

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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**Cover letter for product:**Trade name : Elecsys Anti-HBs II  
Product code : 08498610190

The product is sold as a kit, and contains the following components:

- R1
- R2
- SA Coat-Beads
- Cal 1
- Cal 2

**The following is an overview of the labeling elements of the kit:****GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements :

**Prevention:**

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

**Response:**

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

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

**Disposal:**

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

**The product was evaluated per International Air Transport Association (IATA) specifications with the following outcome:**

Not assigned by regulation

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**SECTION 1: IDENTIFICATION**

Product name : R1

**Manufacturer or supplier's details**Company : Roche Diagnostics Australia  
Pty LimitedAddress : 2 Julius Avenue  
North Ryde, NSW 2113, Australia  
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619  
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

**Recommended use of the chemical and restrictions on use**Recommended use : Laboratory chemicals  
Refer to product literature for further details.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Skin sensitisation : Category 1

**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements :

**Prevention:**

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of  
the workplace.

P280 Wear protective gloves.

**Response:**

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

P333 + P313 If skin irritation or rash occurs: Get medical  
advice/ attention.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

P362 + P364 Take off contaminated clothing and wash it before reuse.

**Disposal:**

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

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

| Chemical name                                     | CAS-No.    | Concentration (% w/w) |
|---|------------|-----------------------|
| Sucrose   | 57-50-1    | < 10                  |
| n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate | 15178-76-4 | < 1                   |
| N-Methylisothiazolone hydrochloride               | 26172-54-3 | >= 0.0015 -< 0.1      |

**SECTION 4. FIRST AID MEASURES**

- General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.
- If inhaled : If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
- Notes to physician : Treat symptomatically.

**SECTION 5. FIREFIGHTING MEASURES**

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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- 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 firefighting : No information available.
- Hazardous combustion products : Nitrogen oxides (NO<sub>x</sub>)  
Sulphur oxides  
Carbon oxides
- Specific extinguishing methods : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
If the product contaminates rivers and lakes or drains inform respective authorities.
- 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.

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**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 vapours/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.  
Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- Hygiene measures : Wash hands before breaks and at the end of workday.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components | CAS-No. | Value type<br>(Form of exposure) | Control parameters /<br>Permissible concentration | Basis  |
|------------|---------|----------------------------------|---|--------|
| Sucrose    | 57-50-1 | TWA                              | 10 mg/m <sup>3</sup>                              | AU OEL |
|            |         | TWA                              | 10 mg/m <sup>3</sup>                              | ACGIH  |

**Engineering measures** : No data available

#### Personal protective equipment

Hand protection

Material : Protective gloves

Remarks : Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

---

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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Colour : colourless

Odour : none

Odour 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.

Self-ignition : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)  
Water solubility : completely miscible

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

---

|  |   |  |
|--|---|--|
| Solubility in other solvents           | : | No data available  |
| Partition coefficient: n-octanol/water | : | No data available  |
| Auto-ignition temperature              | : | No data available  |
| Decomposition temperature              | : | No data available  |
| Viscosity                              |   |  |
| Viscosity, dynamic                     | : | No data available  |
| Viscosity, kinematic                   | : | No data available  |
| Explosive properties                   | : | No data available  |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Particle characteristics               |   |  |
| Particle Size Distribution             | : | Not applicable   |

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**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |   |
|------------------------------------|---|---|
| Reactivity                         | : | No dangerous reaction known under conditions of normal use. |
| Chemical stability                 | : | Stable under normal conditions.                             |
| Possibility of hazardous reactions | : | No decomposition if stored and applied as directed.         |
| Conditions to avoid                | : | No data available   |
| Incompatible materials             | : | Strong oxidizing agents<br>Not applicable                   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.              |

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified due to lack of data.

**Components****Sucrose:**

Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**N-Methylisothiazolone hydrochloride:**

- Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg  
Method: OECD Test Guideline 425
- Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Skin corrosion/irritation**

Not classified due to lack of data.

**Product:**

Remarks : May cause skin irritation and/or dermatitis.

**Components****N-Methylisothiazolone hydrochloride:**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Causes severe burns.

**Serious eye damage/eye irritation**

Not classified due to lack of data.

**Product:**

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

**Components****n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

Result : Irritating to eyes.  
Remarks : May cause irreversible eye damage.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**N-Methylisothiazolone hydrochloride:**

Result : Risk of serious damage to eyes.

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified due to lack of data.

**Product:**

Remarks : Causes sensitisation.

**Components****n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

Result : May cause sensitisation by skin contact.

Remarks : Causes sensitisation.

**N-Methylisothiazolone hydrochloride:**

Test Type : Local lymph node assay (LLNA)

Method : OECD Test Guideline 429

Result : The product is a skin sensitiser, sub-category 1A.

