



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
according to HPR, Schedule 1

Printing date 10/27/2020

Reviewed on 08/14/2015

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
92430 Marnes-la-Coquette
Phone: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
e-mail: fds-msds.fr@bio-rad.com

Bio-Rad laboratories (Canada) Ltd.
2403 Guénette Montreal,
Montréal (Québec) H4R 2E9
Phone: (800) 361-1808
Fax: (514) 334-0872

· **Information department:** Customer support.· **Emergency telephone number:** See item 16**2 Hazard identification**· **Classification of the substance or mixture**

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

Aquatic Acute 3 H402 Harmful to aquatic life.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **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.

Harmful to aquatic life.

Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

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

Contaminated work clothing should not be allowed out of the workplace.

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Trade name: FGAL NEG, 1.7 ml

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Avoid release to the environment.

Wear protective gloves.

If on skin: Wash with plenty of soap and water.

Take off contaminated clothing and wash it before reuse.

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.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

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)	≤0.1% w/w
	<div> <div></div> <div>Acute Toxicity (Oral) - Category 3, H301; Acute Toxicity (Dermal) - Category 2, H310; Acute Toxicity (Inhalation) - Category 2, H330</div> </div>	
	<div> <div></div> <div>Skin Corrosion - Category 1C, H314; Serious Eye Damage - Category 1, H318</div> </div>	
	<div> <div></div> <div>Aquatic Acute 1, H400; Aquatic Chronic 1, H410</div> </div>	
	<div> <div></div> <div>Skin Sensitizer - Category 1A, H317</div> </div>	

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.

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Trade name: FGAL NEG, 1.7 ml

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- **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.
- **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.

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according to HPR, Schedule 1

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Reviewed on 08/14/2015

Trade name: FGAL NEG, 1.7 ml

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- **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.
- **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.
 - **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.

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Trade name: FGAL NEG, 1.7 ml

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- **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:**
 - **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.

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.

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Trade name: FGAL NEG, 1.7 ml

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· **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation:** Must be specially treated adhering to official regulations.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT/TDG, ADN, IMDG, IATA | Void |
| · ADR | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT/TDG, 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.

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Trade name: FGAL NEG, 1.7 ml

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· **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

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:**

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

· **Contact:**

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

CANADA

Bio-Rad laboratories (Canada) Ltd.,
2403 Guénette Montreal,
Montreal (Québec) H4R 2E9

Phone : (800) 361-1808

Fax : (514) 334-0872

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

Safety Data Sheet
according to HPR, Schedule 1

Printing date 10/27/2020

Reviewed on 08/14/2015

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
92430 Marnes-la-Coquette
Phone: +33 (0)1 47 95 60 00
Fax: +33 (0)1 47 41 91 33
e-mail: fds-msds.fr@bio-rad.com

Bio-Rad laboratories (Canada) Ltd.
2403 Guénette Montreal,
Montréal (Québec) H4R 2E9
Phone: (800) 361-1808
Fax: (514) 334-0872

· **Information department:** Customer support.· **Emergency telephone number:** See item 16**2 Hazard identification**· **Classification of the substance or mixture**

Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

Aquatic Acute 3 H402 Harmful to aquatic life.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

· **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.

Harmful to aquatic life.

Harmful to aquatic life with long lasting effects.

· **Precautionary statements**

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

Contaminated work clothing should not be allowed out of the workplace.

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Reviewed on 08/14/2015

Trade name: FGAL POS, 1.7 ml

(Contd. of page 1)

Avoid release to the environment.

Wear protective gloves.

If on skin: Wash with plenty of soap and water.

Take off contaminated clothing and wash it before reuse.

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.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**

Health = 0

Fire = 0

Reactivity = 0

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)	≤0.1% w/w
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	<div> <div></div> <div>Skin Corrosion - Category 1C, H314; Serious Eye Damage - Category 1, H318</div> </div>	
	<div> <div></div> <div>Aquatic Acute 1, H400; Aquatic Chronic 1, H410</div> </div>	
	<div> <div></div> <div>Skin Sensitizer - Category 1A, H317</div> </div>	

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.

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Trade name: FGAL POS, 1.7 ml

(Contd. of page 2)

- **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.
- **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.

(Contd. on page 4)

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Reviewed on 08/14/2015

Trade name: FGAL POS, 1.7 ml

(Contd. of page 3)

- **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.
- **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.
 - **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.

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Safety Data Sheet

according to HPR, Schedule 1

Printing date 10/27/2020

Reviewed on 08/14/2015

Trade name: FGAL POS, 1.7 ml

(Contd. of page 4)

- **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:**
 - **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.

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.

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Trade name: FGAL POS, 1.7 ml

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· **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation:** Must be specially treated adhering to official regulations.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT/TDG, ADN, IMDG, IATA | Void |
| · ADR | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT/TDG, 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.

(Contd. on page 7)

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Safety Data Sheet

according to HPR, Schedule 1

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Reviewed on 08/14/2015

Trade name: FGAL POS, 1.7 ml

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· **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

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:**

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

· **Contact:**

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

CANADA

Bio-Rad laboratories (Canada) Ltd.,
2403 Guénette Montreal,
Montreal (Québec) H4R 2E9

Phone : (800) 361-1808

Fax : (514) 334-0872

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods
DOT: US Department of Transportation
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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative