

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

ElisaRSR™ IA-2 Ab Version 2
Catalogue no: IAE/96/2 (96 well)

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

Detection of IA-2 antibodies in human serum

1.3 Details of the supplier of the safety data sheet:

RSR Limited
Parc Ty Glas, Llanishen, Cardiff, CF14 5DU, United Kingdom
Phone: +4429 2068 9299 (Office hours only)
Fax: +4429 2075 7770
Email: info@rsrltd.com

1.4 Emergency telephone number:

MHRA Adverse Incident Centre: +4420 3080 7080


SECTION 2: Hazards identification**2.1 Classification of the substance or mixture**

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

| Kit Component | Hazard Classification | Hazard Statements |
|----------------------------------|------------------------------------|-------------------|
| Streptavidin Peroxidase (SA-POD) | Skin Sensitisation, Category 1 | H317 |
| Peroxidase Substrate (TMB) | Reproductive Toxicity, Category 1B | H360D |

2.2 Label elements

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

| STREPTAVIDIN PEROXIDASE (SA-POD) | |
|-----------------------------------|---|
| Hazard pictogram |  Signal word: Warning |
| Hazard statement(s) | |
| H317 | May cause an allergic skin reaction |
| Precautionary statement(s) | |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection |
| P302 + P352 | IF ON SKIN: Wash with plenty of soap and water |
| P333 + P313 | If skin irritation or rash occurs: Get medical advice/attention |
| P362 + P364 | Take off contaminated clothing and wash it before reuse |

PEROXIDASE SUBSTRATE (TMB)

Hazard pictogram



Signal word: Danger

Hazard statement(s)

H360D May damage the unborn child

Precautionary statement(s)

| | |
|-------------|---|
| P280 | Wear protective gloves/protective clothing/eye protection/face protection |
| P308 + P313 | IF exposed or concerned: Get medical advice/attention |

2.3 Other Hazards

All other kit components not listed in section 2.1 and 2.2 do not contain hazardous ingredients in concentrations which meet the criteria for classification according to Regulation (EC) No. 1272/2008. However, ingestion or exposure to large amounts from improper handling can be potentially hazardous.

This kit contains both animal and human proteins and should be treated as a potential biohazard. All animal and human sera have been tested to ensure the absence of infectious agents but all materials should be handled as though capable of transmitting infectious disease and disposed of accordingly.

The following precautionary statements should be taken into consideration:

P233, P270, P281, P301 + P330, P302 + P352, P304 + P340, P305 + P351 + P338 (see section 16 for full text).

SECTION 3: Composition/information on ingredients**3.1 Substances**

Not applicable

3.2 Mixtures

Hazardous ingredients according to Regulation (EC) No. 1272/2008:

| PEROXIDASE SUBSTRATE (TMB) | | | | |
|---|---------|--------|-----------------|-------------|
| Ingredient(s) | CAS No. | EC No. | Classification | Conc. (v/v) |
| Enhanced K-Blue® Substrate | N/A | N/A | Repr. 1B; H360D | 100% |
| <i>Contains N-methyl-2-pyrrolidone:</i> | | | | |
| <i>Included in the Candidate List of Substances of Very High Concern (SVHC) for Authorisation according to Regulation (EC) No. 1907/2006 (REACH).</i> | | | | |
| <i>CAS No. 872-50-4</i> | | | | |
| <i>EC No. 212-828-1</i> | | | | |
| <i>Concentration: 1-5%</i> | | | | |
| <i>Classification: Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335; Repr. 1B, H360D</i> | | | | |

