>201-064-4</td>
<td>77-86-1</td>
<td>&lt;2.0%</td>
<td>na</td>
<td>na</td>
</tr>
</tbody>
</table>

NADH Reagent K7105
The manufacturer lists no ingredients as hazardous according to Regulation (EC) 1272/2008 (CLP).

Salicylate Calibrator K7107
The Hazard Classification listed refers to the chemical at a pure concentration. It has been determined that the remaining ingredient(s) of these components are not classified as hazardous chemicals due to their physical and/or chemical nature and/or concentration in solution.

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>EC No.</th>
<th>CAS No.</th>
<th>Conc (w/v)</th>
<th>Reg. 1272/2008</th>
<th>Dir. 67/548/EEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Salicylate</td>
<td>200-198-0</td>
<td>54-21-7</td>
<td>&lt;0.1%</td>
<td>H302 H319</td>
<td>R22 R36</td>
</tr>
<tr>
<td>Sodium azide</td>
<td>247-852-1</td>
<td>26628-22-8</td>
<td>&lt;0.1%</td>
<td>H300 H400 H410</td>
<td>R28 R32 R50/53</td>
</tr>
</tbody>
</table>
4. First Aid Measures

4.1 Description of first aid measures
General advice: No special measures required. Consult a physician in case of complaints.
After Inhaling: Remove affected person to fresh air and get medical attention if necessary.
After Skin Contact: In case of skin contact, immediately wash thoroughly with soap and water.
After Eye contact: Rinse eyes for a few minutes with water while lifting the eye lids. If irritation persists, consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
The severity of the symptoms described will vary dependant of the concentration and the length of exposure.

4.3 Indication of any immediate medical attention and special treatment needed
No recommendation given, but first aid may still be required in case of accidental exposure, inhalation or ingestion of this chemical. If in doubt, get medical attention promptly.

5. Firefighting Measures

5.1 Extinguishing Media
Water, carbon dioxide, dry chemical powder or foam. Use extinguishing media appropriate to surrounding fire conditions.

5.2 Special hazards arising from the substance or mixture
No defined special hazards are known.

5.3 Advice for firefighters
Wear fully protective suit and self-contained breathing apparatus for firefighting if necessary.

6. Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures
Wear appropriate protective clothing, such as laboratory coat, gloves and safety glasses/goggles.

6.2 Environmental precautions
Contain spill to prevent migration. Avoid discharge into drains.

6.3 Methods and material for containment and cleaning up
Soak up and remove with absorbent materials and dispose of as hazardous waste. Clean floor and all other contaminated objects with water.

6.4 Reference to other sections
See sections 8 and 13.

7. Handling and Storage

7.1 Precautions for safe handling
Use good laboratory procedures and wear appropriate protective clothing, see section 8.

7.2 Conditions for safe storage, including any incompatibilities
Store all components according to instructions given on the label at 2 – 8°C. Protect from light.

7.3 Specific end use(s)
This product is intended for laboratory use by professional users only.

8. Exposure Controls / Personal Protection

8.1 Control Parameters
Components with exposure limits: it does not contain substances with exposure limit values.
Except sodium azide: TWA value 0.1 mg/m³ (in EU).

8.2 Exposure Controls
Handle in accordance with good industrial hygiene and safety practice.
Wash hands before breaks and at the end of the work day.

Personal protective equipment
Eye/face protection: goggles with UN EN166 (and subsequent updates), or other international standard certification.
Skin protection: laboratory coats, gloves with UN EN374 (and subsequent updates), or other international standard certification.
Body protection: laboratory coats.
Respiratory protection: not required.
9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Component</th>
<th>a) Appearance</th>
<th>b) Odour</th>
<th>d) pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salicylate Enzyme Reagent</td>
<td>Liquid, colourless</td>
<td>Odourless</td>
<td>7.60</td>
</tr>
<tr>
<td>NADH Reagent</td>
<td>Liquid, colourless</td>
<td>Odourless</td>
<td>10.40</td>
</tr>
<tr>
<td>Salicylate Calibrator</td>
<td>Liquid, colourless</td>
<td>Odourless</td>
<td>7.30</td>
</tr>
</tbody>
</table>

