

medac Safety Data Sheet according to Regulation (EC) No. 1907/2006

Printing date 26.11.2013

Version number 1

Revision: 26.11.2013

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

1.1 Product identifier

Trade name: HiDef Detection™ HRP Polymer System (954D series), HiDef Detection™ AP Polymer System (962D series)

Article number: 954D-10, 954D-20, 954D-30, 954D40, 962D-10, 962D-20, 962D-30, 962D-40

Registration number

The dangerous components are a mixture of several substances (see chapter 3). Registration numbers are not available for these substances as the substances or their use are exempted from registration according to Article 2 REACH Regulation (EC) No. 1907/2006, the annual tonnage does not require registration or the registration is envisaged for a later registration deadline.

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

Sector of Use SU20 Health services

Product category PC21 Laboratory chemicals

Process category PROC15 Use as laboratory reagent

Application of the substance / the preparation Immunochemical reagent for detection / auxiliary reagent

Uses advised against In-vitro diagnosis.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Distributor:

Manufacturer:

Cell Marque

6600 Sierra College Blvd.

Rocklin, CA 95677, USA

Distributor:

medac

Gesellschaft für klinische Spezialpräparate mbH

Theaterstr. 6

D-22880 Wedel

Phone: ++49-4103-8006-0

Informing department:

Geschäftseinheit Diagnostika

k.dreesbach@medac.de

1.4 Emergency telephone number:

Giftinformationszentrum-Nord, Phone: ++49 551 19 240 (service in German and English, 24 hours permanently accessible).

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

Classification according to Directive 67/548/EEC or Directive 1999/45/EC



Xi; Sensitising

R43: May cause sensitisation by skin contact.

Information concerning particular hazards for human and environment: Void.

Classification system:

The classification is in line with Regulation (EC) No. 1272/2008. It is expanded, however, by information from technical literature and by information furnished by supplier companies.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms GHS07

Signal word Warning

Hazard-determining components of labelling:

mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

Hazard statements

H317 May cause an allergic skin reaction.

(Contd. on page 2)

GB

medac Safety Data Sheet according to Regulation (EC) No. 1907/2006

Printing date 26.11.2013

Version number 1

Revision: 26.11.2013

Trade name: HiDef Detection™ HRP Polymer System (954D series), HiDef Detection™ AP Polymer System (962D series)

(Contd. of page 1)

Precautionary statements

P280 Wear protective gloves / protective clothing / eye protection
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P501 Dispose of contents/container in accordance with regional/national regulations.

Additional information: Void.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Substance(s) does/do not meet the criteria for PBT according to Regulation (EC) No 1907/2006, Annex XIII.

vPvB: Substance(s) does/do not meet the criteria for vPvB according to Regulation (EC) No 1907/2006, Annex XIII.









SECTION 3: Composition/information on ingredients

3.1. Chemical characterisation: substances Not applicable. Product is a mixture.

3.2 Chemical characterization: Mixtures

Description: Water based solution

Dangerous components:

CAS: 55965-84-9 Index number: 613-167-00-5	mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)  T R23/24/25;  C R34;  Xi R43;  N R50/53  Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331  Skin Corr. 1B, H314  Aquatic Acute 1, H400; Aquatic Chronic 1, H410  Skin Sens. 1, H317	< 0.1%
---	--	--------

SVHC Not applicable.

Additional information For the wording of the listed risk phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information First aider: Take care of self-protection.

After inhalation

Supply fresh air.
Seek medical treatment in case of complaints.

After skin contact

Remove contaminated clothes.
Instantly wash with water and soap and rinse thoroughly.
If symptoms develop, consult doctor.

After eye contact

Rinse eyes cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
In case of onset of symptoms consult doctor.

After swallowing

Let rinse out mouth and then drink plenty of water.
In case of disorders consult doctor.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

Information for doctor

Show Safety Data Sheet.
Treatment according to symptoms.

Danger No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents Product itself does not burn. Use fire fighting measures that suit the environment.

For safety reasons unsuitable extinguishing agents For this mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture In the event of fire formation of toxic gases possible.

(Contd. on page 3)

medac Safety Data Sheet according to Regulation (EC) No. 1907/2006

Printing date 26.11.2013

Version number 1

Revision: 26.11.2013

Trade name: HiDef Detection™ HRP Polymer System (954D series), HiDef Detection™ AP Polymer System (962D series)

(Contd. of page 2)

5.3 Advice for firefighters

Protective equipment:

In case of burning of a larger amount:

Stay in the danger area only with self-contained breathing apparatus.