| STREPTAVIDIN PEROXIDASE (SA-POD) | | | | |
|---|---------|---------------------|--------------------|-------------|
| Ingredient(s) | CAS No. | EC No. | Classification | Conc. (v/v) |
| Stabilzyme® HRP Conjugate Stabilizer | N/A | N/A | Skin Sens. 1; H317 | >99% |
| <i>Contains CMIT/MIT: Mixture, 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):</i> | | | | |
| CAS No. 55965-84-9 | | | | |
| EC No. 613-167-00-5 | | | | |
| Concentration: 0.0024% | | | | |
| Classification: Acute Tox. 3 (Oral, Dermal & Inhalation) H301, H311 & H331; Skin Corr. 1B, H314; Skin Sens. 1, H317; Aquatic Acute 1, H400; Aquatic chronic 1, H410 | | | | |
| <u>Specific Concentration Limits:</u> | | | | |
| $C \geq 0.0015\%$ | | Skin Sens. 1, H317 | | |
| $0.06\% \leq C < 0.6\%$ | | Eye Irrit. 2, H319 | | |
| $0.06\% \leq C < 0.6\%$ | | Skin Irrit. 2, H315 | | |
| $C \geq 0.6\%$ | | Skin Corr. 1B, H314 | | |

IA-2-Biotin, reconstitution buffer for IA-2-Biotin, calibrators and controls contain animal proteins and/or human proteins and should be treated as potential biohazards.

The following kit components contain ingredients which are considered hazardous but are not present in high enough concentrations to be classified under Regulation (EC) No. 1272/2008.

| Kit Component | Ingredient(s) | Concentration |
|---------------------------------------|--|-------------------------|
| Reconstitution Buffer for IA-2-Biotin | Sodium azide | 0.05% w/v |
| Diluent for SA-POD | 2-Chloroacetamide N-Methylisothiazolone (MIT) | 0.098% w/v 0.02% w/v |
| Reaction Enhancer | MIT Oxypyryon | 0.2% w/v 0.2% w/v |
| Stop Solution | Sulphuric acid | 0.25M (< 5.0% v/v) |
| Calibrators and Controls | Sodium azide | 0.05% w/v |

| Ingredient | CAS No. | EC No. | Classification GHS/CLP |
|-------------------|------------|-----------|---|
| 2-Chloroacetamide | 79-07-2 | 201-174-2 | Acute Tox. 3 (Oral), Skin Sens. 1, Repr. 2; H301, H317, H361f |
| MIT | 26172-54-3 | 247-499-3 | Skin Corr. 1B, Eye Dam. 1, Skin Sens. 1, Resp. Sens. 1; H314, H317, H318, H334 |
| Oxypyryon | 822-89-9 | 212-506-0 | Acute Tox. 4, Eye Irrit. 2, STOT SE 3; H302, H319, H335 |

| Ingredient | CAS No. | EC No. | Classification GHS/CLP |
|----------------|------------|-----------|--|
| Sodium Azide | 26628-22-8 | 247-852-1 | Acute Tox. 2 (Oral & Inhalation), Acute Tox. 1 (Dermal), STOT RE 2, Aquatic Acute 1, Aquatic Chronic 1; H300, H310, H330, H373, H400, H410, EUH302 |
| Sulphuric Acid | 7664-93-9 | 231-639-5 | Met. Corr. 1, Skin Corr. 1A; H290, H314 |

The full text for the hazard statements can be found in section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

After skin contact

Wash off skin thoroughly with water for at least 15 minutes. Remove contaminated clothing. In severe cases or if skin is broken, OBTAIN MEDICAL ATTENTION.

After eye contact

Separate eyelids with fingers and flush eye with copious amounts of water for at least 15 minutes. OBTAIN MEDICAL ATTENTION.

After Inhalation

Remove from exposure, rest and keep warm. If breathing becomes difficult, OBTAIN MEDICAL ATTENTION.

After Ingestion

If patient is conscious, wash out mouth with water and give plenty of water to drink. OBTAIN MEDICAL ATTENTION.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Use water, dry powder or foam as appropriate to supporting fire.

