

cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

SECTION 1. IDENTIFICATION

Product name : cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Product code : 09211128190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

-

Address : 9115 Hague Road

Indianapolis, IN 46250

USA

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 the OSHA Hazard Communication Standard (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 GHS Label elements contains the resulting labelling for the kit

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

POS CTL

GHS Classification

Not a hazardous substance or mixture.

Components

No hazardous ingredients

FABA PC / POS CTL



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

GHS Classification

Combustible dust

Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
Poly(oxy-1,2-ethanediyl), .alpha	25322-68-3	>= 70 - < 90
hydroomegahydroxy-		
Albumins, blood serum	9048-46-8	>= 1 - < 5
Sodium phosphate, monobasic,	10049-21-5	>= 1 - < 5
monohydrate		
Ribonuclease	9001-99-4	< 0.1

Actual concentration is withheld as a trade secret

Flu NC / NEG CTL

GHS Classification

Not a hazardous substance or mixture.

Components

No hazardous ingredients

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.

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.

Rinse mouth with water.

Most important symptoms

and effects, both acute and

delayed

None known.



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

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

media

High volume water jet

Specific hazards during fire

fighting

No information available.

Hazardous combustion prod: :

ucts

In case of fire hazardous decomposition products may be

produced such as:

Gaseous hydrogen chloride (HCI).

Sodium oxides

Oxides of phosphorus

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Special protective equipment :

for fire-fighters

Wear self-contained breathing apparatus for firefighting if

necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Refer to protective measures listed in sections 7 and 8.

Environmental precautions : 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

Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

Pick up and arrange disposal without creating dust.

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 ap-

plication area.

Dispose of rinse water in accordance with local and national

regulations.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated pla-



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

ce.

Electrical installations / working materials must comply with

the technological safety standards.

Further information on stor-

age conditions

See label, package insert or internal guidelines

Further information on stor-

age stability

No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

POS CTL

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

FABA PC / POS CTL

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Poly(oxy-1,2- ethanediyl), .alphahydro- .omegahydroxy-	25322-68-3	TWA (aero- sol)	10 mg/m3	US WEEL
Ribonuclease	9001-99-4	IOEL	0.00006 mg/m3	Roche In- dustrial Hy- giene Com- mittee (RIHC)

Flu NC / NEG CTL

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Hand protection

In case of contact through splashing:

Material : Nitrile rubber
Break through time : > 30 min
Glove thickness : > 0.11 mm

In case of full contact:

Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.

Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

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

POS CTL

Appearance : liquid

Color : colorless

Odor : none

Odor Threshold : No data available

pH : 8.0

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) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : ca. 1 g/cm3



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

FABA PC / POS CTL

Appearance : (lyophilized)

Color : No data available

Odor : Not applicable

Odor Threshold : Not applicable

pH : Not applicable

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) : Sustains combustion

Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Upper explosion limit / Upper

flammability limit

No data available



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

Lower explosion limit / Lower : No data available

flammability limit

Vapor pressure No data available

Relative vapor density Not applicable

Relative density No data available

Solubility(ies)

Water solubility soluble

Solubility in other solvents No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature No data available

Decomposition temperature No data available

Viscosity

Viscosity, dynamic Not applicable

Viscosity, kinematic Not applicable

Explosive properties Not explosive

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

Flu NC / NEG CTL

Appearance liquid

Color light pink

Odor No data available

Odor Threshold No data available

pΗ

Melting point/range No data available

Boiling point/boiling range 212 °F / 100 °C

Flash point does not flash

Evaporation rate No data available



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability 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

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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 reac-

tions

No decomposition if stored and applied as directed.

Incompatible materials : Strong oxidizing agents



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

SECTION 11. TOXICOLOGICAL INFORMATION

POS CTL

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.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

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.

FABA PC / POS CTL

Acute toxicity

Not classified based on available information.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Acute oral toxicity : Acute toxicity estimate (Rat): > 5,000 mg/kg



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

Method: Expert judgment

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

Test atmosphere: dust/mist Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Expert judgment

Sodium phosphate, monobasic, monohydrate:

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 401

Remarks: Based on data from similar materials

No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat, male and female): > 0.83 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rabbit): > 7,940 mg/kg

Remarks: anhydrous substance

Ribonuclease:

Acute oral toxicity : Acute toxicity estimate: > 5,001 mg/kg

Method: Expert judgment

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

Test atmosphere: dust/mist Method: Expert judgment

Acute dermal toxicity : Acute toxicity estimate: > 5,001 mg/kg

Method: Expert judgment

Skin corrosion/irritation

Not classified based on available information.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Remarks : This information is not available.

Sodium phosphate, monobasic, monohydrate:

Species : Rabbit Exposure time : 4 h

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Remarks : This information is not available.

