

Vitamin D total G2 Elecsys cobas e 100Version
1.2Revision Date:
06-02-2016Date of last issue: 04-21-2016
Date of first issue: 12-18-2015**SECTION 1. IDENTIFICATION**

Product name : Vitamin D total G2 Elecsys cobas e 100
Product code : 07464215190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
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Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone:

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Ca-
nada)

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**

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

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H290 May be corrosive to metals.
H315 Causes skin irritation.
H318 Causes serious eye damage.

Precautionary Statements :

Prevention:

P234 Keep only in original container.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

P332 + P313 If skin irritation occurs: Get medical advice/ attention.

P362 Take off contaminated clothing and wash before reuse.

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P390 Absorb spillage to prevent material damage.

Storage:

P406 Store in corrosive resistant container with a resistant inner liner.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**R1****GHS Classification**

Not a hazardous substance or mixture.

Substance name : Vit.D total Gen2 Elecsys R1

Hazardous ingredients

No hazardous ingredients

R2**GHS Classification**

Not a hazardous substance or mixture.

Substance name : Vit.D total Gen2 Elecsys R2

Hazardous ingredients

No hazardous ingredients

Beads (MP)**GHS Classification**

Not a hazardous substance or mixture.

Substance name : SA Coat-Bead Elecsys (bottle)

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	≥ 1 - < 5

PT1**GHS Classification**

Serious eye damage

H318: Causes serious eye damage.

Category 1

Substance name : Vit.D total Gen2 Elecsys PT1

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
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Ethylene carbonate	96-49-1	>= 1 - < 5
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PT2**GHS Classification**

Corrosive to Metals	H290: May be corrosive to metals.
Category 1	
Skin irritation	H315: Causes skin irritation.
Category 2	
Eye irritation	H319: Causes serious eye irritation.
Category 2A	
Substance name	: Vit.D total Gen2 Elecsys PT2

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Sodium hydroxide	1310-73-2	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

General advice	: Move out of dangerous area. Consult a physician. 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	: Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty. If on skin, rinse well with water. If on clothes, remove clothes.
In case of eye contact	: Small amounts splashed into eyes can cause irreversible tissue damage and blindness. In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Continue rinsing eyes during transport to hospital. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	: Clean mouth with water and drink afterwards plenty of water. Keep respiratory tract clear. Do NOT induce vomiting. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital.

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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 cir-
cumstances and the surrounding environment.

Unsuitable extinguishing
media : High volume water jet

Specific hazards during fire
fighting : Do not allow run-off from fire fighting to enter drains or water
courses.

Further information : Collect contaminated fire extinguishing water separately. This
must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must
be disposed of in accordance with local regulations.

Special protective equipment
for fire-fighters : Wear self-contained breathing apparatus for firefighting if nec-
essary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Use personal protective equipment.
tive equipment and emer-
gency procedures : 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 contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the ap-
plication area.
Dispose of rinse water in accordance with local and national

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regulations.

To prevent leaks or spillages from spreading, provide a suitable liquid retention system.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.

Technical measures/Precautions : See label, package insert or internal guidelines

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
R1
Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

R2
Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Beads (MP)
Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0

PT1
Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters

Ingredients	CAS-No.
Ethylene carbonate	96-49-1

PT2

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Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sodium hydroxide	1310-73-2	C	2 mg/m ³	ACGIH
		C	2 mg/m ³	NIOSH REL
		TWA	2 mg/m ³	OSHA Z-1
		C	2 mg/m ³	OSHA P0

Engineering measures : No data available

Personal protective equipment

Hand protection

Material : Protective gloves

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
Wear face-shield and protective suit for abnormal processing problems.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
R1

Appearance : liquid

Color : colorless

Odor : none

Odor Threshold : No data available

pH : 6.3 - 6.5 (25 °C)

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (liquids) : Does not sustain combustion.

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Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available
Density	: 1.030 g/cm ³
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
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

R2

Appearance	: liquid
Color	: colorless
Odor	: none
Odor Threshold	: No data available
pH	: 8.5 - 8.7 (25 °C)
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (liquids)	: Does not sustain combustion.
Upper explosion limit	: No data available
Lower explosion limit	: No data available

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Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.008 g/cm ³
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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

Beads (MP)

Appearance	:	liquid
Color	:	colorless
Odor	:	none
Odor Threshold	:	No data available
pH	:	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)	:	Does not sustain combustion.
Flammability (liquids)	:	The product is not flammable.
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available

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Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.01 g/cm ³ (20 °C)
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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

PT1

Appearance	:	liquid
Color	:	colorless
Odor	:	none
Odor Threshold	:	No data available
pH	:	5.4 - 5.6 (25 °C)
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (liquids)	:	Does not sustain combustion.
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available

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Relative density	:	No data available
Density	:	1.012 g/cm ³
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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

PT2

Appearance	:	liquid
Color	:	colorless
Odor	:	odorless
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 (liquids)	:	Does not sustain combustion.
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available

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Density	:	1.026 g/cm ³
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
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Metal corrosion rate	:	Corrosive to metals

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.