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type : Maximisation Test

Species : Guinea pig

Method : OECD Test Guideline 406

Result : positive

Remarks : Based on data from similar materials

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Chronic toxicity****Germ cell mutagenicity**

Not classified due to lack of data.

**Components****Sucrose:**Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**N-Methylisothiazolone hydrochloride:**

- Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Method: OECD Test Guideline 476  
Result: negative  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 474  
Result: negative  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Test Type: unscheduled DNA synthesis assay  
Species: Rat (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 486  
Result: negative  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Carcinogenicity**

Not classified due to lack of data.

**Components****Sucrose:**

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

**n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

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

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**Reproductive toxicity**

Not classified due to lack of data.

**Components****N-Methylisothiazolone hydrochloride:**

Effects on foetal development : Species: Rat  
Application Route: Oral  
Dose: 40 mg/kg bw/day  
Result: No effects on foetal development  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**STOT - single exposure**

Not classified due to lack of data.

**Components****Sucrose:**

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

**n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

Assessment : May cause respiratory irritation.

**STOT - repeated exposure**

Not classified due to lack of data.

**Components****Sucrose:**

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

**Repeated dose toxicity****Components****N-Methylisothiazolone hydrochloride:**

Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Species : Dog

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

NOAEL : 40.9 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Aspiration toxicity**

Not classified due to lack of data.

**Components****Sucrose:**

No data available

**Further information****Product:**

Remarks : No data available

**ComponentsSucrose:**

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

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Sucrose:****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**n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:****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

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**N-Methylisothiazolone hydrochloride:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Persistence and degradability****Components:****N-Methylisothiazolone hydrochloride:**

- Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Bioaccumulative potential****Components:****Sucrose:**

- Partition coefficient: n-octanol/water : log Pow: -3.7 (20 °C)

**n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

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

**N-Methylisothiazolone hydrochloride:**

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (20 °C)  
Method: OECD Test Guideline 107

### Mobility in soil

No data available

### Other adverse effects

#### Product:

Additional ecological information : No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Do not re-use empty containers.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

#### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction : Not applicable

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

(passenger aircraft)

### IMDG-Code

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 EmS Code : Not applicable  
 Marine pollutant : Not applicable

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

Not applicable

### National Regulations

#### ADG

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 Hazchem Code : Not applicable

### Special precautions for user

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

## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : Schedule 6 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

### The components of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

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

Bovine Serum Albumin

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Protein / Antigen from bovine Origin  
n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate  
hydroxyl-2-pyridone  
MAB / PAB

|       |   |   |
|-------|---|---|
| NZIoC | : | Not in compliance with the inventory                        |
| ENCS  | : | Not in compliance with the inventory                        |
| ISHL  | : | Not in compliance with the inventory                        |
| KECI  | : | Not in compliance with the inventory                        |
| PICCS | : | Not in compliance with the inventory                        |
| IECSC | : | Not in compliance with the inventory                        |
| TCSI  | : | Not in compliance with the inventory                        |
| TSCA  | : | Product contains substance(s) not listed on TSCA inventory. |
| TECI  | : | Not in compliance with the inventory                        |

### SECTION 16: ANY OTHER RELEVANT INFORMATION

Revision Date : 22.12.2025  
Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average  
AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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 -

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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

AU / EN/ 2404

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**SECTION 1: IDENTIFICATION**

Product name : R2

**Manufacturer or supplier's details**Company : Roche Diagnostics Australia  
Pty LimitedAddress : 2 Julius Avenue  
North Ryde, NSW 2113, Australia  
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619  
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

**Recommended use of the chemical and restrictions on use**Recommended use : Laboratory chemicals  
Refer to product literature for further details.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Skin sensitisation : Category 1

**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements :

**Prevention:**

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of  
the workplace.

P280 Wear protective gloves.

**Response:**

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

P333 + P313 If skin irritation or rash occurs: Get medical  
advice/ attention.

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

P362 + P364 Take off contaminated clothing and wash it before reuse.

**Disposal:**

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name                                     | CAS-No.    | Concentration (% w/w) |
|---|------------|-----------------------|
| Sucrose   | 57-50-1    | < 10                  |
| n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate | 15178-76-4 | < 1                   |
| N-Methylisothiazolone hydrochloride               | 26172-54-3 | >= 0.0015 -< 0.1      |

### SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.
- If inhaled : If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
- Notes to physician : Treat symptomatically.

### SECTION 5. FIREFIGHTING MEASURES

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

- 
- 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 firefighting : No information available.
- Hazardous combustion products : Nitrogen oxides (NO<sub>x</sub>)  
Sulphur oxides  
Carbon oxides
- Specific extinguishing methods : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
If the product contaminates rivers and lakes or drains inform respective authorities.
- 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 vapours/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Smoking, eating and drinking should be prohibited in the application area.

