

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

## ISD Everolimus PC Elecsys

Version  
1.0

Revision Date:  
04.03.2015

Date of last issue: -  
Date of first issue: 04.03.2015

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Commercial Product Name : ISD Everolimus PC Elecsys  
Mat.-No./ Genisys-No. : 07294131190

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended restrictions : For professional users only.  
on use

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
-  
Sandhoferstrasse 116  
68305 Mannheim  
E-mail address : mannheim.umweltschutz@roche.com  
Telephone : +496217590  
Telefax : +496217592890  
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

#### 1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203  
Roche Diagnostics GmbH  
  
Centre for detoxification: : Mainz +49(0)6131-19240  
Munich +49(0)89-19240

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

##### Additional Labelling:

EUH210 Safety data sheet available on request.

#### 2.3 Other hazards

See SECTION 3

### SECTION 3: Composition/information on ingredients

#### Level 1 - 3

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### Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

### Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

### Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
Edetic acid disodium salt dihydrate (EDTA- 2Na-2H <sub>2</sub> O)	6381-92-6	Xn; Xn; R20	Acute Tox. 4; H332	>= 1 - < 10

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

- General advice : Do not leave the victim unattended.
- If inhaled : Move to fresh air.  
If unconscious place in recovery position and seek medical advice.  
If symptoms persist, call a physician.
- In case of skin contact : If on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
Remove contact lenses.  
Protect unharmed eye.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.

### 4.2 Most important symptoms and effects, both acute and delayed

None known.

### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

#### 5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

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

### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Avoid dust formation.

#### 6.2 Environmental precautions

Environmental precautions : Local authorities should be advised if significant spillages cannot be contained.

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Pick up and arrange disposal without creating dust.  
Sweep up and shovel.  
Keep in suitable, closed containers for disposal.

#### 6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.

Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

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### 7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Advice on common storage : No materials to be especially mentioned.
- Storage class (TRGS 510) : 11, Combustible Solids
- Other data : No decomposition if stored and applied as directed.

### 7.3 Specific end use(s)

- Specific use(s) : Laboratory chemicals

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### **Level 1 - 3**

Contains no substances with occupational exposure limit values.

### 8.2 Exposure controls

#### **Personal protective equipment**

- Eye protection : Safety glasses

#### Hand protection

- Material : Protective gloves

- Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. 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. 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. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

- Skin and body protection : Protective suit

- Respiratory protection : No personal respiratory protective equipment normally required.

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

##### **Level 1 - 3**

Appearance	: (lyophilised)
Colour	: red brown
Odour	: characteristic very faint
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: Sustains combustion
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: soluble
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

#### 9.2 Other information

##### **Level 1 - 3**

No data available

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

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### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : Stable under recommended storage conditions.  
No hazards to be specially mentioned.

### 10.4 Conditions to avoid

No data available

### 10.5 Incompatible materials

No data available

### 10.6 Hazardous decomposition products

No data available

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

#### **Level 1 - 3**

#### **Acute toxicity**

Not classified based on available information.

#### **Components:**

#### **Edetic acid disodium salt dihydrate (EDTA-2Na-2H<sub>2</sub>O):**

Acute oral toxicity : LD<sub>50</sub> Oral (Rat): > 2.000 mg/kg  
Test substance: anhydrous substance

LD<sub>50</sub> Oral (Rabbit): 2.300 mg/kg

Acute inhalation toxicity : LC<sub>50</sub> (Rat): 1 - 5 mg/l  
Exposure time: 6 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Test substance: anhydrous substance

Acute toxicity estimate: 1,5 mg/l  
Test atmosphere: dust/mist  
Method: Expert judgement

#### **Skin corrosion/irritation**

Not classified based on available information.

#### **Serious eye damage/eye irritation**

Not classified based on available information.

#### **Respiratory or skin sensitisation**

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

#### **Germ cell mutagenicity**

Not classified based on available information.

#### **Components:**

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### Edetic acid disodium salt dihydrate (EDTA-2Na-2H<sub>2</sub>O):

Genotoxicity in vitro : Test Type: Ames test  
Remarks: In vitro tests did not show mutagenic effects

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Not classified based on available information.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Aspiration toxicity

Not classified based on available information.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Level 1 - 3

#### Components:

#### Edetic acid disodium salt dihydrate (EDTA-2Na-2H<sub>2</sub>O):

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): ca. 320 mg/l  
Exposure time: 96 h  
Test substance: anhydrous substance  
  
LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): > 100 mg/l  
Exposure time: 24 h

Toxicity to algae : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l  
Exposure time: 72 h

Toxicity to bacteria : EC50 (Pseudomonas putida): 56 mg/l  
Exposure time: 8 h  
Test substance: anhydrous substance

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

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### 12.2 Persistence and degradability

#### **Level 1 - 3**

##### Components:

##### **Edetic acid disodium salt dihydrate (EDTA-2Na-2H<sub>2</sub>O):**

Biodegradability : Biodegradation: 3 %  
Method: Directive 67/548/EEC Annex V, C.4.C.  
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

Biochemical Oxygen Demand (BOD) : 10 mg/g  
Incubation time: 5 d

### 12.3 Bioaccumulative potential

#### **Level 1 - 3**

No data available

### 12.4 Mobility in soil

#### **Level 1 - 3**

No data available

### 12.5 Results of PBT and vPvB assessment

#### **Level 1 - 3**

Not relevant

### 12.6 Other adverse effects

#### **Level 1 - 3**

No data available

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

## SECTION 14: Transport information

### 14.1 UN number

Not regulated as a dangerous good



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### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

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

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

Remarks : Not applicable

## SECTION 15: Regulatory information

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

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances  
Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.  
Not applicable

Water contaminating class : WGK 1 slightly water endangering  
(Germany)

### **Level 1 - 3**

#### **Labelling (REGULATION (EC) No 1272/2008)**

Not a hazardous substance or mixture.

#### **Additional Labelling:**

EUH210 Safety data sheet available on request.

### 15.2 Chemical Safety Assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

## SECTION 16: Other information

#### **Full text of R-Phrases**

R20 : Harmful by inhalation.

#### **Full text of H-Statements**

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H332 : Harmful if inhaled.

### Full text of other abbreviations

Acute Tox. : Acute toxicity

### Further information

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.

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