



cobas PIK3CA Mutation Test

Version
1.11

Revision Date:
08-28-2024

Date of last issue: 08-28-2024
Date of first issue: 12-15-2015

Cover letter for product:

Trade name : cobas PIK3CA Mutation Test
Product code : 06523013190

The product is sold as a kit, and contains the following components:

- PIK3CA MMX-1
- PIK3CA MMX-2
- PIK3CA MMX-3
- PIK3CA MC
- MGAC
- DNA SD

The following is an overview of the labeling elements of the kit:

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

The product was evaluated per International Air Transport Association (IATA) specifications with the following outcome:

Not assigned by regulation

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SECTION 1. IDENTIFICATION

Product name : PIK3CA MMX-1

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
Canada)
1-703-527-3887
(International)
Recommended use of the chemical and restrictions on use
Recommended use : Laboratory chemicals
Refer to product literature for further details.
SECTION 2. HAZARDS IDENTIFICATION
GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
1,2,3-Propanetriol	56-81-5	>= 5 - < 10
Methane, 1,1'-sulfinylbis-	67-68-5	>= 1 - < 5
Potassium chloride (KCl)	7447-40-7	>= 1 - < 5
Uracil DNA Glycosylase	59088-21-0	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES



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- 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 : None known.
- 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 circumstances and the surrounding environment.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : Carbon oxides
Sulfur oxides
Metal oxides
Gaseous hydrogen chloride (HCl).
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances 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, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.



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Environmental precautions : 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.

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.

Further information on storage conditions : See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,2,3-Propanetriol	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
Methane, 1,1'-sulfinylbis-	67-68-5	TWA	250 ppm	US WEEL
Uracil DNA Glycosylase	59088-21-0	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available



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Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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 : Safety glasses
Skin and body protection : Protective suit
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Color : purple
Odor : No data available
Odor Threshold : No data available
pH : 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



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- Flammability (solid, gas) : The product is not flammable., 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
- Density : 1.04 g/cm3
- 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 reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.
- Conditions to avoid : No data available

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Incompatible materials : No data available

Hazardous decomposition products : No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION
Acute toxicity

Not classified due to lack of data.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**1,2,3-Propanetriol:**

Acute oral toxicity : LC50 (Mouse): 11,500 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m³
Exposure time: 7 h
Test atmosphere: vapor
GLP: no
Assessment: The component/mixture is minimally toxic after short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg
GLP: no

Methane, 1,1'-sulfinylbis-:

Acute oral toxicity : LD50 (Rat, male and female): 28,300 mg/kg
Method: OECD Test Guideline 401
GLP: no

Acute inhalation toxicity : LC0 (Rat, male and female): > 5.33 mg/l
Exposure time: 4 h
Test atmosphere: vapor
Method: OECD Test Guideline 403
GLP: yes

Acute dermal toxicity : LD50 Dermal (Rat, male and female): 40,000 mg/kg
GLP: no

Potassium chloride (KCl):

Acute oral toxicity : LD50 (Rat, female): 3,020 mg/kg
GLP: No information available.

Skin corrosion/irritation

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Components:
1,2,3-Propanetriol:

Species : Rabbit
Exposure time : 24 h
Result : No skin irritation
GLP : no

Methane, 1,1'-sulfinylbis-:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
GLP : yes
Remarks : Mild skin irritation

Potassium chloride (KCl):

Species : reconstructed human epidermis (RhE)
Exposure time : 20 min
Method : OECD Test Guideline 439
Result : No skin irritation
GLP : yes

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:
1,2,3-Propanetriol:

Species : Rabbit
Result : No eye irritation
Exposure time : 7 d
GLP : no

Methane, 1,1'-sulfinylbis-:

Species : Rabbit
Exposure time : 24 h
Method : OECD Test Guideline 405
GLP : No information available.
Remarks : Mild eye irritation

Potassium chloride (KCl):

Result : No eye irritation
Exposure time : 60 min
GLP : yes

Respiratory or skin sensitization
Skin sensitization

Not classified due to lack of data.

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Not classified due to lack of data.

Components:**1,2,3-Propanetriol:**

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

Methane, 1,1'-sulfinylbis-:

Test Type : Local lymph node assay (LLNA)

Species : Mouse

Assessment : Does not cause skin sensitization.

Method : OECD Test Guideline 429

GLP : No information available.

Assessment : Mild eye irritation, Mild skin irritation

Germ cell mutagenicity

Not classified due to lack of data.

Components:**1,2,3-Propanetriol:**Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative
GLP: No information available.Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: No information available.**Methane, 1,1'-sulfinylbis-:**Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: No information available.

Test Type: sister chromatid exchange assay



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Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 479
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Rat (male and female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Dose: 200, 1000, 5000 mg/kg/d
Method: OECD Test Guideline 474
GLP: yes

Potassium chloride (KCl):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: positive
GLP: No information available.

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Method: OECD Test Guideline 473
Result: positive
GLP: No information available.

Carcinogenicity

Not classified due to lack of data.

Components:

1,2,3-Propanetriol:

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
GLP : No information available.
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.

Potassium chloride (KCl):

Species : Rat, male
Application Route : Oral



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Exposure time : 2 Years
 GLP : No information available.
 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.

OSHA No 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 due to lack of data.

Components:

1,2,3-Propanetriol:

Effects on fertility : Test Type: Two-generation study
 Species: Rat, male and female
 Application Route: Oral
 Dose: 2000 mg/kg bw/day
 Fertility: NOAEL: 2,000 mg/kg body weight
 GLP: no

Effects on fetal development : Species: Rabbit, female
 Application Route: Oral
 Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day
 Duration of Single Treatment: 29 d
 Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day
 GLP: no

Methane, 1,1'-sulfinylbis-:

Effects on fertility : Species: Rat, male and female
 Application Route: Oral
 Dose: 100, 300, 1000 mg/kg bw/day
 Fertility: NOAEL: 1,000 mg/kg body weight
 Method: OECD Test Guideline 421
 GLP: yes

Effects on fetal development : Species: Rat, female
 Application Route: Oral
 Dose: 200, 1000, 5000 milligram per kilogram
 Duration of Single Treatment: 10 d
 Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
 Method: OECD Test Guideline 414
 GLP: yes

Potassium chloride (KCl):



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Effects on fetal development : Species: Rat, female
 Application Route: Oral
 Dose: 3.1, 14.4, 66.8, 310 mg/kg bw
 Duration of Single Treatment: 6 - 15 d
 General Toxicity Maternal: NOAEL: 310 mg/kg body weight
 Developmental Toxicity: NOAEL: 310 mg/kg body weight
 GLP: No information available.

STOT-single exposure
 Not classified due to lack of data.

Components:

Uracil DNA Glycosylase:

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

STOT-repeated exposure
 Not classified due to lack of data.

Components:

Uracil DNA Glycosylase:

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

Repeated dose toxicity

Components:

1,2,3-Propanetriol:

Species : Rat, male and female
 NOAEL : 4580 mg/kg
 NOAEL : 4,580 mg/kg
 Application Route : Oral
 Exposure time : 90 d
 Number of exposures : daily
 Dose : 4580 - 25,800 mg/kg/day
 GLP : no

Species : Rat, male and female
 Application Route : Inhalation
 Test atmosphere : dust/mist
 Exposure time : 13 Weeks
 Number of exposures : 6 hours/day, 5 days/week
 Dose : 33, 165 and 660 mg/m3
 GLP : No information available.

Species : Rat
 NOAEL : 5040 mg/kg
 NOAEL : 5,040 mg/kg
 Application Route : Dermal
 Exposure time : 45 Weeks

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Number of exposures : 8 hours/day, 5 days/week
 Dose : 0.5-4.0 ml/kg
 GLP : no

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

Methane, 1,1'-sulfinylbis-:

Species : Monkey, male and female
 NOAEL : 2970 mg/kg
 NOAEL : 2,970 mg/kg
 Application Route : Oral
 Exposure time : 87 Weeks
 Dose : 990, 2970, 8910 mg/kg
 Method : OECD Test Guideline 452
 GLP : no

Species : Rat, male and female
 NOAEC : 2783 mg/l
 Application Route : Inhalation
 Test atmosphere : vapor
 Exposure time : 13 Weeks
 Dose : 0.310, 0.964, 2.783 mg/l
 Method : OECD Test Guideline 413
 GLP : yes

Species : Monkey, male and female
 NOAEL : > 8910 mg/kg
 NOAEL : > 8,910 mg/kg
 Application Route : Dermal
 Exposure time : 18 Months
 Dose : 990, 2970, 8910 mg/kg bw/da
 Method : OECD Test Guideline 452
 GLP : no

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

Potassium chloride (KCl):

Species : Rat, male
 NOAEL : 1,820 mg/kg
 Application Route : Oral
 Exposure time : 2 y
 Dose : 110, 450, 1820 mg/kg bw/day
 GLP : No information available.

Aspiration toxicity

Not classified due to lack of data.

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No data available

SECTION 12. ECOLOGICAL INFORMATION
Ecotoxicity**Product:****Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

Components:**1,2,3-Propanetriol:**Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
GLP: noToxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 1,955 mg/l
End point: mortality
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
GLP: noToxicity to algae/aquatic plants : (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l
End point: Growth rate
Exposure time: 8 d
Test Type: static test
GLP: noToxicity to microorganisms : EC50 (Pseudomonas putida): > 10,000 mg/l
End point: Growth rate
Exposure time: 16 h
Test Type: static test
GLP: No information available.**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

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the environment

Methane, 1,1'-sulfinylbis-:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 25,000 mg/l
 End point: mortality
 Exposure time: 96 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 203
 GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 24,600 mg/l
 Exposure time: 48 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 202
 GLP: No information available.

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 17,000 mg/l
 End point: Growth rate
 Exposure time: 72 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 201
 GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): 10 - 100 mg/l
 Exposure time: 0.5 h
 Analytical monitoring: no
 Method: ISO 8192
 GLP: No information available.

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Potassium chloride (KCl):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 880 mg/l
 End point: mortality
 Exposure time: 96 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 203
 GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 660 mg/l
 End point: Immobilization
 Exposure time: 48 h



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Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: No information available.

Toxicity to algae/aquatic plants : NOEC (Desmodesmus subspicatus (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 209
GLP: no

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

Uracil DNA Glycosylase:

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:

1,2,3-Propanetriol:

Biodegradability : aerobic

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Inoculum: activated sludge
 Concentration: 226 mg/l
 Result: Readily biodegradable.
 Biodegradation: 94 %
 Exposure time: 24 h
 GLP: no

Methane, 1,1'-sulfinylbis-:

Biodegradability : aerobic
 Inoculum: activated sludge
 Concentration: 2 mg/l
 Result: Not readily biodegradable.
 Biodegradation: 31 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301D
 GLP: yes

Potassium chloride (KCl):

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulative potential
Components:
1,2,3-Propanetriol:

Partition coefficient: n-octanol/water : log Pow: -1.75 (77 °F / 25 °C)
 pH: 7.4
 Method: OECD Test Guideline 107
 GLP: no

Methane, 1,1'-sulfinylbis-:

Partition coefficient: n-octanol/water : log Pow: -1.35 (68 °F / 20 °C)
 pH: 7
 GLP: No information available.

Potassium chloride (KCl):

Partition coefficient: n-octanol/water : Remarks: Not applicable

Uracil DNA Glycosylase:

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

Mobility in soil

No data available

Other adverse effects
Product:



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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.

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

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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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



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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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM1 Intermediate or Final VOC's (40 CFR 60.489):

1,2,3-Propanetriol	56-81-5	>= 5 - < 10 %
Methane, 1,1'-sulfinylbis-	67-68-5	>= 1 - < 5 %

Clean Water Act

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

Potassium hydroxide (K(OH))	1310-58-3	>= 0.1 - < 1 %
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-	60-00-4	>= 0 - < 0.1 %

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

Potassium hydroxide (K(OH))	1310-58-3	>= 0.1 - < 1 %
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-	60-00-4	>= 0 - < 0.1 %

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

1,2,3-Propanetriol	56-81-5
Sodium azide (Na(N3))	26628-22-8

Pennsylvania Right To Know

Water	7732-18-5
1,2,3-Propanetriol	56-81-5
Methane, 1,1'-sulfinylbis-	67-68-5
Potassium hydroxide (K(OH))	1310-58-3
Sodium azide (Na(N3))	26628-22-8

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern



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Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants

1,2,3-Propanetriol 56-81-5

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.
 - 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
 - Tetrasodium ethylenediaminetetraacetate dihydrate
 - Uracil DNA Glycosylase
- 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 : 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.

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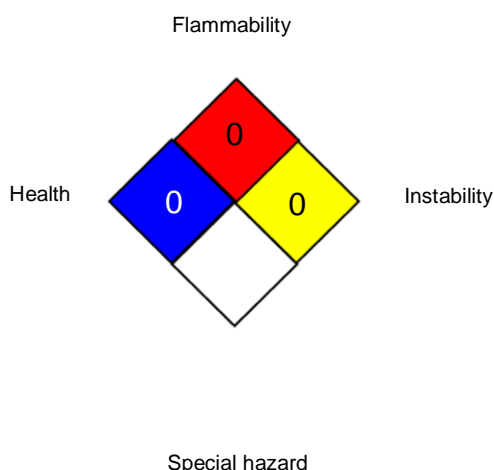
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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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.

Full text of other abbreviations

- OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
- OSHA P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average
- US WEEL / TWA : 8-hr TWA

AIIIC - 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



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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; TECl - 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

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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.

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SECTION 1. IDENTIFICATION

Product name : PIK3CA MMX-2

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
 Canada)
 1-703-527-3887
 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
 Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Methane, 1,1'-sulfinylbis-	67-68-5	>= 5 - < 10
1,2,3-Propanetriol	56-81-5	>= 5 - < 10
Potassium chloride (KCl)	7447-40-7	>= 1 - < 5
Uracil DNA Glycosylase	59088-21-0	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES



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- 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 : None known.

- 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 circumstances and the surrounding environment.

- Specific hazards during fire fighting : No information available.

- Hazardous combustion products : Carbon oxides
Sulfur oxides
Metal oxides
Gaseous hydrogen chloride (HCl).

- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances 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, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.



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Environmental precautions : 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.

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.

Further information on storage conditions : See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Methane, 1,1'-sulfinylbis-	67-68-5	TWA	250 ppm	US WEEL
1,2,3-Propanetriol	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
Uracil DNA Glycosylase	59088-21-0	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available



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Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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 : Safety glasses
Skin and body protection : Protective suit
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Color : purple
Odor : No data available
Odor Threshold : No data available
pH : 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



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- Flammability (solid, gas) : The product is not flammable., 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
- Density : 1.04 g/cm3
- 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 reactions : Stable under recommended storage conditions.
No hazards to be specially mentioned.
- Conditions to avoid : No data available

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Incompatible materials : No data available

Hazardous decomposition products : No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION
Acute toxicity

Not classified due to lack of data.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**Methane, 1,1'-sulfinylbis-:**

Acute oral toxicity : LD50 (Rat, male and female): 28,300 mg/kg
Method: OECD Test Guideline 401
GLP: no

Acute inhalation toxicity : LC0 (Rat, male and female): > 5.33 mg/l
Exposure time: 4 h
Test atmosphere: vapor
Method: OECD Test Guideline 403
GLP: yes

Acute dermal toxicity : LD50 Dermal (Rat, male and female): 40,000 mg/kg
GLP: no

1,2,3-Propanetriol:

Acute oral toxicity : LC50 (Mouse): 11,500 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m³
Exposure time: 7 h
Test atmosphere: vapor
GLP: no
Assessment: The component/mixture is minimally toxic after short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg
GLP: no

Potassium chloride (KCl):

Acute oral toxicity : LD50 (Rat, female): 3,020 mg/kg
GLP: No information available.

Skin corrosion/irritation

Not classified due to lack of data.

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Date of first issue: 12-15-2015**Components:****Methane, 1,1'-sulfinylbis-:**

Species : Rabbit
 Exposure time : 4 h
 Method : OECD Test Guideline 404
 GLP : yes
 Remarks : Mild skin irritation

1,2,3-Propanetriol:

Species : Rabbit
 Exposure time : 24 h
 Result : No skin irritation
 GLP : no

Potassium chloride (KCl):

Species : reconstructed human epidermis (RhE)
 Exposure time : 20 min
 Method : OECD Test Guideline 439
 Result : No skin irritation
 GLP : yes

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:**Methane, 1,1'-sulfinylbis-:**

Species : Rabbit
 Exposure time : 24 h
 Method : OECD Test Guideline 405
 GLP : No information available.
 Remarks : Mild eye irritation

1,2,3-Propanetriol:

Species : Rabbit
 Result : No eye irritation
 Exposure time : 7 d
 GLP : no

Potassium chloride (KCl):

Result : No eye irritation
 Exposure time : 60 min
 GLP : yes

Respiratory or skin sensitization**Skin sensitization**

Not classified due to lack of data.

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Not classified due to lack of data.

Components:**Methane, 1,1'-sulfinylbis-:**

Test Type : Local lymph node assay (LLNA)
 Species : Mouse
 Assessment : Does not cause skin sensitization.
 Method : OECD Test Guideline 429
 GLP : No information available.

Assessment : Mild eye irritation, Mild skin irritation

1,2,3-Propanetriol:

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

Germ cell mutagenicity

Not classified due to lack of data.

Components:**Methane, 1,1'-sulfinylbis-:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
 Test system: Salmonella typhimurium
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 471
 Result: negative
 GLP: No information available.

Test Type: Chromosome aberration test in vitro
 Test system: Chinese hamster ovary cells
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 473
 Result: negative
 GLP: No information available.

Test Type: sister chromatid exchange assay
 Test system: Chinese hamster ovary cells
 Metabolic activation: with and without metabolic activation
 Method: OECD Test Guideline 479
 Result: negative
 GLP: No information available.

Genotoxicity in vivo : Test Type: In vivo micronucleus test
 Species: Rat (male and female)
 Cell type: Bone marrow
 Application Route: Intraperitoneal injection
 Dose: 200, 1000, 5000 mg/kg/d
 Method: OECD Test Guideline 474
 GLP: yes

1,2,3-Propanetriol:



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Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative
GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: No information available.

Potassium chloride (KCl):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: positive
GLP: No information available.

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Method: OECD Test Guideline 473
Result: positive
GLP: No information available.

Carcinogenicity

Not classified due to lack of data.