Dispose of rinse water in accordance with local and national regulations.

Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

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

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Further information on storage stability : No decomposition if stored and applied as directed.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components | CAS-No. | Value type<br>(Form of exposure) | Control parameters /<br>Permissible concentration | Basis  |
|------------|---------|----------------------------------|---|--------|
| Sucrose    | 57-50-1 | TWA                              | 10 mg/m <sup>3</sup>                              | AU OEL |
|            |         | TWA                              | 10 mg/m <sup>3</sup>                              | ACGIH  |

Engineering measures : No data available

#### Personal protective equipment

Hand protection

Material : Protective gloves

Remarks : Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Colour : No data available

Odour : none

Odour 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.

Self-ignition : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Solubility(ies)  
Water solubility : completely miscible

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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|  |   |  |
|--|---|--|
| Solubility in other solvents           | : | No data available  |
| Partition coefficient: n-octanol/water | : | No data available  |
| Auto-ignition temperature              | : | No data available  |
| Decomposition temperature              | : | No data available  |
| Viscosity                              |   |  |
| Viscosity, dynamic                     | : | No data available  |
| Viscosity, kinematic                   | : | No data available  |
| Explosive properties                   | : | No data available  |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Particle characteristics               |   |  |
| Particle Size Distribution             | : | Not applicable   |

---

**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |   |
|------------------------------------|---|---|
| Reactivity                         | : | No dangerous reaction known under conditions of normal use. |
| Chemical stability                 | : | Stable under normal conditions.                             |
| Possibility of hazardous reactions | : | No decomposition if stored and applied as directed.         |
| Conditions to avoid                | : | No data available   |
| Incompatible materials             | : | Strong oxidizing agents<br>Not applicable                   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.              |

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified due to lack of data.

**Components****Sucrose:**

Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**N-Methylisothiazolone hydrochloride:**

- Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg  
Method: OECD Test Guideline 425
- Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Skin corrosion/irritation**

Not classified due to lack of data.

**Product:**

Remarks : May cause skin irritation and/or dermatitis.

**Components****N-Methylisothiazolone hydrochloride:**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Causes severe burns.

**Serious eye damage/eye irritation**

Not classified due to lack of data.

**Product:**

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

**Components****n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

Result : Irritating to eyes.  
Remarks : May cause irreversible eye damage.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

---

**N-Methylisothiazolone hydrochloride:**

Result : Risk of serious damage to eyes.

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified due to lack of data.

**Product:**

Remarks : Causes sensitisation.

**Components****n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

Result : May cause sensitisation by skin contact.

Remarks : Causes sensitisation.

**N-Methylisothiazolone hydrochloride:**

Test Type : Local lymph node assay (LLNA)

Method : OECD Test Guideline 429

Result : The product is a skin sensitiser, sub-category 1A.

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type : Maximisation Test

Species : Guinea pig

Method : OECD Test Guideline 406

Result : positive

Remarks : Based on data from similar materials

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Chronic toxicity****Germ cell mutagenicity**

Not classified due to lack of data.

**Components****Sucrose:**Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**N-Methylisothiazolone hydrochloride:**

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

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Method: OECD Test Guideline 476  
Result: negative

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 474  
Result: negative  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type: unscheduled DNA synthesis assay  
Species: Rat (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 486  
Result: negative

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Carcinogenicity**

Not classified due to lack of data.

**Components****Sucrose:**

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

**n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

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

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**Reproductive toxicity**

Not classified due to lack of data.

**Components****N-Methylisothiazolone hydrochloride:**

Effects on foetal development : Species: Rat  
Application Route: Oral  
Dose: 40 mg/kg bw/day  
Result: No effects on foetal development  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**STOT - single exposure**

Not classified due to lack of data.

**Components****Sucrose:**

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

**n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

Assessment : May cause respiratory irritation.

**STOT - repeated exposure**

Not classified due to lack of data.

**Components****Sucrose:**

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

**Repeated dose toxicity****Components****N-Methylisothiazolone hydrochloride:**

Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Species : Dog

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

NOAEL : 40.9 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Aspiration toxicity**

Not classified due to lack of data.

