

012/01/2021

Kit Components, US

Product code:	Description
CAGS-1, CAGS-2, CAGS-5, CAGS-20	SCoV-2 Ag <i>Detect</i> TM Rapid Self-Test Kit Emergency Use Authorization (EUA) Only

Components:

800276	SCoV-2 Ag <i>Detect</i> TM Rapid Test Cassette
201100	Lysis Buffer
201049	Sterile Nasal Swabs

1 Identification

· **Product Identifier**

- **Trade Name:** SCoV-2 Ag Detect™ Rapid Test Cassette
- **Relevant identified uses of the substance or mixture and uses advised against:**
- **Product Description:** Test Cassette - For use under Emergency Use Authorization (EUA) Only
- **Details of the Supplier of the Safety Data Sheet:**
- **Manufacturer/Supplier:**
InBios International, Inc.
307 Westlake Avenue North, Suite 300
Seattle, WA 98109
Ph: 206-344-5821 Fax: 206-344-5823
- **Emergency telephone number:**
For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC Day or Night
Within USA and Canada: 1-800-424-9300 or Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

2 Hazard(s) Identification

- **Classification of the substance or mixture:**
The product does not need classification according to OSHA HazCom Standard 29 CFR paragraph (d) of §1910.1200(g) and GHS Rev 03.
- **Label elements:**
- **GHS Hazard pictograms:** Non-Regulated Material
- **GHS Signal word:** Non-Regulated Material
- **GHS Hazard statements:** Non-Regulated Material
- **Unknown acute toxicity:**
0 % of the mixture consists of component(s) of unknown toxicity.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**

Health = 0
Fire = 0
Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**

Health = 0
Fire = 0
Physical Hazard = 0
- **Hazard(s) not otherwise classified (HNOC):** None known

3 Composition/Information on Ingredients

- **Chemical characterization:** Not Applicable
- **Description:** Non-Regulated Material
- **Dangerous Components:** Non-Regulated Material

4 First-Aid Measures

- **Description of first aid measures**
- **General information:** No special measures required.

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- **After inhalation:** No special measures required.
- **After skin contact:** Generally, the product does not irritate the skin.
- **After eye contact:** Flush with water should contact with eyes occur.
- **After swallowing:** Do not swallow. Use First Aid for choking
- **Information for doctor**
- **Most important symptoms and effects, both acute and delayed:** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed:**
No further relevant information available.

5 Fire-Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray.
- **For safety reasons unsuitable extinguishing agents:** No further relevant information is available.
- **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters**
- **Special Protective Equipment for firefighters:**
No further relevant information is available.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures:** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Dispose of the collected material once bagged in household trash.
- **Reference to other sections:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling**
- **Precautions for safe handling:** Use standard precautions for handling household chemicals.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Do not store with food, water, or other comestibles.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s):** Test Cassette - For use under Emergency Use Authorization (EUA) only

8 Exposure Controls/Personal Protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters:**
- **Components with occupational exposure limits:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** No further relevant information is available.

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- **Exposure controls:**
- **Personal protective equipment**
- **General protective and hygienic measures:** Wash hands or use hand sanitizer prior to handling cassette and starting test
- **Breathing equipment:** Not required.
- **Protection of hands:** Wash hands or use hand sanitizer prior to handling cassette and starting test.
- **Material of gloves:** Not Applicable.
- **Penetration time of glove material:** Not applicable.
- **Eye protection:** Do not allow contact with eyes. Protection not required.

9 Physical and Chemical Properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Test Cassette

Color: Various

- **Odor:** Odorless

- **Odor threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

Melting point/Melting range: Not determined.

Boiling point/Boiling range: Not determined.

- **Flash point:** Not determined

- **Flammability (solid, gaseous):** Product is not flammable.

- **Ignition temperature:** Not applicable

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Not determined.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

- **Vapor pressure:** Not applicable.

- **Density:**

Relative density: Not determined.

Vapor density: Not applicable.

Evaporation rate: Not applicable.

- **Solubility in / Miscibility with:**

Water: Not applicable.

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

Dynamic: Not applicable.

Kinematic: Not applicable.

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- **Solvent content:**
 - **Organic solvents:** 0.0 %
 - **Solids content:** 100.0 %
- **Other information:** No further relevant information available.

10 Stability and Reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects:**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:** No data available.
- **Primary irritant effect:**
- **On the skin:** No irritation effect.
- **On the eye:** No irritating effect.
- **Additional toxicological information:**
 When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
 The substance is not subject to classification.

- **Carcinogenic categories:**

- **IARC (International Agency for Research on Cancer):**

None of the ingredients are listed.

- **NTP (National Toxicology Program):**

None of the ingredients are listed.

- **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

12 Ecological Information

- **Toxicity:**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability:** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential:** No further relevant information available.
- **Mobility in soil:** No further relevant information available.
- **Additional ecological information:**
- **General notes:** None.
- **Results of PBT and vPvB assessment:**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

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13 Disposal Considerations

- **Waste treatment methods**
- **Recommendation:**
Used test materials should be bagged and then go into normal household trash.
- **Uncleaned packaging**
- **Recommendation:** Materials should be bagged and then go into normal household trash.