Components:

1,2,3-Propanetriol:

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
GLP : No information available.
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.

Potassium chloride (KCl):

Species : Rat, male
Application Route : Oral
Exposure time : 2 Years

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GLP : No information available.
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.

OSHA No 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 due to lack of data.

Components:
Methane, 1,1'-sulfinylbis-:

Effects on fertility : Species: Rat, male and female
Application Route: Oral
Dose: 100, 300, 1000 mg/kg bw/day
Fertility: NOAEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 421
GLP: yes

Effects on fetal development : Species: Rat, female
Application Route: Oral
Dose: 200, 1000, 5000 milligram per kilogram
Duration of Single Treatment: 10 d
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Method: OECD Test Guideline 414
GLP: yes

1,2,3-Propanetriol:

Effects on fertility : Test Type: Two-generation study
Species: Rat, male and female
Application Route: Oral
Dose: 2000 mg/kg bw/day
Fertility: NOAEL: 2,000 mg/kg body weight
GLP: no

Effects on fetal development : Species: Rabbit, female
Application Route: Oral
Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day
Duration of Single Treatment: 29 d
Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day
GLP: no

Potassium chloride (KCl):

Effects on fetal development : Species: Rat, female

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Application Route: Oral
Dose: 3.1, 14.4, 66.8, 310 mg/kg bw
Duration of Single Treatment: 6 - 15 d
General Toxicity Maternal: NOAEL: 310 mg/kg body weight
Developmental Toxicity: NOAEL: 310 mg/kg body weight
GLP: No information available.

STOT-single exposure

Not classified due to lack of data.

Components:

Uracil DNA Glycosylase:

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

STOT-repeated exposure

Not classified due to lack of data.

Components:

Uracil DNA Glycosylase:

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

Repeated dose toxicity

Components:

Methane, 1,1'-sulfinylbis-:

Species : Monkey, male and female
NOAEL : 2970 mg/kg
NOAEL : 2,970 mg/kg
Application Route : Oral
Exposure time : 87 Weeks
Dose : 990, 2970, 8910 mg/kg
Method : OECD Test Guideline 452
GLP : no

Species : Rat, male and female
NOAEC : 2783 mg/l
Application Route : Inhalation
Test atmosphere : vapor
Exposure time : 13 Weeks
Dose : 0.310, 0.964, 2.783 mg/l
Method : OECD Test Guideline 413
GLP : yes

Species : Monkey, male and female
NOAEL : > 8910 mg/kg
NOAEL : > 8,910 mg/kg
Application Route : Dermal
Exposure time : 18 Months

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Dose : 990, 2970, 8910 mg/kg bw/da
 Method : OECD Test Guideline 452
 GLP : no

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

1,2,3-Propanetriol:

Species : Rat, male and female
 NOAEL : 4580 mg/kg
 NOAEL : 4,580 mg/kg
 Application Route : Oral
 Exposure time : 90 d
 Number of exposures : daily
 Dose : 4580 - 25,800 mg/kg/day
 GLP : no

Species : Rat, male and female
 Application Route : Inhalation
 Test atmosphere : dust/mist
 Exposure time : 13 Weeks
 Number of exposures : 6 hours/day, 5 days/week
 Dose : 33, 165 and 660 mg/m³
 GLP : No information available.

Species : Rat
 NOAEL : 5040 mg/kg
 NOAEL : 5,040 mg/kg
 Application Route : Dermal
 Exposure time : 45 Weeks
 Number of exposures : 8 hours/day, 5 days/week
 Dose : 0.5-4.0 ml/kg
 GLP : no

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

Potassium chloride (KCl):

Species : Rat, male
 NOAEL : 1,820 mg/kg
 Application Route : Oral
 Exposure time : 2 y
 Dose : 110, 450, 1820 mg/kg bw/day
 GLP : No information available.

Aspiration toxicity

Not classified due to lack of data.

Components:
Uracil DNA Glycosylase:

No data available

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SECTION 12. ECOLOGICAL INFORMATION
Ecotoxicity**Product:****Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

Components:**Methane, 1,1'-sulfinylbis-**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 25,000 mg/l
 End point: mortality
 Exposure time: 96 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 203
 GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 24,600 mg/l
 Exposure time: 48 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 202
 GLP: No information available.

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 17,000 mg/l
 End point: Growth rate
 Exposure time: 72 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 201
 GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): 10 - 100 mg/l
 Exposure time: 0.5 h
 Analytical monitoring: no
 Method: ISO 8192
 GLP: No information available.

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

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1,2,3-Propanetriol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
GLP: no

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 1,955 mg/l
End point: mortality
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
GLP: no

Toxicity to algae/aquatic plants : (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l
End point: Growth rate
Exposure time: 8 d
Test Type: static test
GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10,000 mg/l
End point: Growth rate
Exposure time: 16 h
Test Type: static test
GLP: No information available.

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

Potassium chloride (KCl):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 880 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 660 mg/l
End point: Immobilization
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: No information available.

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Toxicity to algae/aquatic plants : NOEC (Desmodesmus subspicatus (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 209
GLP: no

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

Uracil DNA Glycosylase:
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:
Methane, 1,1'-sulfinylbis-

Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 2 mg/l
Result: Not readily biodegradable.
Biodegradation: 31 %



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Exposure time: 28 d
Method: OECD Test Guideline 301D
GLP: yes

1,2,3-Propanetriol:

Biodegradability : aerobic
Inoculum: activated sludge
Concentration: 226 mg/l
Result: Readily biodegradable.
Biodegradation: 94 %
Exposure time: 24 h
GLP: no

Potassium chloride (KCl):

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulative potential

Components:

Methane, 1,1'-sulfinylbis-:

Partition coefficient: n-octanol/water : log Pow: -1.35 (68 °F / 20 °C)
pH: 7
GLP: No information available.

1,2,3-Propanetriol:

Partition coefficient: n-octanol/water : log Pow: -1.75 (77 °F / 25 °C)
pH: 7.4
Method: OECD Test Guideline 107
GLP: no

Potassium chloride (KCl):

Partition coefficient: n-octanol/water : Remarks: Not applicable

Uracil DNA Glycosylase:

Partition coefficient: n-octanol/water : Remarks: 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



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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.

