1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade Name: Gama GT Reagent R1
Article n°: 2160XXX
MS: 80115310254

1.2 Relevant identified uses of the substance or mixture and uses advised against
Reagent for *in-vitro* diagnostics in human samples
For professional use only.

1.3 Manufacturer
Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.
Tel: +(55 21) 2623-1367
e-mail: kovalent@kovalent.com.br

1.4 Emergency telephone number
Tel: +(55 21) 2623-1367 – Costumer Service from 8am to 5pm
0800 015 1414

In case of emergency – 24 hours service
0800-722-6001 – RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica)

2 Hazards Identification

2.1 Classification of the substance or mixture
Classification according to ABNT NBR 14725
This mixture is classified as not hazardous.

2.2 Label elements

Labelling (CLP)

Hazard statements: Not applicable

Precautionary statements: Not applicable

Special labelling

H210 - Safety data sheet available on request.

2.3 Other hazards
No risks worthy of mention.

3 Composition/information on ingredients

3.1 Substances
Not applicable

3.2 Mixtures
Chemical characterization: Aqueous solution

Ingredient	Designation	Content	Classification
EC No. 209-127-8 CAS 556-50-3	N-Glycylglycine	< 2%	Eye Irrit. 2; H319.

Full text of H- and EUH-statements: see section 16.

Additional information: Contains Sodium azide (0.95 g/L) as preservative.

4 First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. If you feel unwell, seek medical advice.

Following skin contact: Change contaminated clothing. Remove residues with water. In case of skin irritation, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Do not induce vomiting without medical advice.
Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

After eye contact: May cause irritations.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

5.2 Special hazards arising from the substance or mixture

In case of fire may be liberated: Nitrogen oxides (NOx), carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus.

Additional information: Do not allow fire water to penetrate surface or groundwater.

6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Do not breathe vapours.
In enclosed areas: Provide fresh air. Wear appropriate protective equipment.

6.2 Environmental precautions

Do not allow to penetrate soil, waterbodies, or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder.
Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

7 Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Do not breathe vapours. Avoid contact with skin and eyes. Keep all containers, equipment and working place clean. Wear appropriate protective equipment. Wash hands before breaks and after work. Do not eat, drink, or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Protect from light.

Hints on joint storage: Do not store together with: Acids, alkalis.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)

No information available.

8 Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: If vapours form, use respiratory protection.
Use filter type A (= against vapours of organic substances) according to EN 14387.

Hand protection: Protective gloves according to EN 374.

Glove material: Nitrile rubber. Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:
Do not breathe vapours. Avoid contact with skin and eyes. Change contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, or smoke.

9 Physical and chemical properties

Physical state at 20 °C and 101.3 kPa:	liquid
Colour:	colourless, clear
Odour:	no characteristic odour
Odour threshold:	No data available
pH:	at 25 °C: 8.3
Melting point/freezing point:	No data available
Initial boiling point and boiling range:	No data available
Flash point/flash point range:	not combustible
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapour pressure:	No data available

Vapour density:	No data available
Density:	at 20°C: 1.011 g/mL
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Particle characteristics:	Not applicable
Explosive properties:	No data available
Oxidizing characteristics:	No data available
Additional information:	No data available

10 Stability and reactivity

10.1 Reactivity
Refer to 10.3.

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
No hazardous reactions known.

10.4 Conditions to avoid
Protect against heat / sun rays.

10.5 Incompatible materials
Acids and alkalis.

10.6 Hazardous decomposition products
No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition: No data available

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral):	Lack of data.
Acute toxicity (dermal):	Lack of data.
Acute toxicity (inhalative):	Lack of data.
Skin corrosion/irritation:	Lack of data.
Serious eye damage/irritation:	Lack of data.
Sensitisation to the respiratory tract:	Lack of data.
Skin sensitisation:	Lack of data.
Germ cell mutagenicity/Genotoxicity:	Lack of data.
Carcinogenicity:	Lack of data.
Reproductive toxicity:	Lack of data.
Effects on or via lactation:	Lack of data.
Specific target organ toxicity (single exposure):	Lack of data.
Specific target organ toxicity (repeated exposure):	Lack of data.
Aspiration hazard:	Lack of data.