**Components****Sucrose:**

No data available

**Further information****Product:**

Remarks : No data available

**ComponentsSucrose:**

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

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Sucrose:****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**n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:****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

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**N-Methylisothiazolone hydrochloride:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Persistence and degradability****Components:****N-Methylisothiazolone hydrochloride:**

- Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Bioaccumulative potential****Components:****Sucrose:**

- Partition coefficient: n-octanol/water : log Pow: -3.7 (20 °C)

**n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate:**

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

**N-Methylisothiazolone hydrochloride:**

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (20 °C)  
Method: OECD Test Guideline 107

### Mobility in soil

No data available

### Other adverse effects

#### Product:

Additional ecological information : No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Do not re-use empty containers.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

#### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction : Not applicable

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

(passenger aircraft)

### IMDG-Code

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 EmS Code : Not applicable  
 Marine pollutant : Not applicable

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

Not applicable

### National Regulations

#### ADG

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 Hazchem Code : Not applicable

### Special precautions for user

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

## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : Schedule 6 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

### The components of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

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

Bovine Serum Albumin

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Protein / Antigen from bovine Origin  
n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate  
hydroxyl-2-pyridone  
MAB / PAB  
NOTUPDATED\_Streptavidin Poly  
Antigen / Protein, from human origin  
Antigen / Protein, recombinant

|       |   |   |
|-------|---|---|
| NZIoC | : | Not in compliance with the inventory                        |
| ENCS  | : | Not in compliance with the inventory                        |
| ISHL  | : | Not in compliance with the inventory                        |
| KECI  | : | Not in compliance with the inventory                        |
| PICCS | : | Not in compliance with the inventory                        |
| IECSC | : | Not in compliance with the inventory                        |
| TCSI  | : | Not in compliance with the inventory                        |
| TSCA  | : | Product contains substance(s) not listed on TSCA inventory. |
| TECI  | : | Not in compliance with the inventory                        |

### SECTION 16: ANY OTHER RELEVANT INFORMATION

Revision Date : 22.12.2025  
Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.  
  
ACGIH / TWA : 8-hour, time-weighted average  
AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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

AU / EN/ 2404

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**SECTION 1: IDENTIFICATION**

Product name : SA Coat-Beads

**Manufacturer or supplier's details**Company : Roche Diagnostics Australia  
Pty LimitedAddress : 2 Julius Avenue  
North Ryde, NSW 2113, Australia  
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619  
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

**Recommended use of the chemical and restrictions on use**Recommended use : Laboratory chemicals  
Refer to product literature for further details.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Skin sensitisation : Category 1

**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements :

**Prevention:**

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of  
the workplace.

P280 Wear protective gloves.

**Response:**

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

P333 + P313 If skin irritation or rash occurs: Get medical  
advice/ attention.

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

P362 + P364 Take off contaminated clothing and wash it before reuse.

**Disposal:**

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name                       | CAS-No.    | Concentration (% w/w) |
|-------------------------------------|------------|-----------------------|
| Sucrose                             | 57-50-1    | < 10                  |
| N-Methylisothiazolone hydrochloride | 26172-54-3 | >= 0.0015 -< 0.1      |

### SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.
- If inhaled : If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
- Notes to physician : Treat symptomatically.

### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

Specific hazards during firefighting : No information available.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Sulphur oxides

Specific extinguishing methods : The product itself does not burn.

Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for firefighters : 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.  
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.  
If the product contaminates rivers and lakes or drains inform respective authorities.

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 vapours/dust.  
Avoid exposure - obtain special instructions before use.

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.  
Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- Hygiene measures : Wash hands before breaks and at the end of workday.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components | CAS-No. | Value type<br>(Form of exposure) | Control parameters /<br>Permissible concentration | Basis  |
|------------|---------|----------------------------------|---|--------|
| Sucrose    | 57-50-1 | TWA                              | 10 mg/m <sup>3</sup>                              | AU OEL |
|            |         | TWA                              | 10 mg/m <sup>3</sup>                              | ACGIH  |

**Engineering measures** : No data available

#### Personal protective equipment

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

Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Filter type : Particulates type

Hand protection

In case of contact through splashing:

Material : Nitrile rubber  
Break through time : > 30 min

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Glove thickness : &gt; 0.11 mm

In case of full contact:

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

Remarks : Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid, Contains microparticles

Colour : clear, colourless, red brown

Odour : odourless

Odour Threshold : No data available

pH : 7.1 - 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

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

|  |   |   |
|--|---|---|
| Flammability (solid, gas)                        | : | The product is not flammable., Does not sustain combustion. |
| Flammability (liquids)                           | : | Does not sustain combustion.                                |
| Self-ignition                                    | : | Not applicable  |
| Upper explosion limit / Upper flammability limit | : | No data available   |
| Lower explosion limit / Lower flammability limit | : | No data available   |
| Vapour pressure                                  | : | No data available   |
| Relative vapour density                          | : | No data available   |
| Relative density                                 | : | No data available   |
| Density  | : | 1.01 g/cm <sup>3</sup> (20 °C)                              |
| Solubility(ies)                                  |   |   |
| Water solubility                                 | : | completely miscible   |
| Solubility in other solvents                     | : | No data available   |
| Partition coefficient: n-octanol/water           | : | No data available   |
| Auto-ignition temperature                        | : | No data available   |
| Decomposition temperature                        | : | No data available   |
| Viscosity  |   |   |
| Viscosity, dynamic                               | : | No data available   |
| Viscosity, kinematic                             | : | No data available   |
| Explosive properties                             | : | Not explosive<br>Expert judgement                           |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing.    |
| Particle characteristics                         |   |   |
| Particle Size Distribution                       | : | Not applicable  |

### SECTION 10. STABILITY AND REACTIVITY

|                    |   |   |
|--------------------|---|---|
| Reactivity         | : | No dangerous reaction known under conditions of normal use. |
| Chemical stability | : | Stable under normal conditions.                             |

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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|                                    |   |   |
|------------------------------------|---|---|
| Possibility of hazardous reactions | : | No decomposition if stored and applied as directed. |
| Conditions to avoid                | : | No data available                                   |
| Incompatible materials             | : | Not applicable                                      |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.      |

---

**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified due to lack of data.

**Components****Sucrose:**

Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg

**N-Methylisothiazolone hydrochloride:**Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg  
Method: OECD Test Guideline 425Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-oneAcute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one**Skin corrosion/irritation**

Not classified due to lack of data.

**Product:**

Remarks : May cause skin irritation and/or dermatitis.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**Components****N-Methylisothiazolone hydrochloride:**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Causes severe burns.

**Serious eye damage/eye irritation**

Not classified due to lack of data.

**Product:**

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

**Components****N-Methylisothiazolone hydrochloride:**

Result : Risk of serious damage to eyes.

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified due to lack of data.

**Product:**

Remarks : Causes sensitisation.

**Components****N-Methylisothiazolone hydrochloride:**

Test Type : Local lymph node assay (LLNA)  
Method : OECD Test Guideline 429  
Result : The product is a skin sensitiser, sub-category 1A.  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type : Maximisation Test  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : positive  
Remarks : Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Chronic toxicity****Germ cell mutagenicity**

Not classified due to lack of data.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**Components****Sucrose:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

**N-Methylisothiazolone hydrochloride:**

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

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Method: OECD Test Guideline 476  
Result: negative

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 474  
Result: negative  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type: unscheduled DNA synthesis assay  
Species: Rat (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 486  
Result: negative

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Carcinogenicity**

Not classified due to lack of data.

**Components****Sucrose:**

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

**Reproductive toxicity**

Not classified due to lack of data.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**Components****N-Methylisothiazolone hydrochloride:**

Effects on foetal development : Species: Rat  
Application Route: Oral  
Dose: 40 mg/kg bw/day  
Result: No effects on foetal development  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**STOT - single exposure**

Based on available data, the classification criteria are not met.

**Product:**

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

**Components****Sucrose:**

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

**STOT - repeated exposure**

Based on available data, the classification criteria are not met.

**Product:**

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

**Components****Sucrose:**

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

**Repeated dose toxicity****Components****N-Methylisothiazolone hydrochloride:**

Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Species : Dog

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

NOAEL : 40.9 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Aspiration toxicity**

Not classified due to lack of data.

**Components****Sucrose:**

No data available

**Further information****Product:**

Remarks : No data available

**ComponentsSucrose:**

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

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Product:****Ecotoxicology Assessment**

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

**Components:****Sucrose:****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**N-Methylisothiazolone hydrochloride:**Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

- The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

### Persistence and degradability

#### Components:

##### **N-Methylisothiazolone hydrochloride:**

Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### Bioaccumulative potential

#### Components:

##### **Sucrose:**

Partition coefficient: n-octanol/water : log Pow: -3.7 (20 °C)

##### **N-Methylisothiazolone hydrochloride:**

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (20 °C)  
Method: OECD Test Guideline 107

### Mobility in soil

No data available

### Other adverse effects

#### Product:

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Additional ecological information : No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

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

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Do not re-use empty containers.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

##### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

##### IMDG-Code

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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

Not applicable

### National Regulations

#### ADG

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 Hazchem Code : Not applicable

### Special precautions for user

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

## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

### The components of this product are reported in the following inventories:

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
 hydroxyl-2-pyridone  
 Beads

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

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

|       |   |   |
|-------|---|---|
| IECSC | : | Not in compliance with the inventory                        |
| TCSI  | : | Not in compliance with the inventory                        |
| TSCA  | : | Product contains substance(s) not listed on TSCA inventory. |
| TECI  | : | Not in compliance with the inventory                        |

### SECTION 16: ANY OTHER RELEVANT INFORMATION

|               |   |            |
|---------------|---|------------|
| Revision Date | : | 22.12.2025 |
| Date format   | : | dd.mm.yyyy |

#### Full text of other abbreviations

|        |   |  |
|--------|---|--|
| ACGIH  | : | USA. ACGIH Threshold Limit Values (TLV)                            |
| AU OEL | : | Australia. Workplace Exposure Standards for Airborne Contaminants. |

|              |   |   |
|--------------|---|---|
| ACGIH / TWA  | : | 8-hour, time-weighted average             |
| AU OEL / TWA | : | Exposure standard - time weighted average |

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of

**Elecsys Anti-HBs II**

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

---

Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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

AU / EN/ 2404

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**SECTION 1: IDENTIFICATION**

Product name : Cal 1

**Manufacturer or supplier's details**Company : Roche Diagnostics Australia  
Pty LimitedAddress : 2 Julius Avenue  
North Ryde, NSW 2113, Australia  
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619  
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

**Recommended use of the chemical and restrictions on use**Recommended use : Laboratory chemicals  
Refer to product literature for further details.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Skin sensitisation : Category 1

**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements :

**Prevention:**

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of  
the workplace.

P280 Wear protective gloves.

**Response:**

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

P333 + P313 If skin irritation or rash occurs: Get medical  
advice/ attention.

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

P362 + P364 Take off contaminated clothing and wash it before reuse.

**Disposal:**

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture  
Chemical nature : Handle as potentially infectious.

**Components**

| Chemical name                       | CAS-No.    | Concentration (% w/w) |
|-------------------------------------|------------|-----------------------|
| N-Methylisothiazolone hydrochloride | 26172-54-3 | >= 0.0015 -< 0.1      |

### SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.

Notes to physician : Treat symptomatically.

### SECTION 5. FIREFIGHTING MEASURES

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

- 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 firefighting : No information available.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Sulphur oxides
- Specific extinguishing methods : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for firefighters : 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.  
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.  
If the product contaminates rivers and lakes or drains inform respective authorities.
- 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 vapours/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Smoking, eating and drinking should be prohibited in the application area.

Dispose of rinse water in accordance with local and national regulations.

Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

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

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Further information on storage stability : No decomposition if stored and applied as directed.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

#### Personal protective equipment

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

#### Hand protection

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

In case of full contact:  
Material : butyl-rubber  
Break through time : > 480 min  
Glove thickness : > 0.4 mm

Remarks : Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Colour : light yellow

Odour : characteristic

Odour 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

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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|  |   |  |
|--|---|--|
| Density                                | : | 1.009 g/cm <sup>3</sup>                                  |
| Solubility(ies)                        | : |  |
| Water solubility                       | : | completely miscible                                      |
| Solubility in other solvents           | : | No data available  |
| Partition coefficient: n-octanol/water | : | No data available  |
| Auto-ignition temperature              | : | No data available  |
| Decomposition temperature              | : | No data available  |
| Viscosity                              | : |  |
| Viscosity, dynamic                     | : | No data available  |
| Viscosity, kinematic                   | : | No data available  |
| Explosive properties                   | : | Not explosive  |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Particle characteristics               | : |  |
| Particle Size Distribution             | : | Not applicable   |

---

**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |   |
|------------------------------------|---|---|
| Reactivity                         | : | No dangerous reaction known under conditions of normal use. |
| Chemical stability                 | : | Stable under normal conditions.                             |
| Possibility of hazardous reactions | : | No decomposition if stored and applied as directed.         |
| Conditions to avoid                | : | No data available   |
| Incompatible materials             | : | Strong oxidizing agents<br>Not applicable                   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.              |

---

**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified due to lack of data.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**Components****N-Methylisothiazolone hydrochloride:**

- Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg  
Method: OECD Test Guideline 425
- Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Skin corrosion/irritation**

Not classified due to lack of data.

**Product:**

- Remarks : May cause skin irritation and/or dermatitis.

**Components****N-Methylisothiazolone hydrochloride:**

- Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Causes severe burns.

**Serious eye damage/eye irritation**

Not classified due to lack of data.

**Product:**

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

**Components****N-Methylisothiazolone hydrochloride:**

- Result : Risk of serious damage to eyes.

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**Respiratory sensitisation**

Not classified due to lack of data.

**Product:**

Remarks : Causes sensitisation.

**Components****N-Methylisothiazolone hydrochloride:**

Test Type : Local lymph node assay (LLNA)  
Method : OECD Test Guideline 429  
Result : The product is a skin sensitiser, sub-category 1A.  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type : Maximisation Test  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : positive  
Remarks : Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Chronic toxicity****Germ cell mutagenicity**

Not classified due to lack of data.

**Components****N-Methylisothiazolone hydrochloride:**

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

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Method: OECD Test Guideline 476  
Result: negative

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 474  
Result: negative  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type: unscheduled DNA synthesis assay  
Species: Rat (male and female)

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Application Route: Oral  
Method: OECD Test Guideline 486  
Result: negative  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Carcinogenicity**

Not classified due to lack of data.

**Reproductive toxicity**

Not classified due to lack of data.