5.2 Special hazards arising from the substance or mixture

May evolve toxic fumes in fire. Hazardous combustion products are not known for kit components but combustion products for the ingredients listed in subsection 3.2 can be found in the following table:

| Ingredient | Hazardous combustion product(s) |
|-------------------|--|
| 2-Chloroacetamide | Carbon oxides, nitrogen oxides (NOx) and hydrogen chloride gas |
| MIT | Carbon oxides, nitrogen oxides (NOx) and sulphur oxides |

| Ingredient | Hazardous combustion product(s) |
|--------------------------------------|--|
| Enhanced K-Blue® Substrate | Burning produces irritating, toxic and obnoxious fumes |
| Oxypyrion | No data available |
| Sodium Azide | Nitrogen oxides (NOx) |
| Stabilzyme® HRP Conjugate Stabilizer | Carbon oxides and nitrogen oxides (NOx) |
| Sulphuric Acid | Sulphur oxides |

5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear appropriate protective clothing as described in subsection 8.2. Ventilate area and avoid breathing vapours, mist or gas.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent any reagents from entering drains.

6.3 Methods and material for containment and cleaning up

Wipe up liquid spills with absorbent paper. For solid spills, sweep up without raising dust. Once pick up is complete, wash site with detergent and water. Decontaminate with a suitable disinfectant solution.

6.4 Reference to other sections

See sections 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Material of human origin has been tested and found non-reactive for HIV 1 and 2 and HCV antibodies and HBsAg. All animal sourced material has been obtained from animals certified as healthy and free from disease. However all potentially biohazardous components should be considered as potentially infectious. Level II containment should be applied.

Do not eat, drink or smoke in the laboratory. Do not pipette by mouth. Avoid skin and eye contact. Wear appropriate protective clothing as described in subsection 8.2. Avoid the use of needles or other sharp implements. Avoid prolonged or repeated exposure. Wash hands thoroughly after handling. Avoid release into drains; in case of accidental spillage, refer to section 6.

7.2 Conditions for safe storage, including any incompatibilities

Keep containers tightly closed. Store in a dry place in the box supplied at a temperature between +2 and +8°C.

7.3 Specific end use(s)

The ElisaRSR™ IA-2 Ab Version 2 Kit is intended for professional use only and to be used solely for the purpose as specified in subsection 1.2. Refer to kit instructions for details.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

No occupational exposure limits exist for any kit components. However, exposure limits apply to the following ingredients (see subsection 3.2 for components containing these substances):

| Value* | Control Parameters | Basis |
|-----------------------|------------------------|--|
| Sodium Azide | | |
| TWA | 0.1 mg/m ³ | UK: EH40 Workplace Exposure Limits (WEL) |
| STEL | 0.3 mg/m ³ | Europe: Commission Directive 2000/39/EC |
| Sulphuric Acid | | |
| TWA | 0.05 mg/m ³ | UK: EH40 Workplace Exposure Limits (WEL) Europe: Commission Directive 2009/161/EU |

Stabilzyme® HRP Conjugate Stabilizer

| | |
|--|--|
| TRGS 900 Occupational exposure limit value | 0.2 mg/m ³ inhalable fraction |
| TRGS 900 Limitation of exposure peaks | 0.4 mg/m ³ inhalable fraction |

*Definitions can be found in section 16

8.2 Exposure controls

Appropriate engineering controls

Good laboratory practice should be followed (see Section 7). Avoid contact with skin or eyes. Wash hands after use.

Individual protection measures (personal protective equipment)

Eye/face protection

Chemical safety glasses or goggles conforming to appropriate government standards such as EN166 (EU) or NIOSH (US).

Skin and body protection

Chemical resistant gloves to be used in accordance with standard EN374 derived from EU Directive 89/686/EEC. Latex or vinyl gloves will provide sufficient protection. Inspect gloves for damage prior to use and change if any sign of degradation. Proper glove removal technique must be used. Wash hands after use.

Respiratory protection

Local exhaust.