Prevent skin contact by keeping a safe distance or by wearing suitable protective clothing.

Additional information

Collect contaminated fire fighting water separately. It must not enter drains.

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid reagent contact with eyes and skin.

6.2 Environmental precautions: Do not empty into drains.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Afterwards clean with water and cleansing agent.

Dispose of the material collected according to respective national regulations.

Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Open and handle container with care.

Prevent contact with skin and eyes.

Information about protection against explosions and fires: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

No further relevant information available.

Storage

Requirements to be met by storerooms and containers: Store at +2 °C to +8 °C.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: The indications are valid for the whole package.

Storage class

Storage class 12 according to the German "Technical Rules for Hazardous Substances (TRGS) 510": Noncombustible liquids.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8: Exposure controls/personal protection

Additional information about design of technical systems: No further data; see Section 7.

8.1 Control parameters

Components with critical values that require monitoring at the workplace:

DNELs Not applicable.

PNECs Not applicable.

Ingredients with biological limit values: Void.

CAS No.	Designation of material	%	Type	Value	Unit
Additional Occupational Exposure Limit Values for possible hazards during processing: Not applicable.					

Additional Occupational Exposure Limit Values for possible hazards during processing: Not applicable.

Additional information: The official lists that were valid during the compilation were used as basis.

8.2 Exposure controls

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See Section 7.

Personal protective equipment

General protective and hygienic measures

The usual precautionary measures should be adhered to in handling the chemicals.

(Contd. on page 4)

GB

medac Safety Data Sheet

according to Regulation (EC) No. 1907/2006

Printing date 26.11.2013

Version number 1

Revision: 26.11.2013

Trade name: HiDef Detection™ HRP Polymer System (954D series), HiDef Detection™ AP Polymer System (962D series)

(Contd. of page 3)

Avoid contact with the eyes and skin.
Remove contaminated clothing immediately.
Do not eat or drink while working.
Keep away from food and beverages.
Wash hands during breaks and at the end of the work.

Breathing equipment: Not required.

Protection of hands: Disposable medical gloves (AQL 1.5)..

Material of gloves

Nitrile rubber, NBR

Natural rubber, NR

Thickness 0.11 mm.

The product quality has to comply with DIN EN 455.

Penetration time of glove material Not applicable.

For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:

Product has not been designed for permanent contact.

For the permanent contact gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Product has not been designed for permanent contact.

As protection from splashes gloves made of the following materials are suitable:

Nitrile rubber, NBR

Natural rubber, NR

Thickness: 0.11 mm.

Eye protection: Safety glasses (DIN EN 166).

Body protection: Protective work clothing.

Limitation and supervision of exposure into the environment Do not empty into drains.

Risk management measures Void.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form:	Fluid
Colour:	Colourless
Smell:	Odourless
Odour threshold:	Not determined.

Important information on protection of health and environment, and on safety.

No further relevant information available.

pH-value: No information available.

Change in condition

Melting point/Melting range:	No information available.
Boiling point/Boiling range:	No information available.

Flash point:	Not applicable.
Inflammability (solid, gaseous)	Not applicable.
Ignition temperature:	Not available.
Decomposition temperature:	No information available.
Self-inflammability:	Not self-inflammable.
Danger of explosion:	Not explosive.
Critical values for explosion:	
Lower:	Not applicable.
Upper:	Not applicable.
Oxidizing properties	Not applicable.
Steam pressure:	No information available.
Density	No information available.
Relative density	No information available.
Vapour density	No information available.
Evaporation rate	No information available.
Solubility in / Miscibility with	
Water:	Fully miscible.

(Contd. on page 5)

GB

medac Safety Data Sheet

according to Regulation (EC) No. 1907/2006

Printing date 26.11.2013

Version number 1

Revision: 26.11.2013

Trade name: HiDef Detection™ HRP Polymer System (954D series), HiDef Detection™ AP Polymer System (962D series)

(Contd. of page 4)

Partition coefficient (n-octanol/water):	Not applicable.
Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
Solvent content:	
Organic solvents:	< 0.1 %
Water:	> 80 %
Solids content:	< 10

9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

10.1 Reactivity The mixture is chemically not reactive.

10.2 Chemical stability The product is chemically stable under the indicated storage conditions.

Thermal decomposition / conditions to be avoided: No decomposition if used and stored according to specifications.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid: No further relevant information available.

10.5 Incompatible materials: No further relevant information available.

10.6 Hazardous decomposition products: No further relevant information available.

Additional information: No further relevant information available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects Data on the toxicity of this mixture are not available.

