

## SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: BIOCREDIT COVID-19 Ag

Catalog No.: G61RHA20

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

1.2.1 Relevant identified uses

In vitro diagnostic reagent.

For professional use only

1.2.2 Uses advised against

No additional information available

1.2.3 Details of the supplier of the safety data sheet

RapiGEN, INC.

3-4F, 16, LS-ro 91 beon-gil, Dongan-gu, Anyang-si, Gyeonggi-do, 14119, Republic of Korea

Tel: +82-31-427-4677 Fax: +82-31-427-4678

1.3 Emergency telephone number

Emergency number: +82-31-427-4677

### **SECTION 2. Hazards identification**

2.1 Classification of the substance or mixture

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

Not classified

Contains Sodium azide (less than 0.1%) - not a hazardous substance at this concentration

2.2 Label elements

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

No labelling applicable

2.3 Other hazards

No additional information available

### **SECTION 3. Composition/information on ingredients**

3.1 Substance

Not applicable

3.2 Mixture

- 3.2.1 This Device mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH annex II.
- 3.2.2 The Assay buffer contained some substances to be mentioned according to the criteria of section 3.2 of REACH annex II.

Name	Product identifier	Contains	Classification according to Regulation (EC) No. 1272/2008 [CLP]
EDTA	(CAS No) 60-00-4 (EC No) 200-449-4	10mM	Eye Irrit. 2; H319
Sodium azide	(CAS No) 26628-22-8 (EC No) 247-852-1	0.09%(w/v)	Acute Tox.2, H300 : Conc.=100% Aquatic Acute 1, H400 Aquatic Chronic 1, H410

### **SECTION 4. First aid measures**

4.1 Description of first aid measures

First-aid measures general: When in doubt or if symptoms are observed, seek medical advice. If unconscious,

place in recovery position and seek medical attention. Never give anything orally to an unconscious person or a person with cramps. Change contaminated

/saturated clothing. Never leave affected person unattended.

First-aid measures after inhalation: Allow victim to breathe fresh air. Allow the victim to rest.

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.

First-aid measures after eye contact: Rinse immediately with plenty of water. Remove contact lenses, if present and

easy to do. Obtain medical attention if pain, irritation, blinking or redness persist.

First-aid measures after ingestion: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2 Most important symptoms and effects, both acute and delayed



4.2.1 Device

Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of

normal use.

4.2.2 Assay buffer

Symptoms/injuries after eye contact: Causes serious eye irritation. 4.3 Indication of any immediate medical attention and special treatment needed

No additional information available

## **SECTION 5. Firefighting measures**

5.1 Extinguishing media

Suitable extinguishing media: Foam. Dry powder. Carbon dioxide. Water spray. Sand.

Unsuitable extinguishing media: Do not use a heavy water stream

5.2 Special hazards arising from the substance or mixture

No additional information available

5.3 Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any

chemical fire. Prevent fire-fighting water from entering environment.

Protection during firefighting: Do not enter fire area without proper protective equipment, including respiratory

protection

### **SECTION 6. Accidental release measures**

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Emergency procedures: Evacuate unnecessary personnel.

6.1.2 For emergency responders

Protective equipment: Equip cleanup crew with proper protection

Emergency procedures: Ventilate area

6.2 Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if Assay buffer enters sewers or public waters.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Store away from other materials.

6.4 Reference to other sections

See Heading 8. Exposure controls and personal protection.

## **SECTION 7. Handling and storage**

7.1 Precautions for safe handling

Precautions for safe handling: Wash hands and other exposed areas with mild soap and water before eating, drinking

or smoking and when leaving work. Provide good ventilation in process area to prevent

formation of vapor.

Hygiene measures: Wash hands thoroughly after handling.

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.

Keep container closed when not in use.

Incompatible products: Strong bases. Strong acids

Incompatible materials: Sources of ignition. Direct sunlight.