SECTION 11. TOXICOLOGICAL INFORMATION**R1****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.

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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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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.

R2**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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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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.

Beads (MP)**Acute toxicity**

Not classified based on available information.

Ingredients:**Sucrose:**

Acute oral toxicity	:	LD50 Oral (Rat): 29,700 mg/kg LD50 Oral (Mouse): 14,000 mg/kg
Acute inhalation toxicity	:	Acute toxicity estimate: > 30 mg/l Method: Expert judgment
Acute dermal toxicity	:	Acute toxicity estimate: > 5,001 mg/kg Method: Expert judgment

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.

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

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.

Ingredients:**Sucrose:**

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

STOT-repeated exposure

Not classified based on available information.

Ingredients:**Sucrose:**

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

Aspiration toxicity

Not classified based on available information.

Ingredients:**Sucrose:**

No data available

Further information**Ingredients:****Sucrose:**

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

PT1**Acute toxicity**

Not classified based on available information.

Ingredients:**Ethylene carbonate:**

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

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2,001 mg/kg

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Skin corrosion/irritation

Not classified based on available information.

Ingredients:**Ethylene carbonate:**

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Causes serious eye damage.

Ingredients:**Ethylene carbonate:**

Result: Risk of serious damage to eyes.

Remarks: May cause irreversible eye damage.

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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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.

Ingredients:**Ethylene carbonate:**

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

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Not classified based on available information.

Ingredients:**Ethylene carbonate:**

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

Aspiration toxicity

Not classified based on available information.

Ingredients:**Ethylene carbonate:**

No data available

PT2**Acute toxicity**

Not classified based on available information.

Skin corrosion/irritation

Causes skin irritation.

Ingredients:**Sodium hydroxide:**

Result: Causes severe burns.

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Causes serious eye irritation.

Ingredients:**Sodium hydroxide:**

Result: Risk of serious damage to eyes.

Remarks: May cause irreversible eye damage.

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.

Ingredients:**Sodium hydroxide:**Genotoxicity in vitro : Test Type: Ames test
Result: negative

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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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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.

Ingredients:**Sodium hydroxide:**

Effects on fertility :

Remarks: No data available

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.

SECTION 12. ECOLOGICAL INFORMATION**R1****Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects**R2**

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No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects***Beads (MP)*****Ecotoxicity****Ingredients:****Sucrose:**Toxicity to fish : LC50: > 100 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

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

Persistence and degradability

No data available

Bioaccumulative potential**Ingredients:****Sucrose:**

Partition coefficient: n-octanol/water : log Pow: -3.67

Mobility in soil

No data available

Other adverse effects**PT1**

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- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 1,000 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
- Toxicity to bacteria : EC50 (Pseudomonas putida): > 10,000 mg/l
Exposure time: 17 h

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

Persistence and degradability

No data available

Bioaccumulative potential**Ingredients:****Ethylene carbonate:**

- Partition coefficient: n-octanol/water : log Pow: -0.34

Mobility in soil

No data available

Other adverse effects**Ingredients:****Ethylene carbonate:**

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

PT2**Ecotoxicity****Ingredients:****Sodium hydroxide:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 45.4 mg/l
Exposure time: 96 h

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LC50 (Leuciscus idus (Golden orfe)): ca. 7 mg/l

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 40.38 mg/l
aquatic invertebrates Exposure time: 48 h**Persistence and degradability**

No data available

Bioaccumulative potential**Ingredients:****Sodium hydroxide:**Partition coefficient: n- : Remarks: Not applicable
octanol/water**Mobility in soil**

No data available

Other adverse effects

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.
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 Regulation****UNRTDG**UN number : UN 1824
Proper shipping name : SODIUM HYDROXIDE SOLUTION
Class : 8
Packing group : II
Labels : 8**IATA-DGR**UN/ID No. : UN 1824
Proper shipping name : Sodium hydroxide solution
Class : 8
Packing group : II
Labels :

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Packing instruction (cargo aircraft) : 855

Packing instruction (passenger aircraft) : 851

IMDG-Code

UN number : UN 1824

Proper shipping name : SODIUM HYDROXIDE SOLUTION

Class : 8

Packing group : II

Labels : 8

EmS Code : F-A, S-B

Marine pollutant : no

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

Not applicable

Domestic regulation**49 CFR**

UN/ID/NA number : UN 1824

Proper shipping name : SODIUM HYDROXIDE SOLUTION

Class : 8

Packing group : II

Labels : Class 8 - Corrosive

ERG Code : 154

Marine pollutant : no

SECTION 15. REGULATORY INFORMATION**R1****EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Hydrochloric acid (theor. 100%)	7647-01-0	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 311/312 Hazards : No SARA Hazards**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.**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).

