

# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

### **SECTION 1. IDENTIFICATION**

Product name : KIT C68/88 CHIKV/DENV 480T CE-IVD

Product code : 08042276190

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

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

nada)

1-703-527-3887 (Internatio-

nal)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

#### **SECTION 2. HAZARDS IDENTIFICATION**

#### GHS classification in accordance with 29 CFR 1910.1200

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 elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H334 May cause allergy or asthma symptoms or breathing diffi-

culties if inhaled.

H360FD May damage fertility. May damage the unborn child.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

P285 In case of inadequate ventilation wear respiratory protec-

tion.

Response:

1/37



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

P304 + P341 IF INHALED: If breathing is difficult, remove per-

son to fresh air and keep comfortable for breathing.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

None known.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

### **PASE**

#### **GHS Classification**

Respiratory sensitization : Category 1

Reproductive toxicity : Category 1B

# **Hazardous ingredients**

Chemical name	CAS-No.	Concentration (% w/w)
glycerol	56-81-5	>= 50 - < 70
Subtilisin	9014-01-1	>= 0.1 - < 1
Boric acid (H3BO3)	10043-35-3	>= 0.1 - < 1

# IC/QS

#### **GHS Classification**

Not a hazardous substance or mixture.

# Hazardous ingredients

No hazardous ingredients

#### EB

### **GHS Classification**

Not a hazardous substance or mixture.

# **Hazardous ingredients**

No hazardous ingredients

# MMX-R2

#### **GHS Classification**

Not a hazardous substance or mixture.

### **Hazardous ingredients**



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

Chemical name	CAS-No.	Concentration (% w/w)
Methane, 1,1'-sulfinylbis-	67-68-5	>= 20 - < 30
glycerol	56-81-5	>= 10 - < 20
Sodium azide (Na(N3))	26628-22-8	>= 0.1 - < 1

### MMX-R1

#### **GHS Classification**

Not a hazardous substance or mixture.

#### Hazardous ingredients

No hazardous ingredients

#### **SECTION 4. FIRST AID MEASURES**

General advice : Move out of dangerous area.

Show this material safety data sheet to the doctor in atten-

dance.

Do not leave the victim unattended.

If inhaled : Call a physician or poison control center immediately.

Move to fresh air.

If unconscious, place in recovery position and seek medical

advice.

In case of skin contact : If on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.

Remove contact lenses. Protect unharmed eye.

Keep eye wide open while rinsing.

If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.

Do not give milk or alcoholic beverages.

Never give anything by mouth to an unconscious person.

If symptoms persist, call a physician. Take victim immediately to hospital.

Rinse mouth with water.

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. FIRE-FIGHTING MEASURES**

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

cumstances and the surrounding environment.

Unsuitable extinguishing : High volume water jet



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

media

Specific hazards during fire

fighting

: 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 fire-fighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Ensure adequate ventilation.

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.

#### **SECTION 7. HANDLING AND STORAGE**

Advice on protection against :

fire and explosion

Normal measures for preventive fire protection.

Advice on safe handling : Avoid formation of aerosol.

Do not breathe vapors/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 ap-

plication area.

Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national

regulations.

Persons susceptible to skin sensitization 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 pla-

ce.

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.



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

Technical : See label, package insert or internal guidelines

measures/Precautions

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **PASE**

# Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
glycerol	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (mist, total dust)	15 mg/m3	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m3	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m3	OSHA P0
Subtilisin	9014-01-1	IOEL	0.00006 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)
		С	0.00006 mg/m3	OSHA P0
		С	0.00006 mg/m3 (crystalline active enzyme)	ACGIH
		ST	0.00006 mg/m3	NIOSH REL
Boric acid (H3BO3)	10043-35-3	TWA (Inhal- able fraction)	2 mg/m3 (Borate)	ACGIH
		STEL (Inhalable fraction)	6 mg/m3 (Borate)	ACGIH

# IC/QS

# Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

# ΕB

# Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

# MMX-R2

# Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Methane, 1,1'-sulfinylbis-	67-68-5	TWA	250 ppm	US WEEL
glycerol	56-81-5	TWA (mist, respirable fraction)	5 mg/m3	OSHA Z-1



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016
1.4 06-10-2017 Date of first issue: 12-01-2015

		TWA (mist, total dust)	15 mg/m3	OSHA Z-1
		TWA (Mist - total dust)	10 mg/m3	OSHA P0
		TWA (Mist - respirable fraction)	5 mg/m3	OSHA P0
Sodium azide (Na(N3))	26628-22-8	С	0.1 ppm (HN3)	NIOSH REL
		C (Vapor)	0.11 ppm (Hydrazoic acid)	ACGIH
		С	0.3 mg/m3 (Sodium azide)	NIOSH REL
		С	0.1 ppm (Ammonia)	OSHA P0
		С	0.3 mg/m3 (Sodium azide)	OSHA P0
		С	0.29 mg/m3 (Sodium azide)	ACGIH

# MMX-R1

#### Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

Personal protective equipment

Respiratory protection : In the case of vapor formation use a respirator with an appro-

ved filter.

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

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**

# **PASE**

Appearance : liquid



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 5.5

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Autoignition temperature : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

: No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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

IC/QS

Appearance : liquid



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : 7.8 - 8.2

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Autoignition temperature : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

: No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

EΒ

Appearance : liquid

Color : No data available



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

Odor : No data available

Odor Threshold : No data available

pH : 8.5

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Autoignition temperature : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

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

MMX-R2

Appearance : liquid

Color : No data available



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

Odor : No data available

Odor Threshold : No data available

pH : 8.1

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Autoignition temperature : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1.104 g/cm3

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

: No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

MMX-R1

Appearance : liquid

Color : No data available



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

Odor : No data available

Odor Threshold : No data available

pH : 6.4

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Autoignition temperature : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

: No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : 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.



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 Date of first issue: 12-01-2015

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

: 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**

### **PASE**

#### **Acute toxicity**

Not classified based on available information.

#### Ingredients:

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

Test atmosphere: vapor Method: Expert judgment

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

Subtilisin:

Acute oral toxicity : LD50 Oral (Rat, male and female): 1,800 mg/kg

Method: OECD Test Guideline 401

Boric acid (H3BO3):

Acute oral toxicity : LD50 Oral (Rat): 2,660 mg/kg

LD50 Oral (Mouse): 3,450 mg/kg

Acute inhalation toxicity : LC0 (Rat): > 2.03 mg/l

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Acute dermal toxicity : LD50 Dermal (Rat): > 2,000 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

# **Ingredients:**

#### Subtilisin:

Result: Skin irritation

Remarks: Extremely corrosive and destructive to tissue.



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

# Boric acid (H3BO3):

Remarks: This information is not available.

# Serious eye damage/eye irritation

Not classified based on available information.

# **Ingredients:**

#### Subtilisin:

Result: Risk of serious damage to eyes. Remarks: May cause irreversible eye damage.

### Boric acid (H3BO3):

Remarks: This information is not available.

# Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

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

# **Ingredients:**

### glycerol:

Assessment: Mild eye irritant, Mild respiratory irritant, No skin irritation

#### Subtilisin:

Assessment: May cause sensitization by inhalation.

Result: The product is a respiratory sensitizer, sub-category 1A.

### Boric acid (H3BO3):

Species: Guinea pig

Assessment: Did not cause sensitization on laboratory animals.

Method: OECD Test Guideline 406

### Germ cell mutagenicity

Not classified based on available information.

#### **Ingredients:**

#### Boric acid (H3BO3):

Genotoxicity in vitro : Test Type: Ames test

Result: negative

Remarks: In vitro tests did not show mutagenic effects

### Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 Date of first issue: 12-01-2015

human carcinogen by IARC.

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

equal to 0.1% is identified as a carcinogen or potential carcino-

gen by OSHA.

NTP No ingredient 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

May damage fertility. May damage the unborn child.

#### Ingredients:

sessment

# Boric acid (H3BO3):

Reproductive toxicity - As-

Presumed human reproductive toxicant, May damage fertility.

May damage the unborn child.

#### STOT-single exposure

Not classified based on available information.

#### Ingredients:

#### Subtilisin:

Target Organs: Respiratory system

Assessment: May cause respiratory irritation.

# Boric acid (H3BO3):

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

# STOT-repeated exposure

Not classified based on available information.

#### Ingredients:

# Boric acid (H3BO3):

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

### Ingredients:

Assessment

# glycerol:

Repeated dose toxicity -

: Mild eye irritant, Mild respiratory irritant, No skin irritation

#### **Aspiration toxicity**

Not classified based on available information.

### IC/QS



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

#### **Acute toxicity**

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

# **Respiratory sensitization**

Not classified based on available information.

### Germ cell mutagenicity

Not classified based on available information.

# Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

**OSHA**No ingredient of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential carcino-

gen by OSHA.

NTP No ingredient 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.

### EB

#### **Acute toxicity**

Not classified based on available information.

# Skin corrosion/irritation

Not classified based on available information.

# Serious eye damage/eye irritation

Not classified based on available information.



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

### Respiratory sensitization

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

#### Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

**OSHA**No ingredient of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential carcino-

gen by OSHA.

NTP No ingredient 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.

### MMX-R2

# **Acute toxicity**

Not classified based on available information.

# **Ingredients:**

# Methane, 1,1'-sulfinylbis-:

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

LD50 Oral (Mouse): 7,920 mg/kg

Acute inhalation toxicity : Acute toxicity estimate: > 30 mg/l

Test atmosphere: vapor Method: Expert judgment

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

#### glycerol:



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016
1.4 06-10-2017 Date of first issue: 12-01-2015

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

Test atmosphere: vapor Method: Expert judgment

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

Sodium azide (Na(N3)):

Acute oral toxicity : LD50 Oral (Rat): 27 mg/kg

LD50 Oral (Mouse): 27 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### **Ingredients:**

### Methane, 1,1'-sulfinylbis-:

Remarks: This information is not available.

# Serious eye damage/eye irritation

Not classified based on available information.

# **Ingredients:**

# Methane, 1,1'-sulfinylbis-:

Remarks: This information is not available.

#### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

# Respiratory sensitization

Not classified based on available information.

### **Ingredients:**

### Methane, 1,1'-sulfinylbis-:

Species: Guinea pig

Result: Does not cause skin sensitization.

Assessment: Mild eye irritation, Mild skin irritation

glycerol:

Assessment: Mild eye irritant, Mild respiratory irritant, No skin irritation

### Germ cell mutagenicity

Not classified based on available information.



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Date of last issue: 05-10-2016 **Revision Date:** 1.4 06-10-2017 Date of first issue: 12-01-2015

### Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

**OSHA** No ingredient of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential carcino-

gen by OSHA.

NTP No ingredient 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.

#### Ingredients:

### Methane, 1,1'-sulfinylbis-:

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

#### Sodium azide (Na(N3)):

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

# STOT-repeated exposure

Not classified based on available information.

#### **Ingredients:**

# Methane, 1,1'-sulfinylbis-:

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

#### Sodium azide (Na(N3)):

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

#### Ingredients:

# Methane, 1,1'-sulfinylbis-:

Repeated dose toxicity -Mild eye irritation, Mild skin irritation

Assessment

# glycerol:

Repeated dose toxicity -

Mild eye irritant, Mild respiratory irritant, No skin irritation

Assessment



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

### **Aspiration toxicity**

Not classified based on available information.

#### Ingredients:

# Methane, 1,1'-sulfinylbis-:

No data available

#### MMX-R1

#### **Acute toxicity**

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

### Serious eye damage/eye irritation

Not classified based on available information.

#### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

### Germ cell mutagenicity

Not classified based on available information.

#### Carcinogenicity

Not classified based on available information.

IARC No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

**OSHA**No ingredient of this product present at levels greater than or

equal to 0.1% is identified as a carcinogen or potential carcino-

gen by OSHA.

