

Material safety data sheet

According to the Regulation (EU) 2015/830

Date: December 29th, 2020

Former Date: October 14th, 2020

SECTION 1: IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product identifier

Product name Actim® ELISA SARS-CoV-2 IgG
Product number 35530ETAC

Components

Component	Symbol	REF no	Quantity	Description
Microtiter plate	MTP 8x12	35501ETAC	1 pcs	Microtiter plate with 8 x 12 strips (96 wells) coated with SARS-CoV-2 antigen.
100x HRP-Conjugate	Ab HRP	35502ETAC	175 µl	One vial of HRP-conjugated monoclonal anti-human IgG antibody concentrate in a stabilizing buffer.
Calibrator (A-F)	CAL A-F	35503ETAC	50 µl	Six vials of Calibrators having ascending concentrations of calibrator material in a stabilizing BSA-based buffer. Does not contain any infectious material.
Control (Neg-Pos)	CTRL NEG-POS	35504ETAC	50 µl	Two vials of Controls having low and high concentrations of calibrator material in a stabilizing BSA-based buffer. Does not contain any infectious material.
Sample Diluent	SPL DIL	35505ETAC	50 ml	One bottle of ready-to-use buffer for diluting the samples, the Calibrators (A-F) and the Controls (Neg-Pos)
25x Wash Solution	BUF WAS	35506ETAC	100 ml	One bottle of wash solution concentrate.
Substrate	SUBS TMB	35507ETAC	20 ml	One bottle of ready-to-use tetramethylbenzidine (TMB) substrate in a stabilizing buffer.
Conjugate Diluent	CONJ DIL	35508ETAC	15 ml	One bottle of ready-to-use buffer for diluting the 100x HRP-Conjugate.
Stop Solution	STOP SOLN	35509ETAC	15 ml	One bottle of ready-to-use 0.5 M sulfuric acid.

REACH registration number

Not applicable according to the Regulation (EC) 1907/2006 article 2.

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

Intended uses

For In Vitro Diagnostic use only. ELISA SARS-CoV-2 IgG is an immunoassay for quantitative detection of specific IgG to SARS-CoV-2 in serum from venous blood samples. The test is intended for professional use to help detect recent COVID-19 infection.

1.3 Details of the supplier of the safety data sheet

Company Actim Oy
Street Address Klövinpellontie 3
Postcode and post office FI-02180 ESPOO FINLAND
Telephone +358-9-547680
E-mail actim@actimtest.com

1.4 Emergency telephone number

Use your local emergency number.

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SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Other components of the product are not classified as dangerous according to the Regulation (EC) 1272/2008.

Stop Solution classification according to Regulation (EC) No 1272/2008 (CLP)
Corrosive to metals (Category 1) H290

2.2 Label elements

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

Other components: None required

Stop Solution:



Hazard pictograms:

Signal word:

Warning

Hazard statement(s):

H290 May be corrosive to metals

Precautionary statement(s):

P234 Keep only in original container

P390 Absorb spillage to prevent material damage

Supplemental Hazard information

(EU):

none

2.3 Other hazards

None known.

SECTION 3 : COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous components according to Regulation (EC) No 1272/2008 (CLP):

Calibrators, Controls, Sample Diluent:

REACH registration number	CAS-, EC- or index number	Concentration	Classification
Sodium azide	CAS No 26628-22-8	< 0.1 %	Acute Tox. 2: H300 Acute Tox. 2: H330 Acute Tox. 1: H310 STOT RE 2: H373 Aquatic Acute 1: H400 Aquatic Chronic 1: H410

Wash Solution:

REACH registration number	CAS-, EC- or index number	Concentration	Classification
Germall™ II	CAS No 78491-02-8	< 2.5 %	Eye Irrit. 2: H319

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Conjugate Diluent:

REACH registration number	CAS-, EC- or index number	Concentration	Classification
CMIT/MIT*	CAS No 55965-84-9	< 15 ppm	Skin Corr. 1C: H314 Skin Sens. 1A: H317 Eye Dam. 1: H318 Acute Tox. 3: H301 Acute Tox. 2: H310 Acute Tox. 2: H330 Aquatic Acute 1: H400 (M=100) Aquatic Chronic 1: H410 (M=100)

* CMIT/MIT = 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) reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC no. 220-239-6] (3:1)

Stop Solution:

Chemical description: Acid solution

Hazardous components according to Annex II of Regulation (EC) No 1907/2006 (REACH):

REACH registration number	CAS-, EC- or index number	Concentration	Classification
Sulfuric acid ⁽¹⁾	CAS no 7664-93-9 EC no 231-639-5	< 5 %	Met. Corr. 1: H290 Skin Corr. 1A: H314

⁽¹⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2015/830

For full test of H-statements: See section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugae Diluent:

General notes: None.