Vitamin D total G2 Elecsys cobas e 100
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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

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

Hydrochloric acid (theor. 100%)	7647-01-0	0.5582 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Hydrochloric acid (theor. 100%)	7647-01-0	0.5582 %
---------------------------------	-----------	----------

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

US State Regulations
Massachusetts Right To Know

Hydrochloric acid (theor. 100%)	7647-01-0	0.1 - 1 %
---------------------------------	-----------	-----------

Pennsylvania Right To Know

Water	7732-18-5	90 - 100 %
Albumin from human serum	70024-90-7	1 - 5 %
Hydrochloric acid (theor. 100%)	7647-01-0	0.1 - 1 %

New Jersey Right To Know

Water	7732-18-5	90 - 100 %
Albumin from human serum	70024-90-7	1 - 5 %
1,3-Bis[tris(hydroxymethyl)methylamino]propane	64431-96-5	1 - 5 %
MAB / PAB	Not Assigned	1 - 5 %

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

CH INV	Not in compliance with the inventory MAB / PAB
DSL	This product contains the following components that are not on the Canadian DSL nor NDSL. 1,3-Bis[tris(hydroxymethyl)methylamino]propane MAB / PAB 1-Hydroxy-2(1H)-Pyridinone
AICS	Not in compliance with the inventory 1,3-Bis[tris(hydroxymethyl)methylamino]propane MAB / PAB 1-Hydroxy-2(1H)-Pyridinone
NZIoC	On the inventory, or in compliance with the inventory
ENCS	Not in compliance with the inventory Water Albumin from human serum 1,3-Bis[tris(hydroxymethyl)methylamino]propane MAB / PAB 1-Hydroxy-2(1H)-Pyridinone

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ISHL	Not in compliance with the inventory Water Albumin from human serum 1,3-Bis[tris(hydroxymethyl)methylamino]propane MAB / PAB 1-Hydroxy-2(1H)-Pyridinone
KECI	Not in compliance with the inventory Albumin from human serum 1,3-Bis[tris(hydroxymethyl)methylamino]propane MAB / PAB 1-Hydroxy-2(1H)-Pyridinone
PICCS	Not in compliance with the inventory Albumin from human serum 1,3-Bis[tris(hydroxymethyl)methylamino]propane MAB / PAB 1-Hydroxy-2(1H)-Pyridinone
IECSC	Not in compliance with the inventory 1,3-Bis[tris(hydroxymethyl)methylamino]propane MAB / PAB 1-Hydroxy-2(1H)-Pyridinone

TSCA list

No substances are subject to a Significant New Use Rule.

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

R2**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Hydrochloric acid (theor. 100%)	7647-01-0	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 311/312 Hazards : No SARA Hazards**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.**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).

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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

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

Hydrochloric acid (theor. 100%)	7647-01-0	0.248 %
---------------------------------	-----------	---------

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

Hydrochloric acid (theor. 100%)	7647-01-0	0.248 %
---------------------------------	-----------	---------

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

US State Regulations

Massachusetts Right To Know

Hydrochloric acid (theor. 100%)	7647-01-0	0.1 - 1 %
---------------------------------	-----------	-----------

Pennsylvania Right To Know

Water	7732-18-5	90 - 100 %
Hydrochloric acid (theor. 100%)	7647-01-0	0.1 - 1 %

New Jersey Right To Know

Water	7732-18-5	90 - 100 %
1,3-Bis[tris(hydroxymethyl)methylamino]propane	64431-96-5	1 - 5 %

