



10/27/2020

KIT COMPONENTS

Product 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
29 CFR Part 1910.1200

Printing date 10/27/2020

Reviewed on 10/27/2020

1 Identification· **Product identifier**· **Trade name:** FGAL NEG, 1.7 ml· **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

· **Information department:** Customer support.· **Emergency telephone number:**

See item 16

This SDS is listed with CHEMTREC 1800-424-9300 / 1-510-741-1000.

Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

2 Hazard(s) identification· **Classification of the substance or mixture**

GHS07

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

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

The product is classified and labeled according to the Globally Harmonized System (GHS).

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

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**

Wear protective gloves/protective clothing/eye protection/face protection.

If on skin: Wash with plenty of water.

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

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

· **Classification system:**· **NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

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Trade name: FGAL NEG, 1.7 ml





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- **HMIS-ratings (scale 0 - 4)**
 - Health = 0
 - Fire = 0
 - Reactivity = 0
- **Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
 - **Description:**
 - Contains components of human origin.
 - Mixture 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%
	Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330	
	Skin Corr. 1C, H314; Eye Dam. 1, H318	
	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
	Skin Sens. 1A, H317	

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:** Immediately call a doctor.
 - **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.
- **Special hazards arising from the substance or mixture** No further relevant information available.

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- **Advice for firefighters**
- **Protective equipment:** No special measures required.

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 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:** 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/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
 - **Components 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 that were valid during the creation were used as basis.
- **Exposure controls**
 - **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.
 - **Breathing equipment:** Suitable respiratory protective device recommended.

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Trade name: FGAL NEG, 1.7 ml

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- **Protection of hands:**
Protective gloves
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- **Eye protection:** Goggles recommended during refilling.

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

- **Form:** Fluid
- **Color:** Light yellow
- **Odor:** Characteristic

· Change in condition

- **Melting point/Melting range:** Undetermined.
- **Boiling point/Boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** 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.

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

- **Carcinogenic categories**

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

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

None of the ingredients is 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:**

Water hazard class 2 (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.

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- **Uncleaned packagings:**

- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· 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":	Void

15 Regulatory information

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

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

None of the ingredient is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

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.

· **Department issuing SDS:**

SDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· **Contact:**

Customer Support

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

USA

Bio-Rad Laboratories

6565 185th Avenue NE

Redmond, WA 98052-5039

Phone Number: 1-800-2BIORAD (1-800-224-6723) or (425) 881-8300 (daytime PST)

· **Date of preparation / last revision** 10/27/2020 / 3

· **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

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

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PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 2: Acute toxicity – Category 2
Skin Corr. 1C: Skin corrosion/irritation – Category 1C
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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Reviewed on 10/27/2020

1 Identification· **Product identifier**· **Trade name:** FGAL POS, 1.7 ml· **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

· **Information department:** Customer support.· **Emergency telephone number:**

See item 16

This SDS is listed with CHEMTREC 1800-424-9300 / 1-510-741-1000.

Use only in the event of a CHEMICAL EMERGENCY involving a SPILL, LEAK, FIRE, EXPLOSION or ACCIDENT with this product.

2 Hazard(s) identification· **Classification of the substance or mixture**

GHS07

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

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

The product is classified and labeled according to the Globally Harmonized System (GHS).

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

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**

Wear protective gloves/protective clothing/eye protection/face protection.

If on skin: Wash with plenty of water.

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

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

· **Classification system:**· **NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

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Trade name: FGAL POS, 1.7 ml





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- **HMIS-ratings (scale 0 - 4)**
 - Health = 0
 - Fire = 0
 - Reactivity = 0
- **Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
 - **Description:**
 - Contains components of human origin.
 - Mixture 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%
	Acute Tox. 3, H301; Acute Tox. 2, H310; Acute Tox. 2, H330	
	Skin Corr. 1C, H314; Eye Dam. 1, H318	
	Aquatic Acute 1, H400; Aquatic Chronic 1, H410	
	Skin Sens. 1A, H317	

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:** Immediately call a doctor.
 - **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.
- **Special hazards arising from the substance or mixture** No further relevant information available.

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Trade name: FGAL POS, 1.7 ml

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- **Advice for firefighters**
- **Protective equipment:** No special measures required.

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 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:** 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/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
 - **Components 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 that were valid during the creation were used as basis.
- **Exposure controls**
 - **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.
 - **Breathing equipment:** Suitable respiratory protective device recommended.

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Trade name: FGAL POS, 1.7 ml

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- **Protection of hands:**
Protective gloves
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- **Eye protection:** Goggles recommended during refilling.

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

- **Form:** Fluid
- **Color:** Light yellow
- **Odor:** Characteristic

· Change in condition

- **Melting point/Melting range:** Undetermined.
- **Boiling point/Boiling range:** Undetermined.

- **Flash point:** Not applicable.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** 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.

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Trade name: FGAL POS, 1.7 ml

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **Primary irritant effect:**

- **on the skin:** No irritant effect.

- **on the eye:** No irritating effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

- **Carcinogenic categories**

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

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

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

None of the ingredients is 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:**

Water hazard class 2 (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.

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- **Uncleaned packagings:**

- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· 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":	Void

15 Regulatory information

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

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

None of the ingredient is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

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.

· **Department issuing SDS:**

SDS / FDS Administr.

Bio-Rad

Marnes-la-Coquette, France

· **Contact:**

Customer Support

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

USA

Bio-Rad Laboratories

6565 185th Avenue NE

Redmond, WA 98052-5039

Phone Number: 1-800-2BIORAD (1-800-224-6723) or (425) 881-8300 (daytime PST)

· **Date of preparation / last revision** 10/27/2020 / 3

· **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

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

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PEL: Permissible Exposure Limit
REL: Recommended Exposure Limit
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 2: Acute toxicity – Category 2
Skin Corr. 1C: Skin corrosion/irritation – Category 1C
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Skin Sens. 1A: Skin sensitisation – Category 1A
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

USA