

LH CalSet II

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : LH CalSet II

Mat.-No./ Genisys-No. : 03561097190

Chemical nature : Handle as potentially infectious.

Manufacturer or supplier's details

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

Telephone : 1-800-428-5074

Emergency telephone 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

Hazard pictograms :



Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
P285 In case of inadequate ventilation wear respiratory protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

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

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.

P363 Wash contaminated clothing before reuse.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS***Calib. Low 1*****GHS Classification**

Respiratory sensitisation, Category 1

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3	>= 0.1 - < 1
α -toluenesulphonyl fluoride	329-98-6	>= 0.1 - < 1

Calib. High 2**GHS Classification**

Respiratory sensitisation, Category 1

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3	>= 0.1 - < 1
α -toluenesulphonyl fluoride	329-98-6	>= 0.1 - < 1

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.

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|-------------------------|--|
| 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 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 | : If the product contaminates rivers and lakes or drains inform respective authorities. |
| 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. |

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION***Calib. Low 1*****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Calib. High 2**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***Calib. Low 1***

Appearance : (lyophilised)

Colour : white

light yellow

Odour : none

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.

Calib. High 2

Appearance : (lyophilised)

Colour : white

light yellow

Odour : none

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

SECTION 11. TOXICOLOGICAL INFORMATION***Calib. Low 1*****Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Components: **α -toluenesulphonyl fluoride:**

Acute oral toxicity : LD50 Oral (Mouse): 200 mg/kg

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Skin corrosion/irritation

Not classified based on available information.

Components:**2-methyl-2H-isothiazol-3-one hydrochloride:**

Result: Causes burns.

 α -toluenesulphonyl fluoride:

Result: Causes burns.

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Not classified based on available information.

Components: **α -toluenesulphonyl fluoride:**

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:**2-methyl-2H-isothiazol-3-one hydrochloride:**

Assessment: May cause sensitisation by skin contact.

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.

Components:

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 α -toluenesulphonyl fluoride:

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

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Components: **α -toluenesulphonyl fluoride:**

No data available

Calib. High 2**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Components: **α -toluenesulphonyl fluoride:**

Acute oral toxicity : LD50 Oral (Mouse): 200 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**2-methyl-2H-isothiazol-3-one hydrochloride:**

Result: Causes burns.

 α -toluenesulphonyl fluoride:

Result: Causes burns.

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Not classified based on available information.

Components: **α -toluenesulphonyl fluoride:**

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:**2-methyl-2H-isothiazol-3-one hydrochloride:**

Assessment: May cause sensitisation by skin contact.

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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.

Components: **α -toluenesulphonyl fluoride:**

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

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Components: **α -toluenesulphonyl fluoride:**

No data available

SECTION 12. ECOLOGICAL INFORMATION***Calib. Low 1*****Ecotoxicity****Components:****2-methyl-2H-isothiazol-3-one hydrochloride:**

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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 α -toluenesulphonyl fluoride:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

Bioaccumulative potential

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).

Calib. High 2**Ecotoxicity****Components:****2-methyl-2H-isothiazol-3-one hydrochloride:**

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

 α -toluenesulphonyl fluoride:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

Product:

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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).
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***Calib. Low 1*****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 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 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

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

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

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

Massachusetts Right To Know

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	90 - 100 %
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New Jersey Right To Know

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

Calib. High 2**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

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 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

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

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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,
lyophilized

Not Assigned

90 - 100 %

New Jersey Right To Know

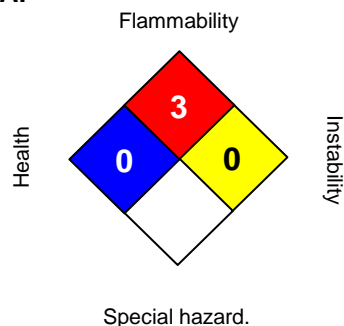
Human serum /-plasma / -hemolysate,
lyophilized

Not Assigned

90 - 100 %

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.

SECTION 16. OTHER INFORMATION**Further information****Calib. Low 1****NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	3
PHYSICAL HAZARD	0

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

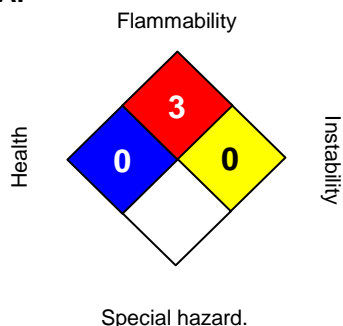
Calib. High 2

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NFPA:**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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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.