NTP No ingredient 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.



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

#### **SECTION 12. ECOLOGICAL INFORMATION**

### **PASE**

**Ecotoxicity** 

Ingredients:

glycerol:

Toxicity to fish : LC50: > 100 mg/l

Exposure time: 96 h

Toxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): > 10,000

mg/l

Toxicity to fish (Chronic tox-

icity)

> 1 mg/l

Toxicity to microorganisms : 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

Subtilisin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 8.2 mg/l

Exposure time: 96 h
Test Type: semi-static test

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.586 mg/l

Exposure time: 48 h Test Type: semi-static test

Method: OECD Test Guideline 202

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): 0.830

mg/l

Exposure time: 72 h Test Type: static test

Method: OECD Test Guideline 201

**Ecotoxicology Assessment** 

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

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



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 Date of first issue: 12-01-2015

Other organisms relevant to

the environment

: No data available

Boric acid (H3BO3):

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 5,600 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 133 mg/l

Exposure time: 48 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

### **Ingredients:**

glycerol:

Biodegradability : Remarks: The product is miscible in water and readily biode-

gradable in both water and soil. Accumulation is not expected.

Subtilisin:

Biodegradability : Biodegradation: 100 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

Remarks: Readily biodegradable, according to appropriate

OECD test.

Boric acid (H3BO3):

Biodegradability : Remarks: The methods for determining biodegradability are

not applicable to inorganic substances.

Impact on Sewage Treat-

ment

Do not discharge product into the aquatic environment without

pretreatment (biological treatment plant).

# **Bioaccumulative potential**

### **Ingredients:**

glycerol:

Partition coefficient: n-

octanol/water

log Pow: -2.66

Subtilisin:

Partition coefficient: n- : log Pow: -3.1 (25 °C)



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 Date of first issue: 12-01-2015

octanol/water pH: 9.2

Boric acid (H3BO3):

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water,

accumulation in organisms is not expected.

Partition coefficient: n-

octanol/water

log Pow: -0.76 (25 °C)

Mobility in soil

No data available

Other adverse effects

# IC/QS

**Ecotoxicity** 

No data available

Persistence and degradability

No data available

**Bioaccumulative potential** 

No data available

Mobility in soil

No data available

Other adverse effects

### EB

**Ecotoxicity** 

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

# MMX-R2

**Ecotoxicity** 

**Ingredients:** 

Methane, 1,1'-sulfinylbis-:



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

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 microorganisms : 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

Toxicity to algae : EC0 (Scenedesmus quadricauda (Green algae)): > 10,000

mg/l

Toxicity to fish (Chronic tox-

icity)

> 1 mg/l

Toxicity to microorganisms : 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

Sodium azide (Na(N3)):

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 1 mg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): < 8 mg/l

Exposure time: 96 h

LC50 (Fish): 0.7 mg/l

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia pulex (Water flea)): 4.2 mg/l

Exposure time: 96 h

Toxicity to algae : IC50 (Scenedesmus quadricauda (Green algae)): 272 mg/l

Exposure time:



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

Toxicity to microorganisms : EC50 (Photobacterium phosphoreum): > 43 mg/l

EC50 (Photobacterium phosphoreum): < 66 mg/l

**Ecotoxicology Assessment** 

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

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

Persistence and degradability

Ingredients:

Methane, 1,1'-sulfinylbis-:

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 biode-

gradable in both water and soil. Accumulation is not expected.

**Bioaccumulative potential** 

**Ingredients:** 

Methane, 1,1'-sulfinylbis-:

Partition coefficient: n-

octanol/water

log Pow: -1.35

glycerol:

Partition coefficient: n-

octanol/water

log Pow: -2.66

Sodium azide (Na(N3)):

Partition coefficient: n-

octanol/water

Remarks: No data available

Mobility in soil

No data available



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

#### Other adverse effects

# MMX-R1

**Ecotoxicity** 

No data available

Persistence and degradability

No data available

**Bioaccumulative potential** 

No data available

Mobility in soil

No data available

Other adverse effects

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods** 

Waste from residues : The product should not be allowed to enter drains, water

courses or the soil.

