

Biogem scarl

MATERIAL SAFETY DATASHEET

SECTION1 PRODUCT AND COMPANY IDENTIFICATION

Product name	COVID-19 QuantiGEM, SARS-CoV2 IgM & IgG ELISA Kit
Application	In vitro Diagnostics
Company	Biogem scarl,
Address	Via Camporeale 1, Area PIP 83031, Ariano Irpino (AV) Italy
email	techincalsupport@biogem.it
Emergency Phone	+39 0825881821
SDS Date	2020-12-16

Identified uses of the substance or mixture and uses advised against

Identified use: For In vitro Diagnostics. Professional use as laboratory reagent.

Advised against: Not for final customer

SECTION 2 HAZARDS IDENTIFICATION

Component Items	Hazardous Ingredient	Concentration	CAS No.
COVID-19 IgG Standard, COVID-19 IgM Standard Anti-humann IgG- and Anti-human IgM- HRP- Conjugated Antibodies	Sodium Azide	<0,1%	26628-22-8
OPD (o-phenylenediamine dihydrochloride)	1,2-Benzenediamine, dihydrochloride Sodium metabisulfite 7681-57-4 (1-5)	<5% <5%	615-28-1 7681-57-4
STOP SOLUTION	Hydrochloric Acid in Water	<10%	7647-01-0

2.1、HAZARD STATEMENT

2.1.1 Sodium Azide

The concentrations of the chemical constituent is below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication Standard 29CFR 1910.1200 and the European Directive 91/155/EEC.

Label elements: None

Hazard pictograms: None

Signal word: None

2.1.2 o-phenylenediamine dihydrochloride (OPD)

Label elements:

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

Hazard pictograms:



Hazard statement:

H302 - Harmful if swallowed

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H341 - Suspected of causing genetic defects

H351 - Suspected of causing cancer

H411 - Toxic to aquatic life with long lasting effects

Signal word: None

2.1.3 Hydrochloric Acid (HCl)

Label elements:

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

Hazard pictograms:



Hazard statement:

H290 - May be corrosive to metals

H314 - Causes severe skin burns and eye damage

H335 - May cause respiratory irritation

Signal word: None

2.2 PRECAUTION STATEMENT

2.2.1 Sodium Azide

P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.

P262 Do not get in eyes, on skin, or on clothing.

P264 Wash skin thoroughly after handling.

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

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing.

P284 Wear respiratory protection.

P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth.
 P302 + P352 + P310 IF ON SKIN: Wash with plenty of water. Immediately call a POISON CENTER/ doctor.
 P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
 Immediately call a POISON CENTER/ doctor.
 P314 Get medical advice/ attention if you feel unwell.
 P361 + P364 Take off immediately all contaminated clothing and wash it before reuse.
 P391 Collect spillage.
 P403 + P233 Store in a well-ventilated place. Keep container tightly closed.
 P405 Store locked up.
 P501 Dispose of contents/container to an approved waste disposal plant.

2.2.2 o-phenylenediamine dihydrochloride (OPD)

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
 P301 + P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
 P201 - Obtain special instructions before use
 P264 - Wash hands thoroughly after handling
 P273 - Avoid release to the environment

2.1.3 Hydrochloric Acid (HCl)

P280 – Wear protective gloves/protective clothing/eye protection/face protection.
 P303 + P361 + P353: IF ON SKIN Take off immediately all contaminated clothing. Rinse skin with water/shower.
 P305 + P351 + P338 + P310 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a doctor.

SECTION 3 INFORMATION ON INGREDIENTS

Component Items	Physical Form	Ingredient	Percent	CAS No.	EC No.
Antigen	Odorless and colorless, liquid	Recombinant protein in Phosphate Buffered Saline with Glycerol	<10%	56-81-5	200-289-5
Antigen and Assay Dilution Buffers	Odorless and colorless, liquid	BSA in Phosphate Buffered Saline	<10%	9048-46-8.	232-936-2
Wash Buffer 1, 10X	Odorless and colorless, liquid	Phosphate Buffered Saline			
Wash Buffer 2, 10X	Odorless and colorless, liquid	Phosphate Buffered Saline with Tween-20	<1%	9005-64	500-018-3
Reference Standard IgG and IgM and HRP-Conjugated antibodies	Odorless and colorless, liquid	Antibodies in Phosphate Buffered Saline with Sodium Azide	<0,02%	26628-22-8	247-852-1
OPD	White, Solid	1,2-Benzenediamine, dihydrochloride Sodium metabisulfite 7681-57-4 (1-5)	<5% <5%	615-28-1 7681-57-4	202-430-6
Substrate Buffer 10X	Odorless and colorless, liquid	Buffered stable hydrogen peroxide (H2O2)	<0,1%	-	-
STOP Solution	Slight pungent and colorless, liquid	Aqueous solution with 3N HCl	<10%	7647-01-0	231-595-7

SECTION 4 FIRST-AID MEASURES

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

Skin contact Wash off immediately with plenty of water for at least 15 minutes. Remove and

wash contaminated clothing and gloves, including the inside, before re-use. Immediate medical attention is required.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Immediate medical attention is required.

INGESTION Never give anything by mouth to an unconscious person. Do not induce vomiting without medical advice. Get medical attention if symptoms occur.

Inhalation Remove to fresh air. If not breathing, give artificial respiration. If symptoms persist, call a doctor.

SECTION 5 FIRE EXTINGUISHING MEASURES

5.1 Suitable extinguishing media

Suitable: Water spray, alcohol-resistant foam, dry chemical, carbon dioxide or appropriate foam. For small fires, use media such as "alcohol" foam, dry chemical or carbon dioxide. For large fires, apply water from as far as possible. Use large quantities of water applied as a mist or spray. Solid streams of water may be ineffective. Cool affected containers with flooding quantities of water.

5.2 Special precautions for fire-fighters

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

5.3 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NO_x), Sulphur oxides, Hydrogen chloride gas.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.1 Person-related safety precautions

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas.

6.2 Measures for environmental protection

Prevent further leakage or spillage if safe to do so. Do not let enter drains. Discharge into the environment must be avoided.

6.3 Measures for containment and cleaning

Contain spillage, and then collect with non-combustible absorbent material (eg. sand, diatomaceous earth, vermiculite). Place in a container for disposal according to local regulations. Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal. Sweep up and shovel. Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations (see section 13). Keep in suitable, closed containers for disposal.

SECTION 7 HANDLING AND STORAGE

7.1 Handling

- Wear appropriate protective clothing and safety gloves.
- Avoid inhalation.
- Avoid contact with eyes, skin and clothing.
- Mechanical exhaust required.
- Keep away from ignition sources, heat and flame.

- No smoking at working site.
- Incompatibilities: Strong oxidizing agents, Strong acids. Handling and unloading should be light, to prevent packaging broken, damp and cause losses.
- Working place should be equipped with appropriate varieties and quantities of fire fighting equipment and leakage emergency treatment equipment.

7.2 Storage

- Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
- Keep away from heat, sparks and flame.
- Keep away from sources of ignition.
- Incompatible: Strong oxidizing agents, Strong acids.
- Storage place should be equipped with appropriate varieties and quantities of fire fighting equipment and leakage emergency treatment equipment.

SECTION 8 EXPOSURE CONTROL/PPE

8.1 Engineering Controls

Mechanical exhaust required. Safety shower and eye bath.

8.2 Personal Protective Equipment

Respiratory: Government approved respirator if needed.

Eye/face: Chemical safety goggles if needed.

Clothing: Wear appropriate protective clothing.

Hand/skin: Protective gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection: Wear suitable protective clothing according to the concentration and amount of the substance at the workplace.

8.3 Other Protect

No smoking, drinking and eating at working site. Wash thoroughly after handling.

SECTION 9 PHYSICAL/CHEMICAL PROPERTIES

9.1 Sodium Azide

Appearance Form	solid
Odor	odorless
Odor Threshold	No data available
pH	10.0 at 65.0 g/l at 25.0 °C (77.0 °F)
Melting point/freezing point	Melting point/range 370 - 425 °C (698 - 797 °F) - ASTM E 537- 76 -
Initial boiling point and boiling range:	300 °C 572 °F - (rigorous decomposition)
Flash point	300.0 °C (572.0 °F) - open cup
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapor pressure	0.01 hPa at 20.0 °C (68.0 °F)
Vapor density	No data available
Relative density	1.85 g/cm ³ at 20.0 °C (68.0 °F)
Water solubility	408 g/l at 20 °C (68 °F)
Partition coefficient	n-octanol/water Not applicable for inorganic substances
Autoignition temperature	309 °C (588 °F) - Relative self-ignition temperature for solids
Decomposition temperature	370 - 425 °C (698 - 797 °F), 0.8 kJ/kg –
Viscosity	No data available
Explosive properties	No data available
Oxidizing properties	No data available
Other safety information	No data available

9.2 o-phenylenediamine dihydrochloride (OPD)

Appearance	Solid	
Odour	Mixture has not been tested	
Odour Threshold	Mixture has not been tested	
Melting point / melting range	°C Mixture has not been tested	°F Mixture has not been tested
Boiling point / boiling range	°C Mixture has not been tested	°F Mixture has not been tested
Flash point	°C Mixture has not been tested	°F Mixture has not been tested
Autoignition temperature	°C Mixture has not been tested	°F Mixture has not been tested
Decomposition temperature	°C Mixture has not been tested	°F Mixture has not been tested
Evaporation rate	Mixture has not been tested	
Flammability (solid, gas)	Not applicable	
Upper explosion limit	Mixture has not been tested	
Lower explosion limit	Mixture has not been tested	
Vapour Pressure	Mixture has not been tested	
Relative density	Mixture has not been tested	
Specific gravity	Mixture has not been tested	
Solubility	Mixture has not been tested	
Partition coefficient: n-octanol/water	no data available	
Viscosity	Mixture has not been tested	
Explosive properties	Mixture has not been tested	
Oxidising properties	Mixture has not been tested	
OTHER INFORMATION	no data available	

9.3 Hydrochloric Acid (HCl)

Odor	Pungent
Odor threshold	No data available
Melting point/freezing point	No data available
Boiling point/Boiling range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits:	No data available
Vapor density	No data available
Vapor pressure	No data available
Relative density	No data available
Solubility in/Miscibility with Water	Soluble
Partition coefficient: n-octanol/water	No data available
Auto igniting	No data available
Decomposition temperature	No data available
Viscosity	No data available

SECTION 10 STABILITY AND REACTIVITY

10.1 Sodium Azide

Reactivity	Contact with acids liberates very toxic gas.
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	No data available
Conditions to avoid	An explosion occurred when a mixture of sodium azide, methylene chloride, dimethyl sulfoxide, and sulfuric acid were being concentrated on a rotary evaporator. Strong heating (decomposition). Exposure to moisture.
Incompatible materials	No data available
Hazardous decomposition products	Hazardous decomposition products formed under fire conditions. - Sodium oxides
Other decomposition products	- No data available

10.2 o-phenylenediamine dihydrochloride (OPD)

Reactivity	No data available
Chemical stability	Stable under recommended storage conditions
Possibility of hazardous reactions	No data available

Conditions to avoid None Known.
Incompatible materials None Known.
Hazardous decomposition products No dangerous reaction known under conditions of normal use
Other decomposition products No known hazardous decomposition products.

10.3 Hydrochloric Acid

Recativity No data available
Chemical stability Stable under recommended storage conditions
Possibility of hazardous reactions No data available
Conditions to avoid None Known.
Incompatible materials Bases, Amines, Alkali metals, Metals, permanganates, for example potassium permanganate, Fluorine, metal acetylides, hexalithium disilicide
Hazardous decomposition products Hazardous decomposition products formed under fire conditions.
- Hydrogen chloride gas
Other decomposition products - No data available

