

Safety Data Sheet

according to Regulation (EU) 2020/878
Revision date: 19/05/2023 Version: 1.0

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

1.1. Product identifier

Product form : Mixture
Trade name : Amerlex Radioassay Controls 31 and 32, Anti-dsDNA standards (A-F)
Other means of identification : Amerlex Radioassay Controls 31 and 32, Component part number(s): 295-520, 295-521, Kit part number(s): QAS114
Anti-dsDNA standards (A-F), Component part number(s): 295-992, 295-993, 295-994, 295-995, 295-996, 295-997, Kit part number(s): IM77/IM771

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Medical Diagnostics

1.2.2. Uses advised against

Restrictions on use : No additional information available

1.3. Details of the supplier of the safety data sheet

Trinity Biotech
I.D.A Business Park
Southern Cross Road
A98 H5C8 Bray, Co. Wicklow - Ireland
Technical Support Group 00353 1 276 9800
www.trinitybiotech.com
autoimmunetechsupport@trinitybiotech.com

1.4. Emergency telephone number

Emergency number : Contact your local Emergency Health Care Provider; Ireland-Technical Support Group 00353-1-276-9800 (operating hours 7:00-18:00)

| Country | Organisation/Company | Address | Emergency number | Comment |
|---------|--|-----------------------------------|--|---------|
| Ireland | National Poisons Information Centre Beaumont Hospital | PO Box 1297 Beaumont Road 9 | +353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7) | |

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

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

No labelling applicable

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

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The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | Conc. | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|------------------|---|-------|---|
| sodium hydroxide | CAS-No.: 1310-73-2 EC-No.: 215-185-5 EC Index-No.: 011-002-00-6 REACH-no: 01-2119457892-27 | < 0.5 | Met. Corr. 1, H290 Skin Corr. 1A, H314 |

Specific concentration limits:

| Name | Product identifier | Specific concentration limits (Conc.) |
|------------------|---|---|
| sodium hydroxide | CAS-No.: 1310-73-2 EC-No.: 215-185-5 EC Index-No.: 011-002-00-6 REACH-no: 01-2119457892-27 | (0.5 ≤ C < 2) Skin Irrit. 2, H315 (0.5 ≤ C < 2) Eye Irrit. 2, H319 (2 ≤ C < 5) Skin Corr. 1B, H314 (5 ≤ C ≤ 100) Skin Corr. 1A, H314 |

Full text of H- and EUH-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. Get medical advice/attention if you feel unwell. |
| First-aid measures after inhalation | : If inhaled and if breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If you feel unwell, seek medical advice. |
| First-aid measures after skin contact | : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash contaminated clothing before reuse. Get medical attention if symptoms occur. |
| First-aid measures after eye contact | : Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for several minutes. Get medical advice/attention if you feel unwell. |
| First-aid measures after ingestion | : Rinse mouth out with water. Do NOT induce vomiting unless directed to do so by medical personnel. Call a POISON CENTER/doctor if you feel unwell. |

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

| | |
|-------------------------------------|--|
| Symptoms/effects after inhalation | : Not expected to present a significant hazard under anticipated conditions of normal use. |
| Symptoms/effects after skin contact | : Not expected to present a significant hazard under anticipated conditions of normal use. |
| Symptoms/effects after eye contact | : Not expected to present a significant eye contact hazard under anticipated conditions of normal use. |
| Symptoms/effects after ingestion | : Not expected to present a significant hazard under anticipated conditions of normal use. |

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

Treat symptomatically.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Dry chemical, CO₂, or water spray or regular foam. Use extinguishing agent suitable for surrounding fire.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Presents no particular fire or explosion hazard. Burning produces stinking and toxic fumes. In case of fire and/or explosion do not breathe fumes.
- Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

- Firefighting instructions : Evacuate the danger area. Move containers from fire area if it can be done without personal risk. Fight fire from safe distance and protected location. Use extinguishing media appropriate for surrounding fire. Use water spray or fog for cooling exposed containers. Prevent fire fighting water from entering the environment.
- Protection during firefighting : Wear a self contained breathing apparatus. Wear fire/flare resistant/retardant clothing. Do not attempt to take action without suitable protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Avoid all contact with skin, eyes, or clothing. Do not inhale vapour.