If inhaled: Move the affected person to fresh air. Keep at rest. If needed: get medical attention.

In case of skin contact: Remove contaminated clothing and wash with soap and water. In case of rash, wound, or other skin irritation: Seek medical advice.

In case of eye contact: Flush with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth and drink plenty of water. Keep under surveillance. If needed: get medical attention.

Stop Solution:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or if necessary shower the affected person thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

By eye contact:

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Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS for the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

4.2 Most important symptoms and effects, both acute and delayed

Calibrators, Controls, Sample Diluent, Wash Solution, Stop Solution:

No relevant information available.

Conjugate, Substrate, Conjugate diluent :

May cause slight irritation of skin, eyes, lungs and gastrointestinal tract. May cause an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Calibrators, Controls, Sample Diluent, Wash Solution, Stop Solution:

No relevant information available.

Conjugate, Substrate, Conjugate diluent :

Show this safety data sheet to a physician or emergency ward.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

Suitable extinguishing media

Water, foam, dry chemical or carbon dioxide

Stop Solution:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use full jet water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

No relevant information available.

Stop Solution:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

When extinguishing surrounding fires use breathing apparatus with an independent source of air.

Stop Solution:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC. Prevent fire-fighting water from contaminating surface or groundwater systems.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Calibrators, Controls, Sample Diluent, Wash Solution:

No special precautions required

Conjugate, Substrate, Conjugate Diluent:

Use personal protective equipment - see section 8.

Stop Solution:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilled product (See section 8).

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6.2 Environmental precautions

Calibrators, Controls, Sample Diluent, Wash Solution:

Dilute with plenty of water.

Conjugate, Substrate, Conjugate Diluent:

Avoid empty into drains. If large amounts of the mixture contaminate sewages, inform appropriate authorities in accordance with local regulations.

Stop Solution:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3 Methods and material for containment and cleaning up

Calibrators, Controls, Sample Diluent, Wash Solution, Stop Solution:

Spillage can be cleaned with water and adsorbent. Clean surfaces with water.

Conjugate, Substrate, Conjugate Diluent:

Absorb spilled liquid and place spillage in a plastic container. Further handling of spillage - see section 13.

6.4 Reference to other sections

Instructions for personal protective clothing in Section 8.

Instructions for disposal of the product in Section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

General occupational hygiene: Do not eat, drink and smoke in work areas. Wash hands after use.

Avoid contact with skin, eyes and clothing.

Stop Solution:

General occupational hygiene: Do not eat, drink and smoke in work areas. Wash hands after use.

Keep containers sealed. It is recommended to have absorbent material available at close proximity to the product. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

7.2 Conditions for safe storage, including any incompatibilities

Calibrators, Controls, Sample Diluent, Wash Solution:

Long-term storage +2...+8 °C.

Conjugate, Substrate, Conjugate Diluent:

Long-term storage +2...+8 °C. Keep container closed when not in use. Protected against light.

Stop Solution:

Store in a cool, dry, well-ventilated location. Avoid sources of heat, radiation, static electricity and contact with food.

7.3 Specific end use(s)

See section 1.2.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Controls parametres

Wash Solution:

Contains no substances with occupational exposure limit values.

Conjugate, Substrate, Conjugate Diluent:

Occupational exposure limits (EH40/2018): None

DNEL/PNEC: No CSR.

Calibrators, Controls, Sample Diluent:

Sodium azide CAS No 26628-22-8	Limit value				National legislation or other provision which gives rise to the limit
	8 h		Short term (15 min)		
	ppm	mg/m ³	ppm	mg/m ³	
Finland	not available	0,1	not available	0,3	Decree of the Ministry of Social Affairs and Health on

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					concentrations known to be harmful (12/14/2016)
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Stop Solution:

Sulfuric acid	Limit value				National legislation or other provision which gives rise to the limit
	8 h		Short term (15 min)		
	ppm	mg/m ³	ppm	mg/m ³	
CAS no 7664-93-9 EC no 231-639-5					
Finland (thoracic fraction)	not available	0,05	not available	0,1	Decree of the Ministry of Social Affairs and Health on concentrations known to be harmful (12/14/2016)

8.2

Exposure controls

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

Engineering controls

Good occupational hygiene practices

Eye/face protection

Not relevant during normal use. Safety goggles (EN166) when there is risk of eye contact.