Endocrine disrupting properties:	No data available
Other information:	Contains Sodium azide (0.95 g/L): After resorption of toxic quantities: Headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.
Symptoms:	After eye contact: May cause irritations.

12 Ecological information

12.1 Toxicity
Aquatic toxicity: Water hazard class: 1 - Slightly hazardous to water

12.2 Persistence and degradability
Further details: No data available

12.3 Bioaccumulative potential
Partition coefficient: n-octanol/water: No data available

12.4 Mobility in soil
No data available

12.5 Other adverse effects
General information: Do not allow to enter groundwater, surface water, or drains.

13 Disposal considerations

13.1 Waste treatment methods

Product:	Special waste. Dispose of waste according to applicable legislation.
Package:	Dispose of waste according to applicable legislation. Non-contaminated packages may be recycled.
Additional information:	Do not reuse empty containers.

14 Transport information

14.1 UN number
ADR/RID, IMDG, IATA-DGR: Not applicable

14.2 UN proper shipping name
ADR/RID, IMDG, IATA-DGR: Not restricted

14.3 Transport hazard class(es)

ADR/RID:	Not applicable
IMDG:	Not applicable
IATA-DGR:	Not applicable
ANTT:	Not applicable

14.4 Risk Number
–

14.5 Packing group
ADR/RID, IMDG, IATA-DGR: Not applicable

14.6 Environmental hazards

Dangerous for the environment:	Substance/mixture is not environmentally hazardous according to regulations.
Marine pollutant:	No

14.7 Special precautions for user
No dangerous good in sense of these transport regulations.

15 Regulatory information

• Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.

• For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.

• This safety data sheet was prepared in accordance with ABNT/NBR 14725:23.

16 Other information

The above information is considered correct but is not intended to be complete and should be used only as a guide. Kovalent is not responsible for any damage resulting from handling or use.

In article XXX: The three X are for the volume

Wording of the H-phrases under paragraph 2 and 3:
H319 = Causes serious eye irritation.
H210 = Safety data sheet available on request.

Abbreviations and acronyms:
ABNT: Associação Brasileira de Normas Técnicas / National Standards Forum
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
ANTT: Agência Nacional de Transporte Terrestre / National Agency of Transportation by Road
AS/NZS: Australian Standards/New Zealand Standards
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
EC: European Community
EN: European Standard
EQ: Excepted quantities
EU: European Union
Eye Irrit.: Eye irritation
GHS: Globally Harmonized System
IATA: International Air Transport Association
IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG Code: International Maritime Dangerous Goods Code
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
MS: Anvisa's Registry Code
NBR: Brazilian technical ordinance
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
pH: Potential of Hydrogen
PNEC: Predicted no-effect concentration
RDC: Resolution from the Directory Board
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
TRGS: Technical Rules for Hazardous Substances
UN: United Nations

1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade Name: Gama GT Reagent R2
Article n°: 2160XXX
MS: 80115310254

1.2 Relevant identified uses of the substance or mixture and uses advised against
Reagent for *in-vitro* diagnostics in human samples
For professional use only.

1.3 Manufacturer
Kovalent do Brasil Ltda.
Rua Cristóvão Sardinha, 110 – Jd. Bom Retiro – São Gonçalo – RJ – Brasil.
Tel: +(55 21) 2623-1367
e-mail: kovalent@kovalent.com.br

1.4 Emergency telephone number
Tel: +(55 21) 2623-1367 – Costumer Service from 8am to 5pm
0800 015 1414

In case of emergency – 24 hours service
0800-722-6001 – RENACIAT (Rede Nacional de Centros de Informação e Assistência Toxicológica)

2 Hazards Identification

2.1 Classification of the substance or mixture
Classification according to ABNT NBR 14725
This mixture is classified as not hazardous.

2.2 Label elements

Labelling (CLP)

Hazard statements:	Not applicable
Precautionary statements:	Not applicable

2.3 Other hazards
No risks worthy of mention.

3 Composition/information on ingredients

3.1 Substances
Not applicable

3.2 Mixtures

Chemical characterization:	Aqueous solution
Additional information:	The product does not contain dangerous substances above limits that need to be mentioned in this section according to applicable legislation. Contains Sodium azide (0.95 g/L) as preservative.

4 First aid measures

4.1 Description of first aid measures

In case of inhalation:	Provide fresh air. If you feel unwell, seek medical advice.
Following skin contact:	Change contaminated clothing. Remove residues with water. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Do not induce vomiting without medical advice. Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed
After eye contact: mild irritant

4.3 Indication of any immediate medical attention and special treatment needed
Treat symptomatically.

5 Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media: Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

5.2 Special hazards arising from the substance or mixture
Fires in the immediate vicinity may cause the development of dangerous vapours.

5.3 Advice for firefighters
Special protective equipment for firefighters: Wear self-contained breathing apparatus.

Additional information: Do not allow fire water to penetrate surface or groundwater.

6 Accidental release measures

6.1 Personal precautions, protective equipment, and emergency procedures
Avoid contact with skin and eyes. Do not breathe vapours.
In enclosed areas: Provide fresh air. Wear appropriate protective equipment.

6.2 Environmental precautions
Do not allow to penetrate soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up
Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder.
Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

6.4 Reference to other sections
Refer additionally to section 8 and 13.

7 Handling and storage

7.1 Precautions for safe handling
Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Do not breathe vapours. Avoid contact with skin and eyes. Keep all containers, equipment and working place clean. Wear appropriate protective equipment. Wash hands before breaks and after work. Do not eat, drink, or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storerooms and containers:
Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Protect from light.

Hints on joint storage: Do not store together with acids and alkalis.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)
No information available.

8 Exposure controls/personal protection

8.1 Control parameters
Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls
Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment
Occupational exposure controls
Respiratory protection: If vapours form, use respiratory protection.
Use filter type A (= against vapours of organic substances) according to EN 14387.

Hand protection: Protective gloves according to EN 374.

Glove material: Nitrile rubber. Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:
Do not breathe vapours. Avoid contact with skin and eyes. Change contaminated clothing. Wash hands before breaks and after work. Do not eat, drink, or smoke when using this product.

Environmental exposure controls
Refer to "6.2 Environmental precautions".

9 Physical and chemical properties

Physical state at 20 °C and 101.3 kPa:	liquid
Colour:	yellowish, clear
Odour:	no characteristic odour
Odour threshold:	No data available
pH:	at 25 °C: 6.0
Melting point/freezing point:	approx. 0°C
Initial boiling point and boiling range:	approx. 100 °C
Flash point/flash point range:	not combustible
Evaporation rate:	No data available
Flammability:	No data available
Explosion limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Density:	at 20°C: 1.003 g/mL
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available

Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity:	No data available
Explosive properties:	No data available
Particle characteristics:	Not applicable
Oxidizing characteristics:	No data available
Additional information:	No data available

10 Stability and reactivity

10.1 Reactivity
Refer to 10.3.

10.2 Chemical stability
Product is stable under normal storage conditions.

10.3 Possibility of hazardous reactions
No hazardous reactions known.

10.4 Conditions to avoid
Protect against heat / sun rays.

10.5 Incompatible materials
Acids and alkalis.

10.6 Hazardous decomposition products
No hazardous decomposition products when regulations for storage and handling are observed.

Thermal decomposition: No data available

11 Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral):	Lack of data.
Acute toxicity (dermal):	Lack of data.
Acute toxicity (inhalative):	Lack of data.
Skin corrosion/irritation:	Lack of data.
Serious eye damage/irritation:	Lack of data.
Sensitisation to the respiratory tract:	Lack of data.
Skin sensitisation:	Lack of data.
Germ cell mutagenicity/Genotoxicity:	Lack of data.
Carcinogenicity:	Lack of data.
Reproductive toxicity:	Lack of data.
Effects on or via lactation:	Lack of data.
Specific target organ toxicity (single exposure):	Lack of data.
Specific target organ toxicity (repeated exposure):	Lack of data.
Aspiration hazard:	Lack of data.
Endocrine disrupting properties:	No data available
Other information:	Contains Sodium azide (0.95 g/L): After resorption of toxic quantities: Headache, dizziness, nausea, cough, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.
Symptoms:	After eye contact: mild irritant

12 Ecological information

12.1 Toxicity
Aquatic toxicity: Water hazard class: 1 - Slightly hazardous to water

12.2 Persistence and degradability
Further details: No data available

12.3 Bioaccumulative potential
Partition coefficient: n-octanol/water: No data available

12.4 Mobility in soil
No data available

12.5 Other adverse effects
General information: Do not allow to enter groundwater, surface water, or drains.

13 Disposal considerations

13.1 Waste treatment methods
Product: Special waste. Dispose of waste according to applicable legislation.

Package: Dispose of waste according to applicable legislation.
Non-contaminated packages may be recycled.

Additional information: Do not reuse empty containers.

14 Transport information

14.1 UN number
ADR/RID, IMDG, IATA, ANTT: Not applicable

14.2 UN proper shipping name
ADR/RID, IMDG, IATA, ANTT: Not restricted

14.3 Transport hazard class(es)
ADR/RID: Not applicable
IMDG: Not applicable
IATA: Not applicable
ANTT: Not applicable

14.4 Risk Number
–

14.5 Packing group
ADR/RID, IMDG, IATA, ANTT: Not applicable

14.6 Environmental hazards
Dangerous for the environment: Substance/mixture is not environmentally hazardous according to regulations
Marine pollutant: No

14.7 Special precautions for user
No dangerous good in sense of these transport regulations.

15 Regulatory information

- Product produced in accordance with the requirements established by RDC 665 of 30/03/2022 and with labeling information in accordance with RDC 206 of 17/11/2006.

- For more details on product disposal refer to RDC 222 of 28/03/2018 and NBR 10004.

- This safety data sheet was prepared in accordance with ABNT/NBR 14725:23.

16 Other information

The above information is considered correct but is not intended to be complete and should be used only as a guide. Kovalent is not responsible for any damage resulting from handling or use.

In article XXX: The three X are for the volume

Abbreviations and acronyms:
ABNT: Associação Brasileira de Normas Técnicas / National Standards Forum
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
ANTT: Agência Nacional de Transporte Terrestre / National Agency of Transportation by Road
AS/NZS: Australian Standards/New Zealand Standards
CAS: Chemical Abstracts Service
CFR: Code of Federal Regulations
CLP: Classification, Labelling and Packaging
DMEL: Derived minimal effect level
DNEL: Derived no-effect level
EC: European Community
EN: European Standard
EQ: Excepted quantities
EU: European Union
GHS: Globally Harmonized System
IATA: International Air Transport Association
IATA-DGR: International Air Transport Association – Dangerous Goods Regulations
IBC Code: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IMDG Code: International Maritime Dangerous Goods Code
MARPOL: Maritime Pollution: The International Convention for the Prevention of Pollution from Ships
MS: Anvisa's Registry Code
NBR: Brazilian technical ordinance
OSHA: Occupational Safety and Health Administration
PBT: Persistent, bioaccumulative and toxic
pH: Potential of Hydrogen
PNEC: Predicted no-effect concentration
RDC: Resolution from the Directory Board
RID: Regulations Concerning the International Carriage of Dangerous Goods by Rail
TRGS: Technical Rules for Hazardous Substances
UN: United Nations