For all components:

- c) Odour threshold: no data available
- e) Melting point / freezing point: similar to H₂O
- f) Boiling point and boiling range: similar to H₂O
- g) Flash point: no data available
- h) Evaporation rate: no data available
- i) Flammability (solid, gas): no data available
- j) Upper/lower flammability or explosive limits: Not explosive
- k) Vapour pressure: no data available
- l) Vapour density: no data available
- m) Relative density: ~1g/ml
- n) Solubility in / miscibility with water: soluble
- o) Partition coefficient: n-octanol/water: no data available
- p) Autoignition temperature: no data available
- q) Decomposition temperature: no data available
- r) Viscosity: no data available
- s) Explosive properties: no data available
- t) Oxidising properties: no data available

9.2 Other information
No other information available.

10. Stability and Reactivity

10.1 Reactivity
No data available.

10.2 Chemical stability
Stable under the recommended storage conditions.

10.3 Possibility of hazardous reactions
Not known when used appropriately.

10.4 Conditions to avoid
Freezing and high temperature.

10.5 Incompatible materials
No data available.

10.6 Hazardous decomposition products
No data available.

11. Toxicological Information

11.1 Information to toxicological effects

**Acute toxicity**
- Disodium EDTA dihydrate: LD50 Oral - rat – >2,000 mg/kg
- Tris-(hydroxymethyl)aminomethane: LD50 Oral - rat – >3,000mg/kg
- LD50 Dermal - rabbit - >5,000 mg/kg
- Sodium azide: LC50 Inhalation - rat - 37 mg/m³
- Remarks: Sense Organs and Special Senses (Nose, Eye, Ear, and Taste): Eye: Other.
- Behavioural: Convulsions or effect on seizure threshold. Lungs, Thorax, or Respiration: Structural or functional change in trachea or bronchi.
- LD50 Dermal - rabbit - 20 mg/kg
- LD50 Oral – rat - 930 mg/kg
- LD50 Oral – mouse - 540 mg/kg
- LD50 Oral – rabbit - 1,700 mg/kg
- LD50 Intraperitoneal – rat - 542 mg/kg
- LD50 Intramuscular – mouse - 760 mg/kg
- LD50 Intraperitoneal – mouse - 500 mg/kg
- LD50 Intravenous – mouse - 500 mg/kg
- LD50 Subcutaneous – mouse - 550 mg/kg
- LD50 Intravenous – rabbit - 415 mg/kg
- LD50 Intravenous – dog - 562 mg/kg

Sodium salicylate:
SAFETY DATA SHEET
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Skin corrosion/irritation
Disodium EDTA dihydrate: rabbit - no skin irritation
Tris-(hydroxymethyl)aminomethane: rabbit - no skin irritation
Sodium azide: no data available
Sodium salicylate: no data available

Serious eye damage/irritation
Disodium EDTA dihydrate: rabbit - no eye irritation.
Tris-(hydroxymethyl)aminomethane: rabbit - no eye irritation
Sodium azide: no data available
Sodium salicylate: rabbit - eye irritation

Respiratory or skin sensitisation
Disodium EDTA dihydrate: no data available.
Tris-(hydroxymethyl)aminomethane: Guinea pig – does not cause skin sensitisation
Sodium azide: no data available
Sodium salicylate: no data available

Germ cell mutagenicity
No data available.

Carcinogenicity
No component of these products present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity
No data available.

Specific target organ toxicity (STOT) – single exposure
Disodium EDTA dihydrate: no data available
Tris-(hydroxymethyl)aminomethane: no data available
Sodium azide: no data available
Sodium salicylate: no data available

Specific target organ toxicity (STOT) – repeated exposure
No data available.

Aspiration Hazard
No data available.

Information on likely routes of exposure: routes of entry anticipated
Oral, dermal, inhalation.

