

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : KIT C-TAQ HIV-1 v2 48T US-IVD

Mat.-No./ Genisys-No. : 05923450190

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

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS***HIV-1 MMX, v2*****GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
dimethyl sulfoxide	67-68-5	>= 10 - < 20
glycerol	56-81-5	>= 10 - < 20

HIV-1 QS, v2**GHS Classification**

Not a hazardous substance or mixture.

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Hazardous components

No hazardous ingredients

CS4 - [CTM Mn2+]**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Mangan(II)-acetate Tetrahydrate	6156-78-1	>= 1 - < 5

HIV-1 H(+)C, v2 (Human Plasma)**GHS Classification**

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

No hazardous ingredients

HIV-1 L(+)C, v2 (Human Plasma)]**GHS Classification**

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

No hazardous ingredients

CTM (-)C (Human Plasma)**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.

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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.
 Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION***HIV-1 MMX, v2*****Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
dimethyl sulfoxide	67-68-5	TWA	250 ppm	US WEEL
glycerol	56-81-5	TWA (mist, respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (mist, total dust)	15 mg/m ³	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m ³	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m ³	OSHA P0

HIV-1 QS, v2**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

CS4 - [CTM Mn2+]**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Mangan(II)-acetate Tetrahydrate	6156-78-1	C	5 mg/m ³ (Manganese)	OSHA Z-1
		C	5 mg/m ³	OSHA P0

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

			(Manganese)	
		TWA	1 mg/m ³ (Manganese)	NIOSH REL
		ST	3 mg/m ³ (Manganese)	NIOSH REL

HIV-1 H(+)/C, v2 (Human Plasma)**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

HIV-1 L(+)/C, v2 (Human Plasma)**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

CTM (-)/C (Human Plasma)**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***HIV-1 MMX, v2***

Appearance	: liquid
pH	: 8.1
Melting point/range	: No data available
Boiling point/boiling range	: No data available

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
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

HIV-1 QS, v2

Appearance	: liquid
pH	: 8.0
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
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

CS4 - [CTM Mn2+]

Appearance	: liquid
pH	: 6.25
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: 1.00 g/cm3

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Solubility(ies)
Water solubility : completely miscible

Auto-ignition temperature : No data available

Thermal decomposition : No data available

HIV-1 H(+)C, v2 (Human Plasma)

Appearance : liquid

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Flammability (solid, gas) : The product is not flammable.

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

HIV-1 L(+)C, v2 (Human Plasma)]

Appearance : liquid

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Flammability (solid, gas) : The product is not flammable.

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

CTM (-)C (Human Plasma)

Appearance : liquid

Melting point/range : No data available

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: The product is not flammable.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Density	: 1.026 g/cm ³
Solubility(ies)	
Water solubility	: completely miscible
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available

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***HIV-1 MMX, v2*****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:**dimethyl sulfoxide:**

Acute oral toxicity : LD50 Oral (Rat): 14,500 mg/kg
LD50 Oral (Mouse): 7,920 mg/kg

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Acute inhalation toxicity : Acute toxicity estimate : > 30 mg/l
Test atmosphere: vapour
Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rat): 40,000 mg/kg

glycerol:

Acute oral toxicity : LD50 Oral (Rat): 12,600 mg/kg

LD50 Oral (Mouse): 4,090 mg/kg

Acute inhalation toxicity : Acute toxicity estimate : > 30 mg/l
Method: Expert judgement

Acute dermal toxicity : LD50 Dermal (Rabbit): 10,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**dimethyl sulfoxide:**

Remarks: This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**dimethyl sulfoxide:**

Remarks: This information is not available.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**dimethyl sulfoxide:**

Species: Guinea pig

Result: Does not cause skin sensitisation.

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.

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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:**dimethyl sulfoxide:**

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

STOT - repeated exposure

Not classified based on available information.

