

KIT COMPONENTSProduct name: **CAP SURVEY FGAL CONTROLS, 30 Tests**Product code: **62804**

Article number	Description	Quantity	Symbols
2.157	FGAL NEG, 1.7 ml	10	GHS07
2.158	FGAL POS, 1.7 ml	20	GHS07

Safety Data Sheet
according to WHS Regulations

Printing date 27.10.2020

Version number 4

Revision: 14.08.2015

Hazardous according to criteria of Safe Work Australia.

1 Identification· **Product identifier**

- **Trade name:** FGAL NEG, 1.7 ml
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**· **Manufacturer/Supplier:**

Bio-Rad
3, Boulevard Raymond Poincaré
F-92430 Marnes-la-Coquette
Tel.: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
e-mail: fds-msds.fr@bio-rad.com

· **Further information obtainable from:** Customer Support.· **Emergency telephone number:** See item 16**2 Hazard(s) Identification**· **Classification of the substance or mixture**

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms** GHS07· **Signal word** Warning· **Hazard-determining components of labelling:**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves.

IF ON SKIN: Wash with plenty of water and soap.

If skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see on this label).

Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Other hazards**
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:**
Contains components of human origin.
Preparation containing hazardous components.

- **Dangerous components:**

55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	0.01-0.1%
	<div style="display: flex; align-items: center;"> <div style="margin-right: 5px;">    </div> <div> Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330 Skin Corr. 1, H314; Eye Dam. 1, H318 Skin Sens. 1A, H317 </div> </div>	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **Description of first aid measures**
 - **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
 - **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
 - **After eye contact:** Rinse opened eye for several minutes under running water.
 - **After swallowing:** Call for a doctor immediately.
 - **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, powder or water spray. Fight larger fires with water spray.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.

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6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**

- Wear protective clothing.

- Wear disposable gloves.

- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

- **Methods and material for containment and cleaning up:**

- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

- **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** Follow good laboratory practices.

- **Information about fire - and explosion protection:** No special measures required.

- **Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** No special requirements.

- **Information about storage in one common storage facility:** Not required.

- **Further information about storage conditions:** None.

- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

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

- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

- The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- **Additional information:** The lists valid during the making were used as basis.

- **Personal protective equipment:**

- **General protective and hygienic measures:**

- Immediately remove all soiled and contaminated clothing

- Wash hands before breaks and at the end of work.

- **Respiratory protection:** Suitable respiratory protective device recommended.

- **Protection of hands:**

- Protective gloves

- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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· **Eye protection:** Goggles recommended during refilling

9 Physical and Chemical Properties

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

· **General Information**

· **Appearance:**

- **Form:** Fluid
- **Colour:** Light yellow
- **Odour:** Characteristic

· **Change in condition**

- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Density:** Not determined.

· **Solubility in / Miscibility with**

- **water:** Fully miscible.

· **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**

· **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:**

- **Skin corrosion/irritation** No irritant effect.

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- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** Sensitisation possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

12 Ecological Information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **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** Must be specially treated adhering to official regulations.
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|--------------|
| <ul style="list-style-type: none"> · UN-Number · ADG, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · UN proper shipping name · ADG · ADN, IMDG, IATA | Void
Void |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class | Void |

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Trade name: FGAL NEG, 1.7 ml

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· Packing group	
· ADG, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

None of the ingredients is listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H301 Toxic if swallowed.

H310 Fatal in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H330 Fatal if inhaled.

· **Department issuing SDS:**

MSDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· **Contact:**

Customer Support

Phone : +33 (0)1 47 95 62 77

AUSTRALIA

Bio-Rad Laboratories Pty. Ltd.

Level 5, 446 Vistoria Road

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Trade name: FGAL NEG, 1.7 ml

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· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity - oral – Category 3

Acute Tox. 2: Acute toxicity - dermal – Category 2

Skin Corr. 1: Skin corrosion/irritation – Category 1

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation – Category 1A

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according to WHS Regulations

Printing date 27.10.2020

Version number 4

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Hazardous according to criteria of Safe Work Australia.

1 Identification· **Product identifier**

- **Trade name:** FGAL POS, 1.7 ml
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**· **Manufacturer/Supplier:**

Bio-Rad
3, Boulevard Raymond Poincaré
F-92430 Marnes-la-Coquette
Tel.: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
e-mail: fds-msds.fr@bio-rad.com

· **Further information obtainable from:** Customer Support.· **Emergency telephone number:** See item 16**2 Hazard(s) Identification**· **Classification of the substance or mixture**

Skin Sens. 1 H317 May cause an allergic skin reaction.

· **Label elements**· **GHS label elements**

The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms** GHS07· **Signal word** Warning· **Hazard-determining components of labelling:**

reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

· **Hazard statements**

May cause an allergic skin reaction.

· **Precautionary statements**

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves.

IF ON SKIN: Wash with plenty of water and soap.

If skin irritation or rash occurs: Get medical advice/attention.

Specific treatment (see on this label).

Dispose of contents/container in accordance with local/regional/national/international regulations.

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Trade name: FGAL POS, 1.7 ml




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- **Other hazards**
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:**
 - Contains components of human origin.
 - Preparation containing hazardous components.

- **Dangerous components:**

55965-84-9	reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)	0.01-0.1%
	<div style="display: flex; align-items: center;"> <div style="margin-right: 5px;">    </div> <div> Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330 Skin Corr. 1, H314; Eye Dam. 1, H318 Skin Sens. 1A, H317 </div> </div>	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- **Description of first aid measures**
 - **After inhalation:**
 - Supply fresh air and to be sure call for a doctor.
 - In case of unconsciousness place patient stably in side position for transportation.
 - **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
 - **After eye contact:** Rinse opened eye for several minutes under running water.
 - **After swallowing:** Call for a doctor immediately.
 - **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, powder or water spray. Fight larger fires with water spray.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.

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6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**

- Wear protective clothing.

- Wear disposable gloves.

- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

- **Methods and material for containment and cleaning up:**

- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

- **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** Follow good laboratory practices.

- **Information about fire - and explosion protection:** No special measures required.

- **Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:** No special requirements.

- **Information about storage in one common storage facility:** Not required.

- **Further information about storage conditions:** None.

- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

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

- **Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

- The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

- **Additional information:** The lists valid during the making were used as basis.

- **Personal protective equipment:**

- **General protective and hygienic measures:**

- Immediately remove all soiled and contaminated clothing

- Wash hands before breaks and at the end of work.

- **Respiratory protection:** Suitable respiratory protective device recommended.

- **Protection of hands:**

- Protective gloves

- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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Trade name: FGAL POS, 1.7 ml

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· **Eye protection:** Goggles recommended during refilling

9 Physical and Chemical Properties

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

· **General Information**

· **Appearance:**

- **Form:** Fluid
- **Colour:** Light yellow
- **Odour:** Characteristic

· **Change in condition**

- **Melting point/freezing point:** Undetermined.
- **Initial boiling point and boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Density:** Not determined.

· **Solubility in / Miscibility with**

- **water:** Fully miscible.

· **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**

· **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:**

- **Skin corrosion/irritation** No irritant effect.

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Trade name: FGAL POS, 1.7 ml

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- **Serious eye damage/irritation** No irritating effect.
- **Respiratory or skin sensitisation** Sensitisation possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

12 Ecological Information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
- **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** Must be specially treated adhering to official regulations.
- **Uncleaned packaging:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|--------------|
| <ul style="list-style-type: none"> · UN-Number · ADG, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · UN proper shipping name · ADG · ADN, IMDG, IATA | Void
Void |
| <ul style="list-style-type: none"> · Transport hazard class(es) · ADG, ADN, IMDG, IATA · Class | Void |

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Trade name: FGAL POS, 1.7 ml

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· Packing group	
· ADG, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Industrial Chemicals**

None of the ingredients is listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H301 Toxic if swallowed.
H310 Fatal in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H330 Fatal if inhaled.

· **Department issuing SDS:**

MSDS / FDS Administr.
Bio-Rad
Marnes-la-Coquette, France

· **Contact:**

Customer Support
Phone : +33 (0)1 47 95 62 77

AUSTRALIA
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Level 5, 446 Vistoria Road

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Gladesville NSW 2111

Phone : +61-2-9914-2800

Fax : +61-2-9914-2888

· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity - oral – Category 3

Acute Tox. 2: Acute toxicity - dermal – Category 2

Skin Corr. 1: Skin corrosion/irritation – Category 1

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1A: Skin sensitisation – Category 1A

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