



Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

SECTION 1. IDENTIFICATION

Product name : Elecsys Anti-HBc II
Product code : 07026790190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-

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 Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

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

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

R1

GHS Classification

Not a hazardous substance or mixture.

Hazardous ingredients

No hazardous ingredients

R2

GHS Classification

Not a hazardous substance or mixture.

Hazardous ingredients

No hazardous ingredients

Elecsys Anti-HBc II

Version
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

Beads (MP)

GHS Classification

Not a hazardous substance or mixture.

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	$\geq 1 - < 5$

Cal 1

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous ingredients

No hazardous ingredients

Cal 2

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous ingredients

No hazardous ingredients

R 0

GHS Classification

Not a hazardous substance or mixture.

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
2,3-Butanediol, 1,4-dimercapto-, (2R,3R)-rel-	3483-12-3	$\geq 1 - < 5$

SECTION 4. FIRST AID MEASURES

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.
Consult a physician after significant exposure.
If unconscious, place in recovery position and seek medical advice.
- In case of skin contact : If skin irritation persists, call a physician.



Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

- If on skin, rinse well with water.
If on clothes, remove clothes.
- 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 : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Elecsys Anti-HBc II

Version
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : Avoid formation of aerosol.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Provide sufficient air exchange and/or exhaust in work rooms.
Dispose of rinse water in accordance with local and national regulations.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Electrical installations / working materials must comply with the technological safety standards.
- 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
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	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

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

Cal 1

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Cal 2

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

R 0

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters

Ingredients	CAS-No.
2,3-Butanediol, 1,4-dimercapto-, (2R,3R)-rel-	3483-12-3

Engineering measures : No data available

Personal protective equipment

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

Hand protection

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

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 : No data available

Odor Threshold : No data available

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

pH	:	7.3 - 7.5 (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.
Self-ignition	:	Not applicable
Autoignition temperature	:	No data available
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
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	:	No data available
Odor Threshold	:	No data available

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

pH	:	7.3 - 7.5 (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.
Self-ignition	:	Not applicable
Autoignition temperature	:	No data available
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
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

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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.
Self-ignition	:	No data available
Autoignition temperature	:	No data available
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	:	1.01 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
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.

Gal 1

Appearance	:	liquid
Color	:	light yellow
Odor	:	characteristic

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

Odor Threshold	:	No data available
pH	:	7.4 (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
Self-ignition	:	No data available
Autoignition temperature	:	No data available
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	:	1.02 g/cm ³
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	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.

Cal 2

Appearance	:	liquid
Color	:	light yellow
Odor	:	characteristic
Odor Threshold	:	No data available

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

pH	:	7.4 (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
Self-ignition	:	No data available
Autoignition temperature	:	No data available
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	:	1.02 g/cm ³
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	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.

R 0

Appearance	:	liquid
Color	:	colorless
Odor	:	none
Odor Threshold	:	No data available
pH	:	4.9 (25 °C)

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Self-ignition	:	No data available
Autoignition temperature	:	No data available
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	:	1.014 g/cm ³
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	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.

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 dangerous reaction known under conditions of normal use. No decomposition if stored and applied as directed.
Conditions to avoid	:	Exposure to light.
Incompatible materials	:	Strong oxidizing agents

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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.

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.

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.

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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.

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.

Beads (MP)

Acute toxicity

Not classified based on available information.

Ingredients:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

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
Test atmosphere: dust/mist

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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.

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:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

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:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

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

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017**Aspiration toxicity**

Not classified based on available information.

Ingredients:**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

No data available

Further information**Ingredients:****.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

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

Cal 1**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.

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

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Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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.

Cal 2**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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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.

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017**R 0****Acute toxicity**

Not classified based on available information.

Ingredients:**2,3-Butanediol, 1,4-dimercapto-, (2R,3R)-rel-:**

Acute oral toxicity : LD50 Oral (Rat): 400 mg/kg

Acute toxicity (other routes of
administration) :Symptoms: May cause cardiac arrhythmia., Convulsions,
Vomiting**Skin corrosion/irritation**

Not classified based on available information.

Ingredients:**2,3-Butanediol, 1,4-dimercapto-, (2R,3R)-rel-:**

Result: Irritating to skin.

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:**2,3-Butanediol, 1,4-dimercapto-, (2R,3R)-rel-:**

Result: Irritating to eyes.

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.

Elecsys Anti-HBc II

Version
1.1

Revision Date:
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Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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.

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

Ecotoxicity

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:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Toxicity to fish : LC50: > 100 mg/l

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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:****.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

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

Mobility in soil

No data available

Other adverse effects**Cal 1****Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects**Cal 2****Ecotoxicity**

No data available

Persistence and degradability

No data available

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017**Bioaccumulative potential**

No data available

Mobility in soil

No data available

Other adverse effects**R 0****Ecotoxicity****Ingredients:****2,3-Butanediol, 1,4-dimercapto-, (2R,3R)-rel-:**Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 27 mg/l
Exposure time: 48 h**Ecotoxicology Assessment**

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:****2,3-Butanediol, 1,4-dimercapto-, (2R,3R)-rel-:**

Partition coefficient: n-octanol/water : log Pow: ca. -0.48

Mobility in soil

No data available

Other adverse effects**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

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

Contaminated packaging : Empty remaining contents.

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

R1

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium phosphate dibasic dihydrate	10028-24-7	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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

Clean Air Act

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

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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 phosphate dibasic dihydrate	10028-24-7	1.3728 %
------------------------------------	------------	----------

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

Sodium phosphate dibasic dihydrate	10028-24-7	1.3728 %
------------------------------------	------------	----------

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 phosphate dibasic dihydrate	10028-24-7
------------------------------------	------------

Pennsylvania Right To Know

Water	7732-18-5
Sodium phosphate dibasic dihydrate	10028-24-7

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California List of Hazardous Substances

Sodium phosphate dibasic dihydrate	10028-24-7
------------------------------------	------------

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

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

hydroxyl-2-pyridone

MAB / PAB

Antigen / Protein, recombinant

AICS : Not in compliance with the inventory

NZIoC : On the inventory, or 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

Elecsys Anti-HBc II

Version
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

TCSI : Not in compliance with the inventory

TSCA : Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

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

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium phosphate dibasic dihydrate	10028-24-7	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

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

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

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 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 phosphate dibasic dihydrate	10028-24-7	1.3728 %
------------------------------------	------------	----------

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

Sodium phosphate dibasic dihydrate	10028-24-7	1.3728 %
------------------------------------	------------	----------

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

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

US State Regulations

Massachusetts Right To Know

Sodium phosphate dibasic dihydrate 10028-24-7

Pennsylvania Right To Know

Water 7732-18-5
Sodium phosphate dibasic dihydrate 10028-24-7

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California List of Hazardous Substances

Sodium phosphate dibasic dihydrate 10028-24-7

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

DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL.
		Bovine Serum Albumin
		PAK<->R-IGG(DET)
		hydroxyl-2-pyridone
		MAB / PAB
AICS	:	Not in compliance with the inventory
NZIoC	:	On the inventory, or 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	:	Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

Beads (MP)

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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

Clean Air Act

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

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 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.

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

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

Pennsylvania Right To Know

Water 7732-18-5

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California Permissible Exposure Limits for Chemical Contaminants

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

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

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

hydroxyl-2-pyridone

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

Beads

AICS	:	Not in compliance with the inventory
NZIoC	:	On the inventory, or 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	:	Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

Cal 1

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 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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

Clean Air Act

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

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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.

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

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid Not Assigned

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

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

Human serum /-plasma / -hemolysate, liquid

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

Gal 2

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

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

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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

Clean Air Act

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

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 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.

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

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, liquid

Not Assigned

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

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

Human serum /-plasma / -hemolysate, liquid

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

PICCS : Not in compliance with the inventory
IECSC : Not in compliance with the inventory
TCSI : Not in compliance with the inventory
TSCA : Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

R 0

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 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : No SARA Hazards

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

Clean Air Act

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

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 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.

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

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

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

Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

Pennsylvania Right To Know

Water

7732-18-5

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

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
ISHL	:	Not in compliance with the inventory
KECI	:	Not 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
TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

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.

Cal 1

GHS label elements

Not a hazardous substance or mixture.

Cal 2

GHS label elements

Not a hazardous substance or mixture.

Elecsys Anti-HBc IIVersion
1.1Revision Date:
06-10-2017Date of last issue: 05-23-2017
Date of first issue: 05-23-2017**R 0****GHS label elements**

Not a hazardous substance or mixture.

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 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

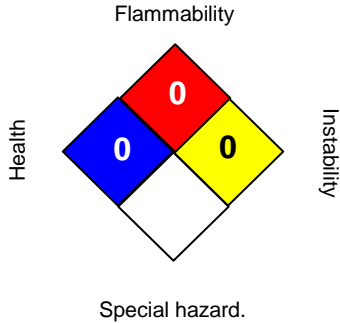
Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

NFPA:



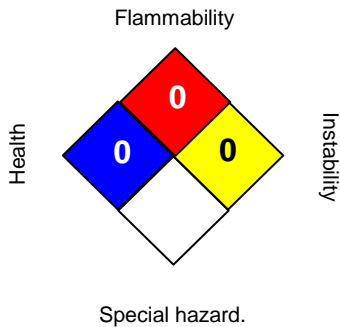
HMIS® IV:

HEALTH	/	0
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.

R2

NFPA:



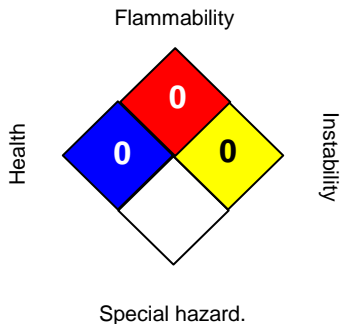
HMIS® IV:

HEALTH	/	0
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.

Beads (MP)

NFPA:



HMIS® IV:

HEALTH	/	0
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.

Cal 1

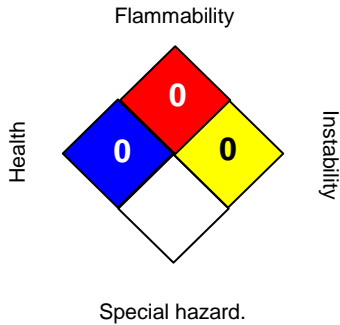
Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

NFPA:



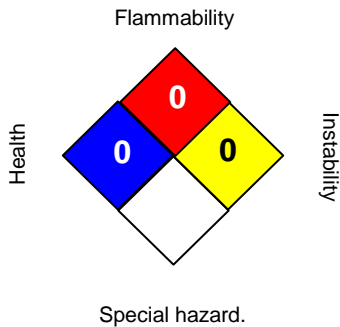
HMIS® IV:

HEALTH	/	0
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.

Cal 2

NFPA:



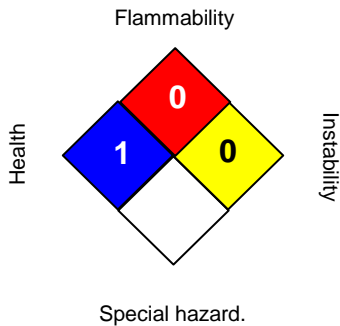
HMIS® IV:

HEALTH	/	0
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.

R 0

NFPA:



HMIS® IV:

HEALTH	/	0
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.

Revision Date : 06-10-2017



Elecsys Anti-HBc II

Version
1.1

Revision Date:
06-10-2017

Date of last issue: 05-23-2017
Date of first issue: 05-23-2017

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 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 / 1611