

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

Not classified as dangerous according to Regulation (EC) 1272/2008 (CLP) or EU Directive 67/548/EEC, Directive 1999/45/EC.

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).







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

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.

Ingredients	EC No.	CAS No.	Conc (w/v)	Reg. 1272/2008	Dir. 67/548/EEC
Sodium Salicylate	200-198-0	54-21-7	<0.1%	 H302 H319	 R22 R36
Sodium azide	247-852-1	26628-22-8	<0.1%	  H300 H400 H410	  R28 R32 R50/53

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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 Inhalation: 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. Remove contaminated clothing and shoes and wash before reuse.
After Eye contact: Rinse eyes for a few minutes with water while lifting the eye lids. If irritation persists, consult a physician.
After swallowing: Rinse mouth with water. Immediately 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

Non-flammable aqueous solutions.

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.

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9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Component	a) Appearance	b) Odour	d) pH
Salicylate Enzyme Reagent	Liquid, colourless	Odourless	7.60
NADH Reagent	Liquid, colourless	Odourless	10.40
Salicylate Calibrator	Liquid, colourless	Odourless	7.30

For all components

c) Odour threshold	no data available
e) Melting point / freezing point	similar to H ₂ O
f) Boiling point and boiling range	similar to H ₂ O
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
	LC50 Inhalation - rat - 37 mg/m ³

Sodium azide:

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.

Sodium salicylate:

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

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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 in 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.

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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.