Acute toxicity:

LD/LC50 values that are relevant for classification:

55965-84-9 mixture of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1)

Oral	LD50	3350 mg/kg (rat)
Dermal	LD50	>5000 mg/kg (rab)
Inhalative	LC50/4 h	0.33 mg/l (rat)

Specific symptoms in biological assay: No further relevant information available.

Primary irritant effect:

on the skin: Slight irritations possible.

on the eye: Slight irritations possible.

after swallowing: Slight mucosal irritations in mouth, pharynx and oesophagus possible.

after inhalation: Slight irritations possible.

Sensitization: Sensitization possible by skin contact.

Other information (about experimental toxicology): No further relevant information available.

Subacute to chronic toxicity: No further relevant information available.

Additional toxicological information: No further relevant information available.

Toxicokinetics, metabolism and distribution No relevant information available.

Acute effects (acute toxicity, irritation and corrosivity) No acute toxicity information available for this product.

Sensitisation May cause sensitisation by skin contact.

Repeated dose toxicity No further relevant information available.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

No indications of CMR effects. Source: ECHA.

SECTION 12: Ecological information

12.1 Toxicity No information available.

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

Other information: No further relevant information available.

(Contd. on page 6)

GB

medac Safety Data Sheet according to Regulation (EC) No. 1907/2006

Printing date 26.11.2013

Version number 1

Revision: 26.11.2013

Trade name: HiDef Detection™ HRP Polymer System (954D series), HiDef Detection™ AP Polymer System (962D series)

(Contd. of page 5)

Behaviour in environmental systems:**Components:** Accumulation in organisms is not to be expected.**12.3 Bioaccumulative potential** Bioaccumulation is not to be expected.**12.4 Mobility in soil** No data available.**Ecotoxicological effects:****Remark:** No further relevant information available.**Additional ecological information:****General notes:**

At present there are no ecotoxicological assessments.

Water hazard class 1 (Self-assessment): slightly hazardous for water.

12.5 Results of PBT and vPvB assessment**PBT:** PBT assessment not available as chemical safety assessment not required/not conducted.**vPvB:** vPvB assessment not available as chemical safety assessment not required/not conducted.**12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product residues have to be disposed of according to the Waste Framework Directive as well as national and regional regulations in each of the latest versions.

Uncleaned packagings:**Recommendation:** Uncleaned packagings have to be disposed of in the same manner as the product residues.

SECTION 14: Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA -

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA -

14.3 Transport hazard class(es)ADR, ADN, IMDG, IATA
Class -**14.4 Packing group**

ADR, IMDG, IATA -

14.5 Environmental hazards:**Marine pollutant:** No**14.6 Special precautions for user** Not applicable.**14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable.

Transport/Additional information:

Not classified as dangerous in the meaning of transport regulations as issued in the latest version.

UN "Model Regulation": -

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**Labelling according to Regulation (EC) No 1272/2008** See Section 2.**Hazard pictograms** See Section 2.**Signal word** See Section 2.**Hazard-determining components of labelling:** See Section 2.**Hazard statements** See Section 2.**Precautionary statements** See Section 2.

(Contd. on page 7)

GB

medac Safety Data Sheet according to Regulation (EC) No. 1907/2006

Printing date 26.11.2013

Version number 1

Revision: 26.11.2013

Trade name: HiDef Detection™ HRP Polymer System (954D series), HiDef Detection™ AP Polymer System (962D series)

(Contd. of page 6)

National regulations

Information about limitation of use:

Take note of the directive on the protection of young people at work in the latest version.

Take note of the directive on the safety and health at work for pregnant and breast feeding workers in the latest version.

Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water (German regulation).

Other regulations, limitations and prohibitive regulations Void.

Substances of very high concern (SVHC) according to REACH, Article 57 Not applicable.

15.2 Chemical safety assessment: A chemical safety assessment has not been carried out.

SECTION 16: Other information

All information and recommendations are believed to be correct as of the date of this Safety Data Sheet but shall not be taken to be all inclusive and shall be used only as a guide. All chemicals and preparations may present unknown hazards and should be used with caution. medac shall not be held liable for any damage resulting from handling or from contact with the above product.

Reasons for alteration

Classification, labelling and corresponding revision in accordance with Regulation (EC) No 1272/2008 (GHS/CLP).

Relevant phrases

H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H331 Toxic if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R34 Causes burns.

R43 May cause sensitisation by skin contact.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Department issuing data specification sheet: Dept. for Product Safety

Contact:

Dr. Karen Dreesbach

k.dreesbach@medac.de

Replaces version from: -

Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organization

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent