

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : KIT CA-SCRN MP PREP/CTL 96T US-IVD

Mat.-No./ Genisys-No. : 03302555018

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

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 + H312 + H332 Harmful if swallowed, in contact with skin
or if inhaled

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ protective clothing.
Response:
P301 + P312 IF SWALLOWED: Call a POISON CENTER or
doctor/ physician if you feel unwell.
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P340 IF INHALED: Remove victim to fresh air and keep
at rest in a position comfortable for breathing.
P312 Call a POISON CENTER or doctor/ physician if you feel

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

unwell.

P330 Rinse mouth.

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***MP (+) C*****GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

MP (-) C**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

MP LYS / CMM LYS**GHS Classification**

Acute toxicity (Oral), Category 4

H302: Harmful if swallowed.

Acute toxicity (Inhalation), Category 4

H332: Harmful if inhaled.

Acute toxicity (Dermal), Category 4

H312: Harmful in contact with skin.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
guanidinium thiocyanate	593-84-0	>= 50 - < 70
(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol	27565-41-9	>= 1 - < 5

MP DIL / CMM DIL**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

MP IC**GHS Classification**

Not a hazardous substance or mixture.

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

Hazardous components

No hazardous ingredients

NHP**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 | : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
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 skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes. |
| 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 | : Clean mouth with water and drink afterwards plenty of water.
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 | : No information available. |
| 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. |
| Unsuitable extinguishing media | : High volume water jet |

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

- | | | |
|---|---|---|
| Specific hazards during firefighting | : | Do not allow run-off from fire fighting to enter drains or water courses. |
| Further information | : | Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations. |
| 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 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.
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. |
| Conditions for safe storage | : | Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards. |

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**MP (+) C****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

MP (-) C**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

MP LYS / CMM LYS**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

MP DIL / CMM DIL**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

MP IC**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

NHP**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Personal protective equipment

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	: 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.
Hygiene measures	: When using do not eat or drink. When using do not smoke. Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**MP (+) C**

Appearance : liquid

pH : 8.0

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Solubility(ies) Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

MP (-) C

Appearance	: liquid
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Solubility(ies) Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

MP LYS / CMM LYS

Appearance	: liquid
pH	: 7.5
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Solubility(ies)	

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

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

MP DIL / CMM DIL

Appearance : liquid

pH : 8.0

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Upper explosion limit : No data available

Lower explosion limit : No data available

Solubility(ies)
Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

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

MP IC

Appearance : liquid

pH : 8.0

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Upper explosion limit : No data available

Lower explosion limit : No data available

Solubility(ies)
Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

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

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

NHP

Appearance	: liquid
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
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 decomposition if stored and applied as directed.
Conditions to avoid	: No data available
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

SECTION 11. TOXICOLOGICAL INFORMATION***MP (+) C*****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
---------------------	---

Skin corrosion/irritation

Not classified based on available information.

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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.

MP (-) C**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

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.

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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.

MP LYS / CMM LYS**Information on likely routes of exposure****Acute toxicity**

Harmful if swallowed, in contact with skin or if inhaled

Product:

Acute oral toxicity : Acute toxicity estimate : 818.31 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate : 2.21 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate : 1,620 mg/kg
Method: Calculation method

Components:**guanidinium thiocyanate:**

Acute oral toxicity : LD50 Oral (Rat): 593 mg/kg

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

Acute inhalation toxicity : Acute toxicity estimate : 1.5 mg/l
Test atmosphere: dust/mist
Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate : 1,100 mg/kg
Method: Expert judgement

(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol:

Acute oral toxicity : LD50 Oral (Rat): 400 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Components:**(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol:**

Result: Irritating to skin.

Remarks: May cause skin irritation in susceptible persons.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

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

Components:**(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol:**

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

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.

Components:**guanidinium thiocyanate:**

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.

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.

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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:**(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol:**

Exposure routes: Inhalation

Target Organs: Respiratory system

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:**(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol:**

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

Aspiration toxicity

Not classified based on available information.

Components:**(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol:**

No data available

MP DIL / CMM DIL**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

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.

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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.

MP IC**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

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.

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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.

NHP**Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

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

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Product:

Remarks: Causes sensitisation.

Germ cell mutagenicity

Not classified based on available information.

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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.

SECTION 12. ECOLOGICAL INFORMATION***MP (+) C*****Ecotoxicity****Product:**

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:

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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).

MP (-) C**Ecotoxicity****Product:**

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).

MP LYS / CMM LYS**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:**guanidinium thiocyanate:**

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89.1 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): 42.4 mg/l
Exposure time: 48 h

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

Ecotoxicology Assessment
Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

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

Other organisms relevant to the environment : No data available

(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol:

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**Components:****guanidinium thiocyanate:**

Partition coefficient: n-octanol/water : log Pow: -1.38

(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol:

Partition coefficient: n-octanol/water : log Pow: -0.48 (20 °C)

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).

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

Components:**(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol:**

Additional ecological information : No data available

MP DIL / CMM DIL**Ecotoxicity****Product:**

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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).

MP IC**Ecotoxicity****Product:**

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).

NHP

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

Ecotoxicity**Product:**

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).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).
The product should not be allowed to enter drains, water courses or the soil.
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.
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

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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**MP (+) C****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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.

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

sodium azide	26628-22-8	0 - 0.1 %
--------------	------------	-----------

Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sodium azide	26628-22-8	0 - 0.1 %

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

New Jersey Right To Know

water

7732-18-5

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.

MP (-) C**EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

sodium hydroxide 1310-73-2 0.0099 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

sodium hydroxide 1310-73-2 0.0099 %

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

Massachusetts Right To Know

sodium azide

26628-22-8

0 - 0.1 %

Pennsylvania Right To Know

water

7732-18-5

90 - 100 %

sodium azide

26628-22-8

0 - 0.1 %

New Jersey Right To Know

water

7732-18-5

90 - 100 %

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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.

MP LYS / CMM LYS**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.

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

guanidinium thiocyanate	593-84-0	50 - 70 %
water	7732-18-5	20 - 30 %
(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol	27565-41-9	1 - 5 %

New Jersey Right To Know

guanidinium thiocyanate	593-84-0	50 - 70 %
water	7732-18-5	20 - 30 %
(R*,R*)-(+/-)-1,4-dimercaptobutane-2,3-diol	27565-41-9	1 - 5 %

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.

MP DIL / CMM DIL**EPCRA - Emergency Planning and Community Right-to-Know Act**

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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.

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

sodium azide	26628-22-8	0 - 0.1 %
--------------	------------	-----------

Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	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.

MP IC**EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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.

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

sodium azide	26628-22-8	0 - 0.1 %
--------------	------------	-----------

Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	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.

NHP**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.

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

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.

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

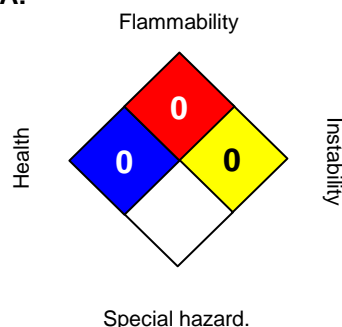
Human serum /-plasma / -hemolysate, liquid Not Assigned 90 - 100 %

New Jersey Right To Know

Human serum /-plasma / -hemolysate, liquid 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**MP (+) C****NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

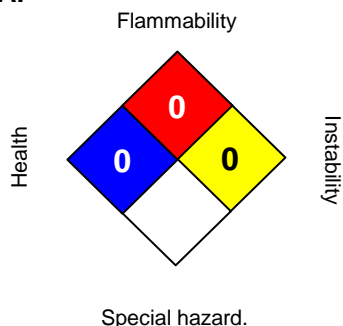
MP (-) C

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

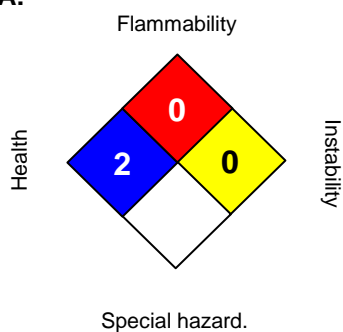
Revision Date 09-18-2014

Print Date 12-06-2014

NFPA:**HMIS III:**

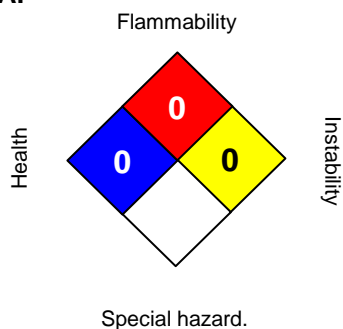
HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

MP LYS / CMM LYS**NFPA:****HMIS III:**

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

MP DIL / CMM DIL**NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

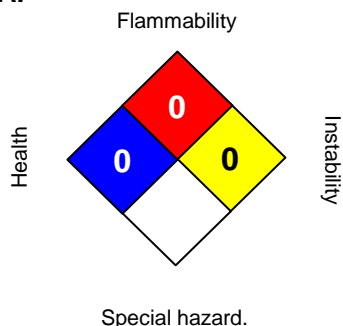
MP IC

KIT CA-SCRN MP PREP/CTL 96T US-IVD

Version 1.3

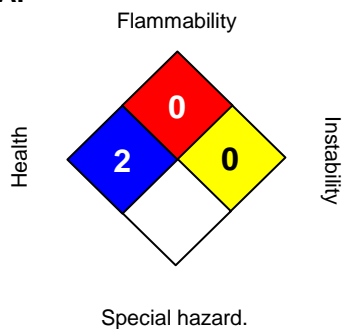
Revision Date 09-18-2014

Print Date 12-06-2014

NFPA:**HMIS III:**

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

**NHP
NFPA:****HMIS III:**

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

Revision Date : 09-18-2014

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.