Components:**dimethyl sulfoxide:**

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

Components:**dimethyl sulfoxide:**

Repeated dose toxicity - : Mild eye irritation, Mild skin irritation
Assessment

glycerol:

Repeated dose toxicity - : Mild eye irritant, Mild respiratory irritant, No skin irritation
Assessment

Aspiration toxicity

Not classified based on available information.

Components:**dimethyl sulfoxide:**

No data available

HIV-1 QS, v2**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.

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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.

CS4 - [CTM Mn2+]**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:**Mangan(II)-acetate Tetrahydrate:**

Acute oral toxicity : LD50 Oral (Rat): 3,730 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Components:**Mangan(II)-acetate Tetrahydrate:**

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:**Mangan(II)-acetate Tetrahydrate:**

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.

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:**Mangan(II)-acetate Tetrahydrate:**

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Mangan(II)-acetate Tetrahydrate:

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

Aspiration toxicity

Not classified based on available information.

Components:**Mangan(II)-acetate Tetrahydrate:**

No data available

HIV-1 H(+)/C, v2 (Human Plasma)**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.

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

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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.

HIV-1 L(+)_C, v2 (Human Plasma)**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.

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.

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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.

CTM (-)C (Human Plasma)**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.

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

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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***HIV-1 MMX, v2*****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

Components:**dimethyl sulfoxide:**

Toxicity to fish : LC50 (Fish): 32,500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 24,600 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): ca. 70,000 mg/l
Exposure time: 0.25 h

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

glycerol:

Toxicity to fish : LC50: > 100 mg/l
Exposure time: 96 h

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Toxicity to algae	: EC0 (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l Exposure time: 7 d
Toxicity to fish (Chronic toxicity)	: > 1 mg/l
Toxicity to bacteria	: EC0 (Pseudomonas putida): > 10,000 mg/l Exposure time: 16 h
Ecotoxicology Assessment	
Acute aquatic toxicity	: This product has no known ecotoxicological effects.
Chronic aquatic toxicity	: This product has no known ecotoxicological effects.
Toxicity Data on Soil	: Not expected to adsorb on soil.
Other organisms relevant to the environment	: No data available

Persistence and degradability**Components:****dimethyl sulfoxide:**

Biodegradability	: Biodegradation: 4 % Exposure time: 1 d
	Biodegradation: 6 % Exposure time: 8 d
	Biodegradation: 29 % Exposure time: 15 d
	Biodegradation: 90 % Exposure time: 28 d Method: OECD Test Guideline 302

glycerol:

Biodegradability	: Remarks: The product is miscible in water and readily biodegradable in both water and soil. Accumulation is not expected.
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Bioaccumulative potential**Components:****dimethyl sulfoxide:**

Partition coefficient: n-octanol/water	: log Pow: -1.35
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glycerol:

Partition coefficient: n-octanol/water	: log Pow: -2.66
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Mobility in soil

No data available

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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).

HIV-1 QS, v2**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

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

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

Other organisms relevant to the environment : No data available

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).

CS4 - [CTM Mn2+]**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

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

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

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Other organisms relevant to the environment : No data available

Components:**Mangan(II)-acetate Tetrahydrate:**

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).

Components:**Mangan(II)-acetate Tetrahydrate:**

Additional ecological information : No data available

HIV-1 H(+)/C, v2 (Human Plasma)**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

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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).

HIV-1 L(+)_C, v2 (Human Plasma)**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).

CTM (-)_C (Human Plasma)**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

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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).
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

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

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***HIV-1 MMX, v2***

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

dimethyl sulfoxide	67-68-5	18.5 %
glycerol	56-81-5	16.8 %

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

glycerol	56-81-5	10 - 20 %
sodium azide	26628-22-8	0 - 0.1 %

Pennsylvania Right To Know

water	7732-18-5	30 - 50 %
dimethyl sulfoxide	67-68-5	10 - 20 %
glycerol	56-81-5	10 - 20 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	30 - 50 %
dimethyl sulfoxide	67-68-5	10 - 20 %
glycerol	56-81-5	10 - 20 %
potassium acetate	127-08-2	1 - 5 %
N-(tri(hydroxymethyl)methyl)glycine	5704-04-1	1 - 5 %

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

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.