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

CH INV	Not in compliance with the inventory 25-Hydroxyvitamine-D2-Biotine-Conjugate
DSL	This product contains the following components that are not on the Canadian DSL nor NDSL. 1,3-Bis[tris(hydroxymethyl)methylamino]propane 1-Hydroxy-2(1H)-Pyridinone 25-Hydroxyvitamine-D2-Biotine-Conjugate
AICS	Not in compliance with the inventory 1,3-Bis[tris(hydroxymethyl)methylamino]propane 1-Hydroxy-2(1H)-Pyridinone 25-Hydroxyvitamine-D2-Biotine-Conjugate
NZIoC	On the inventory, or in compliance with the inventory
ENCS	Not in compliance with the inventory Water 1,3-Bis[tris(hydroxymethyl)methylamino]propane 1-Hydroxy-2(1H)-Pyridinone 25-Hydroxyvitamine-D2-Biotine-Conjugate
ISHL	Not in compliance with the inventory Water 1,3-Bis[tris(hydroxymethyl)methylamino]propane 1-Hydroxy-2(1H)-Pyridinone

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25-Hydroxyvitamine-D2-Biotine-Conjugate

KECI

Not in compliance with the inventory
1,3-Bis[tris(hydroxymethyl)methylamino]propane
1-Hydroxy-2(1H)-Pyridinone
25-Hydroxyvitamine-D2-Biotine-Conjugate

PICCS

Not in compliance with the inventory
1,3-Bis[tris(hydroxymethyl)methylamino]propane
1-Hydroxy-2(1H)-Pyridinone
25-Hydroxyvitamine-D2-Biotine-Conjugate

IECSC

Not in compliance with the inventory
1,3-Bis[tris(hydroxymethyl)methylamino]propane
1-Hydroxy-2(1H)-Pyridinone
25-Hydroxyvitamine-D2-Biotine-Conjugate

TSCA list

No substances are subject to a Significant New Use Rule.

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

Beads (MP)**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 311/312 Hazards : No SARA Hazards**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.**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 I 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.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

US State Regulations
Massachusetts Right To Know

Sucrose	57-50-1	1 - 5 %
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Pennsylvania Right To Know

Water	7732-18-5	90 - 100 %
Sucrose	57-50-1	1 - 5 %

New Jersey Right To Know

Water	7732-18-5	90 - 100 %
Sucrose	57-50-1	1 - 5 %
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	1 - 5 %

California Permissible Exposure Limits for Chemical Contaminants

Sucrose	57-50-1
---------	---------

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

CH INV	Not in compliance with the inventory Beads
DSL	This product contains the following components that are not on the Canadian DSL nor NDSL. 1-Hydroxy-2(1H)-Pyridinone Beads
AICS	Not in compliance with the inventory 1-Hydroxy-2(1H)-Pyridinone Beads
NZIoC	On the inventory, or in compliance with the inventory
ENCS	Not in compliance with the inventory Water Sucrose 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid Albumin from bovine plasma 1-Hydroxy-2(1H)-Pyridinone 2-Methyl-4-isothiazolin-3-on, hydrochloride Beads
ISHL	Not in compliance with the inventory Water Sucrose 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid Albumin from bovine plasma 1-Hydroxy-2(1H)-Pyridinone 2-Methyl-4-isothiazolin-3-on, hydrochloride Beads
KECI	Not in compliance with the inventory 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid 1-Hydroxy-2(1H)-Pyridinone Beads

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PICCS	Not in compliance with the inventory 1-Hydroxy-2(1H)-Pyridinone Beads
IECSC	Not in compliance with the inventory 1-Hydroxy-2(1H)-Pyridinone Beads

TSCA list

No substances are subject to a Significant New Use Rule.

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

PT1**EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium hydroxide	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 311/312 Hazards : Acute Health Hazard**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.**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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Ethylene carbonate	96-49-1	4.565 %
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Clean Water Act

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

Sodium hydroxide	1310-73-2	0.151 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium hydroxide	1310-73-2	0.151 %
------------------	-----------	---------

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

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Vitamin D total G2 Elecsys cobas e 100

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US State Regulations

Massachusetts Right To Know

Ethylene carbonate	96-49-1	1 - 5 %
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Pennsylvania Right To Know

Water	7732-18-5	90 - 100 %
Ethylene carbonate	96-49-1	1 - 5 %
Sodium hydroxide	1310-73-2	0.1 - 1 %

New Jersey Right To Know

Water	7732-18-5	90 - 100 %
Ethylene carbonate	96-49-1	1 - 5 %

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

CH INV	On the inventory, or in compliance with the inventory
DSL	All components of this product are on the Canadian DSL
AICS	On the inventory, or in compliance with the inventory
NZIoC	On the inventory, or in compliance with the inventory
ENCS	Not in compliance with the inventory Water 1,4-Dithiothreitol (DTT)
ISHL	Not in compliance with the inventory Water 1,4-Dithiothreitol (DTT)
KECI	Not in compliance with the inventory 1,4-Dithiothreitol (DTT)
PICCS	On the inventory, or in compliance with the inventory
IECSC	On the inventory, or 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.