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

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

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



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

Methane, 1,1'-sulfinylbis-	67-68-5	>= 5 - < 10 %
1,2,3-Propanetriol	56-81-5	>= 5 - < 10 %

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-ethanediybis[N-(carboxymethyl)-Potassium hydroxide (K(OH))	60-00-4	>= 0.1 - < 1 %
Potassium hydroxide (K(OH))	1310-58-3	>= 0 - < 0.1 %

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

Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-Potassium hydroxide (K(OH))	60-00-4	>= 0.1 - < 1 %
Potassium hydroxide (K(OH))	1310-58-3	>= 0 - < 0.1 %

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

1,2,3-Propanetriol	56-81-5
Sodium azide (Na(N3))	26628-22-8

Pennsylvania Right To Know

Water	7732-18-5
Methane, 1,1'-sulfinylbis-	67-68-5
1,2,3-Propanetriol	56-81-5
Glycine, N,N'-1,2-ethanediybis[N-(carboxymethyl)-Sodium azide (Na(N3))	60-00-4
Potassium hydroxide (K(OH))	26628-22-8
	1310-58-3

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals



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Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants

1,2,3-Propanetriol 56-81-5

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.
 - Uridine 5'-(tetrahydrogen triphosphate), 2'-deoxy-
 - Guanosine 5'-(tetrahydrogen triphosphate), 2'-deoxy-
 - Adenosine 5'-(tetrahydrogen triphosphate), 2'-deoxy-
 - Cytidine 5'-(tetrahydrogen triphosphate), 2'-deoxy-
 - Tetrasodium ethylenediaminetetraacetate dihydrate
 - Primer / Oligonucleotide / Probe
 - Thymidine 5'-(tetrahydrogen triphosphate), 3'-deoxy-, trilithium salt
 - Uracil DNA Glycosylase
- 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 : 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.

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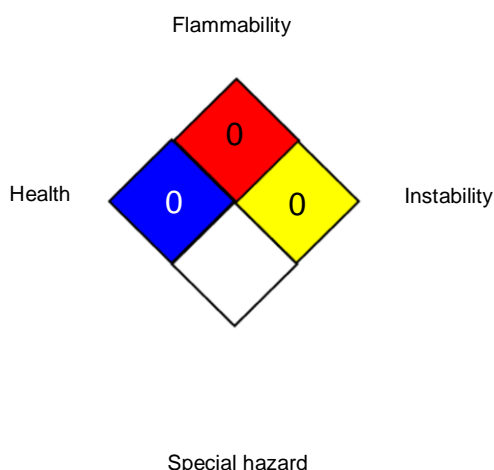
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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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.

Full text of other abbreviations

- OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
- OSHA P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average
- US WEEL / TWA : 8-hr TWA

AIIIC - 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



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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

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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.

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SECTION 1. IDENTIFICATION

Product name : PIK3CA MMX-3

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
Canada)
1-703-527-3887
(International)
Recommended use of the chemical and restrictions on use
Recommended use : Laboratory chemicals
Refer to product literature for further details.
SECTION 2. HAZARDS IDENTIFICATION
GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
1,2,3-Propanetriol	56-81-5	>= 5 - < 10
Methane, 1,1'-sulfinylbis-	67-68-5	>= 1 - < 5
Potassium chloride (KCl)	7447-40-7	>= 1 - < 5
Uracil DNA Glycosylase	59088-21-0	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES



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- 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 : None known.
- 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 circumstances and the surrounding environment.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : Carbon oxides
Sulfur oxides
Metal oxides
Gaseous hydrogen chloride (HCl).
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances 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, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.



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Environmental precautions : 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.

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.

Further information on storage conditions : See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
1,2,3-Propanetriol	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
Methane, 1,1'-sulfinylbis-	67-68-5	TWA	250 ppm	US WEEL
Uracil DNA Glycosylase	59088-21-0	IOEL	0.00006 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available



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Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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 : Safety glasses

Skin and body protection : Protective suit

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : clear, purple

Odor : No data available

Odor Threshold : No data available

pH : 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



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- Flammability (solid, gas) : The product is not flammable., 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
- Density : 1.04 g/cm3
- 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
Expert judgment
- 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

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Incompatible materials : No data available

Hazardous decomposition products : No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION
Acute toxicity

Not classified due to lack of data.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**1,2,3-Propanetriol:**

Acute oral toxicity : LC50 (Mouse): 11,500 mg/kg

Acute inhalation toxicity : LC50 (Rat, male): 275000 mg/m³
Exposure time: 7 h
Test atmosphere: vapor
GLP: no
Assessment: The component/mixture is minimally toxic after short term inhalation.

Acute dermal toxicity : LD50 (Guinea pig, male and female): 56,750 mg/kg
GLP: no

Methane, 1,1'-sulfinylbis-:

Acute oral toxicity : LD50 (Rat, male and female): 28,300 mg/kg
Method: OECD Test Guideline 401
GLP: no

Acute inhalation toxicity : LC0 (Rat, male and female): > 5.33 mg/l
Exposure time: 4 h
Test atmosphere: vapor
Method: OECD Test Guideline 403
GLP: yes

Acute dermal toxicity : LD50 Dermal (Rat, male and female): 40,000 mg/kg
GLP: no

Potassium chloride (KCl):

Acute oral toxicity : LD50 (Rat, female): 3,020 mg/kg
GLP: No information available.

Skin corrosion/irritation

Not classified due to lack of data.

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Components:
1,2,3-Propanetriol:

Species : Rabbit
Exposure time : 24 h
Result : No skin irritation
GLP : no

Methane, 1,1'-sulfinylbis-:

Species : Rabbit
Exposure time : 4 h
Method : OECD Test Guideline 404
GLP : yes
Remarks : Mild skin irritation

Potassium chloride (KCl):

Species : reconstructed human epidermis (RhE)
Exposure time : 20 min
Method : OECD Test Guideline 439
Result : No skin irritation
GLP : yes

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:
1,2,3-Propanetriol:

Species : Rabbit
Result : No eye irritation
Exposure time : 7 d
GLP : no

Methane, 1,1'-sulfinylbis-:

Species : Rabbit
Exposure time : 24 h
Method : OECD Test Guideline 405
GLP : No information available.
Remarks : Mild eye irritation

Potassium chloride (KCl):

Result : No eye irritation
Exposure time : 60 min
GLP : yes

Respiratory or skin sensitization
Skin sensitization

Not classified due to lack of data.

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Respiratory sensitization

Not classified due to lack of data.

Components:
1,2,3-Propanetriol:

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

Methane, 1,1'-sulfinylbis-:

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 429
GLP : No information available.

Assessment : Mild eye irritation, Mild skin irritation

Germ cell mutagenicity

Not classified due to lack of data.

Components:
1,2,3-Propanetriol:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Result: negative
GLP: No information available.

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: negative
GLP: No information available.

Methane, 1,1'-sulfinylbis-:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: No information available.

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 473
Result: negative
GLP: No information available.

Test Type: sister chromatid exchange assay



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Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 479
Result: negative
GLP: No information available.

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Rat (male and female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Dose: 200, 1000, 5000 mg/kg/d
Method: OECD Test Guideline 474
GLP: yes

Potassium chloride (KCl):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
GLP: yes

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 476
Result: positive
GLP: No information available.

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster lung cells
Method: OECD Test Guideline 473
Result: positive
GLP: No information available.

Carcinogenicity

Not classified due to lack of data.

Components:

1,2,3-Propanetriol:

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
GLP : No information available.
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.

Potassium chloride (KCl):

Species : Rat, male
Application Route : Oral



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Exposure time : 2 Years
 GLP : No information available.
 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.

OSHA No 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 due to lack of data.

Components:

1,2,3-Propanetriol:

Effects on fertility : Test Type: Two-generation study
 Species: Rat, male and female
 Application Route: Oral
 Dose: 2000 mg/kg bw/day
 Fertility: NOAEL: 2,000 mg/kg body weight
 GLP: no

Effects on fetal development : Species: Rabbit, female
 Application Route: Oral
 Dose: 11.8, 54.8, 254.5, 1180 mg/kg bw/day
 Duration of Single Treatment: 29 d
 Developmental Toxicity: NOAEL: 1,180 mg/kg bw/day
 GLP: no

Methane, 1,1'-sulfinylbis-:

Effects on fertility : Species: Rat, male and female
 Application Route: Oral
 Dose: 100, 300, 1000 mg/kg bw/day
 Fertility: NOAEL: 1,000 mg/kg body weight
 Method: OECD Test Guideline 421
 GLP: yes

Effects on fetal development : Species: Rat, female
 Application Route: Oral
 Dose: 200, 1000, 5000 milligram per kilogram
 Duration of Single Treatment: 10 d
 Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
 Method: OECD Test Guideline 414
 GLP: yes

Potassium chloride (KCl):



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Effects on fetal development : Species: Rat, female
 Application Route: Oral
 Dose: 3.1, 14.4, 66.8, 310 mg/kg bw
 Duration of Single Treatment: 6 - 15 d
 General Toxicity Maternal: NOAEL: 310 mg/kg body weight
 Developmental Toxicity: NOAEL: 310 mg/kg body weight
 GLP: No information available.

STOT-single exposure
 Not classified due to lack of data.

Components:

Uracil DNA Glycosylase:

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

STOT-repeated exposure
 Not classified due to lack of data.

Components:

Uracil DNA Glycosylase:

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

Repeated dose toxicity

Components:

1,2,3-Propanetriol:

Species : Rat, male and female
 NOAEL : 4580 mg/kg
 NOAEL : 4,580 mg/kg
 Application Route : Oral
 Exposure time : 90 d
 Number of exposures : daily
 Dose : 4580 - 25,800 mg/kg/day
 GLP : no

Species : Rat, male and female
 Application Route : Inhalation
 Test atmosphere : dust/mist
 Exposure time : 13 Weeks
 Number of exposures : 6 hours/day, 5 days/week
 Dose : 33, 165 and 660 mg/m3
 GLP : No information available.

Species : Rat
 NOAEL : 5040 mg/kg
 NOAEL : 5,040 mg/kg
 Application Route : Dermal
 Exposure time : 45 Weeks

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Number of exposures : 8 hours/day, 5 days/week
 Dose : 0.5-4.0 ml/kg
 GLP : no

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

Methane, 1,1'-sulfinylbis-:

Species : Monkey, male and female
 NOAEL : 2970 mg/kg
 NOAEL : 2,970 mg/kg
 Application Route : Oral
 Exposure time : 87 Weeks
 Dose : 990, 2970, 8910 mg/kg
 Method : OECD Test Guideline 452
 GLP : no

Species : Rat, male and female
 NOAEC : 2783 mg/l
 Application Route : Inhalation
 Test atmosphere : vapor
 Exposure time : 13 Weeks
 Dose : 0.310, 0.964, 2.783 mg/l
 Method : OECD Test Guideline 413
 GLP : yes

Species : Monkey, male and female
 NOAEL : > 8910 mg/kg
 NOAEL : > 8,910 mg/kg
 Application Route : Dermal
 Exposure time : 18 Months
 Dose : 990, 2970, 8910 mg/kg bw/da
 Method : OECD Test Guideline 452
 GLP : no

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

Potassium chloride (KCl):

Species : Rat, male
 NOAEL : 1,820 mg/kg
 Application Route : Oral
 Exposure time : 2 y
 Dose : 110, 450, 1820 mg/kg bw/day
 GLP : No information available.

Aspiration toxicity

Not classified due to lack of data.



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Components:

Uracil DNA Glycosylase:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:

1,2,3-Propanetriol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
GLP: no

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 1,955 mg/l
End point: mortality
Exposure time: 48 h
Test Type: static test
Analytical monitoring: no
GLP: no

Toxicity to algae/aquatic plants : (Scenedesmus quadricauda (Green algae)): > 10,000 mg/l
End point: Growth rate
Exposure time: 8 d
Test Type: static test
GLP: no

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 10,000 mg/l
End point: Growth rate
Exposure time: 16 h
Test Type: static test
GLP: No information available.

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

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the environment

Methane, 1,1'-sulfinylbis-:

- Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 25,000 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: yes
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 24,600 mg/l
Exposure time: 48 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 202
GLP: No information available.
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 17,000 mg/l
End point: Growth rate
Exposure time: 72 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 201
GLP: yes
- Toxicity to microorganisms : EC50 (activated sludge): 10 - 100 mg/l
Exposure time: 0.5 h
Analytical monitoring: no
Method: ISO 8192
GLP: No information available.

Ecotoxicology Assessment

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Potassium chloride (KCl):

- Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 880 mg/l
End point: mortality
Exposure time: 96 h
Test Type: static test
Analytical monitoring: yes
Method: OECD Test Guideline 203
GLP: No information available.
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 660 mg/l
End point: Immobilization
Exposure time: 48 h

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Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 202
 GLP: No information available.

Toxicity to algae/aquatic plants : NOEC (Desmodesmus subspicatus (green algae)): > 100 mg/l
 End point: Growth rate
 Exposure time: 72 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 201
 GLP: yes

EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
 End point: Growth rate
 Exposure time: 72 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 201
 GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l
 End point: Respiration inhibition
 Exposure time: 3 h
 Test Type: static test
 Analytical monitoring: yes
 Method: OECD Test Guideline 209
 GLP: no

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

Uracil DNA Glycosylase:
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:
1,2,3-Propanetriol:

Biodegradability : aerobic

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Inoculum: activated sludge
 Concentration: 226 mg/l
 Result: Readily biodegradable.
 Biodegradation: 94 %
 Exposure time: 24 h
 GLP: no

Methane, 1,1'-sulfinylbis-:

Biodegradability : aerobic
 Inoculum: activated sludge
 Concentration: 2 mg/l
 Result: Not readily biodegradable.
 Biodegradation: 31 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301D
 GLP: yes

Potassium chloride (KCl):

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Bioaccumulative potential
Components:
1,2,3-Propanetriol:

Partition coefficient: n-octanol/water : log Pow: -1.75 (77 °F / 25 °C)
 pH: 7.4
 Method: OECD Test Guideline 107
 GLP: no

Methane, 1,1'-sulfinylbis-:

Partition coefficient: n-octanol/water : log Pow: -1.35 (68 °F / 20 °C)
 pH: 7
 GLP: No information available.

Potassium chloride (KCl):

Partition coefficient: n-octanol/water : Remarks: Not applicable

Uracil DNA Glycosylase:

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

Mobility in soil

No data available

Other adverse effects
Product:



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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.

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

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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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



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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).

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

1,2,3-Propanetriol	56-81-5	>= 5 - < 10 %
Methane, 1,1'-sulfinylbis-	67-68-5	>= 1 - < 5 %

Clean Water Act

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

Potassium hydroxide (K(OH))	1310-58-3	>= 0.1 - < 1 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Potassium hydroxide (K(OH))	1310-58-3	>= 0.1 - < 1 %
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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

1,2,3-Propanetriol	56-81-5
Sodium azide (Na(N3))	26628-22-8

Pennsylvania Right To Know

Water	7732-18-5
1,2,3-Propanetriol	56-81-5
Methane, 1,1'-sulfinylbis-	67-68-5
Potassium hydroxide (K(OH))	1310-58-3
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



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California Permissible Exposure Limits for Chemical Contaminants

1,2,3-Propanetriol 56-81-5

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

- AICC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.
 - Uridine 5'-(tetrahydrogen triphosphate), 2'-deoxy-, trisodium salt
 - 2'-Deoxyguanosine 5'-triphosphate trisodium salt
 - 2'-Deoxycytidine 5'-triphosphate disodium salt
 - Adenosine 5'-(tetrahydrogen triphosphate), 2'-deoxy-
 - Thymidine 5'-(tetrahydrogen triphosphate), sodium salt
 - Primer / Oligonucleotide / Probe
 - Tetrasodium ethylenediaminetetraacetate dihydrate
 - Uracil DNA Glycosylase
- 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 : 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.

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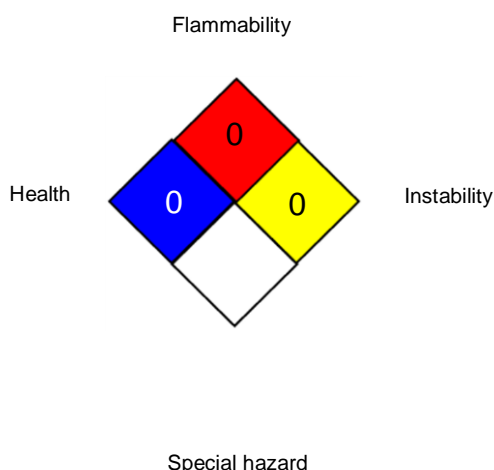
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SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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.

Full text of other abbreviations

- OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)
- OSHA P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average
- US WEEL / TWA : 8-hr TWA

AIIIC - 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



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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; TECl - 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

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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.

US / Z8 / 2304



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SECTION 1. IDENTIFICATION

Product name : PIK3CA MC

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
 Canada)
 1-703-527-3887
 (International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
 Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2)	139-33-3	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.



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- 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 : None known.
- 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 circumstances and the surrounding environment.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances 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, 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.



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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.

Further information on storage conditions : See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2) The value is given in analogy to the following substances: Edetic acid	139-33-3	IOEL	1.5 mg/m3	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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:



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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 : Safety glasses
Skin and body protection : Protective suit
Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : colorless

Odor : none

Odor Threshold : No data available

pH : ca. 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) : The product is not flammable., 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

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Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.006 g/cm ³
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 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 decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION
Acute toxicity

Not classified due to lack of data.

Components:**Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):**

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Acute oral toxicity : LD50 Oral (Rat): > 2,000 - 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 1 - < 5 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The component/mixture is moderately toxic after short term inhalation.

Skin corrosion/irritation

Not classified due to lack of data.

Components:**Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):**

Result : No skin irritation

Serious eye damage/eye irritation

Not classified due to lack of data.

Components:**Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):**

Result : No eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Components:**Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):**

Test Type : Maximization Test
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Method : OECD Test Guideline 406

Germ cell mutagenicity

Not classified due to lack of data.

Carcinogenicity

Not classified due to lack of data.

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 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.

cobas PIK3CA Mutation Test
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Not classified due to lack of data.

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Components:**Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):**

Routes of exposure : inhalation (dust/mist/fume)
 Target Organs : Respiratory Tract
 Assessment : May cause damage to organs through prolonged or repeated exposure.