**Components****N-Methylisothiazolone hydrochloride:**

Effects on foetal development : Species: Rat  
Application Route: Oral  
Dose: 40 mg/kg bw/day  
Result: No effects on foetal development  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**STOT - single exposure**

Not classified due to lack of data.

**STOT - repeated exposure**

Not classified due to lack of data.

**Repeated dose toxicity****Components****N-Methylisothiazolone hydrochloride:**

Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Species : Dog  
NOAEL : 40.9 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Aspiration toxicity**

Not classified due to lack of data.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**Further information****Product:**

Remarks : No data available

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****N-Methylisothiazolone hydrochloride:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Persistence and degradability****Components:****N-Methylisothiazolone hydrochloride:**

- Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Bioaccumulative potential****Components:****N-Methylisothiazolone hydrochloride:**

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (20 °C)  
Method: OECD Test Guideline 107

### Mobility in soil

No data available

### Other adverse effects

#### Product:

Additional ecological information : No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Do not re-use empty containers.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

#### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction : Not applicable

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

(passenger aircraft)

### IMDG-Code

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 EmS Code : Not applicable  
 Marine pollutant : Not applicable

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

Not applicable

### National Regulations

#### ADG

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 Hazchem Code : Not applicable

### Special precautions for user

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

## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)  
 Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

### The components of this product are reported in the following inventories:

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

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

hydroxyl-2-pyridone

|       |   |   |
|-------|---|---|
| NZIoC | : | Not in compliance with the inventory                        |
| ENCS  | : | Not in compliance with the inventory                        |
| ISHL  | : | Not in compliance with the inventory                        |
| KECI  | : | Not in compliance with the inventory                        |
| PICCS | : | Not in compliance with the inventory                        |
| IECSC | : | Not in compliance with the inventory                        |
| TCSI  | : | Not in compliance with the inventory                        |
| TSCA  | : | Product contains substance(s) not listed on TSCA inventory. |
| TECI  | : | Not in compliance with the inventory                        |

### SECTION 16: ANY OTHER RELEVANT INFORMATION

Revision Date : 22.12.2025

Date format : dd.mm.yyyy

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of

**Elecsys Anti-HBs II**

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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

AU / EN/ 2404

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**SECTION 1: IDENTIFICATION**

Product name : Cal 2

**Manufacturer or supplier's details**Company : Roche Diagnostics Australia  
Pty LimitedAddress : 2 Julius Avenue  
North Ryde, NSW 2113, Australia  
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619  
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

**Recommended use of the chemical and restrictions on use**Recommended use : Laboratory chemicals  
Refer to product literature for further details.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Skin sensitisation : Category 1

**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements :

**Prevention:**

P261 Avoid breathing mist or vapours.

P272 Contaminated work clothing should not be allowed out of  
the workplace.

P280 Wear protective gloves.

**Response:**

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

P333 + P313 If skin irritation or rash occurs: Get medical  
advice/ attention.

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

P362 + P364 Take off contaminated clothing and wash it before reuse.

**Disposal:**

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

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture  
Chemical nature : Handle as potentially infectious.

**Components**

| Chemical name                       | CAS-No.    | Concentration (% w/w) |
|-------------------------------------|------------|-----------------------|
| N-Methylisothiazolone hydrochloride | 26172-54-3 | >= 0.0015 -< 0.1      |

### SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.

Notes to physician : Treat symptomatically.

### SECTION 5. FIREFIGHTING MEASURES

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

- 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 firefighting : No information available.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NOx)  
Sulphur oxides
- Specific extinguishing methods : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for firefighters : 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.  
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.  
If the product contaminates rivers and lakes or drains inform respective authorities.
- 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 vapours/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Smoking, eating and drinking should be prohibited in the application area.

Dispose of rinse water in accordance with local and national regulations.

Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

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

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Further information on storage stability : No decomposition if stored and applied as directed.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

#### Personal protective equipment

Hand protection

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

In case of full contact:  
Material : butyl-rubber  
Break through time : > 480 min  
Glove thickness : > 0.4 mm

Remarks : Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. The suitability for a specific

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

workplace should be discussed with the producers of the protective gloves.