Environmental exposure controls

Prevent further leakage or spillage if safe to do so. Prevent any reagents from entering drains.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

| Kit component | Appearance | Odour | pH | Solubility |
|---------------------------------------|-----------------------------------|----------------------------|------|------------|
| IA-2 Coated Wells | Colourless polystyrene microplate | None | N/A | N/A |
| IA-2-Biotin | White solid | None | N/A | In water |
| Reconstitution Buffer for IA-2-Biotin | Blue liquid | None | ~8.0 | N/A |
| Streptavidin Peroxidase (SA-POD) | Pale brown/yellow liquid | None | N/A | N/A |
| Diluent for SA-POD | Colourless liquid | None | ~7.5 | N/A |
| Peroxidase Substrate (TMB) | Colourless to slight blue liquid | None | N/A | N/A |
| Reaction Enhancer | Pink liquid | None | ~7.3 | N/A |
| Stop Solution (0.25M sulphuric acid) | Colourless liquid | May be slightly sulphurous | <1.0 | N/A |
| Concentrated Wash Solution | Colourless liquid | None | ~7.6 | N/A |
| Calibrators and Controls | Pale yellow liquid | None | N/A | N/A |

There is no information available for the following categories: odour threshold, melting/freezing point, initial boiling point/boiling range, flash point, evaporation rate, flammability (solid, gas), upper/lower flammability or explosive limits, vapour pressure, vapour density, relative density, partition coefficient, autoignition temperature, decomposition temperature, viscosity, explosive properties or oxidising properties.

9.2 Other information

All liquid components are miscible with water in all proportions.

SECTION 10: Stability and reactivity**10.1 Reactivity**

Data is not available on the reactivity of individual kit components but is given, where available, on ingredients listed in subsection 3.2.

Sulphuric acid is a strong oxidising agent and has a corrosive effect. There is no data available on the other ingredients.

10.2 Chemical stability

All components of the ElisaRSR™ IA-2 Ab Version 2 Kit have been found stable for stated shelf life when stored under the recommended conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known for kit components although, hazardous reactions occur for the following ingredients listed in subsection 3.2:

| Ingredient | Hazardous Reaction |
|----------------|--|
| Sodium Azide | Risk of explosion and/or toxic gas formation exists with heavy metals, bromine, lead, chromyl chloride, dichloromethane, dimethylsulfate, halogenated hydrocarbon, acid, carbon disulphide, sulphuric acid, copper and nitric acid. Generates dangerous gases or fumes with acids and water, leading to the release of hydrazoic acid. Violent reactions possible with nitrates, benzoyl chloride and potassium nitrate. |
| Sulphuric Acid | Violent reactions possible with: Water, alkali metals, alkali compounds, ammonia, aldehydes, acetonitrile, alkaline earth metals, alkalines, acids, alkaline earth compounds, metals, metal alloys, oxides of phosphorus, phosphorus, hydrides, halogen-halogen compounds, oxyhalogenic compounds, permanganates, nitrates, carbides, combustible substances, organic solvent, acetylidene, nitriles, organic nitro compounds, anilines, peroxides, picrates, nitrides, lithium silicide, iron (III) compounds, bromates, chlorates, amines, perchlorates and hydrogen peroxide. |

10.4 Conditions to avoid

Peroxidase substrate (TMB) is light sensitive and therefore the bottle should be kept tightly closed when not in use and stored in a dark place.

Proteins, oxyprion, sodium azide and sulphuric acid are heat sensitive and storage or use at the improper temperature may compromise the integrity of the kit.

10.5 Incompatible materials

No data is known for kit components but the following data is known for ingredients listed in subsection 3.2:

| Ingredient | Incompatible materials |
|--------------------------------------|---|
| 2-Chloroacetamide | Strong oxidising agents, strong acids, strong bases and strong reducing agents |
| Enhanced K-Blue® Substrate | None known |
| MIT | Strong oxidising agents |
| Oxyprion | No data available |
| Sodium Azide | Aluminium and heavy metals |
| Stabilzyme® HRP Conjugate Stabilizer | None known |
| Sulphuric Acid | Animal and vegetable tissues. Metals. Contact with metals liberates hydrogen gas. |

10.6 Hazardous decomposition products

No decomposition products are formed if kit is stored and used under the specified storage and handling conditions.