7.3 Specific end use(s)

No additional information available

## SECTION 8. Exposure controls/personal protection

8.1 Control parameters

No additional information available

8.2 Exposure controls

Personal protective equipment: Avoid all unnecessary exposure

Hand protection: Wear protective gloves

Eye protection: Chemical goggles or safety glasses Respiratory protection: A risk assessment is required Other information: Do not eat, drink or smoke during use.

## **SECTION 9. . Physical and chemical properties**



9.1 Device information on basic physical and chemical properties

Physical state:

Color: Not applicable Not applicable Odor: Odor threshold: No data available No data available Relative evaporation rate(butylacetate=1): No data available

No data available Melting point: Freezing point: No data available Boiling point: No data available Flash point: No data available

Auto-ignition temperature: No data available

Decomposition temperature: No data available Flammability (solid, gas): Non flammable Vapour pressure: No data available Relative vapour density at 20 °C: No data available Relative density: No data available

Solubility: No data available

Log Pow: No data available Viscosity, kinematic: No data available

Viscosity, dynamic: No data available

**Explosive properties:** No data available Oxidizing properties: No data available **Explosive limits:** No data available 9.2 Assay buffer information on basic physical and chemical properties

Physical state: Liquid Color: Colorless

Odor: Characteristic Odor threshold: No data available

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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: No data available Decomposition temperature: No data available Flammability (solid, gas): Non flammable Vapour pressure: No data available Relative vapour density at 20 °C: No data available Relative density: No data available Solubility: No data available Log Pow: No data available

Viscosity, kinematic: No data available Viscosity, dynamic: No data available Explosive properties: No data available Oxidizing properties: No data available **Explosive limits:** No data available

9.3 Other information

Minimum ignition energy: No data available

## **SECTION 10. Stability and reactivity**

10.1 Reactivity

No additional information available

10.2 Chemical stability

Not established.

10.3 Possibility of hazardous reactions

Not established.

10.4 Conditions to avoid



Direct sunlight. Extremely high or low temperatures

10.5 Incompatible materials Strong acids. Strong bases.

10.6 Hazardous decomposition products 10.6.1 Device: Not established.

10.6.2 Assay buffer: Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides

(NOx), Hydrogen chloride gas.

## **SECTION 11. Toxicological information**

Device: Not classified Acute toxicity:

Assay buffer

Name	Criteria	Result
Tris hydrochloride	LD50 Oral, Rat	5,000 mg/kg
Tween 20	LD50 Oral, Rabbit	38,900 mg/kg
Sodium chloride	LD50 Oral, Rat	3,550 mg/kg
Sodium azide	LD50 Oral, Rat	27mg/Kg
EDTA	LD50 Oral, Rat	4500mg/Kg
Polyvinylpyrrolidone	LD50 Oral, Rat	100,000mg/kg
Gelatin	LD50 Oral, Rat	5000mg/Kg

Not classified Skin corrosion/irritation:

Based on available data, the classification criteria are not met.

Some assay buffer components may cause irritation or sensitization in sensitive

individuals.

Serious eve damage/irritation: Device: Not classified

Based on available data, the classification criteria are not met.

Assay buffer:

Name	Criteria	Result
Tween 20	Rabbit	Eye irritation
EDTA	Rabbit	Eye irritation

Respiratory or skin sensitization: Device: Not classified

Based on available data, the classification criteria are not met.

Name	Criteria	Result
Tris hydrochloride	Rabbit	Mild skin irritation

Germ cell mutagenicity: Not classified

Based on available data, the classification criteria are not met.

Not classified Carcinogenicity:

Based on available data, the classification criteria are not met

No component of this product present at levels greater than or equal to 0.1% is identified

as probable, possible or confirmed human carcinogen by IARC.

