SAFETY DATA SHEET

cobas Integra FP-Calibrator Valproinacid

Version	Revision Date:	Date of last issue: 09-18-2019
1.7	02-06-2021	Date of first issue: 11-12-2015

SECTION 1. IDENTIFICATION

Product name : cobas Integra FP-Calibrator Valproinacid

Product code : 20730890322

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-

Address : 9115 Hague Road
Indianapolis, IN 46250
USA

Telephone : 1-800-428-5074

Emergency telephone
In case of emergencies : CHEMTREC 1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section GHS Label elements contains the resulting labelling for the kit

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Calibrator A

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Components

No hazardous ingredients

Calibrator B

GHS Classification

Not a hazardous substance or mixture.
Chemical nature : Handle as potentially infectious.

Components

No hazardous ingredients

Calibrator C

GHS Classification

Not a hazardous substance or mixture.
Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
Methanol	67-56-1	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

Calibrator D

GHS Classification

Not a hazardous substance or mixture.
Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
Methanol	67-56-1	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

Calibrator E

GHS Classification

Not a hazardous substance or mixture.
Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
Methanol	67-56-1	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

Calibrator F

GHS Classification

Not a hazardous substance or mixture.
Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
Methanol	67-56-1	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice	:	Do not leave the victim unattended.
If inhaled	:	Move to fresh air. Consult a physician after significant exposure. If unconscious, place in recovery position and seek medical advice.
In case of skin contact	:	If on skin, rinse well with water.
In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	None known.
Notes to physician	:	The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	No information available.
Further information	:	Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Ensure adequate ventilation. Refer to protective measures listed in sections 7 and 8.
Environmental precautions	:	Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Normal measures for preventive fire protection.
Advice on safe handling	:	Avoid formation of aerosol. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national regulations.
Conditions for safe storage	:	Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
Further information on storage stability	:	No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Calibrator A

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Calibrator B

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Calibrator C

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parameters / Permissible	Basis

		exposure)	concentration	
Methanol	67-56-1	TWA	200 ppm	ACGIH
		STEL	250 ppm	ACGIH
		TWA	200 ppm 260 mg/m3	NIOSH REL
		ST	250 ppm 325 mg/m3	NIOSH REL
		TWA	200 ppm 260 mg/m3	OSHA Z-1
		TWA	200 ppm 260 mg/m3	OSHA P0
		STEL	250 ppm 325 mg/m3	OSHA P0

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam-pling time	Permissible concentra-tion	Basis
Methanol	67-56-1	Methanol	Urine	End of shift (As soon as possible after exposure ceases)	15 mg/l	ACGIH BEI

Calibrator D

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame-ters / Permissible concentration	Basis
Methanol	67-56-1	TWA	200 ppm	ACGIH
		STEL	250 ppm	ACGIH
		TWA	200 ppm 260 mg/m3	NIOSH REL
		ST	250 ppm 325 mg/m3	NIOSH REL
		TWA	200 ppm 260 mg/m3	OSHA Z-1
		TWA	200 ppm 260 mg/m3	OSHA P0
		STEL	250 ppm 325 mg/m3	OSHA P0

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam-pling time	Permissible concentra-tion	Basis
Methanol	67-56-1	Methanol	Urine	End of shift (As soon as possible after exposure	15 mg/l	ACGIH BEI

				ceases)		

Calibrator E

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Methanol	67-56-1	TWA	200 ppm	ACGIH
		STEL	250 ppm	ACGIH
		TWA	200 ppm 260 mg/m3	NIOSH REL
		ST	250 ppm 325 mg/m3	NIOSH REL
		TWA	200 ppm 260 mg/m3	OSHA Z-1
		TWA	200 ppm 260 mg/m3	OSHA P0
		STEL	250 ppm 325 mg/m3	OSHA P0

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Methanol	67-56-1	Methanol	Urine	End of shift (As soon as possible after exposure ceases)	15 mg/l	ACGIH BEI

Calibrator F

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Methanol	67-56-1	TWA	200 ppm	ACGIH
		STEL	250 ppm	ACGIH
		TWA	200 ppm 260 mg/m3	NIOSH REL
		ST	250 ppm 325 mg/m3	NIOSH REL
		TWA	200 ppm 260 mg/m3	OSHA Z-1
		TWA	200 ppm 260 mg/m3	OSHA P0
		STEL	250 ppm 325 mg/m3	OSHA P0

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis

Methanol	67-56-1	Methanol	Urine	End of shift (As soon as possible after exposure ceases)	15 mg/l	ACGIH BEI

Engineering measures : No data available

Personal protective equipment

Respiratory protection : In the case of vapor formation use a respirator with an approved filter.