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION
Ecotoxicity**Product:****Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

Components:**Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):**

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 100 mg/l
 Exposure time: 96 h
 Test Type: static test
 Remarks: nominal concentration
 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: static test
 Method: DIN 38412
 Remarks: nominal concentration

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
 Exposure time: 72 h
 Test Type: static test
 Remarks: Based on data from similar materials

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Toxicity to fish (Chronic toxicity) : NOEC (Danio rerio (zebra fish)): \geq 36.9 mg/l
Exposure time: 35 d
Test Type: flow-through test
Method: OECD Test Guideline 210
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC20 (activated sludge): > 500 mg/l
Exposure time: 30 min
Method: OECD Test Guideline 209

Persistence and degradability
Components:
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Biodegradability : aerobic
Result: Not readily biodegradable.
Method: OECD Test Guideline 301D
Remarks: Based on data from similar materials

Bioaccumulative potential
Components:
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt (1:2):

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 1.8
Exposure time: 28 d
Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: -4.3 (77 °F / 25 °C)
pH: 4.5

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.



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Contaminated packaging : 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

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

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).



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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

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 : 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
- 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 : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not in compliance with the inventory

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TSCA list

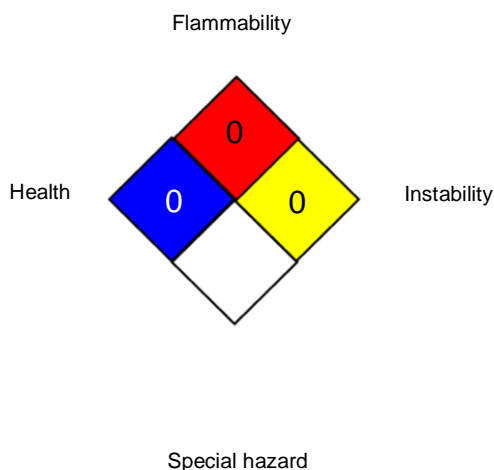
No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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.

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



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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

Revision Date : 08-28-2024

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.

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SECTION 1. IDENTIFICATION

Product name : MGAC

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : 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



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- 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 : None known.
- 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 circumstances and the surrounding environment.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances 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, 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.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.



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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.
- Further information on storage conditions : See label, package insert or internal guidelines
- Materials to avoid : No materials to be especially mentioned.
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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 : Safety glasses
- Skin and body protection : Protective suit
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.



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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid

- Color : colorless

- Odor : No data available

- Odor Threshold : No data available

- pH : No data available

- 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., 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

- Density : 1.0 g/cm³

- Solubility(ies)
 - Water solubility : completely miscible

 - Solubility in other solvents : No data available

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



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- 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 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 decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Skin corrosion/irritation

Not classified due to lack of data.

Serious eye damage/eye irritation

Not classified due to lack of data.

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Germ cell mutagenicity

Not classified due to lack of data.



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Carcinogenicity

Not classified due to lack of data.

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 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 due to lack of data.

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

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).



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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.

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

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

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.



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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 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.

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 : This product contains the following components that are not on the Canadian DSL nor NDSL.
Magnesium di(acetate)Tetrahydrate
- NZIoC : On the inventory, or in compliance with the inventory
- ENCS : On the inventory, or in compliance with the inventory
- ISHL : On the inventory, or 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

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- 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

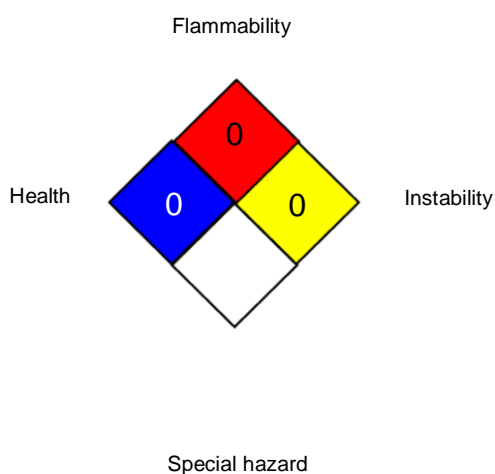
No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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.

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

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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; TECL - 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

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SECTION 1. IDENTIFICATION

Product name : DNA SD

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
Canada)
1-703-527-3887
(International)

Recommended use of the chemical and restrictions on use

Recommended use : Laboratory chemicals
Refer to product literature for further details.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : 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



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- 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 : None known.
- 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 circumstances and the surrounding environment.
- Specific hazards during fire fighting : No information available.
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances 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, 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.
- Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.



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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.
- Further information on storage conditions : See label, package insert or internal guidelines
- Materials to avoid : No materials to be especially mentioned.
- Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

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 : Safety glasses
- Skin and body protection : Protective suit
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.



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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid

- Color : colorless

- Odor : odorless

- Odor Threshold : No data available

- pH : 8.7

- 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., 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

- Density : 1 g/cm³

- Solubility(ies)
 - Water solubility : completely miscible

 - Solubility in other solvents : No data available

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



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- 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 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 decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified due to lack of data.

Skin corrosion/irritation

Not classified due to lack of data.

Serious eye damage/eye irritation

Not classified due to lack of data.

Respiratory or skin sensitization

Skin sensitization

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Germ cell mutagenicity

Not classified due to lack of data.



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Carcinogenicity

Not classified due to lack of data.

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 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 due to lack of data.

STOT-single exposure

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

SECTION 12. ECOLOGICAL INFORMATION

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).



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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.

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

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

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.



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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 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

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

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TSCA : All substances listed as active on the TSCA inventory
TECI : Not in compliance with the inventory

TSCA list

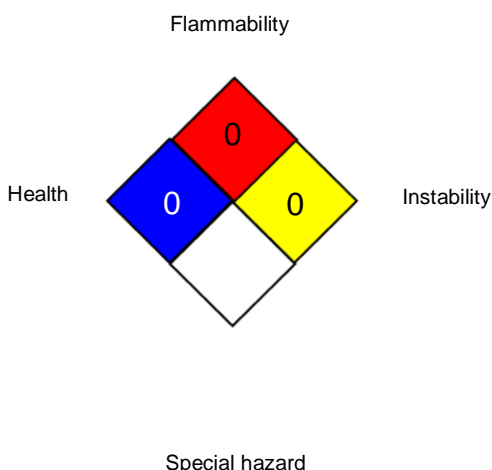
No substances are subject to a Significant New Use Rule.

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



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.

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 -



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