SECTION 11 TOXICOLOGICAL INFORMATION

11.1 Sodium Azide

Acute toxicity
LD50 Oral - Rat - 27 mg/kg Remarks: (RTECS)
LC50 Inhalation - Rat - male and female - 4 h - 0.054 - 0.52 mg/l (US-EPA)
LD50 Dermal - Rabbit - 20 mg/kg Remarks: (RTECS) No data available
Skin corrosion/irritation Skin - In vitro study Result: No skin irritation (OECD Test Guideline 439)
Serious eye damage/eye irritation Eyes - Bovine cornea Result: No eye irritation - 4 h (OECD Test Guideline 437)
Respiratory or skin sensitization Local lymph node assay (LLNA) – Mouse Result: negative (OECD Test Guideline 429)
Germ cell mutagenicity No data available
Mutagenicity (mammal cell test): chromosome aberration. Chinese hamster ovary cells Result: negative
unscheduled DNA synthesis assay Chinese hamster lung cells Result: negative
sister chromatid exchange assay Chinese hamster ovary cells Result: negative
Carcinogenicity IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
ACGIH: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
Reproductive toxicity No data available
Specific target organ toxicity - single exposure No data available
Specific target organ toxicity - repeated exposure Oral - May cause damage to organs through prolonged or repeated exposure. - Brain Aspiration hazard No data available
Additional Information RTECS: VY8050000
To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

11.1 o-phenylenediamine dihydrochloride (OPD)

No information available

11.2 Hydrochloric Acid

Acute toxicity
LD50 Oral - Rat - 1530 mg/kg
LD50 Dermal - Rabbit - 2730 mg/kg
LC50 Inhalation- Rat - 850 mg/m³ 1 h
Skin corrosion/irritation: Can cause severe burns
Serious eye damage/irritation: Can cause severe burns
Respiratory or skin sensitization: No data available
Germ cell mutagenicity: No data available
Carcinogenicity: No data available

Reproductive toxicity: No data available
Aspiration hazard: Can cause severe burns
Ingestion: May be harmful if swallowed. Causes burns.
Skin contact: May be harmful if absorbed through skin. Causes burns.
Eye contact: Causes eye burns.

SECTION 12 ECOLOGICAL INFORMATION

12.1 Sodium Azide

Ecotoxicity

Toxicity to fish flow-through test LC50 Oncorhynchus mykiss (rainbow trout) - 2.84 mg/l - 96 h (OECD Test Guideline 203)

Toxicity to algae static test ErC50 - Pseudokirchneriella subcapitata - 0.35 mg/l - 96 h (OECD Test Guideline 201)

Persistence and degradability The methods for determining the biological degradability are not applicable to inorganic substances.

Bioaccumulative potential No data available

Mobility in soil No data available

Results of PBT and vPvB assessment PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

Other adverse effects An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

Very toxic to aquatic life with long lasting effects. No data available

12.2 o-phenylenediamine dihydrochloride (OPD)

Ecotoxicity No data available

Persistence and degradability No data available

Bioaccumulative potential No data available

Mobility in soil No data available

Results of PBT and vPvB assessment This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other adverse effects No data available

12.3 Hydrochloric Acid

Ecotoxicity

Toxicity to fish LC50 - Gambusia affinis (Mosquito fish) - 282 mg/l - 96 h (Hydrochloric Acid)
Remarks: (IUCLID)

Persistence and degradability The methods for determining the biological degradability are not applicable to inorganic substances.

Bioaccumulative potential No data available

Mobility in soil No data available

Results of PBT and vPvB assessment PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

Other adverse effects May be harmful to aquatic organisms due to the shift of the pH. Do not empty into drains. Harmful effect due to pH shift. Discharge into the environment must be avoided.

Very toxic to aquatic life with long lasting effects. No data available

SECTION 13 DISPOSAL CONSIDERATION

13.1 Disposal methods

Dispose of waste in accordance to applicable national, regional, or local regulations. Burn in a chemical incinerator equipped with an afterburner and scrubber b highly flammable. Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material.

13.2 Contaminated packaging

Dispose in the same manner as unused product.

SECTION 14 TRANSPORT INFORMATION

RID/ADR: These substances are considered to be non-hazardous for transport.

IATA: Non-Hazardous for Air Transport.

IMO: Non-Hazardous for Sea Transport.

SECTION 15 REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture	
Substances of Very High Concern	None.
Restricted substances under EC 1907/2006, Annex XVII	None.
Substances listed under Annex I of Regulation (EC) No 689/2008	None.
Restricted substances under Annex V of Regulation (EC) No 689/2008	None.
Substances under Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC	None.

SECTION 16 OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. We make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigation to determine the suitability of the information for their particular purposes. In no way shall we be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising from using the above information.

This material safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008 and its amendments.