HIV-1 QS, v2**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 %
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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 %
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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.

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

CS4 - [CTM Mn2+]**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 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Mangan(II)-acetate Tetrahydrate	6156-78-1	1.23 %
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Clean Air Act

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 12 (40 CFR 61):

Mangan(II)-acetate Tetrahydrate	6156-78-1	1.23 %
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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:

acetic acid	64-19-7	0.0099 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

acetic acid	64-19-7	0.0099 %
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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 %
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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 %
Mangan(II)-acetate Tetrahydrate	6156-78-1	1 - 5 %

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

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.

HIV-1 H(+)/C, v2 (Human Plasma)**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

water	7732-18-5	90 - 100 %
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New Jersey Right To Know

water	7732-18-5	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.

HIV-1 L(+)/C, v2 (Human Plasma)**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.

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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

water	7732-18-5	90 - 100 %
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New Jersey Right To Know

water	7732-18-5	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.

CTM (-)C (Human Plasma)**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).

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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

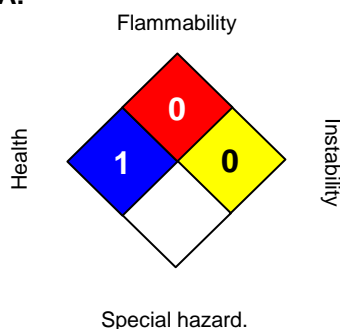
Human serum /-plasma / -hemolysate, liquid Not Assigned 90 - 100 %

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
HIV-1 MMX, v2
NFPA:

HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

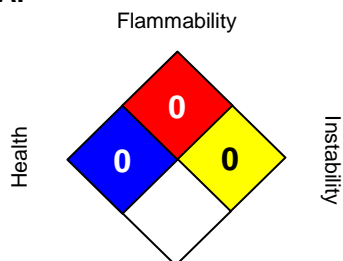
HIV-1 QS, v2

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

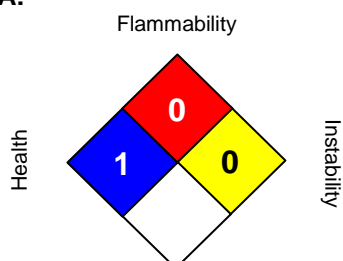
NFPA:

Special hazard.

HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

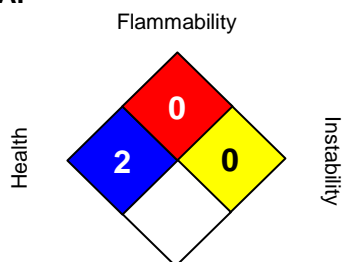
CS4 - [CTM Mn2+]**NFPA:**

Special hazard.

HMIS III:

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

HIV-1 H(+)C, v2 (Human Plasma)**NFPA:**

Special hazard.

HMIS III:

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

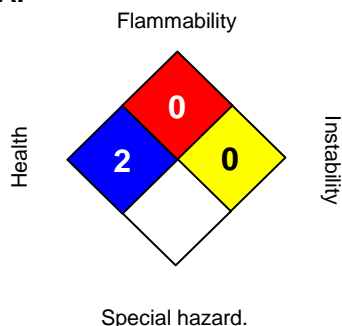
HIV-1 L(+)C, v2 (Human Plasma)]

KIT C-TAQ HIV-1 v2 48T US-IVD

Version 1.4

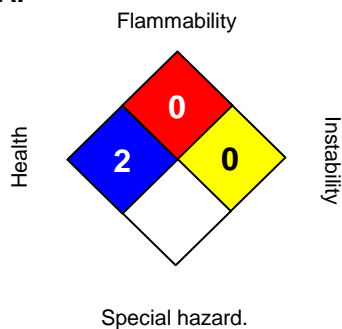
Revision Date 09-18-2014

Print Date 12-06-2014

NFPA:**HMIS III:**

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

CTM (-)C (Human Plasma)**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.