	Materials Safety Data Sheet <i>Acc. to ISO/DIS 11014</i>		Document No.	MSDS-643-2
	Product name	GENEDIA W COVID-19 Ag	Page	1 / 8

1. Product and company identification

- A. Product Name : GENEDIA W COVID-19 Ag
- B. Recommended use of the chemical and restriction on use: In vitro diagnostic use only
- C. Name : GRENCROSS MEDICAL SCIENCE CORP.
 Address : 26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun, Chungcheongbuk-do, Korea
 Emergency phone number : +82-31-260-9300 (Green-call service)
 Fax number : +82-31-260-9416
 Web : <http://www.greencrossms.com>

2. Hazards identification

- A. Hazard.Risk Classification
 No data available
- B. Label elements including precautionary statements (GHS)
 No data available
- C. Other Hazard.Risk which are not included in the classification criteria
 No data available


3. Composition/Information on ingredients

It consists of Test device, Extraction solution, Sample developing screw cap and Sterilized swabs for sample collection.

Contents	Chemical Name	CAS No	Weight (%)
Test device	Mouse anti-COVID 19 Ag monoclonal antibody- Colloidal gold conjugate	-	≤ 0.2 w/v %
	Mouse anti-COVID 19 Ag monoclonal antibody	-	< 0.2 w/v %
	Goat anti-Mouse IgG	-	< 0.2 w/v %
Extraction solution	Trizma base	77-86-1	< 4 w/v %
	TWEEN 20	9005-64-5	< 1.5 v/v %
	Sodium azide	26628-22-8	0.1 w/v %
	Triton X-100	9002-93-1	< 1.5 v/v %
	CHAPS	331717-45-4	≤ 1 w/v %
	Casein	9000-71-9	≤ 1 w/v %
	Sodium chloride	16495-13-9	< 1 w/v %

4. First aid measures

- A. Inhalation
 If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give

	Materials Safety Data Sheet <i>Acc. to ISO/DIS 11014</i>		Document No.	MSDS-643-2
	Product name	GENEDIA W COVID-19 Ag	Page	2 / 8

oxygen. Get medical attention.

B. Ingestion

Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately. Loosen tight clothing such as a collar, tie, belt or waistband.

C. Skin contact

In case of contact, immediately flush skin with plenty of water. Remove contaminated clothing and shoes. Cold water may be used. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention.

D. Eye contact

Remove contact lenses during work. In case of contact, immediately flush eyes with plenty of water at least 15 minutes. Cold water may be used. Get medical attention.

5. Fire-Fighting measures

A. Suitable (and unsuitable) extinguishing media

Suitable : Not applicable.

Use an extinguishing agent suitable for surrounding fires.

B. Specific hazards arising from the chemical

Flammability of the Product : Non-flammable.

Autoignition Temperature : Not applicable.

Flash Points : Not applicable.

Flammable Limits : Not applicable.

Fire Hazards in Presence of Various Substances : Not applicable.

Explosion Hazards in Presence of Various Substances : Not considered as a product presenting risks of explosion.

Special Remarks on Fire Hazards : Not available.

C. Special protective equipment and precautions for fire-fighters

Wear suitable protective gear. Keep safe distance and extinguish.

6. Accidental release measures

A. Personal precautions, protective equipment and emergency procedures


Use latex gloves when handling infectious materials. Wash hands thoroughly after handling.

Avoid breathing vapours, mist or gas. Change contaminated clothing immediately.

Use personal protective equipment. - see section 8.

B. Environmental precautions and protective procedures

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided. Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow to evacuate through the sanitary system.

	Materials Safety Data Sheet <i>Acc. to ISO/DIS 11014</i>		Document No.	MSDS-643-2
	Product name	GENEDIA W COVID-19 Ag	Page	3 / 8


- C. Methods and materials for containment and cleaning up
Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.
Dispose of all specimens and materials used in the test by autoclaving for a minimum 1 hour at 121°C. Liquid wastes which were used should be discarded after mixing it with 1% sodium hypochlorite for more than 1 hour.