Do not contaminate ponds, waterways or ditches with chemi-

cal 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 Regulations

**UNRTDG** 

Not regulated as a dangerous good

**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

**Domestic regulation** 

**49 CFR** 



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

Not regulated as a dangerous good

#### **SECTION 15. REGULATORY INFORMATION**

#### PASE

### **EPCRA - Emergency Planning and Community Right-to-Know**

#### 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 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Acute Health Hazard

Chronic Health Hazard

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 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).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (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 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

glycerol 56-81-5 50 %

#### **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

### **US State Regulations**

# Massachusetts Right To Know

glycerol 56-81-5

# Pennsylvania Right To Know

glycerol 56-81-5 Water 7732-18-5

# California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

#### **California Permissible Exposure Limits for Chemical Contaminants**

glycerol 56-81-5



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016
1.4 06-10-2017 Date of first issue: 12-01-2015

# The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Subtilisin

Tetrasodium ethylenediaminetetraacetate dihydrate

AICS : On the inventory, or in compliance with the inventory

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : On the inventory, or in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : On the inventory, or in compliance with the inventory

TSCA : Not On TSCA Inventory

#### **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

### IC/QS

### **EPCRA - Emergency Planning and Community Right-to-Know**

#### **CERCLA Reportable Quantity**

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

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

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

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

# SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

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 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).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

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

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

#### **Clean Water Act**

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

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

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

# **US State Regulations**

### Massachusetts Right To Know

Sodium azide (Na(N3)) 26628-22-8

#### Pennsylvania Right To Know

Water 7732-18-5 Sodium azide (Na(N3)) 26628-22-8

#### California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

#### The ingredients of this product are reported in the following inventories:

DSL : All components of this product are on the Canadian DSL

AICS : On the inventory, or in compliance with the inventory

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : On the inventory, or in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : On TSCA Inventory



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

#### **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

# EΒ

### **EPCRA - Emergency Planning and Community Right-to-Know**

#### **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 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

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 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).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

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

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

### **Clean Water Act**

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

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

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

### **US State Regulations**

#### Massachusetts Right To Know

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

### Pennsylvania Right To Know

Water 7732-18-5

# California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

### The ingredients of this product are reported in the following inventories:

DSL : All components of this product are on the Canadian DSL



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

AICS : On the inventory, or in compliance with the inventory

NZIoC : On the inventory, or in compliance with the inventory

ENCS : On the inventory, or in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : On the inventory, or in compliance with the inventory

PICCS : On the inventory, or in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : On the inventory, or in compliance with the inventory

TSCA : On TSCA Inventory

#### **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

### MMX-R2

# **EPCRA - Emergency Planning and Community Right-to-Know**

#### **CERCLA Reportable Quantity**

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

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

# SARA 304 Extremely Hazardous Substances Reportable Quantity

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

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

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 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).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

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 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

Methane, 1,1'-sulfinylbis- 67-68-5 27.7473 % alycerol 56-81-5 15.8316 %

#### **Clean Water Act**

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

Glycine, N,N'-1,2- 60-00-4 0.0039 %

ethanediylbis[N-(carboxymethyl)-

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

Glycine, N,N'-1,2- 60-00-4 0.0039 %

ethanediylbis[N-(carboxymethyl)-

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

#### **US State Regulations**

# Massachusetts Right To Know

glycerol 56-81-5 Sodium azide (Na(N3)) 26628-22-8

#### Pennsylvania Right To Know

 Water
 7732-18-5

 Methane, 1,1'-sulfinylbis-glycerol
 67-68-5

 Acetic acid, potassium salt (1:1)
 127-08-2

 Glycine, N-[2-hydroxy-1,1-bis(hydroxymethyl)ethyl]-Sodium azide (Na(N3))
 5704-04-1