Skin protection

Work clothing appropriate for laboratory work if splash potential exists. In case of prolonged or repeated work: Wear protective gloves (EN374) e.g. of nitrile. Breakthrough time: approximately 3 hours.

Respiratory protection

Not relevant during normal use.

Thermal hazards

Information not available for the product.

Environmental exposure controls

Not needed when operating in normal laboratory scale.

Stop Solution:

Appropriate engineering controls

Good occupational hygiene practices

Eye / face protection

Safety glasses against splash/projections, in accordance with EN 166:2001

Skin protection

Work clothing appropriate for laboratory work

Hand protection

Nitrile or neoprene gloves, in accordance with EN ISO 374-1:2016; EN 16523-1:2015; EN 420:2003+A1:2009

Respiratory protection

Not needed when operating in normal laboratory scale. The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

Additional emergency measures

Emergency shower and eyewash station

Environmental exposure controls

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information of basic physical and chemical properties

Appearance	Conjugate, Conjugate Diluent: Yellow/brown slightly cloudy liquid Calibrators, Controls, Wash Solution, Stop Solution: Colourless, clear liquid Sample Diluent: Red, clear liquid Substrate: Clear liquid
Odour	Odourless
Odour threshold	Not relevant
pH	Conjugate: 6.6–7.2 Calibrators, Controls: 7.7–7.8 (at 20 °C) Sample Diluent: 7.6–7.9 (at 20 °C) Conjugate Diluent: 6.8–7.2 Wash Solution: 7.0–7.2 (at 20 °C) Stop Solution: <1 (at 20 °C)
Melting point / freezing point	Information not available for the product
Initial boiling point and boiling range	~100 °C
Flash point	Not relevant
Evaporation rate	Information not available for the product
Flammability (solid, gas)	Not relevant
Upper/lower flammability or explosive limits	Not relevant
Vapour pressure	Information not available for the product
Vapour density	Information not available for the product
Relative density	Conjugate, Substrate, Conjugate Diluent: ~1 g/ml Sample Diluent: 1.01 g/ml (at 20 °C) Wash Solution: 1.16 g/ml (at 20 °C)
Solubility(ies)	Completely soluble in water
Partition coefficient; n-octanol/water	Information not available for the product
Auto-ignition temperature	Not relevant
Decomposition temperature	Information not available for the product
Viscosity	Information not available for the product
Explosive properties	Not relevant
Oxidising properties	Not relevant

9.2 Other information

Information not available for the product.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

Information not available for the product or no known hazardous reactions.

Stop Solution:

Strong acid. Risk of hazardous reaction with bases. Has a corrosive effect.

10.2 Chemical stability

The product is stable if stored according to the section 7.

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10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Excessive heating and freezing.

10.5 Incompatible materials

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

None known.

Stop Solution:

Metals, bases.

10.6 Hazardous decomposition products

No known decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Conjugate, Substrate:

No declarable substances.

Information on likely routes of exposure: Skin and ingestion.

Symptoms (inhalation): Inhalation is unlikely when used as recommended.

Symptoms (Skin): May cause slight irritation.

Symptoms (Eyes): May cause slight irritation.

Symptoms (Ingestion): May cause slight irritation of the gastrointestinal tract.

Chronic effects: None known.

Conjugate Diluent:

Hazard class	Data (CMIT/MIT)	Test	Data source
Acute toxicity, Inhalation:	LC ₅₀ (rat) > 4.62 mg/l/4H (vapours)	No info	EU Biocide
Acute toxicity, Dermal:	LD ₅₀ (rabbit) = 660 mg/kg	No info	EU Biocide
Acute toxicity, Oral:	LD ₅₀ (rat) = 457 mg/kg	No info	EU Biocide
Corrosion/irritation:	Corrosive, rabbit	OECD 404	EU Biocide
Sensitization:	Skin sensitization	Buehler	EU Biocide
CMR:	No available or applicable data.	-	-

Information on likely routes of exposure: Skin, lungs and ingestion.

Symptoms (inhalation): Inhalation of atomized liquid may cause irritation of the upper respiratory tract.

Symptoms (Skin): May cause irritation with redness.

Symptoms (Eyes): May cause irritation with redness.

Symptoms (Ingestion): Ingestion of large amounts can cause irritation with nausea and stomach ache.

Chronic effects: Frequent contact with skin may cause sensitization. Symptoms are redness, swelling and itching.

Wash Solution:

Acute toxicity

For the mixture: based on available data, the classification criteria are not met.

Germall™ II:

Oral: LD50 rat: > 2000 mg/kg. LD50 rabbit > 2000 mg/kg

Skin corrosion/irritation	For the mixture: based on available data, the classification criteria are not met. <i>Germall™ II:</i> <i>No skin irritation. Remarks: May cause skin irritation in susceptible persons.</i>
Serious eye damage/irritation	For the mixture: based on available data, the classification criteria are not met. <i>Germall™ II:</i> <i>Irritating to eyes. Remarks: Product dust may be irritating to eyes, skin and respiratory system. Causes serious eye irritation.</i>
Respiratory or skin sensitisation	For the mixture: based on available data, the classification criteria are not met. <i>Germall™ II:</i> <i>Test Type: Maximisation Test. Species: Guinea pig. Assessment: Did not cause sensitisation on laboratory animals.</i>
Germ cell mutagenicity	For the mixture: based on available data, the classification criteria are not met. <i>Germall™ II:</i> <i>Test Type: Ames test: Metabolic activation: with and without metabolic activation. Result: negative</i> <i>Test Type: Chromosome aberration test in vitro: Metabolic activation: with and without metabolic activation. Result: negative.</i> <i>Test Type: In vivo micronucleus test: Test species: Mouse (male and female). Application Route: Oral. Method: Mutagenicity (micronucleus test). Result: negative. Application Route: Oral. Method: OECD Test Guideline 486. Result: negative.</i>
Carcinogenicity	For the mixture: based on available data, the classification criteria are not met.
Reproductive toxicity	For the mixture: based on available data, the classification criteria are not met. <i>Germall™ II:</i> <i>Test Type: Embryo-foetal development: Species: Rat. Application Route: Oral. Dose: 500 milligram per kilogram.</i>
STOT-single exposure	For the mixture: based on available data, the classification criteria are not met.
STOT-repeated exposure	For the mixture: based on available data, the classification criteria are not met. <i>Germall™ II:</i> <i>Species: Rat, male and female. NOEL: 200 mg/kg. Application Route: Oral. Exposure time: 90-day.</i>
Aspiration hazard	For the mixture: based on available data, the classification criteria are not met.
Other information	For the mixture: based on available data, the classification criteria are not met.

Sample Diluent, Calibrators, Controls:

Acute toxicity	For the mixture: based on available data, the classification criteria are not met. <i>Sodium azide:</i> <i>Acute oral toxicity: LD50 rat: 27 mg/kg (RTECS).</i> <i>Acute inhalation toxicity: LC50 rat: 0,054–0,52 mg/l, exposure time 4 h, test atmosphere dust/mist (US-EPA, ECHA).</i> <i>Symptoms: Inhalation may lead to the formation of oedemas in the respiratory tract. Symptoms may be delayed.</i> <i>Acute dermal toxicity: LD50 rabbit: 20 mg/kg (ECHA).</i>
Skin corrosion/irritation	For the mixture: based on available data, the classification criteria are not met. <i>Sodium azide:</i> <i>No skin irritation (ECHA).</i>

Serious eye damage/irritation	For the mixture: based on available data, the classification criteria are not met. <i>Sodium azide:</i> <i>No eye irritation (OECD 437).</i>
Respiratory or skin sensitisation	For the mixture: based on available data, the classification criteria are not met. <i>Sodium azide:</i> <i>Sensitisation test result negativa (mouse, dermal, OECD 429).</i>
Germ cell mutagenicity	For the mixture: based on available data, the classification criteria are not met.
Carcinogenicity	For the mixture: based on available data, the classification criteria are not met.
Reproductive toxicity	For the mixture: based on available data, the classification criteria are not met.
STOT-single exposure	For the mixture: based on available data, the classification criteria are not met.
STOT-repeated exposure	For the mixture: based on available data, the classification criteria are not met.
Aspiration hazard	For the mixture: based on available data, the classification criteria are not met.
Other information	For the mixture: based on available data, the classification criteria are not met.