Symptoms related to the physical, chemical and toxicological characteristics

Sodium Azide
Inhalation May be harmful if inhaled. May cause respiratory tract irritation.
Ingestion May be fatal if swallowed.
Skin May be fatal if absorbed through skin. May cause skin irritation.
Eyes May cause eye irritation.

Delayed and immediate effects as well as chronic effects from short and long-term exposure
No data available.

Effects of chronic exposure
No data available.

Additional Information
Disodium EDTA dihydrate To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Tris-(hydroxymethyl)aminomethane To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.
Sodium salicylate Salicylic acid and other salicylates are transferred into breast milk. Animal and human data suggest that the reduced clearance of salicylates be neonates may result in drug accumulation and toxic effects even when repeated exposures are small. Because of these concerns, the WHO Working Group on Human Lactation classified salicylates as unsafe for use by nursing women.
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12. Ecological Information
12.1 Toxicity:
Disodium EDTA dihydrate:
Toxicity to fish LC50 – Leuciscus idus (Golden orfe) - >500 mg/l - 96 h
Toxicity to daphnia and other aquatic invertebrates - EC50 - Daphnia - >100 mg/l - 24 h
Toxicity to algae - EC50 - Algae - 10 - 100 mg/l - 72 h
Tris-(hydroxymethyl)aminomethane:
Toxicity to daphnia and other aquatic invertebrates - EC50 – Daphnia (water flea) - >980 mg/l - 48 h
Toxicity to algae - EC50 - Algae – 397 mg/l - 72 h
Sodium azide:
Toxicity to daphnia and other aquatic invertebrates - EC50 - Daphnia pulex (Water flea) - 4.2 mg/l - 48 h
Sodium salicylate:
Toxicity to fish LC50 - Pimephales promelas (fathead minnow) - 1,370 mg/l - 96 h

12.2 Persistence and degradability
Disodium EDTA dihydrate: Readily biodegradable
Tris-(hydroxymethyl)aminomethane: Readily biodegradable
Sodium salicylate: no data available

12.3 Bioaccumulative potential
No data available.

12.4 Mobility in soil
No data available.

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6 Other adverse effects
Sodium azide: Very toxic to aquatic life with long lasting effects.

13. Disposable Considerations
13.1 Waste treatment methods
Waste should be disposed of in accordance with federal, state and local environmental control regulations. If appropriate, contact a licensed disposal company.

14. Transport Information
The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1 UN number
No data available.

14.2 UN proper shipping name
Not dangerous goods.

14.3 Transport hazard class(es)
No data available.

14.4 Packing group
No data available.

14.5 Environmental Hazards
No data available.

14.6 Special precautions for user
No data available.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No data available.

15. Regulatory Information
This data sheet is according to 1907/2006/EC, Registration, evaluation and authorisation of chemicals regulation (REACH), 1272/2008/EC, Classification, labelling and packaging regulation (CLP), 453/2010/EC, Compilation of safety data sheets regulations (SDS), amending 1907/2006/EC
This product is classified and labelled according to EU regulations 1272/2008. There is no labelling requirement.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
No data available.

15.2 Chemical safety assessment
No chemical safety assessment has been carried out.
SAFETY DATA SHEET
According to Regulation (EC) 1907/2006 (REACH) and Regulation (EC) 453/2010

16. Other Information

Disclaimer: To the best of our knowledge, the above information is believed to be accurate but does not purport to be all inclusive and shall be used only as a guide and is provided without warranty of any kind. The recipient of the product is responsible for observing all applicable laws and regulations.

Relevant phrases from section 3:

Reg. 1272/2008
H300 fatal if swallowed.
H302 harmful if swallowed.
H315 causes skin irritation.
H319 causes serious eye irritation.
H335 may cause respiratory irritation.
H410 very toxic to aquatic life with long lasting effects.

Dir. 67/548/CEE
R22 harmful if swallowed.
R28 very toxic if swallowed.
R32 contact with acids liberates very toxic gas.
R36 irritating to eyes.
R36/37/38 irritating to eyes, respiratory system and skin.
R50/53 very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.