#### California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

### California Permissible Exposure Limits for Chemical Contaminants

glycerol 56-81-5

#### The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Uridine 5'-(tetrahydrogen triphosphate), 2'-deoxy-

Guanosine 5'-(tetrahydrogen triphosphate), 2'-deoxy-

Adenosine 5'-(tetrahydrogen triphosphate), 2'-deoxy-

Cytidine 5'-(tetrahydrogen triphosphate), 2'-deoxy-

Primer / Oligonucleotide / Probe

AICS : Not in compliance with the inventory



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

TCSI : Not in compliance with the inventory

TSCA : Not On TSCA Inventory

#### **TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

### MMX-R1

# **EPCRA - Emergency Planning and Community Right-to-Know**

#### **CERCLA Reportable Quantity**

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

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

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

<sup>\*:</sup> Calculated RQ exceeds reasonably attainable upper limit.

# SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

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 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).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (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 C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016
1.4 06-10-2017 Date of first issue: 12-01-2015

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

#### **Clean Water Act**

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

Acetic acid 64-19-7 0.0009 % Potassium hydroxide 1310-58-3 0.000 %

(K(OH))

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

 Acetic acid
 64-19-7
 0.0009 %

 Potassium hydroxide
 1310-58-3
 0.00 %

(K(OH))

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

#### **US State Regulations**

# Massachusetts Right To Know

Sodium azide (Na(N3)) 26628-22-8

Pennsylvania Right To Know

Water 7732-18-5 Sodium azide (Na(N3)) 26628-22-8

# California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

#### The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Acetic acid, manganese(2+) salt, tetrahydrate

AICS : On the inventory, or in compliance with the inventory

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : On the inventory, or in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : On the inventory, or in compliance with the inventory

TSCA : Not On TSCA Inventory

### **TSCA list**

No substances are subject to a Significant New Use Rule.



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

No substances are subject to TSCA 12(b) export notification requirements.

### **PASE**

### **GHS** label elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H360FD May damage fertility. May damage the unborn child.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

P285 In case of inadequate ventilation wear respiratory protec-

tion.

Response:

P304 + P341 IF INHALED: If breathing is difficult, remove per-

son to fresh air and keep comfortable for breathing.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

# IC/QS

#### **GHS** label elements

Not a hazardous substance or mixture.

# EΒ

#### **GHS** label elements

Not a hazardous substance or mixture.

### MMX-R2

### **GHS** label elements

Not a hazardous substance or mixture.

#### MMX-R1



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

#### **GHS** label elements

Not a hazardous substance or mixture.

#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials: bw - Body weight: CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan): ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals: OECD - Organization for Economic Co-operation and Development: OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory: TSCA - Toxic Substances Control Act (United States): UN - United Nations: UNRTDG -United Nations Recommendations on the Transport of Dangerous Goods: vPvB - Very Persistent and Very Bioaccumulative

Further information

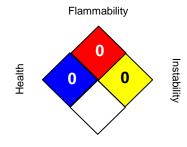
#### PASE



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

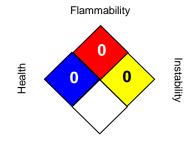
### NFPA:



Special hazard.

#### NFPA:

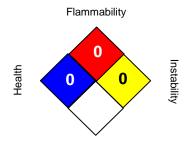
IC/QS



Special hazard.

# ΕB

### NFPA:



Special hazard.

MMX-R2

#### HMIS® IV:

HEALTH	*	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### HMIS® IV:

HEALTH	1	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

# HMIS® IV:



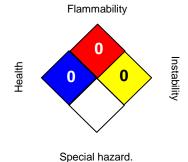
HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.



# KIT C68/88 CHIKV/DENV 480T CE-IVD

Version Revision Date: Date of last issue: 05-10-2016 1.4 06-10-2017 Date of first issue: 12-01-2015

### NFPA:



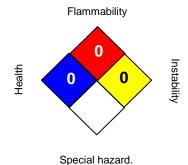
### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### MMX-R1

# NFPA:



# HMIS® IV:

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Revision Date : 06-10-2017

The information provided in this Material 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.

US / Z8 / 1611