14 Transport Information

- **UN-Number:**
- **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:**
- **DOT, ADR/ADN, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR/ADN, ADN, IMDG, IATA**
- **Class:** Non-Regulated Material
- **Packing group:**
- **DOT, ADR/ADN, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

15 Regulatory Information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- **SARA (Superfund Amendments and Reauthorization):**

· **Section 355 (extremely hazardous substances):**

None of the ingredients are listed.

· **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

· **TSCA (Toxic Substances Control Act):**

None of the ingredients are listed.

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients are listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients are listed.

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· **Carcinogenic categories:**

· **EPA (Environmental Protection Agency):**

None of the ingredients are listed.

· **TLV (Threshold Limit Value established by ACGIH):**

None of the ingredients are listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health):**

None of the ingredients are listed.

· **GHS label elements:** Non-Regulated Material

· **Hazard pictograms:** Non-Regulated Material

· **Signal word:** Non-Regulated Material

· **Hazard statements:** Non-Regulated Material

· **National regulations:**

None of the ingredients are listed.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· **Date of last revision/ revision number:** 12/01/2021

· **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road

ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

Prod: Product Number

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety and Health

OSHA: Occupational Safety & Health Administration

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Trade Name: Lysis Buffer
Product number: 201100

Safety Data Sheet (SDS)
OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

Version: 12/01/2021

1 Identification

- **Product Identifier**
- **Trade name:** Lysis Buffer
- **Relevant identified uses of the substance or mixture and uses advised against:**
- **Product Description:** Test Kit Scientific Reagent - For use under Emergency Use Authorization (EUA) only
- **Details of the Supplier of the Safety Data Sheet:**
- **Manufacturer/Supplier:**
InBios International, Inc.
307 Westlake Avenue North
Suite 300
Seattle, WA 98109
Ph: 206-344-5821 Fax: 206-344-5823
- **Emergency telephone number:**
For Chemical Emergency Spill, Leak, Fire, Exposure, or Accident
Call CHEMTREC Day or Night
Within USA and Canada: 1-800-424-9300 or Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

2 Hazard(s) Identification

- **Classification of the substance or mixture:**
The product does not need classification according to OSHA HazCom Standard 29 CFR paragraph (d) of §1910.1200(g) and GHS Rev 03.
- **Label elements:**
- **GHS label elements:** Non-Regulated Material
- **GHS Hazard pictograms:** Non-Regulated Material
- **GHS Signal word:** Non-Regulated Material
- **Hazard statements:** Non-Regulated Material
- **Unknown acute toxicity:**
0 % of the mixture consists of component(s) of unknown toxicity.
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**

Health = 0
Fire = 0
Reactivity = 0
- **HMIS-ratings (scale 0 - 4)**

Health = 0
Fire = 0
Reactivity = 0
- **Hazard(s) not otherwise classified (HNOC):** None known

3 Composition/Information on Ingredients

- **Chemical characterization: Mixtures**
- **Description:** Reagent mixture
- **Dangerous Components:** Non-Regulated Material

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Trade Name: Lysis Buffer
Product number: 201100

Safety Data Sheet (SDS)

OSHA HazCom Standard 29 CFR 1910.1200(g) and GHS Rev 03.

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4 First-Aid Measures

- **Description of first aid measures:**
- **After inhalation:** Consult medical provider.
- **After skin contact:**
Immediately wash with water and soap and rinse thoroughly.
If skin irritation occurs, consult a medical provider.
- **After eye contact:**
Rinse opened eye for at least 15 minutes under running water. If symptoms persist, consult a medical provider.
- **After swallowing:** Do not ingest. If swallowed consult a medical provider.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed:** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed:**
No further relevant information available.

5 Fire-Fighting Measures

- **Extinguishing media:**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture:** No further relevant information available.
- **Advice for firefighters:**
- **Special Protective equipment for firefighters:**
None required.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures:** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Do not allow product to contact skin or eyes during cleaning up.
- **Reference to other sections:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling**
- **Precautions for safe handling:** Use standard precautions for handling household chemicals
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities:**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Do not store with food, water or other comestibles.
- Store at room temperature 15-30°C (59-86°F). Storage above or below these temperatures can impact the performance of the test.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep dropper bottle unopened until use.
- **Specific end use(s):** Test Kit Scientific Reagent - For use under Emergency Use Authorization (EUA) only

8 Exposure Controls/Personal Protection

- **Additional information about design of technical systems:** No further data; see section 7.

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Trade Name: Lysis Buffer
 Product number: 201100

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· **Control parameters:**

· **Components with occupational exposure limits:**

Not Applicable

PEL	Long-term value: N/A
REL	Ceiling limit value: N/A
TLV	Ceiling limit value: N/A

· **Additional information:**

· **Exposure controls:**

· **Personal protective equipment:** Not required

· **General protective and hygienic measures:**

The usual precautionary measures for handling household chemicals should be followed. Keep away from foodstuffs, beverages and feed.
 Wash hands before breaks and at the end of work.

· **Breathing equipment:** Not required.

· **Protection of hands:** Avoid contact with hands. Wash hands prior to and after administration of test.

· **Eye protection:** Avoid contact with eyes.

9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Liquid
Color:	Colorless
Odor:	Odorless
Odor threshold:	Not determined.

· **pH-value @ 20 °C (68 °F):** 7.4

· **Change in condition**

Melting point/Melting range:	Not determined.
Boiling point/Boiling range:	Not determined

· **Flash point:** None

· **Flammability (solid, gaseous):** Not applicable.

· **Ignition temperature:** Not determined

· **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

· **Vapor pressure @ 20 °C (68 °F):** Not determined.

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Trade Name: Lysis Buffer
 Product number: 201100

Safety Data Sheet (SDS)
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- **Density:**
 - Relative density:* Not determined.
 - Vapor density:* Not determined.
 - Evaporation rate:* Not determined.
- **Solubility in / Miscibility with:**
 - Water:* Fully miscible.
- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:* Not determined.
 - Kinematic:* Not determined.
- **Solvent content:**
 - Organic solvents:* 0.0 %
- **Other information:** No further relevant information available.

10 Stability and Reactivity

- **Reactivity:** No further relevant information available.
- **Chemical stability:** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological Information

- **Information on toxicological effects:**
- **Acute toxicity:**
- **Primary irritant effect:**
- **On the skin:** Irritant to skin and mucous membranes.
- **On the eye:** Irritating effect.
- **Additional toxicological information:**
 The product shows the following dangers according to internally approved calculation methods for preparations:
 Irritant

- **Carcinogenic categories:**

<ul style="list-style-type: none"> · IARC (International Agency for Research on Cancer): Not Applicable
<ul style="list-style-type: none"> · NTP (National Toxicology Program): None of the ingredients are listed.
<ul style="list-style-type: none"> · OSHA-Ca (Occupational Safety & Health Administration): None of the ingredients are listed.

12 Ecological Information

- **Toxicity:**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability:** No further relevant information available.

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Trade Name: Lysis Buffer
 Product number: 201100

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- **Behavior in environmental systems:**
- **Bioaccumulative potential:** No further relevant information available.
- **Mobility in soil:** No further relevant information available.
- **Additional ecological information:**
- **General notes:** None
- **Results of PBT and vPvB assessment:**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects:** No further relevant information available.

13 Disposal Considerations

- **Waste treatment methods:**
- **Recommendation:**
Used test materials should be bagged and then may go into normal household trash.
- **Uncleaned packagings:**
- **Recommendation:** Materials should be bagged and then may go into normal household trash

14 Transport Information

- **UN-Number:**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **UN proper shipping name:**
- **DOT, ADR, ADN, IMDG, IATA** Non-Regulated Material
- **Transport hazard class(es):**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class:** Non-Regulated Material
- **Packing group:**
- **DOT, ADR, IMDG, IATA** Non-Regulated Material
- **Environmental hazards:** Not applicable.
- **Special precautions for user:** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

15 Regulatory Information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- **SARA (Superfund Amendments and Reauthorization):**

· **Section 355 (extremely hazardous substances):**

Non Applicable

· **Section 313 (Specific toxic chemical listings):**

Non Applicable

· **TSCA (Toxic Substances Control Act):**

Non-Applicable

· **California Proposition 65:**

· **Chemicals known to cause cancer:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

Trade Name: Lysis Buffer
Product number: 201100

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· Chemicals known to cause reproductive toxicity for males:
None of the ingredients are listed.
· Chemicals known to cause developmental toxicity:
None of the ingredients are listed.
· Carcinogenic categories:
· EPA (Environmental Protection Agency):
None of the ingredients are listed.
· TLV (Threshold Limit Value established by ACGIH):
Not Applicable
· NIOSH-Ca (National Institute for Occupational Safety and Health):
None of the ingredients are listed.
· GHS label elements Non-Regulated Material
· Hazard pictograms: Non-Regulated Material
· Signal word: Non-Regulated Material
· Hazard statements: Non-Regulated Material
· National regulations:
The product is subject to be classified according with the latest version of the regulations on hazardous substances.
· State Right to Know: Non-Regulated Material
· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other Information

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create warranty, expressed or implied, and shall not establish a legally valid contractual relationship. It is the responsibility of the user to determine applicability of this information and the suitability of the material or product for any particular purpose.

· Date of preparation / last revision: 12/01/2021

· **Abbreviations and acronyms:**

ADR: The European Agreement concerning the International Carriage of Dangerous Goods by Road
 ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
 IMDG: International Maritime Code for Dangerous Goods
 DOT: US Department of Transportation
 IATA: International Air Transport Association
 ACGIH: American Conference of Governmental Industrial Hygienists
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 NFPA: National Fire Protection Association (USA)
 HMIS: Hazardous Materials Identification System (USA)
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 NIOSH: National Institute for Occupational Safety
 OSHA: Occupational Safety & Health
 TLV: Threshold Limit Value
 PEL: Permissible Exposure Limit
 REL: Recommended Exposure Limit