PT2

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium hydroxide	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.

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- SARA 311/312 Hazards** : Acute Health Hazard
- SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
- 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

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

Sodium hydroxide	1310-73-2	2.729 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium hydroxide	1310-73-2	2.729 %
------------------	-----------	---------

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

US State Regulations
Massachusetts Right To Know

Sodium hydroxide	1310-73-2	1 - 5 %
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Pennsylvania Right To Know

Water	7732-18-5	90 - 100 %
Sodium hydroxide	1310-73-2	1 - 5 %

New Jersey Right To Know

Water	7732-18-5	90 - 100 %
Sodium hydroxide	1310-73-2	1 - 5 %

California List of Hazardous Substances

Sodium hydroxide	1310-73-2
------------------	-----------

California Permissible Exposure Limits for Chemical Contaminants

Sodium hydroxide	1310-73-2
------------------	-----------

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

CH INV	On the inventory, or in compliance with the inventory
DSL	All components of this product are on the Canadian DSL
AICS	On the inventory, or in compliance with the inventory
NZIoC	On the inventory, or in compliance with the inventory
ENCS	Not in compliance with the inventory Water

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ISHL	Not in compliance with the inventory Water
KECI	On the inventory, or in compliance with the inventory
PICCS	On the inventory, or in compliance with the inventory
IECSC	On the inventory, or 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.

R1**GHS label elements**

Not a hazardous substance or mixture.

R2**GHS label elements**

Not a hazardous substance or mixture.

Beads (MP)**GHS label elements**

Not a hazardous substance or mixture.

PT1**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H318 Causes serious eye damage.

Precautionary Statements : **Prevention:**
P280 Wear eye protection/ face protection.

Response:
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

PT2

Vitamin D total G2 Elecsys cobas e 100Version
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Hazard pictograms

:



Signal Word

: Warning

Hazard Statements

: H290 May be corrosive to metals.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

Precautionary Statements

: **Prevention:**
P234 Keep only in original container.
P264 Wash skin thoroughly after handling.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.
P390 Absorb spillage to prevent material damage.
Storage:
P406 Store in corrosive resistant container with a resistant inner liner.**SECTION 16. OTHER INFORMATION****Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; 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

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Roche

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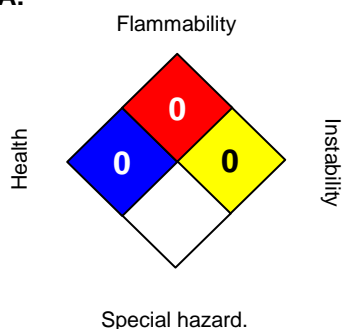
Date of last issue: 04-21-2016
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Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory 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

Further information

R1

NFPA:



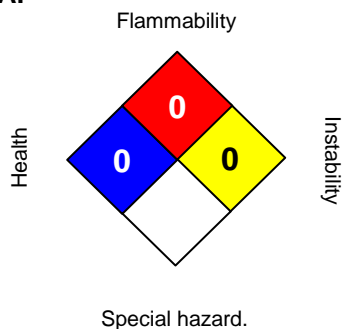
HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

R2

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

SAFETY DATA SHEET

Roche

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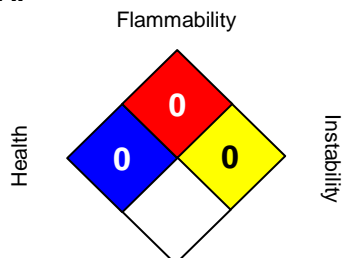
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Beads (MP)

NFPA:



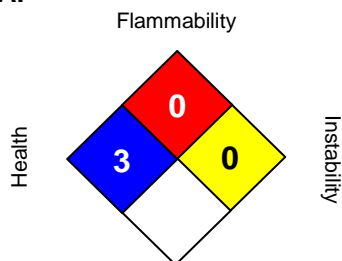
HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

PT1

NFPA:



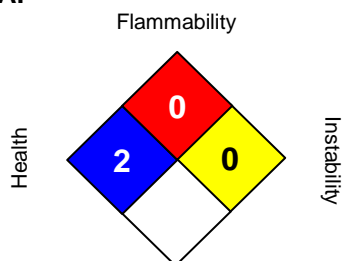
HMIS III:

HEALTH	3
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

PT2

NFPA:



HMIS III:

HEALTH	3
FLAMMABILITY	0
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date : 06-02-2016

The information provided in this Material 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 re-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.

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US / Z8 / 1511