6.1.1. For non-emergency personnel

- Protective equipment : Wear recommended personal protective equipment. Refer to section 8.2.
- Emergency procedures : No action shall be taken without appropriate training or involving any personal risk. Evacuate unnecessary personnel. Ventilate spillage area. Avoid contact with skin and eyes. Do not touch or walk on the spilled product.

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".
- Emergency procedures : Stop leak if safe to do so. Ventilate area. Do not touch spilled material.

6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- For containment : Stop leak without risks if possible. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Caution : this product can cause the floor to be slippery.
- Methods for cleaning up : Move containers from spill area. Ventilate spillage area. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Clean contaminated surfaces with an excess of water. Keep in suitable, closed containers for disposal.
- Other information : Dispose of via an authorised person/ licensed waste disposal contractor or by other suitable waste treatment techniques. Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Do not get in eyes, on skin, or on clothing. Ensure good ventilation of the work station. Obtain special instructions before use. Do not breathe vapours, mist. Wear recommended personal protective equipment – refer to Section 8.2. Provide local exhaust or general room ventilation.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety procedures. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke when using this product. Wash contaminated clothing before reuse. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Direct sunlight, Incompatible materials, Protect from freezing, Avoid high temperatures. Keep away from food, drink and animal feedingstuffs. Keep container tightly closed. Containers which are opened should be properly resealed and kept upright to prevent leakage. Store in accordance with local, regional, national or international regulation.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

| sodium hydroxide (1310-73-2) | |
|--|---------------------------------------|
| Ireland - Occupational Exposure Limits | |
| Local name | Sodium hydroxide |
| OEL STEL | 2 mg/m ³ |
| Regulatory reference | Chemical Agents Code of Practice 2021 |

8.1.2. Recommended monitoring procedures

| Monitoring methods | |
|--------------------|--|
| Monitoring methods | Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents. Refer to all applicable national, international and local regulations or provisions. Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. Workplace atmospheres. Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy. |

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Handle in accordance with good industrial hygiene and safety procedures. Avoid all unnecessary exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

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

8.2.2.1. Eye and face protection

Eye protection:

Even though no specific eye irritation data are available, wear eye protection appropriate to conditions of use when handling this material. ISO 16321-1

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. Skin protection appropriate to the conditions of use should be provided

Hand protection:

Wear suitable gloves resistant to chemical penetration. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. ISO 374-1

8.2.2.3. Respiratory protection

Respiratory protection:

No respiratory protection needed under normal use conditions. Where excessive vapour, mist, or dust may result, use approved respiratory protection equipment. EN 149

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment. Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---|---------------------------------------|
| Physical state | : Liquid |
| Colour | : According to product specification. |
| Odour | : According to product specification. |
| Odour threshold | : Not available |
| Melting point | : Not available |
| Freezing point | : Not available |
| Boiling point | : Not available |
| Flammability | : Not applicable |
| Lower explosion limit | : Not available |
| Upper explosion limit | : Not available |
| Flash point | : Not available |
| Auto-ignition temperature | : Not available |
| Decomposition temperature | : Not available |
| pH | : Not available |
| Viscosity, kinematic | : Not available |
| Solubility | : Not available |
| Partition coefficient n-octanol/water (Log Kow) | : Not available |
| Vapour pressure | : Not available |
| Vapour pressure at 50°C | : Not available |

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| | |
|---------------------------------|------------------|
| Density | : Not available |
| Relative density | : Not available |
| Relative vapour density at 20°C | : Not available |
| Particle characteristics | : Not applicable |

