

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : CalproSmart™
 Product code : CAL0250, CAL0240 og CAL0230

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses

Main use category : Consumer use
 Use of the substance/mixture : For in vitro diagnostic use.

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Calpro AS
 Arnstein Arnebergsvei 30
 1366 Lysaker
 T +47 40 00 42 79
mail@calpro.no - calpro.no

1.4. Emergency telephone number

| Country | Official advisory body | Address | Emergency number | Comment |
|----------------|---|--|------------------------------------|---------------------------|
| United Kingdom | National Poisons Information Service (Newcastle Unit) | Claremont Place Newcastle-upon-Tyne, Newcastle | +44 191 2606182 +44 191 2606180 | Hours of operation: 24hrs |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

The product is seen as a medical device (Directive 90/385/EEC, 93/42/EEC, 98/79/EC) and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | Conc. (% w/w) | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|--------------|--|---------------|---|
| sodium azide | (CAS-No.) 26628-22-8 (EC-No.) 247-852-1 (EC Index-No.) 011-004-00-7 (REACH-no) 01-2119457019-37 | 0.1 | Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

| | | | |
|---|---|---|--|
| reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) | (CAS-No.) 55965-84-9 (EC Index-No.) 613-167-00-5 (REACH-no) N/A | < 0.1 | Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Dermal), H310 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1B, H314 Skin Sens. 1, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) |
| Specific concentration limits: | | | |
| Name | Product identifier | Specific concentration limits | |
| reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) | (CAS-No.) 55965-84-9 (EC Index-No.) 613-167-00-5 (REACH-no) N/A | (0.0015 =<C < 100) Skin Sens. 1, H317 (0.06 =<C < 0.6) Eye Irrit. 2, H319 (0.06 =<C < 0.6) Skin Irrit. 2, H315 (0.6 =<C < 100) Skin Corr. 1B, H314 | |

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

| | |
|---------------------------------------|---|
| First-aid measures general | : Never give anything by mouth to an unconscious person. Call a poison center or a doctor if you feel unwell. |
| First-aid measures after inhalation | : Call a POISON CENTER/doctor if you feel unwell. |
| First-aid measures after skin contact | : Wash skin with plenty of water. If skin irritation occurs: Get medical advice/attention. |
| First-aid measures after eye contact | : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In all cases of doubt, or when symptoms persist, seek medical attention. |
| First-aid measures after ingestion | : Rinse mouth. Get medical advice/attention if you feel unwell. |

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects : No known effects from this product.

4.3. Indication of any immediate medical attention and special treatment needed

No specific first aid measures noted.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂), water spray, sand, earth.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable according to national regulations concerning flammable goods.
Hazardous decomposition products in case of fire : Asphyxiating gases/vapours/fumes. Carbon oxides (CO, CO₂). nitrogen oxides (NO_x) and sulphur oxides. Hydrogen chloride. Magnesium oxide fumes. sodium oxide.

5.3. Advice for firefighters

Firefighting instructions : Fight fire with normal precautions from a reasonable distance. Eliminate all ignition sources if safe to do so. Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ensure adequate ventilation, especially in confined areas. Do not breathe vapour.
Concerning personal protective equipment to use, see section 8.

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate area. Evacuate unnecessary personnel. Only qualified personnel equipped with suitable protective equipment may intervene.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

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6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Exposure controls and personal protection. See Heading 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Handle as biohazardous infectious material.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep in original container.
Incompatible materials : Refer to Section 10 on Incompatible Materials.
Storage temperature : 2 - 8 °C

7.3. Specific end use(s)

No additional data.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| sodium azide (26628-22-8) | | |
|---------------------------|-------------------------------|---|
| United Kingdom | Local name | Sodium azide |
| United Kingdom | WEL TWA (mg/m ³) | 0.1 mg/m ³ (as NaN ₃) |
| United Kingdom | WEL STEL (mg/m ³) | 0.3 mg/m ³ (as NaN ₃) |
| United Kingdom | Remark (WEL) | Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity) |

8.2. Exposure controls

Hand protection:

In case of repeated or prolonged contact wear gloves. Wear rubber gloves or Latex gloves. Nitrile rubber. Neoprene. Layer thickness : 0,10mm. Breakthrough time : >480 min. STANDARD EN 374.

Eye protection:

No special eye protection equipment recommended under normal conditions of use. Use splash goggles when eye contact due to splashing is possible. STANDARD EN 166.

Skin and body protection:

Wear suitable protective clothing. Lab coat.

Respiratory protection:

Not required

Environmental exposure controls:

Avoid release to the environment.

Other information:

Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Prefilled plastic device for sampling, filled with 5.0 mL extraction buffer.
Colour : Buffer: Clear.
Odour : None.

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| | |
|--|----------------------|
| Odour threshold | : No data available |
| pH | : 7.8 - 8.2 |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : No data available |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Auto-ignition temperature | : Not self-igniting. |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : No data available |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Density | : ≈ 1 g/ml |
| Solubility | : Soluble in water. |
| Log Pow | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : Not explosive. |
| Oxidising properties | : Non flammable. |
| Explosive limits | : No data available |

9.2. Other information

Additional information : None to our knowledge.

SECTION 10: Stability and reactivity

10.1. Reactivity

No incompatible groups noted.

10.2. Chemical stability

Stable under the prescribed storage conditions.

10.3. Possibility of hazardous reactions

Copper alloys. Lead compounds : Explosive vapour/air mixtures may be formed.

10.4. Conditions to avoid

None to our knowledge.