Not classified Reproductive toxicity:

Based on available data, the classification criteria are not met

Specific target organ toxicity (single exposure): Not classified

Based on available data, the classification criteria are not met

Specific target organ toxicity (repeated exposure):

Device: Not classified

Based on available data, the classification criteria are not met

Assav buffer:

Name	Criteria	Result
Sodium azide	Brain	May cause damage to organs through prolonged
		or repeated exposure

Not classified Aspiration hazard:

Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms: Not classified

Based on available data, the classification criteria are not met

## **SECTION 12. Ecological information**

12.1 Toxicity



12.1.1 Device: No additional information available

12.1.2 Assay buffer

Name	Criteria	Result
	LC50 - fish	460 mg/L - 96 h
	EC50 - other microorganisms(Water	> 117 mg/L - 48 h
Tris hydrochloride	flea)	
	ErC50 - algae	397 mg/L - 144 h
	EC50 - bacteria	> 1,000 mg/L - 3 h
	LC50 - fish	4 ~ 8.9 mg/L - 96 h
Tween 20	LC50 - other microorganisms(Water	18 ~ 26 mg/L - 48 h
	flea)	
Sodium chloride	LD50 - fish	5840mg/L – 96h
Socialii cilioride	LD50 – Daphnia magna(Water flea)	4136mg/L – 48h
Sodium azide	LC50 - fish	2.96 mg/L - 96 h
Souluili azide	EC50 - algae	0.348 mg/L - 96 h
EDTA	LC50 - fish	41mg/L – 96h
EDIA	EC50 – Daphinia magna(water flea)	625mg/L – 24h

12.2 Persistence and degradability

Persistence and degradability: Not established.

12.3 Bioaccumulative potential

12.3.1 Device: Not established.

12.3.2 Assay buffer:

Name	Criteria	Result
FDTA	Lepomis macrochirus	80 $\mu\mathrm{g}/\mathrm{L}$ - 28d at 21 $^{\circ}\mathrm{C}$
EDTA	Bioconcentration factor(BCF)	1.8

## 12.4 Mobility in soil

No additional information available

12.5 Results of PBT and vPvB assessment

No additional information available

12.6 Other adverse effects

No additional information available

## **SECTION 13. Disposal considerations**

13.1 Waste treatment methods

Waste 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 / RID / IMDG / IATA / AND

14.1 UN number

Not regulated for transport

14.2 UN proper shipping name

Proper Shipping Name (ADR):
Proper Shipping Name (IMDG):
Proper Shipping Name (IATA):
Proper Shipping Name (ADN):
Proper Shipping Name (RID):
Not applicable
Not applicable

14.3 Transport hazard class(es)

Transport hazard class(es) (ADR):

Transport hazard class(es) (IMDG):

Transport hazard class(es) (IATA):

Transport hazard class(es) (ADN):

Transport hazard class(es) (RID):

Not applicable

Not applicable

Not applicable

14.4 Packing group

Packing group (ADR):
Packing group (IMDG):
Packing group (IATA):
Packing group (ADN):
Not applicable
Not applicable
Not applicable



Packing group (RID): Not applicable

14.5 Environmental hazards

Dangerous for the environment: No Marine pollutant: No

Other information: No supplementary information available

14.6 Special precautions for user

- Overland transport

No data available

- Transport by sea

No data available

- Air transport

No data available

- Inland waterway transport

Not subject to ADN: No

- Rail transport

Carriage prohibited (RID): No

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

15.1.1 EU-Regulations

Contains no substances with Annex XVII of CLP restrictions.

Contains no REACH Annex XIV substances

15.1.2. National regulations

Republic of Korea Chemicals Control Act, No.15105

15.2 Chemical safety assessment

No chemical safety assessment has been carried out

### **SECTION 16. Other information**

Data sources: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December

2008 on classification, labelling and packaging of substances and mixtures, amending and repealing

Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006.

Other information: Device: None

Assay buffer

Name	Criteria	Result
	Fatal if swallowed or in contact with	H300, H310
Sodium azide	skin	
	Very toxic to aquatic life	H400, H410

### SDS EU (REACH Annex II)

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.