May evolve toxic fumes in fire. Thermal decomposition products are not known for the kit components but hazardous combustion products of the ingredients listed in subsection 3.2 can be found in subsection 5.2

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

The kit components have not been directly tested for their toxicological effects, therefore no information is known for these mixtures. The following toxicological data is known for ingredients listed in subsection 3.2:

(a) Acute toxicity

**Definitions can be found in section 16*

| Ingredient | Measurement* | Value | Species |
|-------------------|--|------------------------|---------|
| 2-Chloroacetamide | LD ₅₀ (Oral) | 138 mg/kg | Rat |
| MIT | LD ₅₀ (Oral) | 175 mg/kg | Rat |
| Oxypyrrion | LD ₅₀ (Oral) | 1.765 mg/kg | Rat |
| | LD ₅₀ (Dermal) | >2000 mg/kg | Rat |
| Sodium Azide | LD ₅₀ (Oral) | 27 mg/kg | Rat |
| | LC ₅₀ (Inhalation) | 0.054 – 0.52 mg/L (4h) | Rat |
| | LD ₅₀ (Dermal) | 20 mg/kg | Rabbit |
| Sulphuric Acid | No data available. Acute inhalation toxicity: mucosal irritations, cough, shortness of breath, possible damage to respiratory tract. | | |

No data available for Enhanced K-Blue® Substrate or Stabilzyme® HRP Conjugate Stabilizer.

(b) Skin corrosion/irritation

| Ingredient | Test/Result |
|----------------------------|--|
| Enhanced K-Blue® Substrate | May cause irritation to skin |
| MIT | Skin (reconstructed human epidermis (RhE) – Corrosive |
| Oxypyrrion | Not classified base on available information. May cause skin irritation in susceptible persons |
| Sodium Azide | In vitro study, human skin model test – No skin irritation |
| Sulphuric Acid | Causes severe burns |

No data available for 2-chloroacetamide or Stabilzyme® HRP Conjugate Stabilizer.

(c) Serious eye damage/irritation

| Ingredient | Test/Result |
|----------------------------|---|
| Enhanced K-Blue® Substrate | May cause irritation to eyes |
| Oxypyrrion | Causes serious eye irritation |
| Sodium Azide | In vitro study, exposure time 4 hours – No eye irritation |
| Sulphuric Acid | Causes serious eye damage – risk of blindness |

No data available for 2-chloroacetamide, MIT or Stabilzyme® HRP Conjugate Stabilizer.

(d) Respiratory or skin sensitisation

| Ingredient | Test/Result |
|--------------------------------------|---|
| 2-Chloroacetamide | Maximisation test, Guinea pig – May cause sensitisation by skin contact |
| Oxypyrrion | Not classified based on available information |
| Sodium Azide | Sensitisation test, Mouse – Negative |
| Stabilzyme® HRP Conjugate Stabilizer | May cause an allergic skin reaction |

No data available for Enhanced K-Blue® Substrate, MIT or sulphuric acid.

(e) Germ cell mutagenicity

| Ingredient | Test/Result |
|-------------------|--|
| 2-Chloroacetamide | Hamster, lungs – Negative Mouse, male and female - Negative |
| MIT | Ames test, Salmonella typhimurium – Negative |
| Oxypyrrion | Not classified based on available information |

No data available for Enhanced K-Blue® Substrate, sodium azide, Stabilzyme® HRP Conjugate Stabilizer or sulphuric acid.

(f) Carcinogenicity

| Ingredient | Test/Result |
|----------------------------|--|
| 2-Chloroacetamide | IARC: No component of this product present at levels ≥0.1% is identified as probable, possible or confirmed human carcinogen by IARC |
| MIT | |
| Enhanced K-Blue® Substrate | Not listed in the National Toxicology Program (NTP) 13th Report on Carcinogens. Not listed in the OSHA standard 1910.1003 Carcinogens. |
| Oxypyrrion | Not classified based on available information |

No data available for sodium azide, Stabilzyme® HRP Conjugate Stabilizer or sulphuric acid.

(g) Reproductive toxicity

| Ingredient | Test/Result |
|----------------------------|---|
| 2-Chloroacetamide | Suspected human reproductive toxicant |
| Enhanced K-Blue® Substrate | May damage the unborn child |
| Oxypyrrion | Not classified based on available information |

No data available for MIT, sodium azide, Stabilzyme® HRP Conjugate Stabilizer or sulphuric acid.

(h) STOT-single exposure

| Ingredient | Test/Result |
|------------|----------------------------------|
| Oxypyrrion | May cause respiratory irritation |

No data available for 2-chloroacetamide, Enhanced K-Blue® Substrate, MIT, sodium azide, Stabilzyme® HRP Conjugate Stabilizer or sulphuric acid.

(i) STOT-repeated exposure

| Ingredient | Test/Result |
|------------|---|
| Oxypyrrion | Not classified based on available information |

No data available for 2-chloroacetamide, Enhanced K-Blue® Substrate, MIT, sodium azide, Stabilzyme® HRP Conjugate Stabilizer or sulphuric acid.

(j) Aspiration hazard

| Ingredient | Test/Result |
|------------|---|
| Oxypyryon | Not classified based on available information |

No data available for 2-chloroacetamide, Enhanced K-Blue® Substrate, MIT, sodium azide, Stabilzyme® HRP Conjugate Stabilizer or sulphuric acid.

SECTION 12: Ecological information

The kit components have not been tested for their ecological effects, therefore no information is known for these mixtures. The following ecological data is known for ingredients listed in subsection 3.2:

12.1 Toxicity

*Definitions can be found in section 16

| Ingredient | Toxicity to | Measurement* | Value (inc. exposure time) |
|--------------------------------------|---|-------------------|----------------------------|
| 2-Chloroacetamide | Fish (<i>Carassius auratus</i> (goldfish)) | LC ₅₀ | 19.8 mg/L (96h) |
| | Daphnia (<i>Daphnia magna</i> (water flea)) | EC ₅₀ | 14 mg/L (48h) |
| MIT | Daphnia (<i>Daphnia magna</i> (water flea)) | EC ₅₀ | 2.33 mg/L (48h) |
| | Algae (<i>Pseudokirchneriella subcapitata</i> (green algae)) | ErC ₅₀ | 0.289 mg/L (72h) |
| | | NOEC | 0.047 mg/L (72h) |
| Oxypyryon | Fish (<i>Oncorhynchus mykiss</i> (rainbow trout)) | LC ₅₀ | 70.7 mg/L (96h) |
| | Fish (<i>Lepomis macrochirus</i> (bluegill sunfish)) | LC ₅₀ | >97.8 mg/L (96h) |
| | Daphnia (<i>Daphnia magna</i> (water flea)) | EC ₅₀ | 78.6 mg/L (48h) |
| Sodium Azide | Fish (<i>Lepomis macrochirus</i> (bluegill sunfish)) | LC ₅₀ | 0.70 mg/L (96h) |
| | Daphnia (<i>Daphnia pulex</i> (water flea)) | EC ₅₀ | 4.2 mg/L (48h) |
| | Algae (mixed culture of green algae) | IC ₅₀ | 272 mg/L |
| | Microorganisms (<i>Photobacterium phosphoreum</i>) | EC ₅₀ | 38.5 mg/L |
| Stabilzyme® HRP Conjugate Stabilizer | Fish (<i>Oncorhynchus mykiss</i> (rainbow trout)) | LC ₅₀ | 0.19 mg/L |
| | Daphnia & other aquatic invertebrates (<i>Crassostrea virginica</i> (eastern oyster)) | EC ₅₀ | 0.028 mg/L |

| Ingredient | Toxicity to | Measurement* | Value (inc. exposure time) |
|--------------------------------------|---|------------------|----------------------------|
| Stabilzyme® HRP Conjugate Stabilizer | Algae (<i>Raphidocelis subcapitata</i> (green algae)) | EC ₅₀ | 0.018 mg/L (72h) |

No data available for Enhanced K-Blue® Substrate or sulphuric acid.