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport. No dangerous reactions known.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use. Hazardous polymerisation: Will not occur.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

Strong bases. Strong acids. Strong oxidizing agents. Strong reducing agents.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

| | |
|-----------------------------------|---|
| Acute toxicity (oral) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (dermal) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (inhalation) | : Not classified (Based on available data, the classification criteria are not met) |
| Skin corrosion/irritation | : Not classified (Based on available data, the classification criteria are not met) |
| Serious eye damage/irritation | : Not classified (Based on available data, the classification criteria are not met) |
| Respiratory or skin sensitisation | : Not classified (Based on available data, the classification criteria are not met) |
| Germ cell mutagenicity | : Not classified (Based on available data, the classification criteria are not met) |
| Carcinogenicity | : Not classified (Based on available data, the classification criteria are not met) |
| Reproductive toxicity | : Not classified (Based on available data, the classification criteria are not met) |
| STOT-single exposure | : Not classified (Based on available data, the classification criteria are not met) |
| STOT-repeated exposure | : Not classified (Based on available data, the classification criteria are not met) |
| Aspiration hazard | : Not classified (Based on available data, the classification criteria are not met) |

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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2. Other information

Other information

: No experimental study on the product is available. The information given is based on our knowledge of the components and the classification of the product is determined by calculation

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)

: Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic)

: Not classified (Based on available data, the classification criteria are not met)

Additional information

: No experimental study on the product is available. The information given is based on our knowledge of the components and the classification of the product is determined by calculation.

sodium hydroxide (1310-73-2)

LC50 - Fish [1]

125 mg/l (96 h, Gambusia affinis)

LC50 - Fish [2]

45.4 mg/l (96 h, Oncorhynchus mykiss)

EC50 - Crustacea [1]

40.38 mg/l (48 h, Daphnia)

12.2. Persistence and degradability

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Persistence and degradability

Biodegradability in water: no data available.

12.3. Bioaccumulative potential

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Bioaccumulative potential

No data available concerning bioaccumulation.

12.4. Mobility in soil

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Ecology - soil

No additional information available.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties

: The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

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12.7. Other adverse effects

Other adverse effects : No additional information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions. Disposal must be carried out using appropriate EWC code.

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

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

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

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SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

| | |
|---------|---|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ATE | Acute Toxicity Estimate |
| BLV | Biological limit value |
| CAS-No. | Chemical Abstract Service number |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| DMEL | Derived Minimal Effect level |
| DNEL | Derived-No Effect Level |
| EC50 | Median effective concentration |
| EC-No. | European Community number |
| EN | European Standard |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |

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| Abbreviations and acronyms: | |
|-----------------------------|---|
| LC50 | Median lethal concentration |
| LD50 | Median lethal dose |
| LOAEL | Lowest Observed Adverse Effect Level |
| NOAEC | No-Observed Adverse Effect Concentration |
| NOAEL | No-Observed Adverse Effect Level |
| NOEC | No-Observed Effect Concentration |
| OEL | Occupational Exposure Limit |
| PBT | Persistent Bioaccumulative Toxic |
| PNEC | Predicted No-Effect Concentration |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SDS | Safety Data Sheet |
| vPvB | Very Persistent and Very Bioaccumulative |
| WGK | Water Hazard Class |

Data sources : ECHA (European Chemicals Agency). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 and all its amendments and modifications. Supplier's safety documents.

Training advice : Training staff on good practice.

| Full text of H- and EUH-statements: | |
|-------------------------------------|--|
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| H290 | May be corrosive to metals. |
| H314 | Causes severe skin burns and eye damage. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| Met. Corr. 1 | Corrosive to metals, Category 1 |
| Skin Corr. 1A | Skin corrosion/irritation, Category 1, Sub-Category 1A |
| Skin Corr. 1B | Skin corrosion/irritation, Category 1, Sub-Category 1B |
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |

Safety Data Sheet (SDS), EU

SDS prepared by: H2 Compliance

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.