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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Colour : light yellow

Odour : characteristic

Odour 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

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.009 g/cm<sup>3</sup>

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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|  |   |  |
|--|---|--|
| Solubility(ies)                        |   |  |
| Water solubility                       | : | completely miscible                                      |
| Solubility in other solvents           | : | No data available  |
| Partition coefficient: n-octanol/water | : | No data available  |
| Auto-ignition temperature              | : | No data available  |
| Decomposition temperature              | : | No data available  |
| Viscosity                              |   |  |
| Viscosity, dynamic                     | : | No data available  |
| Viscosity, kinematic                   | : | No data available  |
| Explosive properties                   | : | Not explosive  |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |
| Particle characteristics               |   |  |
| Particle Size Distribution             | : | Not applicable   |

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**SECTION 10. STABILITY AND REACTIVITY**

|                                    |   |   |
|------------------------------------|---|---|
| Reactivity                         | : | No dangerous reaction known under conditions of normal use. |
| Chemical stability                 | : | Stable under normal conditions.                             |
| Possibility of hazardous reactions | : | No decomposition if stored and applied as directed.         |
| Conditions to avoid                | : | No data available   |
| Incompatible materials             | : | Strong oxidizing agents<br>Not applicable                   |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.              |

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified due to lack of data.

**Components****N-Methylisothiazolone hydrochloride:**

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

- Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg  
Method: OECD Test Guideline 425
- Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Skin corrosion/irritation**

Not classified due to lack of data.

**Product:**

Remarks : May cause skin irritation and/or dermatitis.

**Components****N-Methylisothiazolone hydrochloride:**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Causes severe burns.

**Serious eye damage/eye irritation**

Not classified due to lack of data.

**Product:**

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

**Components****N-Methylisothiazolone hydrochloride:**

Result : Risk of serious damage to eyes.

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified due to lack of data.

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**Product:**

Remarks : Causes sensitisation.

**Components****N-Methylisothiazolone hydrochloride:**

Test Type : Local lymph node assay (LLNA)  
Method : OECD Test Guideline 429  
Result : The product is a skin sensitiser, sub-category 1A.  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type : Maximisation Test  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : positive  
Remarks : Based on data from similar materials  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Chronic toxicity****Germ cell mutagenicity**

Not classified due to lack of data.

**Components****N-Methylisothiazolone hydrochloride:**

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

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Method: OECD Test Guideline 476  
Result: negative

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 474  
Result: negative  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Test Type: unscheduled DNA synthesis assay  
Species: Rat (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 486  
Result: negative

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Carcinogenicity**

Not classified due to lack of data.

**Reproductive toxicity**

Not classified due to lack of data.

**Components****N-Methylisothiazolone hydrochloride:**

Effects on foetal development : Species: Rat  
Application Route: Oral  
Dose: 40 mg/kg bw/day  
Result: No effects on foetal development  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**STOT - single exposure**

Not classified due to lack of data.

**STOT - repeated exposure**

Not classified due to lack of data.

**Repeated dose toxicity****Components****N-Methylisothiazolone hydrochloride:**

Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Species : Dog  
NOAEL : 40.9 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Aspiration toxicity**

Not classified due to lack of data.

**Further information****Product:**

Remarks : No data available

**Elecsys Anti-HBs II**Version  
3.1Revision Date:  
22.12.2025Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****N-Methylisothiazolone hydrochloride:**

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

**Persistence and degradability****Components:****N-Methylisothiazolone hydrochloride:**

- Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Bioaccumulative potential****Components:****N-Methylisothiazolone hydrochloride:**

- Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).
- Partition coefficient: n- : log Pow: ca. -0.44 (20 °C)

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

octanol/water

Method: OECD Test Guideline 107

### Mobility in soil

No data available

### Other adverse effects

#### Product:

Additional ecological information : No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

- Waste from residues : Do not dispose of waste into sewer.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.
- Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Do not re-use empty containers.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Environmentally hazardous : no

#### IATA-DGR

UN/ID No. : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Packing instruction (cargo aircraft) : Not applicable  
Packing instruction (passenger aircraft) : Not applicable

#### IMDG-Code

UN number : Not applicable  
Proper shipping name : Not applicable

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

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

Not applicable

### National Regulations

#### ADG

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

### Special precautions for user

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

## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

### The components of this product are reported in the following inventories:

AiIC : Not in compliance with the inventory

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

Human serum /-plasma / -hemolysate, liquid  
hydroxyl-2-pyridone

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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|       |   |   |
|-------|---|---|
| ISHL  | : | Not in compliance with the inventory                        |
| KECI  | : | Not in compliance with the inventory                        |
| PICCS | : | Not in compliance with the inventory                        |
| IECSC | : | Not in compliance with the inventory                        |
| TCSI  | : | Not in compliance with the inventory                        |
| TSCA  | : | Product contains substance(s) not listed on TSCA inventory. |
| TECI  | : | Not in compliance with the inventory                        |

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### SECTION 16: ANY OTHER RELEVANT INFORMATION

Revision Date : 22.12.2025  
Date format : dd.mm.yyyy

#### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation

**Elecsys Anti-HBs II**

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
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and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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

AU / EN/ 2404

# SAFETY DATA SHEET



## Elecsys Anti-HBs II

Version  
3.1

Revision Date:  
22.12.2025

Date of last issue: 22.12.2025  
Date of first issue: 24.09.2018

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