12.2 Persistence and degradability

| Ingredient | Test/Result |
|--------------------------------------|---|
| 2-Chloroacetamide | Biodegradability: aerobic, exposure time 28 days Results: 94% - Readily degradable. |
| MIT | Biodegradability: aerobic, exposure time 28 days Results: 0% - Not readily degradable. |
| Oxypyryon | Biodegradability: 94% - Readily degradable. |
| Stabilzyme® HRP Conjugate Stabilizer | Not rapidly degradable. |

No data available for Enhanced K-Blue® Substrate, sodium azide or sulphuric acid.

12.3 Bioaccumulative potential

| Ingredient | Test/Result |
|--------------------------------------|--|
| Oxypyryon | Low Pow: -0.64 |
| Sodium Azide | Partition coefficient: n-octanol/water - log Pow: 0.3 (Bioaccumulation is not expected) |
| Stabilzyme® HRP Conjugate Stabilizer | Log Kow: >5 (significant bioaccumulation) |

No data available for 2-chloroacetamide, Enhanced K-Blue® Substrate, MIT or sulphuric acid.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

| Ingredient | Test/Result |
|-------------------|---|
| 2-Chloroacetamide | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of ≥0.1%. |
| Oxypyryon | |
| Sodium Azide | |

No data available for Enhanced K-Blue® Substrate, MIT, Stabilzyme® HRP Conjugate Stabilizer or sulphuric acid.

12.6 Other adverse effects

The concentrations of ingredients listed in subsection 3.2 are below the acceptable limit for hazardous substances; the ecological risk is minimal. However, it is recommended that reagents do not enter drains in large quantities.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Chemical and biological residues are classified as special waste and as such, are covered by regulations which may vary according to location. Contact your local waste disposal authority for advice or pass to a licensed disposal company. Observe all national and local environmental regulations. Contaminated packaging should be disposed of using the same routes.

SECTION 14: Transport information

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

Transport of this product can be carried out at ambient temperature but in the event of delays store at 2 – 8°C with all reagents contained within the packaging provided.

14.1 UN number

Not applicable.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

See sections 6 to 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.**

Enhanced K-Blue® Substrate contains N-methyl-2-pyrrolidone which is included in the Candidate List of Substances of Very High Concern (SVHC) for Authorisation according to Regulation (EC) No. 1907/2006 (REACH).

15.2 Chemical safety assessment

Not applicable.

SECTION 16: Other information

This SDS has been compiled in accordance with Commission Regulation (EC) No. 1907/2006 as amended by Commission Regulation (EU) 2015/830.

All information provided on ingredients listed in subsection 3.2 has been obtained from the appropriate chemical safety data sheets.

Full text of precautionary phrases (listed in subsection 2.3) and hazard statements (listed in subsection 3.2) according to Regulation (EC) No. 1272/2008:

P233: Keep container tightly closed.

P270: Do not eat, drink or smoke when using this product.

P281: Use personal protective equipment as required.

P301 + P330: IF SWALLOWED rinse mouth.

P302 + P352: IF ON SKIN: Wash with plenty of soap and water.

P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing.

H290: May be corrosive to metals.

H300: Fatal if swallowed.

H301: Toxic if swallowed.

H302: Harmful if swallowed.

H310: Fatal in contact with skin.

H311: Toxic in contact with skin.

H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H319: Causes serious eye irritation.

H330: Fatal if inhaled.

H331: Toxic if inhaled.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335: May cause respiratory irritation.

H360D: May damage the unborn child.

H361f: Suspected of damaging fertility.

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.

EUH032: Contact with acids liberates very toxic gas.

Definitions:

LC50 = The lethal concentration of a substance that kills 50% of the test population within a designated period.

LD50 = Lethal dose for 50% of the test population.

EC50 = The effective concentration of a substance that causes adverse effects in 50% of the test population within a designated period.

ErC50 = The concentration of a substance which results in 50% reduction in growth rate of the test population relative to the control within 72 hours exposure.

IC50 = The inhibition concentration of a substance that causes a 50% inhibition of growth of the test population relative to the control within a designated period.

NOEC = No-observed-effect-concentration. The highest concentration at which no toxic effects are observed.

STEL = Short term exposure limit (15 minute reference period).

TWA = Time weighted average, long term exposure limit (8 hour reference period).

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