Hand protection

In case of contact through splashing:

Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:

Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles

Skin and body protection : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Calibrator A

Appearance : liquid

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.02 g/cm3
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

Calibrator B

Appearance	:	liquid

Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.02 g/cm3
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available

Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

Calibrator C

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.02 g/cm3
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available

Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

Calibrator D

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available

Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.02 g/cm3
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

Calibrator E

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.

Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.02 g/cm3
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

Calibrator F

Appearance	:	liquid
Color	:	No data available
Odor	:	No data available
Odor Threshold	:	No data available
pH	:	No data available

Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Does not sustain combustion.
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.02 g/cm3
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.

Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No decomposition if stored and applied as directed.
Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Calibrator A

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Calibrator B

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Calibrator C

Acute toxicity

Not classified based on available information.

Components:

Methanol:

Acute inhalation toxicity : LC50 (Cat): 43.68 mg/l

Exposure time: 6 h
Test atmosphere: vapor
GLP: No information available.
Assessment: The component/mixture is toxic after short term inhalation.

Acute dermal toxicity : LD50 (Rabbit): 17,100 mg/kg
Method: No information available.
GLP: No information available.
Assessment: The component/mixture is toxic after single contact with skin.

Skin corrosion/irritation

Not classified based on available information.

Components:

Methanol:

Species	:	Rabbit
Exposure time	:	20 h
Result	:	No skin irritation
GLP	:	no

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Methanol:

Species	:	Rabbit
Result	:	No eye irritation
GLP	:	no

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Methanol:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitization on laboratory animals.
GLP	:	no

Germ cell mutagenicity

Not classified based on available information.

Components:

Methanol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Ames test
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Micronucleus test
Test system: Chinese hamster lung cells
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse (male and female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Dose: 1920; 3200; 4480 mg/kg
Method: OECD Test Guideline 474
Result: negative
GLP: No information available.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Methanol:

Effects on fertility : Species: Mouse, male
Application Route: Oral
Dose: 1000 mg/kg bw/day
Duration of Single Treatment: 5 d
General Toxicity Parent: LOAEC: 1,000 mg/kg body weight
GLP: No information available.

Application Route: inhalation (vapor)
Dose: 0.27, 0.8, 2.39 mg/L air
Duration of Single Treatment: 165 d
General Toxicity Parent: NOAEC: 2.39 mg/l
Method: OECD Test Guideline 415
GLP: No information available.

Species: Rat, male and female
Application Route: Inhalation
Dose: 0.013, 0.13, 1.3 mg/L air
Duration of Single Treatment: 153 d
General Toxicity Parent: NOAEC: 1.3 mg/l
Method: OECD Test Guideline 416
GLP: no

Effects on fetal development : Species: Mouse, female
Application Route: Oral
Dose: 5000 mg/kg bw/day
Duration of Single Treatment: 6 - 10 d
General Toxicity Maternal: NOAEL: 5,000 mg/kg body weight
Teratogenicity: LOAEL: 5,000 mg/kg body weight
GLP: No information available.

Species: Rat, female
Application Route: inhalation (vapor)
Dose: 270, 1330, 6650 mg/m³ air
Duration of Single Treatment: 7 - 17 d
General Toxicity Maternal: NOAEC: 1.33 mg/l
Teratogenicity: NOAEC F1: 1.33 mg/l
Method: OECD Test Guideline 414
GLP: No information available.

STOT-single exposure

Not classified based on available information.

Components:

Methanol:

Target Organs : Eyes
Assessment : Causes damage to organs.

STOT-repeated exposure

Not classified based on available information.

Components:

Methanol:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Calibrator D

Acute toxicity

Not classified based on available information.

Components:

Methanol:

Acute inhalation toxicity	:	LC50 (Cat): 43.68 mg/l Exposure time: 6 h Test atmosphere: vapor GLP: No information available. Assessment: The component/mixture is toxic after short term inhalation.
Acute dermal toxicity	:	LD50 (Rabbit): 17,100 mg/kg Method: No information available. GLP: No information available. Assessment: The component/mixture is toxic after single contact with skin.

Skin corrosion/irritation

Not classified based on available information.

Components:

Methanol:

Species	:	Rabbit
Exposure time	:	20 h
Result	:	No skin irritation
GLP	:	no

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Methanol:

Species	:	Rabbit
Result	:	No eye irritation
GLP	:	no

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Methanol:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitization on laboratory animals.

GLP : no

Germ cell mutagenicity

Not classified based on available information.

Components:

Methanol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Ames test
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Micronucleus test
Test system: Chinese hamster lung cells
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse (male and female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Dose: 1920; 3200; 4480 mg/kg
Method: OECD Test Guideline 474
Result: negative
GLP: No information available.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Methanol:

Effects on fertility : Species: Mouse, male
Application Route: Oral

Dose: 1000 mg/kg bw/day
Duration of Single Treatment: 5 d
General Toxicity Parent: LOAEC: 1,000 mg/kg body weight
GLP: No information available.

Application Route: inhalation (vapor)
Dose: 0.27, 0.8, 2.39 mg/L air
Duration of Single Treatment: 165 d
General Toxicity Parent: NOAEC: 2.39 mg/l
Method: OECD Test Guideline 415
GLP: No information available.

Species: Rat, male and female
Application Route: Inhalation
Dose: 0.013, 0.13, 1.3 mg/L air
Duration of Single Treatment: 153 d
General Toxicity Parent: NOAEC: 1.3 mg/l
Method: OECD Test Guideline 416
GLP: no

Effects on fetal development : Species: Mouse, female
Application Route: Oral
Dose: 5000 mg/kg bw/day
Duration of Single Treatment: 6 - 10 d
General Toxicity Maternal: NOAEL: 5,000 mg/kg body weight
Teratogenicity: LOAEL: 5,000 mg/kg body weight
GLP: No information available.

Species: Rat, female
Application Route: inhalation (vapor)
Dose: 270, 1330, 6650 mg/m³ air
Duration of Single Treatment: 7 - 17 d
General Toxicity Maternal: NOAEC: 1.33 mg/l
Teratogenicity: NOAEC F1: 1.33 mg/l
Method: OECD Test Guideline 414
GLP: No information available.

STOT-single exposure

Not classified based on available information.

Components:

Methanol:

Target Organs : Eyes
Assessment : Causes damage to organs.

STOT-repeated exposure

Not classified based on available information.

Components:

Methanol:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Calibrator E

Acute toxicity

Not classified based on available information.

Components:

Methanol:

Acute inhalation toxicity	:	LC50 (Cat): 43.68 mg/l Exposure time: 6 h Test atmosphere: vapor GLP: No information available. Assessment: The component/mixture is toxic after short term inhalation.
Acute dermal toxicity	:	LD50 (Rabbit): 17,100 mg/kg Method: No information available. GLP: No information available. Assessment: The component/mixture is toxic after single contact with skin.

Skin corrosion/irritation

Not classified based on available information.

Components:

Methanol:

Species	:	Rabbit
Exposure time	:	20 h
Result	:	No skin irritation
GLP	:	no

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Methanol:

Species	:	Rabbit
Result	:	No eye irritation
GLP	:	no

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Methanol:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitization on laboratory animals.
GLP	:	no

Germ cell mutagenicity

Not classified based on available information.

Components:

Methanol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Ames test
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Micronucleus test
Test system: Chinese hamster lung cells
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse (male and female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Dose: 1920; 3200; 4480 mg/kg
Method: OECD Test Guideline 474
Result: negative
GLP: No information available.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Methanol:

Effects on fertility	:	Species: Mouse, male Application Route: Oral Dose: 1000 mg/kg bw/day Duration of Single Treatment: 5 d General Toxicity Parent: LOAEC: 1,000 mg/kg body weight GLP: No information available. Application Route: inhalation (vapor) Dose: 0.27, 0.8, 2.39 mg/L air Duration of Single Treatment: 165 d General Toxicity Parent: NOAEC: 2.39 mg/l Method: OECD Test Guideline 415 GLP: No information available. Species: Rat, male and female Application Route: Inhalation Dose: 0.013, 0.13, 1.3 mg/L air Duration of Single Treatment: 153 d General Toxicity Parent: NOAEC: 1.3 mg/l Method: OECD Test Guideline 416 GLP: no
Effects on fetal development	:	Species: Mouse, female Application Route: Oral Dose: 5000 mg/kg bw/day Duration of Single Treatment: 6 - 10 d General Toxicity Maternal: NOAEL: 5,000 mg/kg body weight Teratogenicity: LOAEL: 5,000 mg/kg body weight GLP: No information available. Species: Rat, female Application Route: inhalation (vapor) Dose: 270, 1330, 6650 mg/m³ air Duration of Single Treatment: 7 - 17 d General Toxicity Maternal: NOAEC: 1.33 mg/l Teratogenicity: NOAEC F1: 1.33 mg/l Method: OECD Test Guideline 414 GLP: No information available.

STOT-single exposure

Not classified based on available information.

Components:

Methanol:

Target Organs	:	Eyes
Assessment	:	Causes damage to organs.

STOT-repeated exposure

Not classified based on available information.

Components:

Methanol:

Assessment	:	The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

Calibrator F

Acute toxicity

Not classified based on available information.

Components:

Methanol:

Acute inhalation toxicity	:	LC50 (Cat): 43.68 mg/l Exposure time: 6 h Test atmosphere: vapor GLP: No information available. Assessment: The component/mixture is toxic after short term inhalation.
Acute dermal toxicity	:	LD50 (Rabbit): 17,100 mg/kg Method: No information available. GLP: No information available. Assessment: The component/mixture is toxic after single contact with skin.

Skin corrosion/irritation

Not classified based on available information.

Components:

Methanol:

Species	:	Rabbit
Exposure time	:	20 h
Result	:	No skin irritation
GLP	:	no

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Methanol:

Species	:	Rabbit
Result	:	No eye irritation
GLP	:	no

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Methanol:

Test Type	:	Maximization Test
Species	:	Guinea pig
Assessment	:	Does not cause skin sensitization.
Method	:	OECD Test Guideline 406
Result	:	Did not cause sensitization on laboratory animals.
GLP	:	no

Germ cell mutagenicity

Not classified based on available information.

Components:

Methanol:

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Ames test
Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Micronucleus test
Test system: Chinese hamster lung cells
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse (male and female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Dose: 1920; 3200; 4480 mg/kg
Method: OECD Test Guideline 474
Result: negative
GLP: No information available.

Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:

Methanol:

Effects on fertility : Species: Mouse, male
Application Route: Oral
Dose: 1000 mg/kg bw/day
Duration of Single Treatment: 5 d
General Toxicity Parent: LOAEC: 1,000 mg/kg body weight
GLP: No information available.

Application Route: inhalation (vapor)
Dose: 0.27, 0.8, 2.39 mg/L air
Duration of Single Treatment: 165 d
General Toxicity Parent: NOAEC: 2.39 mg/l
Method: OECD Test Guideline 415
GLP: No information available.

Species: Rat, male and female
Application Route: Inhalation
Dose: 0.013, 0.13, 1.3 mg/L air
Duration of Single Treatment: 153 d
General Toxicity Parent: NOAEC: 1.3 mg/l
Method: OECD Test Guideline 416
GLP: no

Effects on fetal development : Species: Mouse, female
Application Route: Oral
Dose: 5000 mg/kg bw/day
Duration of Single Treatment: 6 - 10 d
General Toxicity Maternal: NOAEL: 5,000 mg/kg body weight
Teratogenicity: LOAEL: 5,000 mg/kg body weight
GLP: No information available.

Species: Rat, female
Application Route: inhalation (vapor)
Dose: 270, 1330, 6650 mg/m³ air
Duration of Single Treatment: 7 - 17 d
General Toxicity Maternal: NOAEC: 1.33 mg/l
Teratogenicity: NOAEC F1: 1.33 mg/l
Method: OECD Test Guideline 414
GLP: No information available.

STOT-single exposure

Not classified based on available information.

Components:

Methanol:

Target Organs	:	Eyes
Assessment	:	Causes damage to organs.

STOT-repeated exposure

Not classified based on available information.

Components:

Methanol:

Assessment	:	The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Calibrator A

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Calibrator B

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

Calibrator C

Ecotoxicity

Components:

Methanol:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 15,400 mg/l End point: mortality Exposure time: 96 h Test Type: flow-through test Analytical monitoring: yes GLP: No information available.
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 18,260 mg/l End point: Immobilization Exposure time: 96 h Test Type: semi-static test Method: OECD Test Guideline 202 GLP: No information available.
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 22,000 mg/l End point: Growth rate Exposure time: 96 h Test Type: static test Method: OECD Test Guideline 201 GLP: No information available.
Toxicity to microorganisms	:	IC50 (activated sludge): > 1,000 mg/l End point: Growth rate Exposure time: 3 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 209 GLP: No information available.

Persistence and degradability

Components:

Methanol:

Biodegradability	:	aerobic Inoculum: activated sludge, non-adapted Concentration: 4 - 200 g/L Result: Readily biodegradable. Biodegradation: 82.7 % Exposure time: 5 d GLP: no
Biochemical Oxygen Demand (BOD)	:	Biochemical oxygen demand 600 - 1,120 mg/g Incubation time: 5 d
Chemical Oxygen Demand (COD)	:	1,420 mg/g
Theoretical oxygen demand	:	1,500 mg/g

(ThOD)
Biochemical Oxygen Demand (BOD)/Theoretical oxygen demand (ThOD) : 76 %

Bioaccumulative potential

Components:

Methanol:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -0.77 (68 °F / 20 °C)

Mobility in soil

No data available

Other adverse effects

Calibrator D

Ecotoxicity

Components:

Methanol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 15,400 mg/l
End point: mortality
Exposure time: 96 h
Test Type: flow-through test
Analytical monitoring: yes
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 18,260 mg/l
End point: Immobilization
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: No information available.

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 22,000 mg/l
End point: Growth rate
Exposure time: 96 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: No information available.

Toxicity to microorganisms : IC50 (activated sludge): > 1,000 mg/l
End point: Growth rate
Exposure time: 3 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 209

GLP: No information available.

Persistence and degradability

Components:

Methanol:

Biodegradability	:	aerobic Inoculum: activated sludge, non-adapted Concentration: 4 - 200 g/L Result: Readily biodegradable. Biodegradation: 82.7 % Exposure time: 5 d GLP: no
Biochemical Oxygen Demand (BOD)	:	Biochemical oxygen demand 600 - 1,120 mg/g Incubation time: 5 d
Chemical Oxygen Demand (COD)	:	1,420 mg/g
Theoretical oxygen demand (ThOD)	:	1,500 mg/g
Biochemical Oxygen Demand (BOD)/Theoretical oxygen demand (ThOD)	:	76 %

Bioaccumulative potential

Components:

Methanol:

Bioaccumulation	:	Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.
Partition coefficient: n-octanol/water	:	log Pow: -0.77 (68 °F / 20 °C)

Mobility in soil

No data available

Other adverse effects

Calibrator E

Ecotoxicity

Components:

Methanol:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 15,400 mg/l End point: mortality Exposure time: 96 h Test Type: flow-through test Analytical monitoring: yes

GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 18,260 mg/l End point: Immobilization Exposure time: 96 h Test Type: semi-static test Method: OECD Test Guideline 202 GLP: No information available.
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 22,000 mg/l End point: Growth rate Exposure time: 96 h Test Type: static test Method: OECD Test Guideline 201 GLP: No information available.
Toxicity to microorganisms	:	IC50 (activated sludge): > 1,000 mg/l End point: Growth rate Exposure time: 3 h Test Type: static test Analytical monitoring: yes Method: OECD Test Guideline 209 GLP: No information available.

Persistence and degradability

Components:

Methanol:

Biodegradability	:	aerobic Inoculum: activated sludge, non-adapted Concentration: 4 - 200 g/L Result: Readily biodegradable. Biodegradation: 82.7 % Exposure time: 5 d GLP: no
Biochemical Oxygen Demand (BOD)	:	Biochemical oxygen demand 600 - 1,120 mg/g Incubation time: 5 d
Chemical Oxygen Demand (COD)	:	1,420 mg/g
Theoretical oxygen demand (ThOD)	:	1,500 mg/g
Biochemical Oxygen Demand (BOD)/Theoretical oxygen demand (ThOD)	:	76 %

Bioaccumulative potential

Components:

Methanol:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -0.77 (68 °F / 20 °C)

Mobility in soil

No data available

Other adverse effects

Calibrator F

Ecotoxicity

Components:

Methanol:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 15,400 mg/l
End point: mortality
Exposure time: 96 h
Test Type: flow-through test
Analytical monitoring: yes
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 18,260 mg/l
End point: Immobilization
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 202
GLP: No information available.

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 22,000 mg/l
End point: Growth rate
Exposure time: 96 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: No information available.

Toxicity to microorganisms : IC50 (activated sludge): > 1,000 mg/l
End point: Growth rate
Exposure time: 3 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 209
GLP: No information available.

Persistence and degradability

Components:

Methanol:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted

Concentration: 4 - 200 g/L
Result: Readily biodegradable.
Biodegradation: 82.7 %
Exposure time: 5 d
GLP: no

Biochemical Oxygen Demand (BOD) : Biochemical oxygen demand
600 - 1,120 mg/g
Incubation time: 5 d

Chemical Oxygen Demand (COD) : 1,420 mg/g

Theoretical oxygen demand (ThOD) : 1,500 mg/g

Biochemical Oxygen Demand (BOD)/Theoretical oxygen demand (ThOD) : 76 %

Bioaccumulative potential

Components:

Methanol:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: -0.77 (68 °F / 20 °C)

Mobility in soil

No data available

Other adverse effects

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

Domestic regulation

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

Calibrator A

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium hydroxide (Na(OH))	1310-73-2	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned
Sodium hydroxide (Na(OH))	1310-73-2

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The ingredients of this product are reported in the following inventories:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Human serum /-plasma / -hemolysate, liquid
AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

Calibrator B

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Methanol	67-56-1	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned
Methanol	67-56-1
Sodium hydroxide (Na(OH))	1310-73-2

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Methanol, 2-propylvaleric acid, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

The ingredients of this product are reported in the following inventories:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Human serum /-plasma / -hemolysate, liquid
AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

Calibrator C

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Methanol	67-56-1	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned
Methanol	67-56-1
Sodium hydroxide (Na(OH))	1310-73-2

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Methanol, 2-propylvaleric acid, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

The ingredients of this product are reported in the following inventories:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Human serum /-plasma / -hemolysate, liquid
AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

Calibrator D

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Methanol	67-56-1	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	No SARA Hazards
SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned
Methanol	67-56-1
Sodium hydroxide (Na(OH))	1310-73-2

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Methanol, 2-propylvaleric acid, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

The ingredients of this product are reported in the following inventories:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Human serum /-plasma / -hemolysate, liquid
AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

Calibrator E

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Methanol	67-56-1	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned
Methanol	67-56-1

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Methanol, 2-propylvaleric acid, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

The ingredients of this product are reported in the following inventories:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Human serum /-plasma / -hemolysate, liquid
AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

Calibrator F

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Methanol	67-56-1	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium hydroxide (Na(OH))	1310-73-2	>= 0 - < 0.1 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid	Not Assigned
Methanol	67-56-1

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including Methanol, 2-propylvaleric acid, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

The ingredients of this product are reported in the following inventories:

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Human serum /-plasma / -hemolysate, liquid
AICS	:	Not in compliance with the inventory
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

Calibrator A

GHS label elements

Not a hazardous substance or mixture.

Calibrator B

GHS label elements

Not a hazardous substance or mixture.

Calibrator C

GHS label elements

Not a hazardous substance or mixture.

Calibrator D

GHS label elements

Not a hazardous substance or mixture.

Calibrator E

GHS label elements

Not a hazardous substance or mixture.

Calibrator F

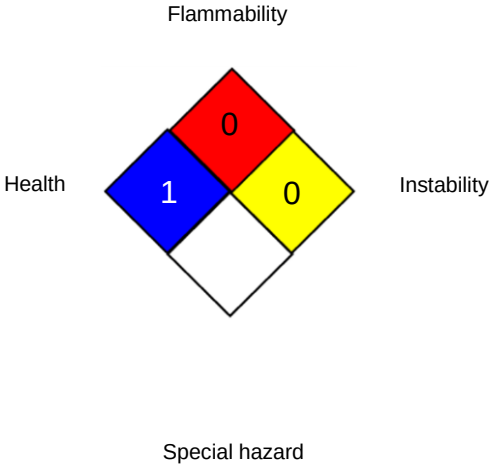
GHS label elements

Not a hazardous substance or mixture.

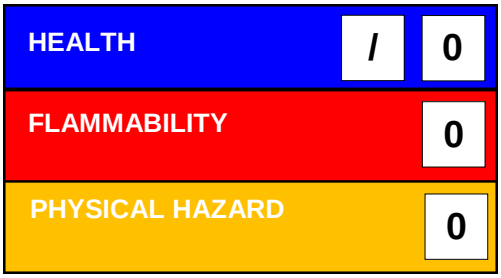
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

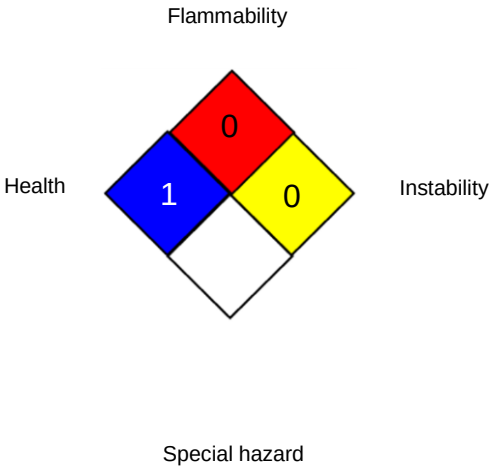


HMIS® IV:

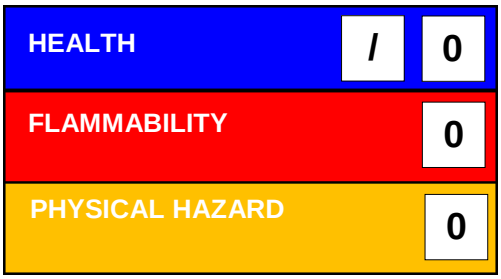


HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

NFPA 704:

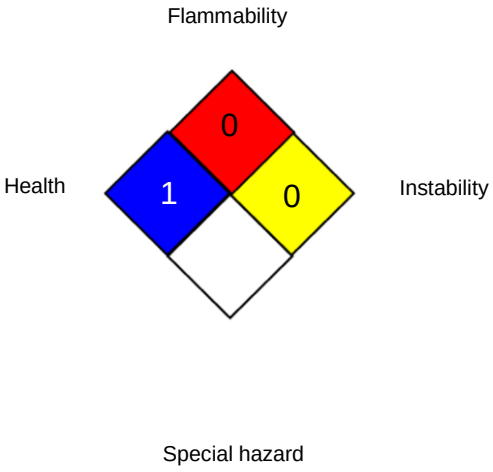


HMIS® IV:

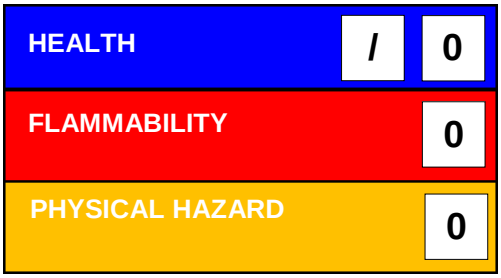


HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

NFPA 704:

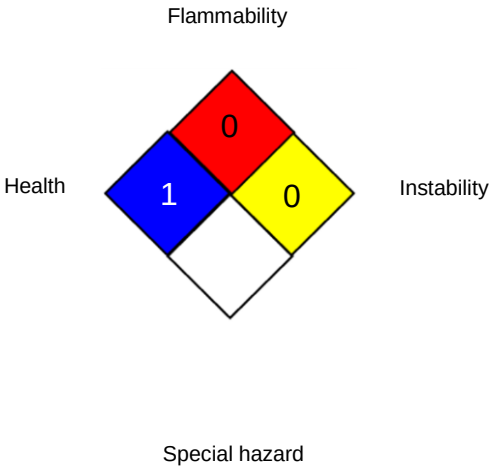


HMIS® IV:

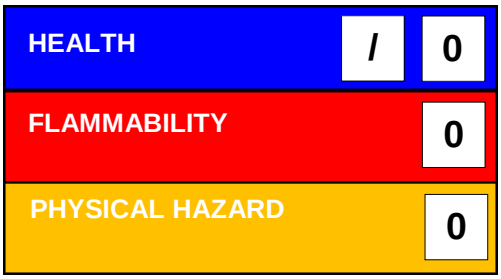


HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

NFPA 704:

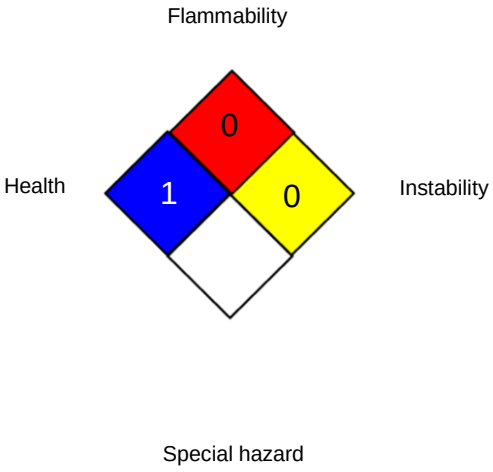


HMIS® IV:

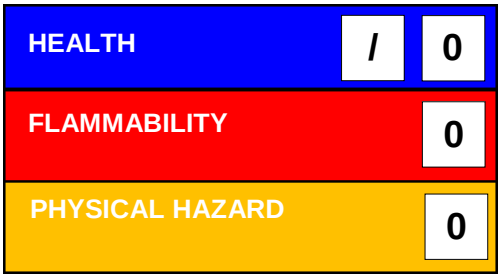


HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

NFPA 704:

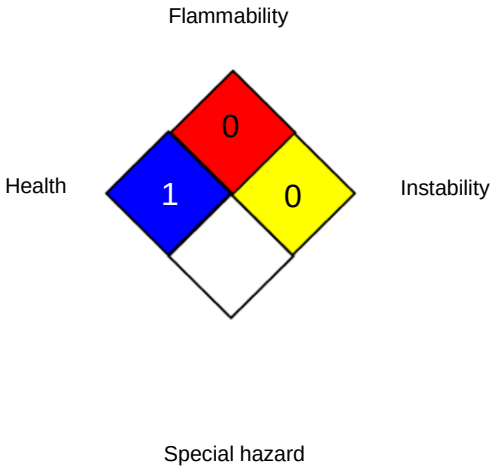


HMIS® IV:

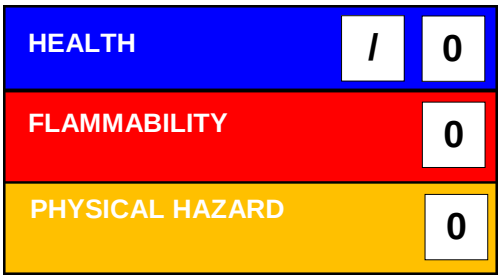


HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

NFPA 704:



HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 02-06-2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 2004