

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012**SECTION 1. IDENTIFICATION**

Product name : FT4 CalSet
Mat.-No./ Genisys-No. : 11731661122

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
-

Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

GHS Label element

Not a hazardous substance or mixture.

Other hazards

None known.

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

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

Cal 2**GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

No hazardous ingredients

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

SECTION 4. FIRST AID MEASURES

- | | |
|---|--|
| General advice | : Do not leave the victim unattended. |
| If inhaled | : Move to fresh air.
If unconscious place in recovery position and seek medical advice.
If symptoms persist, call a physician. |
| In case of skin contact | : If on skin, rinse well with water. |
| In case of eye contact | : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist. |
| If swallowed | : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water. |
| 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. |
| Specific hazards during fire-fighting | : 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 | : Refer to protective measures listed in sections 7 and 8. |
| Environmental precautions | : Local authorities should be advised if significant spillages cannot be contained. |

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
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 : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.

Materials to avoid : No materials to be especially mentioned.

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

Contains no substances with occupational exposure limit values.

Cal 2**Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Eye protection : Safety glasses

Skin and body protection : Protective suit

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES***Cal 1***

Appearance : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

pH : 7.6

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.

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.02 g/cm³

Solubility(ies)

Water solubility : completely miscible

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available

Explosive properties : No data available

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

Cal 2

Appearance : liquid

Colour : colourless

Odour : none

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

Odour Threshold	: No data available
pH	: 7.6
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.
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: 1.02 g/cm ³
Solubility(ies)	
Water solubility	: completely miscible
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	: No data available
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

SECTION 11. TOXICOLOGICAL INFORMATION***Cal 1***

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012**Acute toxicity**

Not classified based on available information.

Product:Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method**Skin corrosion/irritation**

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

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.

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.

Cal 2**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.

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012**Serious eye damage/eye irritation**

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Cal 1****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

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012**Mobility in soil**

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : 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).

Cal 2**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**Product:**

Ozone-Depletion Potential : 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 : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012**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**Cal 1**

TSCA list : Not relevant

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 311/312 Hazards : No SARA Hazards**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 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 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 I 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.

SAFETY DATA SHEET



FT4 CalSet

Version
1.4

Revision Date:
04-24-2015

Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

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 %
-------	-----------	------------

New Jersey Right To Know

water	7732-18-5	90 - 100 %
-------	-----------	------------

California Prop 65

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

The components of this product are reported in the following inventories:

REACH	: Not in compliance with the inventory
	: hydroxyl-2-pyridone
	: 2-methyl-2H-isothiazol-3-one hydrochloride
	: ethanol
	: Albumins, blood serum
	: TBG, bovine
	: 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
	: sodium chloride
	: DL-thyroxin
CH INV	: Not in compliance with the inventory
	: TBG, bovine
TSCA	: Not On TSCA Inventory
	: hydroxyl-2-pyridone
	: TBG, bovine
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL.
	: hydroxyl-2-pyridone
	: TBG, bovine
AICS	: Not in compliance with the inventory

FT4 CalSet

 Version
1.4

 Revision Date:
04-24-2015

 Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

	: hydroxyl-2-pyridone
	: TBG, bovine
NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: Not in compliance with the inventory
	: water
	: hydroxyl-2-pyridone
	: 2-methyl-2H-isothiazol-3-one hydrochloride
	: Albumins, blood serum
	: TBG, bovine
	: 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
	: DL-thyroxin
ISHL	: Not in compliance with the inventory
	: water
	: hydroxyl-2-pyridone
	: 2-methyl-2H-isothiazol-3-one hydrochloride
	: Albumins, blood serum
	: TBG, bovine
	: 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
	: DL-thyroxin
KECI	: Not in compliance with the inventory
	: hydroxyl-2-pyridone
	: TBG, bovine
	: 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
	: DL-thyroxin
PICCS	: Not in compliance with the inventory
	: hydroxyl-2-pyridone
	: TBG, bovine
IECSC	: Not in compliance with the inventory

FT4 CalSetVersion
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

: hydroxyl-2-pyridone

: TBG, bovine

: DL-thyroxin

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

Cal 2**TSCA list** : Not relevant**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 311/312 Hazards : No SARA Hazards**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 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 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 %

FT4 CalSet

 Version
1.4

 Revision Date:
04-24-2015

 Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

New Jersey Right To Know

water

7732-18-5

90 - 100 %

California Prop 65

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

The components of this product are reported in the following inventories:
REACH

- : Not in compliance with the inventory
- : hydroxyl-2-pyridone
- : 2-methyl-2H-isothiazol-3-one hydrochloride
- : ethanol
- : Albumins, blood serum
- : TBG, bovine
- : 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
- : sodium chloride
- : DL-thyroxin

CH INV

- : Not in compliance with the inventory
- : TBG, bovine

TSCA

- : Not On TSCA Inventory
- : hydroxyl-2-pyridone
- : TBG, bovine

DSL

- : This product contains the following components that are not on the Canadian DSL nor NDSL.
- : hydroxyl-2-pyridone
- : TBG, bovine

AICS

- : Not in compliance with the inventory
- : hydroxyl-2-pyridone
- : TBG, bovine

NZIoC

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

ENCS

- : Not in compliance with the inventory
- : water

FT4 CalSet
Version
1.4Revision Date:
04-24-2015Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

	: hydroxyl-2-pyridone
	: 2-methyl-2H-isothiazol-3-one hydrochloride
	: Albumins, blood serum
	: TBG, bovine
	: 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
	: DL-thyroxin
ISHL	: Not in compliance with the inventory
	: water
	: hydroxyl-2-pyridone
	: 2-methyl-2H-isothiazol-3-one hydrochloride
	: Albumins, blood serum
	: TBG, bovine
	: 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
	: DL-thyroxin
KECI	: Not in compliance with the inventory
	: hydroxyl-2-pyridone
	: TBG, bovine
	: 4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid
	: DL-thyroxin
PICCS	: Not in compliance with the inventory
	: hydroxyl-2-pyridone
	: TBG, bovine
IECSC	: Not in compliance with the inventory
	: hydroxyl-2-pyridone
	: TBG, bovine
	: DL-thyroxin

Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

SAFETY DATA SHEET

Roche

FT4 CalSet

Version
1.4

Revision Date:
04-24-2015

Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

Cal 1

GHS Label element

Not a hazardous substance or mixture.

Cal 2

GHS Label element

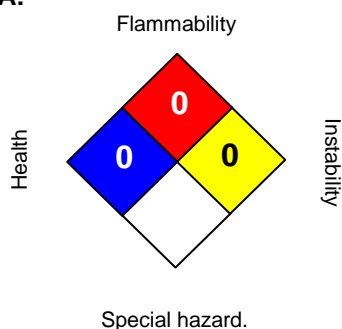
Not a hazardous substance or mixture.

SECTION 16. OTHER INFORMATION

Further information

Cal 1

NFPA:



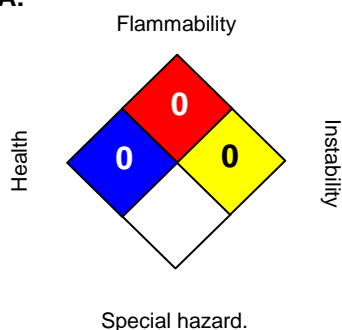
HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

Cal 2

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

Revision Date : 04-24-2015

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

SAFETY DATA SHEET



FT4 CalSet

Version
1.4

Revision Date:
04-24-2015

Date of last issue: 09-18-2014
Date of first issue: 11-08-2012

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 / EN