Sodium azide:

Systemic effects: Dizziness, headache, nausea, vomiting, cough, shortness of breath, CNS disorders, convulsions, circulatory collapse, collapse, unconsciousness, tachycardia, drop in blood pressure. Other dangerous properties can not be excluded. This substance should be handled with particular care.

Stop Solution:

Acute toxicity	For the mixture: no data available.
Skin corrosion/irritation	For the mixture: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for this effect. For more information see section 3.
Serious eye damage/irritation	For the mixture: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for this effect. For more information see section 3.
Respiratory or skin sensitisation	For the mixture: no data available.
Germ cell mutagenicity	For the mixture: no data available.
Carcinogenicity	For the mixture: no data available.
Reproductive toxicity	For the mixture: no data available.
STOT-single exposure	For the mixture: no data available.
STOT-repeated exposure	For the mixture: no data available.
Aspiration hazard	For the mixture: no data available.
Other information	For the mixture: no data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Conjugate Diluent:

Aquatic	Data (CMIT/MIT)	Test (Media)	Data source
Fish	LC ₅₀ (Salmo gairdneri, 96h) = 0.19 mg/l	No info	EU Biocide
Crustacean	EC ₅₀ (Crassostrea virginica, 48h) = 0.028 mg/l	No info	EU Biocide
Algae	EC ₅₀ (Selenastrum cap. 72h) = 0.018 mg/l	No info	EU Biocide

Conjugate, Substrate:

No declarable substances.

Wash Solution, Stop Solution:

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For the mixture: No relevant information available.

Calibrators, Controls, Sample Diluent:

For the mixture: No relevant information available.

Sodium azide:

Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,7 mg/l; 96 h (ECOTOX Database).

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia pulex (Water flea)): 4,2 mg/l; 48 h (ECOTOX Database). Toxicity to algae/aquatic plants: IC50 (mixed culture of green algae): 272 mg/l; (Lit.). Toxicity to micro-organisms: EC50 (Photobacterium phosphoreum: 38,5 mg/l; (Lit.).

12.2 Persistence and degradability

Calibrators, Controls, Sample Diluent, Stop Solution:

For the mixture: No relevant information available.

Conjugate Diluent:

CMIT/MIT is not readily biodegradable (<56%, 28d, OECD 301B).

Conjugate, Substrate:

No declarable substances

Wash Solution:

For the mixture: No relevant information available.

Germall™ II: Biodegradability: Biodegradation: 24 %. Exposure time: 28 d. Remarks: Not readily biodegradable. Stability in water: Degradation half life (DT50): 12 h (20,4 °C) pH: 7.

12.3 Bioaccumulative potential

Calibrators, Controls, Sample Diluent, Stop Solution:

For the mixture: No relevant information available.

Sodium azide: Partition coefficient: n-octanol/water log Pow: 0.3 OECD Test Guideline 117. Bioaccumulation is not expected.

Conjugate Diluent:

CMIT/MIT: $1 < \text{Log Kow} < 3$ – Possible moderate bioaccumulative.

Conjugate, Substrate:

No declarable substances

Wash Solution:

For the mixture: No relevant information available.

Germall™ II: Remarks: The substance has low potential for bioaccumulation.

12.4 Mobility in soil

Conjugate, Calibrators, Controls, Sample Diluent, Substrate, Conjugate Diluent, Stop Solution:

Information not available for the product.

Wash Solution:

For the mixture: No relevant information available.

Germall™ II: Adsorption/Soil: Medium: Soil: Koc: < 2.

12.5 Results of PBT and vPvB assessment

This mixture contains no components considered to be either PBT or vPvB

12.6 Other adverse effects

Conjugate, Substrate, Conjugate Diluent:

None known.

Wash Solution:

For the mixture: No relevant information available.

Germall™ II: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Toxic to aquatic life.

Sample Diluent, Calibrators, Controls:

For the mixture: No relevant information available.

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Sodium azide:

Biological effects: Forms toxic mixtures in water, dilution measures notwithstanding. Herbicide. Nematocidal effect. Discharge into the environment must be avoided.

Stop Solution:

Avoid releasing to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

Product / Packaging disposal Small amounts of product can be disposed of to the sewer system if rinsed with plenty of water. Package can be rinsed with water and disposed as burnable waste.

Waste treatment-relevant information Waste treatment in compliance with local and national regulations.

Sewage disposal-relevant information Large amount of product must not be disposed of to the sewer.

Other disposal recommendations No relevant information available.

Stop Solution:

Waste treatment-relevant information Waste treatment in compliance with local and national regulations. Type of waste (Regulation (EU) No 1357/2014): HP4 Irritant — skin irritation and eye damage

Sewage disposal-relevant information Large amount of product must not be disposed of to the sewer.

Product / Packaging disposal Small amounts of product can be disposed of to the sewer system if rinsed with plenty of water. Empty package can be rinsed with water and disposed as burnable waste.

Other disposal recommendations No relevant information available.

SECTION 14: TRANSPORT INFORMATION

14.1 UN number

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

None

Stop Solution:

ADR 2019/RID 2019: UN3264 IMDG 39-18: UN3264 IATA/ICAO 2020: UN3264

14.2 UN proper shipping name

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

None

Stop Solution:

ADR 2019/RID 2019: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (sulfuric acid solution)
IMDG 39-18: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (sulfuric acid solution)
IATA/ICAO 2020: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (sulfuric acid solution)

14.3 Transport hazard classes

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

None

Stop Solution:

ADR 2019/RID 2019: 8 IMDG 39-18: 8 IATA/ICAO 2020: 8

14.4 Packing group

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

None

Stop Solution:

Trade name: Actim® ELISA SARS-CoV-2 IgG

Date: December 29th, 2020

Former date: October 14th, 2020

ADR2019/RID 2019: III

IMDG 39-18: III

IATA/ICAO 2020: III

14.5 Environmental hazards

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

None

Stop Solution:

ADR2019/RID 2019: no

IMDG 39-18: no

IATA/ICAO 2020: no

14.6 Special precautions for user

Conjugate, Calibrators, Controls, Sample Diluent, Wash Solution, Substrate, Conjugate Diluent:

None

Stop Solution:

ADR2019/RID 2019:

IMDG 39-18: no

IATA/ICAO 2020: no

Special regulations: 274

Special regulations: 223, 274

Tunnel restriction code: E

EmS codes: F-A, S-B

Physico-Chemical properties:
see section 9

Physico-Chemical properties:
see section 9

Physico-Chemical properties:
see section 9

Limited quantities: 5 L

Limited quantities: 5 L

Segregation group: SGG1

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

Not relevant.

SECTION 15: REGULATORY INFORMATION

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

No need for additional information.

15.2 Chemical safety assessment

No CSR

SECTION 16: OTHER INFORMATION

Changes to previous version

New safety data sheet

Abbreviations and acronyms

CMR = Carcinogenicity, mutagenicity and reproductive toxicity.

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

ECHA = European Chemicals Agency

EC₅₀ = Effect Concentration 50 %

FW = Fresh Water

LC₅₀ = Lethal Concentration 50 %

LD₅₀ = Lethal Dose 50 %

PBT = Persistent, Bioaccumulative, Toxic

PNEC = Predicted No-Effect Concentration

vPvB = very Persistent, very Bioaccumulative

MARPOL: International Convention for the Prevention of Pollution from Ships

IBC: International Bulk Chemical

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation
PBT: persistent, bioaccumulative and toxic

Trade name: Actim® ELISA SARS-CoV-2 IgG

Date: December 29th, 2020

Former date: October 14th, 2020

Relevant statements

Calibrators, Controls, Sample Diluent:

H300 Fatal if swallowed.

H310 Fatal in contact with skin.

H330 Fatal 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.

Conjugate Diluent:

H301: Toxic if swallowed.

H310: Fatal in contact with skin.

H330: Fatal if inhaled.

H314: Causes severe skin burns and eye damage.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

EUH071: Corrosive to the respiratory tract.

EUH208: Contains ... May produce an allergic reaction.

EUH210: Safety data sheet available on request.

Wash Solution:

H319 Causes serious eye irritation.

Stop Solution:

H290 May be corrosive to metals

H314 Causes severe skin burns and eye damage

Literature references and sources for data

Not applicable.

Methods used for classification

Regulation (EC) 1272/2008.

Training advice

Actim Oy, see section 1.3.

Instructions for use is delivered within each kit. Follow the instructions of use. End users need to have necessary information, advice, and instructions available.

Disclaimer

The information provided in this Safety Data Sheet is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions and is not to be considered a warranty or quality specification. The information is believed to be correct at the date of publishing but they are mentioned as guidelines and do not absolutely guarantee all properties of the product. Information above is not legally binding and Actim Oy is not responsible for any harm related to use or handling of the product.