

Version 1.3 Revision Date 09-19-2014 Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : Rubella IgG CC 5 Elecsys

Mat.-No./ Genisys-No. : 05917832160

Chemical nature : Handle as potentially infectious.

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or

Canada)

1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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

GHS Label element

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

F1

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

No hazardous ingredients

F2

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.



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Hazardous components

No hazardous ingredients

F3

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

No hazardous ingredients

F4

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

No hazardous ingredients

F5

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

No hazardous ingredients

SECTION 4. 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.

Notes to physician : The first aid procedure should be established in consultation



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with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES

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

circumstances and the surrounding environment.

Specific hazards during

firefighting

: No information available.

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment

for firefighters

Wear self-contained breathing apparatus for firefighting if

necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Avoid dust formation.

Environmental precautions : Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for

containment and cleaning up

: Pick up and arrange disposal without creating dust.

Sweep up and shovel.

Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the

application area.

Conditions for safe storage : Electrical installations / working materials must comply with

the technological safety standards.

Materials to avoid : No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

F1

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

F2

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

F3



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Components with workplace control parameters

Contains no substances with occupational exposure limit values.

F4

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

F5

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally

required.

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.

Eye protection : Safety glasses

Skin and body protection : Protective suit

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

practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

F1

Appearance : (lyophilised)

Colour : white

light yellow

Odour : none

pH : 6.9 - 7.1, (25 °C)(as aqueous solution)

Flash point : does not flash

Flammability (solid, gas) : Sustains combustion

Solubility(ies)

Water solubility : completely soluble



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Oxidizing properties : The substance or mixture is not classified as oxidizing.

F2

Appearance : (lyophilised)

Colour : white

light yellow

Odour : none

pH : 6.9 - 7.1, (25 °C)(as aqueous solution)

Flash point : does not flash

Flammability (solid, gas) : Sustains combustion

Solubility(ies)

Water solubility : completely soluble

Oxidizing properties : The substance or mixture is not classified as oxidizing.

F3

Appearance : (lyophilised)

Colour : white

light yellow

Odour : none

pH : 6.9 - 7.1, (25 °C)(as aqueous solution)

Flash point : does not flash

Flammability (solid, gas) : Sustains combustion

Solubility(ies)

Water solubility : completely soluble

Oxidizing properties : The substance or mixture is not classified as oxidizing.

F4

Appearance : (lyophilised)

Colour : white

light yellow

Odour : none

pH : 6.9 - 7.1, (25 °C)(as aqueous solution)

Flash point : does not flash



Version 1.3 Revision Date 09-19-2014 Print Date 12-06-2014

Flammability (solid, gas) : Sustains combustion

Solubility(ies)

Water solubility : completely soluble

Oxidizing properties : The substance or mixture is not classified as oxidizing.

F5

Appearance : (lyophilised)

Colour : white

light yellow

Odour : none

pH : 6.9 - 7.1, (25 °C)(as aqueous solution)

Flash point : does not flash

Flammability (solid, gas) : Sustains combustion

Solubility(ies)

Water solubility : completely soluble

Oxidizing properties : The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : Stable under normal conditions.

Possibility of hazardous

reactions

: No dangerous reaction known under conditions of normal use.

Stable under recommended storage conditions.

No hazards to be specially mentioned.

Conditions to avoid : Exposure to moisture.

Incompatible materials : Strong oxidizing agents

Hazardous decomposition

products

: No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

F1

Information on likely routes of exposure

Acute toxicity

Not classified based on available information.



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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.

Carcinogenicity

Not classified based on available information.

IARC 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.

ACGIH No component of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential

carcinogen by ACGIH.

OSHA No component of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential

carcinogen by OSHA.

NTP No component of this product present at levels greater than or

equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

F2

Information on likely routes of exposure

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.



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F4

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STOT - single exposure

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Acute toxicity

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STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

F1

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation 40 CFR Protection of Environment; Part 82 Protection of

Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks This product neither contains, nor was manufactured with a

Class I or Class II ODS as defined by the U.S. Clean Air Act

Section 602 (40 CFR 82, Subpt. A, App.A + B).

F2

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation 40 CFR Protection of Environment; Part 82 Protection of

Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks This product neither contains, nor was manufactured with a

Class I or Class II ODS as defined by the U.S. Clean Air Act

Section 602 (40 CFR 82, Subpt. A, App.A + B).

F3



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Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation 40 CFR Protection of Environment; Part 82 Protection of

Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks This product neither contains, nor was manufactured with a

Class I or Class II ODS as defined by the U.S. Clean Air Act

Section 602 (40 CFR 82, Subpt. A, App.A + B).

F4

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation 40 CFR Protection of Environment; Part 82 Protection of

Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks This product neither contains, nor was manufactured with a

Class I or Class II ODS as defined by the U.S. Clean Air Act

Section 602 (40 CFR 82, Subpt. A, App.A + B).

F5

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available



Version 1.3 Revision Date 09-19-2014 Print Date 12-06-2014

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation 40 CFR Protection of Environment; Part 82 Protection of

Stratospheric Ozone - CAA Section 602 Class I Substances

Remarks This product neither contains, nor was manufactured with a

Class I or Class II ODS as defined by the U.S. Clean Air Act

Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Special treatment as infectious material is mandatory in

compliance with local regulations (disinfection and

incineration).

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

International Regulation

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

F1

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

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

SARA 304 Extremely Hazardous Substances Reportable Quantity



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

SARA 302 : No chemicals in this material are subject to the reporting

requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

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

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

Clean Water Act

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

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

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

Massachusetts Right To Know

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, Not Assigned 90 - 100 %

lyophilized

New Jersey Right To Know

Human serum /-plasma / -hemolysate, Not Assigned 90 - 100 %

lyophilized

California Prop 65 : This product does not contain any chemicals known to State

of California to cause cancer, birth defects, or any other

reproductive harm.

F2

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

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

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

SARA 302 : No chemicals in this material are subject to the reporting

requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act



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

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

Massachusetts Right To Know

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, Not Assigned 90 - 100 %

lyophilized

New Jersey Right To Know

Human serum /-plasma / -hemolysate, Not Assigned 90 - 100 %

lyophilized

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lyophilized



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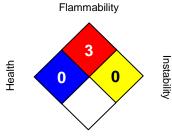


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SECTION 16. OTHER INFORMATION

Further information

F1 NFPA:



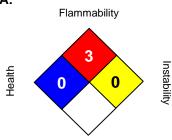
Special hazard.

HMIS III:

HEALTH	0
FLAMMABILITY	3
PHYSICAL HAZARD	0

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

F2 NFPA:



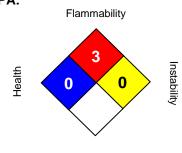
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HMIS III:

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FLAMMABILITY	3
PHYSICAL HAZARD	0

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F3 NFPA:



Special hazard.

HMIS III:

HEALTH	0
FLAMMABILITY	3
PHYSICAL HAZARD	0

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F4



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NFPA: Flammability Instability

Special hazard.

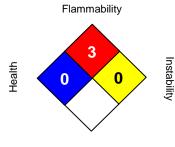
HMIS III:

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FLAMMABILITY	3
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight, 2 = Moderate, 3 = High

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F5 NFPA:



Special hazard.

HMIS III:

HEALTH	0
FLAMMABILITY	3
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,

2 = Moderate, 3 = High

4 = Extreme, * = Chronic

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