Sodium phosphate, monobasic, monohydrate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Sodium phosphate, monobasic, monohydrate:

Test Type : Local lymph node assay (LLNA)

Species : Mouse

Method : OECD Test Guideline 429

Result : Does not cause skin sensitization.
Remarks : Based on data from similar materials

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:

Sodium phosphate, monobasic, monohydrate:

Remarks : 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.

Ribonuclease:

Remarks : 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.

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.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

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:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

Albumins, blood serum:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

Sodium phosphate, monobasic, monohydrate:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

Ribonuclease:

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:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Albumins, blood serum:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Sodium phosphate, monobasic, monohydrate:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Ribonuclease:

Assessment : The substance or mixture is not classified as specific target

organ toxicant, repeated exposure.

Aspiration toxicity

Not classified based on available information.



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

No data available

Sodium phosphate, monobasic, monohydrate:

No data available

Ribonuclease:

No data available

Further information

Components:

Albumins, blood serum:

Remarks : Health injuries are not known or expected under normal use.

Flu NC / NEG CTL

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.

OSHANo component of this product present at levels greater than or equal to 0.1% is

on OSHA's list of regulated carcinogens.

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.



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

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

POS CTL

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

FABA PC / POS CTL

Ecotoxicity

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Toxicity to fish : LC50: > 100 mg/l

Exposure time: 96 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

Albumins, blood serum:

Ecotoxicology Assessment

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

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



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

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

Other organisms relevant to

the environment

No data available

Sodium phosphate, monobasic, monohydrate:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

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

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

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

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h

Test Type: Growth inhibition

Remarks: Based on data from similar materials

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

Ribonuclease:

Toxicity to fish : LC50: > 100 mg/l

Exposure time: 96 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:

Sodium phosphate, monobasic, monohydrate:

Biodegradability : Remarks: The methods for determining biodegradability are



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

not applicable to inorganic substances.

Bioaccumulative potential

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:
Partition coefficient: n
: Remarks: No data available

octanol/water

Albumins, blood serum:

Partition coefficient: n-

octanol/water

: Remarks: No data available

Sodium phosphate, monobasic, monohydrate:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-

octanol/water

: Remarks: No data available

Ribonuclease:

Partition coefficient: n-

octanol/water

: Remarks: No data available

Mobility in soil

No data available

Other adverse effects

Components:

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-:

Adsorbed organic bound

halogens (AOX)

: Remarks: Not applicable

Sodium phosphate, monobasic, monohydrate:

Additional ecological infor-

mation

: No data available

Flu NC / NEG CTL

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

Other adverse effects

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Special treatment as infectious material is mandatory in com-

pliance with local regulations (disinfection and incineration). 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

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,

IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

POS CTL

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

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

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

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

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

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

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

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

KECI : Not in compliance with the inventory

PICCS : Not 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 : Product contains substance(s) not listed on TSCA inventory.

TECI: Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

FABA PC / POS CTL

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 : Combustible dust

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):

Poly(oxy-1,2- 25322-68-3 >= 70 - < 90 %

ethanediyl), .alpha.hydro-.omega.-hydroxy-

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.



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

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

307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

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

Pennsylvania Right To Know

Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-Sodium chloride (NaCl) 25322-68-3 7647-14-5

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

non hazardous compounds (liquid)

Glycols

Modified alkyl carboxylate

Ribonuclease

NZIoC : Not 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 : Product contains substance(s) not listed on TSCA inventory.

TECI: Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

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

Flu NC / NEG CTL

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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

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

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Bovine Serum Albumin

D-Glutamic acid

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 : On the inventory, or in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

TECI: Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

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

POS CTL

GHS label elements

Not a hazardous substance or mixture.

FABA PC / POS CTL

GHS label elements

Signal Word : Warning

Hazard Statements : May form combustible dust concentrations in air.

Flu NC / NEG CTL

GHS label elements

Not a hazardous substance or mixture.



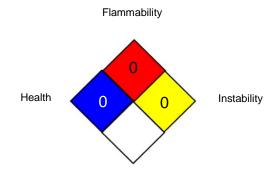
cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

SECTION 16. OTHER INFORMATION

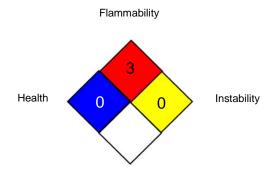
Further information

NFPA 704:



Special hazard

NFPA 704:



Special 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.

HMIS® IV:

HEALTH	1	1
FLAMMABILITY		3
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.



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

NFPA 704:

Health O O Instability

Special 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.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; 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; TECI - Thailand Existing Chemicals 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



cobas® SARS-CoV-2 & Influenza A/B Quality Control Kit

Version Revision Date: Date of last issue: 10-12-2021 2.0 03-29-2022 Date of first issue: 05-11-2020

Revision Date : 03-29-2022

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.

US / Z8 / 2104