7. Handling and storage

- A. Precautions for safe handling
When using extraction solution, be careful not to get on eyes, skin, or clothing. Do not eat, drink or smoke when using this product. Carefully open the cap before opening. Avoid inhalation of steam or mist generated by heated substances.
There are no other specific handling requirements, but disposable gloves should be worn when testing samples with this configuration, and short-term contact and repeated and prolonged exposures should be avoided by wiping hands clean after the test.
- B. Conditions for safe storage
Store in 2 ~ 30°C.
Keep container tightly closed.

8. Exposure controls & personal protection

- A. Exposure standards for chemicals and biological exposure standards.
National regulation : No data available
ACGIH regulation : No data available
Biological exposure standard : No data available
- B. Appropriate engineering controls
Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective occupational exposure limits.
- C. Personal protective equipment
- Respiratory protection**
The type of protective respirator must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- Eye protection**
The type of protective safety goggles must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- Hands protection**
The type of protective glove must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- Body protection**

	Materials Safety Data Sheet <i>Acc. to ISO/DIS 11014</i>		Document No.	MSDS-643-2
	Product name	GENEDIA W COVID-19 Ag	Page	4 / 8

Complete suit protecting against chemicals, the type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided. Do not eat near work area. Wash hands before breaks and after work.


Personal Protection in Case of a Large Spill

Splash goggles. Full suit. Boots. Gloves. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Consult local authorities for acceptable exposure limits.

9. Physical and chemical properties

A. Appearance	Colorless liquid	K. Vapor pressure	The highest known value is 3.2 kPa (23.8 mmHg) (at 20°C)
B. Odour	No data available	L. Solubility	Easily soluble in cold water, hot water, methanol, acetone.
C. Odour threshold	No data available	M. Vapor density	No data available
D. pH	Neutral	N. Relative density	No data available
E. Melting point/ freezing point	May start to solidify at 0°C (32°F) based on data for: water.	O. Partition coefficient: n-octanol/water	No data available
F. Initial boiling point and boiling range	The lowest known values is 100°C (212°F)(water)	P. Auto-ignition temperature	No data available
G. Flash point	No data available	Q. Decomposition temperature	No data available
H. Evaporation rate	0.36 (water) compared to (n-butyl acetate= 1).	R. Viscosity	No data available
I. Flammability (solid, gas)	No data available	S. Molecular mass	Not applicable
J. Upper/lower flammability or explosive limits	No data available		

	Materials Safety Data Sheet <i>Acc. to ISO/DIS 11014</i>		Document No.	MSDS-643-2
	Product name	GENEDIA W COVID-19 Ag	Page	5 / 8

10. Stability and reactivity

- A. Chemical stability and possibility of hazardous reactions
Stable for 12 months from the date of manufacture under recommended storage conditions(2~30°C).
- B. Conditions to avoid
High temperature, freezing, humidity, heat, and spark.
- C. Incompatible materials
Combustible materials and metals
- D. Hazardous decomposition products
No data available

11. Toxicological information

Due to its small amount and low concentration, there is little toxicological risk.

- A. Information on the likely routes of exposure
Ingestion, inhalation and contact with skin.
- B. Health hazards information

Acute toxic

Chemical Name	LD50(oral, rat/mouse)	LD50(dermal, rat/rabbit)	LC50(inhalation, rat/mouse)
Sodium azide	No data available	Rabbit : 20 mg/kg	Rat : 37 mg/m ³
Water, Distilled	No data available	No data available	No data available

Skin corrosive/irritant

May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

May cause eye irritation with susceptible persons.

Respiratory sensitization

No data available

Skin sensitization

No data available

Carcinogenicity

Industrial Safety and Health Act : No data available

Labor Ministry Notice : No data available

IARC : No data available

OSHA : No data available

ACGIH : No data available


NTP : No data available

EU CLP : No data available

Germ Cell Mutagenicity

No data available

Reproductive toxicity

	Materials Safety Data Sheet <i>Acc. to ISO/DIS 11014</i>		Document No.	MSDS-643-2
	Product name	GENEDIA W COVID-19 Ag	Page	6 / 8

No data available

Specific target organ toxicity (single exposure)

No data available

Specific target organ toxicity (repeated exposure)

No data available

Aspiration hazard

No data available

12. Ecological information


- A. Aquatic and terrestrial ecotoxicity
 - Toxicity to fish : No data available
 - Toxicity to algae : No data available
 - Toxicity to crustaceans : No data available
- B. Persistence and degradability
 - No data available
- C. Bio accumulative potential
 - No data available
- D. Mobility in soil
 - No data available
- E. Other adverse effects
 - Do not dispose of water, waste water or soil.
 - Due to its small amount and low concentration, there is little ecological risk.

13. Disposal considerations

- A. Disposal method
 - The solid waste used in the test should be autoclaved at 121 ° C for more than 1 hour.
 - Liquid wastes which were used should be discarded after mixing it with 1% sodium hypochlorite for more than 1 hour.
 - Dispose in accordance with local, regional, national and international regulations.
- B. Disposal precaution (including the disposal method of contaminated container and packaging)
 - Dispose in accordance with local, regional, national and international regulations.

14. Transport information

- A. UN number : No data available
- B. UN proper shipping name : Not classified as dangerous in the meaning of transport regulations.
- C. Transport hazard class : No data available
- D. Packing group (if applicable) : No data available
- E. Marine pollution (yes/no) : No data available

	Materials Safety Data Sheet <i>Acc. to ISO/DIS 11014</i>		Document No.	MSDS-643-2
	Product name	GENEDIA W COVID-19 Ag	Page	7 / 8


- F. Special precaution which a user to be aware of or needs to comply with in connection with transport or conveyance either within or outside their premises : No data available
- G. IATA : Not regulated as dangerous goods

15. Regulatory information

- A. Chemicals known to cause cancer
None of the ingredients is listed.
- B. Chemicals known to cause reproductive toxicity
None of the ingredients is listed
- C. Cancerogenity categories
EPA (Environmental Protection Agency):
None of the ingredients is listed
IARC (International Agency for Reseach on Cancer):
None of the ingredients is listed
NTP (National Toxicology Program) :
None of the ingredients is listed
TLV(Threshold Limit Value established by ACGIH) :
None of the ingredients is listed
MAK(German Maximum Workplace Concentration) :
None of the ingredients is listed
NIOSH-Ca(National Institute for Occupational Safety and Health) :
None of the ingredients is listed
OSHA-Ca(Occupational Safety & Health Administration) :
None of the ingredients is listed
- D. Hazard-determining components of labelling
None of the ingredients is listed
Due to sodium azide small amount and low concentration, there is little risk.
- E. Risk phrases
Harmful if swallowed
- F. Safety phrases
This material and its container must be disposed of in a safe way. Wear suitable protective clothing.
If swallowed, seek medical advice immediately and show this MSDS.
- G. National regulations
- H. Water hazard class
Generally not hazardous for water.

16. Other information

- A. Information source and references
KOSHA

	Materials Safety Data Sheet <i>Acc. to ISO/DIS 11014</i>		Document No.	MSDS-643-2
	Product name	GENEDIA W COVID-19 Ag	Page	8 / 8

NCIS

- B. Issuing date : 2020.07.01.
- C. Revision number and date : 2.0 (2020.12.07.)
- D. Others

Due to sodium azide small amount and low concentration, there is little risk.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guideline of GRENCROSS MEDICAL SCIENCE CORP. shall not be held liable for any damage resulting from handling or from contact with above product. Final determination of suitability of any material is the sole responsibility of user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that are the only hazards that exist.