10.5. Incompatible materials

Strong acids and oxidants. Strong reducing agents. Amines. Halogenated hydrocarbons. Metals. Chlorides. Hydrazine [(NH₂)₂]. dimethyl sulphate.

10.6. Hazardous decomposition products

Stable under normal temperature conditions and recommended use.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-----------------------------|--|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |

| sodium azide (26628-22-8) | |
|---------------------------|----------|
| LD50 oral rat | 27 mg/kg |
| LD50 dermal rat | 50 mg/kg |
| LD50 dermal rabbit | 20 mg/kg |

| reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9) | |
|--|-----------|
| LD50 oral rat | 64 mg/kg |
| LD50 dermal rabbit | 300 mg/kg |

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| | |
|-----------------------------------|--|
| LC50 inhalation rat (mg/l) | 3 mg/l/4h |
| Skin corrosion/irritation | : Not classified pH: 7.8 - 8.2 |
| Additional information | : Based on available data, the classification criteria are not met |
| Serious eye damage/irritation | : Not classified pH: 7.8 - 8.2 |
| Additional information | : Based on available data, the classification criteria are not met |
| Respiratory or skin sensitisation | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| Germ cell mutagenicity | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| Carcinogenicity | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| Reproductive toxicity | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| STOT-single exposure | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| STOT-repeated exposure | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |
| Aspiration hazard | : Not classified |
| Additional information | : Based on available data, the classification criteria are not met |

SECTION 12: Ecological information

12.1. Toxicity

| | |
|---|---|
| Ecology - general | : Based on available data, the classification criteria are not met. |
| Hazardous to the aquatic environment, short-term (acute) | : Not classified |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified |

| sodium azide (26628-22-8) | |
|---------------------------|---|
| LC50 fish 1 | 0.7 mg/l (96 hours - Lepomis macrochirus) |
| EC50 Daphnia 1 | 4.2 mg/l (48 hours - Daphnia pulex) |

| reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9) | |
|--|---|
| LC50 fish 1 | 0.19 mg/l (96 hours - Rainbow trout) |
| EC50 Daphnia 1 | 0.16 mg/l (48 hours - Daphnia magna) |
| ErC50 (algae) | 0.027 mg/l (EC50, 72 hours - Selenastrum capricornutum) |

12.2. Persistence and degradability

| CalproSmart™ | |
|-------------------------------|----------|
| Persistence and degradability | No data. |

| reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9) | |
|--|--|
| Biodegradation | 39 - 62 % (28 days, method: OECD 301B) |

12.3. Bioaccumulative potential

| CalproSmart™ | |
|---------------------------|----------|
| Bioaccumulative potential | Unknown. |

| reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1) (55965-84-9) | |
|--|-------|
| Bioconcentration factor (BCF REACH) | < 100 |
| Log Pow | < 3 |

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12.4. Mobility in soil

| CalproSmart™ | |
|----------------|----------|
| Ecology - soil | No data. |

12.5. Results of PBT and vPvB assessment

| CalproSmart™ | |
|--|--|
| This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII | |
| This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII | |

12.6. Other adverse effects

Other adverse effects : None to our knowledge.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|--|---|
| Regional legislation (waste) | : Handle as biohazardous infectious material. |
| Waste treatment methods | : Collect in marked containers and deliver to approved depot. Disposal to licensed waste disposal site in accordance with local Waste Disposal Authority. |
| Product/Packaging disposal recommendations | : Dispose in a safe manner in accordance with local/national regulations. |
| Ecology - waste materials | : Avoid release to the environment. |
| European List of Waste (LoW) code | : 18 02 03 - wastes whose collection and disposal is not subject to special requirements in order to prevent infection |

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

| ADR | IMDG | IATA | ADN | RID |
|---|----------------|----------------|----------------|----------------|
| 14.1. UN number | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.2. UN proper shipping name | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.3. Transport hazard class(es) | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.4. Packing group | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| 14.5. Environmental hazards | | | | |
| Not applicable | Not applicable | Not applicable | Not applicable | Not applicable |
| No supplementary information available | | | | |

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU-Regulations

Contains no substance on the REACH candidate list

Contains no substance subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

National regulations

EC-regulation 453/2010/EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

SDS ID : 304725

Data sources : EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits. In vitro diagnostic medical devices, EU-regulation 1272/2008/EC, article 1, paragraph 5d.

| Full text of H- and EUH-statements: | |
|-------------------------------------|--|
| Acute Tox. 1 (Dermal) | Acute toxicity (dermal), Category 1 |
| Acute Tox. 2 (Dermal) | Acute toxicity (dermal), Category 2 |
| Acute Tox. 2 (Oral) | Acute toxicity (oral), Category 2 |
| Acute Tox. 3 (Inhalation) | Acute toxicity (inhal.), Category 3 |
| Acute Tox. 3 (Oral) | Acute toxicity (oral), Category 3 |
| Aquatic Acute 1 | Hazardous to the aquatic environment — Acute Hazard, Category 1 |
| Aquatic Chronic 1 | Hazardous to the aquatic environment — Chronic Hazard, Category 1 |
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| Skin Corr. 1B | Skin corrosion/irritation, Category 1B |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| Skin Sens. 1 | Skin sensitisation, Category 1 |
| STOT RE 2 | Specific target organ toxicity — Repeated exposure, Category 2 |
| H300 | Fatal if swallowed. |
| H301 | Toxic if swallowed. |
| H310 | Fatal in contact with skin. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H317 | May cause an allergic skin reaction. |
| H319 | Causes serious eye irritation. |
| H331 | Toxic if inhaled. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |