



VENTANA anti-E-cadherin (36) Mouse Monoclonal Primary Antibody

Version
3.0

Revision Date:
06-27-2024

Date of last issue: 04-13-2023
Date of first issue: 11-27-2015

SECTION 1. IDENTIFICATION

Product name : VENTANA anti-E-cadherin (36) Mouse Monoclonal Primary Antibody

Product code : 05905290001

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


Recommended use : Laboratory chemicals
Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

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

Skin sensitization : Category 1

GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**
P261 Avoid breathing mist or vapors.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.

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Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P333 + P313 If skin irritation or rash occurs: Get medical advice/
attention.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Dipotassium hydrogen phosphate 3 hydrate	16788-57-1	$\geq 1 - < 5$
Caseins	9000-71-9	$\geq 1 - < 5$
Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	55965-84-9	$\geq 0.0015 - < 0.06$
L-Tryptophan	73-22-3	< 0.1
L-Glutamic acid, N-[4-[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)methyl]amino]benzoyl]-	59-30-3	< 0.1
Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1:1)	67-03-8	< 0.1
Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1)	67-48-1	< 0.1
3-Pyridinecarboxamide	98-92-0	< 0.1
.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1)	137-08-6	< 0.1
Riboflavin	83-88-5	< 0.1
1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-	58-85-5	< 0.1
Vitamin B12	68-19-9	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.



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Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

- If inhaled : Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.
- 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 : May cause an allergic skin reaction.
- 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.
- Hazardous combustion products : Oxides of phosphorus
Carbon oxides
- 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



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- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains. 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 : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). 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 : Do not breathe vapors/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Dispose of rinse water in accordance with local and national regulations. Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
- 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

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
L-Tryptophan	73-22-3	IOEL	10 mg/m ³	Roche Industrial Hy-

SAFETY DATA SHEET



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				giene Com- mittee (RIHC)
L-Glutamic acid, N-[4-[[[(2-amino-3,4-dihydro-4-oxo-6-pteridinyl)methyl]amino]benzoyl]-	59-30-3	IOEL	0.1 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)
Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1)	67-03-8	IOEL	3 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)
Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1)	67-48-1	IOEL	10 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)
3-Pyridinecarboxamide	98-92-0	IOEL	5 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)
.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1)	137-08-6	IOEL	10 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)
Riboflavin	83-88-5	IOEL	0.5 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)
1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-	58-85-5	IOEL	0.4 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)
Vitamin B12	68-19-9	IOEL	0.6 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)

Engineering measures : No data available

Personal protective equipment

Hand protection

In case of contact through splashing:
 Material : Nitrile rubber
 Break through time : > 30 min
 Glove thickness : > 0.11 mm



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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 : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : colorless

Odor : none

Odor Threshold : No data available

pH : 7.2 - 7.4

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) : The product is not flammable., Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available



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- 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 : 1.019 g/cm³
- Solubility(ies)
 - Solubility in other solvents : No data available
- Partition coefficient: n-octanol/water : No data available
- Autoignition temperature : No data available
- Decomposition temperature : Hazardous decomposition products formed under fire conditions.
- 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 : Reacts with the following substances:
 - Oxidizing agents
 - No decomposition if stored and applied as directed.
- Conditions to avoid : Heat.
- Incompatible materials : None.
- Hazardous decomposition products : In case of fire hazardous decomposition products may be produced such as:
 - Carbon oxides

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SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Components:**Dipotassium hydrogen phosphate 3 hydrate:**

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 420
Test substance: anhydrous substance
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No mortality observed at this dose.

Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Acute oral toxicity : LD50 Oral (Rat, male): 64 mg/kg

Acute inhalation toxicity : LC50 (Rat, male and female): 0.33 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 Dermal (Rabbit, male): 87.12 mg/kg

L-Tryptophan:

Acute oral toxicity : LD50 Oral (Rat): > 16,000 mg/kg

L-Glutamic acid, N-[4-[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)methyl]amino]benzoyl]-:

Acute oral toxicity : LD50 Oral (Rat): > 8,000 mg/kg
LD50 Oral (Mouse): 10,000 mg/kg

Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1:1):

Acute oral toxicity : LD50 Oral (Rat, male and female): 12,340 mg/kg

Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1):

Acute oral toxicity : LD50 Oral (Rat): 3,400 mg/kg
LD50 Oral (Mouse): 3,900 mg/kg
Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l
Test atmosphere: dust/mist
Method: Expert judgment

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Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgment

3-Pyridinecarboxamide:

Acute oral toxicity : LD50 (Mouse, male and female): > 2,500 mg/kg
Method: OECD Test Guideline 423
GLP: yes
Assessment: The substance or mixture has no acute oral toxicity
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat, male and female): > 3.8 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 436
GLP: yes
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit, male and female): > 2,000 mg/kg
Method: OECD Test Guideline 402
GLP: yes
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: No mortality observed at this dose.

.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):

Acute oral toxicity : LD50 Oral (Rat): > 10,000 mg/kg
LD50 Oral (Mouse): 10,000 mg/kg

Riboflavin:

Acute oral toxicity : LD50 Oral (Mouse): > 2,001 mg/kg
LD50 Oral (Rat): > 10,000 mg/kg

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

Acute oral toxicity : LD50 Oral (Rat): > 20,000 mg/kg
LD50 Oral (Mouse): > 10,000 mg/kg

Vitamin B12:

Acute oral toxicity : LD50 Oral (Mouse): > 5,000 mg/kg

Skin corrosion/irritation

Not classified due to lack of data.

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Remarks : May cause skin irritation and/or dermatitis.

Components:**Dipotassium hydrogen phosphate 3 hydrate:**Species : Rabbit
Result : No skin irritation**Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one (3:1):**

Result : Corrosive after 1 to 4 hours of exposure

L-Tryptophan:

Remarks : This information is not available.

L-Glutamic acid, N-[4-[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)l)methyl]amino]benzoyl]-:

Remarks : This information is not available.

Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1:1):Method : OECD Test Guideline 439
Result : No skin irritation
GLP : yes**Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1):**

Remarks : This information is not available.

3-Pyridinecarboxamide:Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation
GLP : yes**.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):**

Remarks : This information is not available.

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
Result : No skin irritation**Vitamin B12:**

Remarks : May cause skin irritation in susceptible persons.

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Not classified due to lack of data.

Product:

Remarks : Vapors may cause irritation to the eyes, respiratory system and the skin.

Components:**Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one (3:1):**Species : Rabbit
Result : Risk of serious damage to eyes.**L-Tryptophan:**

Remarks : This information is not available.

L-Glutamic acid, N-[4-[[[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)]methyl]amino]benzoyl]-:

Remarks : This information is not available.

Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1:1):Result : Irritating to eyes.
Method : OECD Test Guideline 492
GLP : yes**Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1):**

Remarks : This information is not available.

3-Pyridinecarboxamide:Species : Rabbit
Result : Irritating to eyes.
Method : OECD Test Guideline 405
GLP : yes
Remarks : May cause irreversible eye damage.**.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):**

Remarks : This information is not available.

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:Species : Rabbit
Result : No eye irritation
Exposure time : 72 h
Method : OECD Test Guideline 405

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Vitamin B12:

Remarks : May irritate eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified due to lack of data.

Product:

Remarks : Causes sensitization.

Components:

Dipotassium hydrogen phosphate 3 hydrate:

Species : Mouse
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 429
Remarks : Based on data from similar materials

Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1):

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Assessment : The product is a skin sensitizer, sub-category 1A.

Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1:1):

Method : OECD Test Guideline 442D
Result : negative
GLP : yes

Method : OECD Test Guideline 442E
Result : negative
GLP : yes

3-Pyridinecarboxamide:

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

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

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



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Vitamin B12:

Remarks : May cause sensitization of susceptible persons.

Germ cell mutagenicity

Not classified due to lack of data.

Components:

Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1:1):

Genotoxicity in vitro : Test Type: Micronucleus test
Test system: mammalian liver cells
Method: OECD Test Guideline 487
Result: negative
GLP: yes

Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Ames test
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

3-Pyridinecarboxamide:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: yes

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse (male and female)
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative



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GLP: yes

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Carcinogenicity

Not classified due to lack of data.

Components:

L-Tryptophan:

Remarks : 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.

Riboflavin:

Remarks : 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.

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

Remarks : 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.

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 due to lack of data.

Components:

3-Pyridinecarboxamide:

Effects on fetal development : Species: Rabbit, female
Application Route: Oral
Dose: 50, 150, 450 mg/kg bw/day
Duration of Single Treatment: 6 - 20 d
General Toxicity Maternal: NOAEL: 50 mg/kg body weight
Embryo-fetal toxicity.: NOAEL: 50 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

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Not classified due to lack of data.

Components:**Dipotassium hydrogen phosphate 3 hydrate:**

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

Caseins:

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

L-Tryptophan:

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

L-Glutamic acid, N-[4-[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)l)methyl]amino]benzoyl]-:

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

.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):

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

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

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

Vitamin B12:

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

STOT-repeated exposure

Not classified due to lack of data.

Components:**Dipotassium hydrogen phosphate 3 hydrate:**

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

Caseins:

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

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

L-Glutamic acid, N-[4-[[[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)methyl]amino]benzoyl]-:

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

Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1):

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

.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):

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

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

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

Vitamin B12:

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

Repeated dose toxicity**Components:****3-Pyridinecarboxamide:**Species : Rat, male and female
NOAEL : 215 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Method : OECD Test Guideline 407
GLP : yes**Aspiration toxicity**

Not classified due to lack of data.

Components:**Dipotassium hydrogen phosphate 3 hydrate:**

No data available

L-Tryptophan:

No data available

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L-Glutamic acid, N-[4-[[[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)]methyl]amino]benzoyl]-:

No data available

.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):

No data available

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

No data available

Vitamin B12:

No data available

Further information

Components:

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

Remarks : Health injuries are not known or expected under normal use.

Vitamin B12:

Remarks : May be harmful by inhalation, ingestion, skin adsorption.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Components:

Dipotassium hydrogen phosphate 3 hydrate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Test Type: semi-static test
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials



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Toxicity to algae/aquatic plants : (Desmodesmus subspicatus (green algae)): > 100 mg/l
 Exposure time: 72 h
 Test Type: Growth inhibition
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
 Exposure time: 3 h
 Test Type: static test
 Method: OECD Test Guideline 209

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Caseins:

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one (3:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.19 mg/l
 Exposure time: 96 h
 Test Type: flow-through test

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.16 mg/l
 Exposure time: 48 h
 Test Type: flow-through test

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 0.0063 mg/l
 Exposure time: 72 h
 Test Type: static test
 Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic toxicity) : NOEC (Cyprinodon sp. (minnow)): 0.02 mg/l
 Exposure time: 38 d
 Test Type: semi-static test
 Method: OECD Test Guideline 210

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia): 0.1 mg/l
Exposure time: 21 d
GLP: yes

M-Factor (Chronic aquatic toxicity) : 100

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

L-Tryptophan:

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

L-Glutamic acid, N-[4-[[[(2-amino-3,4-dihydro-4-oxo-6-pteridinyl)methyl]amino]benzoyl]-:

Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : NOEC (Daphnia magna (Water flea)): 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 51.8 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
End point: mortality

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Exposure time: 96 h
Test Type: static test
Method: OECD Test Guideline 203
GLP: yes
Remarks: nominal concentration

NOEC (Oncorhynchus mykiss (rainbow trout)): 100 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Method: OECD Test Guideline 203
GLP: yes
Remarks: nominal concentration

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

NOEC (Daphnia magna (Water flea)): 58 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202
GLP: yes
Remarks: nominal concentration

Toxicity to algae/aquatic plants : EbC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: yes

NOEC (Desmodesmus subspicatus (green algae)): 100 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201
GLP: yes

Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1):

Toxicity to fish : LC50 (Fish): > 100 mg/l
Exposure time: 96 h

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.



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Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

3-Pyridinecarboxamide:

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 1,000 mg/l
 End point: mortality
 Exposure time: 96 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 203
 GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
 End point: Immobilization
 Exposure time: 24 h
 Test Type: static test
 Analytical monitoring: no
 Method: OECD Test Guideline 202
 GLP: yes

Toxicity to algae/aquatic plants : EbC50 (Selenastrum capricornutum (green algae)): > 1,000 mg/l
 Exposure time: 72 h
 Test Type: static test
 Analytical monitoring: no
 Method: OECD Test Guideline 201
 GLP: yes

Toxicity to microorganisms : NOEC (Pseudomonas putida): 4,235 mg/l
 End point: Growth rate
 Exposure time: 18 h
 Test Type: static test
 Analytical monitoring: no
 Method: OECD Test Guideline 209
 GLP: yes

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):

Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): > 1,000 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203

NOEC (Oncorhynchus mykiss (rainbow trout)): > 1,000 mg/l
 Exposure time: 96 h



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Method: OECD Test Guideline 203

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Riboflavin:

Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): > 500 mg/l
Exposure time: 96 h

Ecotoxicology Assessment

Acute aquatic toxicity : Harmful to aquatic life.

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): 500 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 203

Toxicity to microorganisms : (activated sludge): 100 mg/l

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Vitamin B12:

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

Persistence and degradability

Components:

Dipotassium hydrogen phosphate 3 hydrate:

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

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Biodegradability : Result: Inherently biodegradable.
Remarks: The 10 day time window criterion is not fulfilled.

Result: Not readily biodegradable.
Method: OECD Test Guideline 301B
GLP: yes

L-Glutamic acid, N-[4-[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)l)methyl]amino]benzoyl]-:

Biodegradability : Biodegradation: 82 %
Exposure time: 14 d
Method: OECD Test Guideline 302

Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1:1):

Biodegradability : aerobic
Inoculum: activated sludge
Result: Readily biodegradable.
Biodegradation: 100 %
Exposure time: 28 d
Method: OECD Test Guideline 301B
GLP: yes

3-Pyridinecarboxamide:

Biodegradability : aerobic
Inoculum: activated sludge, non-adapted
Concentration: 34 mg/l
Result: Readily biodegradable.
Biodegradation: 96 %
Exposure time: 28 d
Method: OECD Test Guideline 301E
GLP: yes

.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):

Biodegradability : Biodegradation: 99 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Remarks: No data available

Riboflavin:

Biodegradability : Biodegradation: 100 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 38 %

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Method: OECD Test Guideline 301C**Bioaccumulative potential****Components:****Dipotassium hydrogen phosphate 3 hydrate:**

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

Partition coefficient: n-octanol/water : Remarks: No data available

Caseins:

Partition coefficient: n-octanol/water : Remarks: No data available

Mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one (3:1):Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 54
Temperature: 68 °F / 20 °C
Concentration: ca. 0.01 mg/l

Partition coefficient: n-octanol/water : log Pow: 0.75

L-Tryptophan:

Partition coefficient: n-octanol/water : log Pow: -1.05

L-Glutamic acid, N-[4-[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)methyl]amino]benzoyl]-:

Partition coefficient: n-octanol/water : log Pow: -2.81

Thiazolium, 3-[(4-amino-2-methyl-5-pyrimidinyl)methyl]-5-(2-hydroxyethyl)-4-methyl-, chloride, hydrochloride (1:1:1):Partition coefficient: n-octanol/water : log Pow: -3.04 (72.5 °F / 22.5 °C)
pH: 7.08
Method: OECD Test Guideline 107
GLP: yes**Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1):**

Partition coefficient: n-octanol/water : Remarks: No data available

3-Pyridinecarboxamide:

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Partition coefficient: n-octanol/water : log Pow: -0.38 (70 °F / 21 °C)
Method: OECD Test Guideline 107
GLP: yes

.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):

Partition coefficient: n-octanol/water : Remarks: No data available

Riboflavin:

Partition coefficient: n-octanol/water : Remarks: No data available

1H-Thieno[3,4-d]imidazole-4-pentanoic acid, hexahydro-2-oxo-, (3aS,4S,6aR)-:

Partition coefficient: n-octanol/water : log Pow: 0.39

Vitamin B12:

Bioaccumulation : Species: Fish
Bioconcentration factor (BCF): 3
Exposure time: 3 d

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: 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).

Components:

L-Glutamic acid, N-[4-[(2-amino-3,4-dihydro-4-oxo-6-pteridiny)]methyl]amino]benzoyl]-:

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

Ethanaminium, 2-hydroxy-N,N,N-trimethyl-, chloride (1:1):

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

Additional ecological information : No data available



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3-Pyridinecarboxamide:

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

.beta.-Alanine, N-[(2R)-2,4-dihydroxy-3,3-dimethyl-1-oxobutyl]-, calcium salt (2:1):

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

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

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the 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 : Respiratory or skin sensitization



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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 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

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

Sodium selenite, pentahydrate	26970-82-1	>= 0 - < 0.1 %
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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

Water	7732-18-5
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Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Vitamin B12	68-19-9
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Washington Chemicals of High Concern

Vitamin B12	68-19-9
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The ingredients of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Glycols

Serum, Calf



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Modified alkyl carboxylate
L-Tyrosine disodiumsalt dihydrate
L-Histidine monohydrochloride monohydrate
anti-E-cadherin (36) MM PAB
Amphotericin B, pure
Globulins, blood plasma
D-Phenylalanine
D-Streptamine, O-2-deoxy-2-(methylamino)-.alpha.-L-glucopyranosyl-(1.->.2)-O-5-deoxy-3-C-(hydroxymethyl)-.alpha.-L-lyxofuranosyl-(1.->.4)-N1,N3-bis(aminoiminomethyl)-, sulfate (2:3)
4-Pyridinecarboxaldehyde, 3-hydroxy-5-(hydroxymethyl)-2-methyl-, hydrochloride (1:1)

- 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 active and not listed on TSCA inventory.
- TECI : Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

Further information

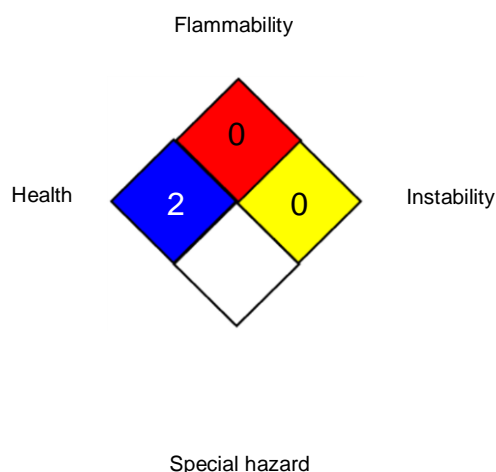
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NFPA 704:



HMIS® IV:

HEALTH	/	2
FLAMMABILITY		0
PHYSICAL HAZARD		0

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

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; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act

SAFETY DATA SHEET



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(United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 06-27-2024

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 / 2304