

KIT COBAS LIAT INFLUENZA A/BVersion
1.2Revision Date:
04-25-2015Date of last issue: 01-13-2015
Date of first issue: 11-14-2014**SECTION 1. IDENTIFICATION**

Product name : KIT COBAS LIAT INFLUENZA A/B

Mat.-No./ Genisys-No. : 07341890190

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 Can-
ada)

1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

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

GHS Label element

Hazard pictograms



Signal word : Danger

Hazard statements : H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P280 Wear eye protection/ face protection.
P284 Wear respiratory protection.
Response:
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON

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CENTER or doctor/ physician.
P342 + P311 If experiencing respiratory symptoms: Call a
POISON CENTER or doctor/ physician.
P362 + P364 Take off contaminated clothing and wash it before
reuse.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**COBAS LIAT INFLUENZA A/B****GHS Classification**

Acute toxicity (Oral) Category 4	H302: Harmful if swallowed.
Acute toxicity (Inhalation) Category 4	H332: Harmful if inhaled.
Acute toxicity (Dermal) Category 4	H312: Harmful in contact with skin.
Serious eye damage Category 1	H318: Causes serious eye damage.
Respiratory sensitisation Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation Category 1	H317: May cause an allergic skin reaction.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
guanidinium thiocyanate	593-84-0	≥ 50 - < 70
Triton X-100	9002-93-1	≥ 1 - < 5
Polyethylene glycol	25322-68-3	≥ 1 - < 5
Proteinase, Tritirachium album serine	39450-01-6	≥ 1 - < 5

SECTION 4. FIRST AID MEASURES

General advice	: Move out of dangerous area. Consult a physician. Show this safety data sheet to the doctor in attendance. Do not leave the victim unattended.
If inhaled	: Call a physician or poison control centre immediately. Move to fresh air. If unconscious place in recovery position and seek medical advice.
In case of skin contact	: If skin irritation persists, call a physician. If on skin, rinse well with water. If on clothes, remove clothes.
In case of eye contact	: Small amounts splashed into eyes can cause irreversible tis- sue damage and blindness. In the case of contact with eyes, rinse immediately with plenty

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- of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do NOT induce vomiting.
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 : None known.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during 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 firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
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.
If the product contaminates rivers and lakes or drains inform respective authorities.
- Methods and materials for : Soak up with inert absorbent material (e.g. sand, silica gel,

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containment and cleaning up

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 vapours/dust.
Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
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 sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.
Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Electrical installations / working materials must comply with the technological safety standards.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
COBAS LIAT INFLUENZA A/B
Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Polyethylene glycol	25322-68-3	TWA (aerosol)	10 mg/m ³	US WEEL

Hazardous components without workplace control parameters

Components	CAS-No.
guanidinium thiocyanate	593-84-0
Triton X-100	9002-93-1
Proteinase, Tritirachium album serine	39450-01-6

Personal protective equipment

Respiratory protection : In the case of vapour formation use a respirator with an approved filter.

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Hand protection

Material : Protective gloves

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

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.

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
COBAS LIAT INFLUENZA A/B

Appearance : liquid

Colour : No data available
 Odour : No data available
 Odour Threshold : No data available
 pH : No data available
 Melting point/freezing point : No data available
 Initial boiling point and boiling range : No data available
 Flash point : not determined

Evaporation rate : No data available
 Flammability (solid, gas) : No data available
 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 : No data available
 Solubility(ies)
 Water solubility : completely miscible

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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

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: No dangerous reaction known under conditions of normal use.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION***COBAS LIAT INFLUENZA A/B*****Acute toxicity**

Harmful if swallowed, in contact with skin or if inhaled

Product:

Acute oral toxicity	: Acute toxicity estimate: 897.53 mg/kg Method: Calculation method
Acute inhalation toxicity	: Acute toxicity estimate: 2.54 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	: Acute toxicity estimate: 1,776 mg/kg Method: Calculation method

Components:**guanidinium thiocyanate:**

Acute oral toxicity	: LD50 Oral (Rat): 593 mg/kg
Acute inhalation toxicity	: Acute toxicity estimate: 1.5 mg/l Test atmosphere: dust/mist Method: Expert judgement
Acute dermal toxicity	: Acute toxicity estimate: 1,100 mg/kg Method: Expert judgement

Triton X-100:

Acute oral toxicity	: LD50 Oral (Rat): 1,900 - 5,000 mg/kg Acute toxicity estimate: 500 mg/kg Method: Expert judgement
Acute dermal toxicity	: LD50 Dermal (Rabbit): > 3,000 mg/kg

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Acute oral toxicity : LD50 Oral (Rat): > 50,000 mg/kg

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

Acute dermal toxicity : LD50 Dermal (Rabbit): > 20,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Components:**Polyethylene glycol:**

Remarks: This information is not available.

Proteinase, Tritirachium album serine:

Result: Irritating to skin.

Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks: May cause irreversible eye damage.

Components:**Triton X-100:**

Result: Risk of serious damage to eyes.

Remarks: May cause irreversible eye damage.

Polyethylene glycol:

Remarks: This information is not available.

Proteinase, Tritirachium album serine:

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Product:

Remarks: Causes sensitisation.

Components:**Proteinase, Tritirachium album serine:**

Assessment: May cause sensitisation by skin contact.

Remarks: Causes sensitisation.

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Assessment: May cause sensitisation by inhalation.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:**guanidinium thiocyanate:**

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

IARC

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

OSHA

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

NTP

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

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:**Polyethylene glycol:**

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

Proteinase, Tritirachium album serine:

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:**Polyethylene glycol:**

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

Proteinase, Tritirachium album serine:

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

Aspiration toxicity

Not classified based on available information.

Components:

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Polyethylene glycol:

No data available

Proteinase, Tritirachium album serine:

No data available

SECTION 12. ECOLOGICAL INFORMATION
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Ecotoxicity
Components:
guanidinium thiocyanate:

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

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

Ecotoxicology Assessment

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

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

 Other organisms relevant to : No data available
the environment

Triton X-100:

 Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 4 - 8.9 mg/l
Exposure time: 96 h

 Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 18 - 26 mg/l
aquatic invertebrates 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 : No data available
the environment

Polyethylene glycol:

 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.

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Other organisms relevant to the environment : No data available

Proteinase, Tritirachium album serine:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Persistence and degradability**Components:****Triton X-100:**

Biodegradability : Biodegradation: > 60 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential**Components:****guanidinium thiocyanate:**

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

Triton X-100:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

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).

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

Components:**Polyethylene glycol:**

Adsorbed organic bound halogens (AOX) : Remarks: Not applicable

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- 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 chemical or used container.
Send to a licensed waste management company.
- Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION**International Regulation****IATA-DGR**

Not regulated as a dangerous good

IMDG-Code

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**COBAS LIAT INFLUENZA A/B****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 : Acute Health Hazard**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

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: 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).

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

glycine	56-40-6	4.9999 %
Polyethylene glycol	25322-68-3	3.9999 %

Clean Water Act

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

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

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

Massachusetts Right To Know

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

Pennsylvania Right To Know

guanidinium thiocyanate	593-84-0	50 - 70 %
trehalose	99-20-7	5 - 10 %
non hazardous compounds (liquid)	Not Assigned	5 - 10 %
glycine	56-40-6	1 - 5 %
trometamol	77-86-1	1 - 5 %
potassium chloride	7447-40-7	1 - 5 %
Triton X-100	9002-93-1	1 - 5 %
Polyethylene glycol	25322-68-3	1 - 5 %

New Jersey Right To Know

guanidinium thiocyanate	593-84-0	50 - 70 %
trehalose	99-20-7	5 - 10 %
non hazardous compounds (liquid)	Not Assigned	5 - 10 %
glycine	56-40-6	1 - 5 %
trometamol	77-86-1	1 - 5 %
potassium chloride	7447-40-7	1 - 5 %
Triton X-100	9002-93-1	1 - 5 %

California Prop 65

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

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

REACH : Not in compliance with the inventory

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	: guanidinium thiocyanate
	: trehalose
	: non hazardous compounds (liquid)
	: glycine
	: trometamol
	: potassium chloride
	: Triton X-100
	: Polyethylene glycol
	: Proteinase, Tritirachium album serine
CH INV	: Not in compliance with the inventory
	: non hazardous compounds (liquid)
	: Triton X-100
TSCA	: Not On TSCA Inventory
	: non hazardous compounds (liquid)
	: Proteinase, Tritirachium album serine
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL.
	: non hazardous compounds (liquid)
	: Proteinase, Tritirachium album serine
AICS	: Not in compliance with the inventory
	: non hazardous compounds (liquid)
	: Proteinase, Tritirachium album serine
NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: Not in compliance with the inventory
	: guanidinium thiocyanate
	: trehalose
	: non hazardous compounds (liquid)
	: Proteinase, Tritirachium album serine
ISHL	: Not in compliance with the inventory

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	: guanidinium thiocyanate
	: non hazardous compounds (liquid)
KECI	: Not in compliance with the inventory
	: guanidinium thiocyanate
	: non hazardous compounds (liquid)
	: Proteinase, Tritirachium album serine
PICCS	: Not in compliance with the inventory
	: trehalose
	: non hazardous compounds (liquid)
	: Proteinase, Tritirachium album serine
IECSC	: Not in compliance with the inventory
	: non hazardous compounds (liquid)

Inventories

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

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GHS Label element

Hazard pictograms



Signal word

: Danger

Hazard statements

: H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled
 H317 May cause an allergic skin reaction.
 H318 Causes serious eye damage.
 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements

: **Prevention:**
 P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P271 Use only outdoors or in a well-ventilated area.
 P272 Contaminated work clothing should not be allowed out of the workplace.
 P280 Wear eye protection/ face protection.
 P280 Wear protective gloves/ protective clothing.
 P285 In case of inadequate ventilation wear respiratory protec-

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tion.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.
P302 + P352 + P312 IF ON SKIN: Wash with plenty of soap and water. Call a POISON CENTER or doctor/ physician if you feel unwell.

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.

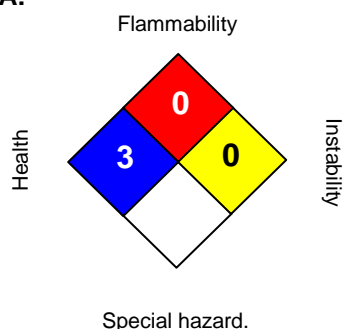
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.

P363 Wash contaminated clothing before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

SECTION 16. OTHER INFORMATION
Further information
COBAS LIAT INFLUENZA A/B
NFPA:

HMIS III:

HEALTH	3*
FLAMMABILITY	1
PHYSICAL HAZARD	0

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

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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.

SAFETY DATA SHEET



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