SAFETY DATA SHEET

Oxycodone Calibrators

Version	Revision Date:	Date of last issue: 10-21-2021
2.0	04-13-2022	Date of first issue: 11-26-2015

SECTION 1. IDENTIFICATION

Product name : Oxycodone Calibrators

Product code : 05178517190

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
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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

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

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

Respiratory sensitization : Category 1

Skin sensitization : Category 1

Reproductive toxicity : Category 1A

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360D May damage the unborn child.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read

and understood.
P261 Avoid breathing mist or vapors.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P285 In case of inadequate ventilation wear respiratory protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Handle as potentially infectious.

Components

Chemical name	CAS-No.	Concentration (% w/w)
Albumins, blood serum	9048-46-8	>= 0.1 - < 1
Formamide, N,N-dimethyl-	68-12-2	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Show this material safety data sheet to the doctor in attendance.
Do not leave the victim unattended.

If inhaled : Call a physician or poison control center immediately.
Move to fresh air.
If unconscious, place in recovery position and seek medical advice.

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

In case of eye contact	:	Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician. Take victim immediately to hospital. Rinse mouth with water.
Most important symptoms and effects, both acute and delayed	:	May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May damage the unborn child.
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.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
Hazardous combustion products	:	No hazardous combustion products are known
Further information	:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Ensure adequate ventilation. Refer to protective measures listed in sections 7 and 8.
Environmental precautions	:	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion	:	Normal measures for preventive fire protection.
Advice on safe handling	:	Avoid formation of aerosol. Do not breathe vapors/dust. Avoid exposure - obtain special instructions before use. Avoid contact with skin and eyes. For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area. Provide sufficient air exchange and/or exhaust in work rooms. Dispose of rinse water in accordance with local and national regulations. Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
Conditions for safe storage	:	Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.
Further information on storage conditions	:	See label, package insert or internal guidelines
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
Formamide, N,N-dimethyl-	68-12-2	TWA	5 ppm	ACGIH
		TWA	10 ppm 30 mg/m3	NIOSH REL
		TWA	10 ppm 30 mg/m3	OSHA Z-1
		TWA	10 ppm 30 mg/m3	OSHA P0

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis

Formamide, N,N-dimethyl-	68-12-2	Total N-Methylfor-mamide	Urine	End of shift (As soon as possible after exposure ceases)	30 mg/l	ACGIH BEI
		N-Acetyl-S-(N-methyl-carbamoyl) cysteine	Urine	End of shift at end of work-week	30 mg/l	ACGIH BEI

Engineering measures : No data available

Personal protective equipment

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

Hand protection

In case of contact through splashing:

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

In case of full contact:

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

Remarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles

Skin and body protection : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : light yellow

Odor : No data available

Odor Threshold	:	No data available
pH	:	5.9 - 6.1
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
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	:	No decomposition if stored and applied as directed.

Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Components:

Formamide, N,N-dimethyl-:

Acute oral toxicity	:	LD50 Oral (Rat, male and female): 3,010 mg/kg Method: OECD Test Guideline 401 Symptoms: Gastrointestinal disturbance
Acute inhalation toxicity	:	Acute toxicity estimate: 11.1 mg/l Exposure time: 4 h Test atmosphere: vapor Method: Expert judgment
Acute dermal toxicity	:	LD50 Dermal (Rabbit): 1,500 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks	:	May cause skin irritation and/or dermatitis.

Components:

Formamide, N,N-dimethyl-:

Species	:	Rabbit
Exposure time	:	20 h
Result	:	No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Remarks	:	Vapors may cause irritation to the eyes, respiratory system and the skin.

Components:

Formamide, N,N-dimethyl-:

Species	:	Rabbit
Result	:	Irritating to eyes.

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

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

Product:

Assessment	:	May cause sensitization by skin contact.
Remarks	:	Expert judgment
Assessment	:	May cause sensitization by inhalation.
Remarks	:	Expert judgment
Remarks	:	Causes sensitization.

Components:

Albumins, blood serum:

Result	:	May cause sensitization by skin contact.
Result	:	May cause sensitization by inhalation.

Formamide, N,N-dimethyl-:

Test Type	:	Local lymph node assay (LLNA)
Species	:	Mouse
Method	:	OECD Test Guideline 406
Result	:	Does not cause skin sensitization.

Germ cell mutagenicity

Not classified based on available information.

Components:

Formamide, N,N-dimethyl-:

Genotoxicity in vitro	:	Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Metabolic activation: with and without metabolic activation Result: negative Test Type: unscheduled DNA synthesis assay Test system: human diploid fibroblasts Metabolic activation: with and without metabolic activation Result: negative Test Type: Microbial mutagenesis assay (Ames test) Test system: Salmonella typhimurium Metabolic activation: with and without metabolic activation Result: negative
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Intraperitoneal injection

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Albumins, blood serum:

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.

Formamide, N,N-dimethyl-:

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.

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

IARC Group 2A: Probably carcinogenic to humans
Formamide, N,N-dimethyl- 68-12-2

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

May damage the unborn child.

Components:

Formamide, N,N-dimethyl-:

Reproductive toxicity - Assessment : May damage the unborn child., Presumed human reproductive toxicant

STOT-single exposure

Not classified based on available information.

Components:

Formamide, N,N-dimethyl-:

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

STOT-repeated exposure

Not classified based on available information.

Components:

Formamide, N,N-dimethyl-:

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

organ toxicant, repeated exposure.

Repeated dose toxicity

Components:

Formamide, N,N-dimethyl-:

Species	:	Rat, male and female
NOAEL	:	238 mg/kg
LOAEL	:	475 mg/kg
Application Route	:	Oral
Exposure time	:	28 days

Aspiration toxicity

Not classified based on available information.

Components:

Formamide, N,N-dimethyl-:

No aspiration toxicity classification

Further information

Components:

Formamide, N,N-dimethyl-:

Remarks	:	Solvents may degrease the skin.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Formamide, N,N-dimethyl-:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 7,100 mg/l Exposure time: 96 h Test Type: flow-through test
Toxicity to daphnia and other aquatic invertebrates	:	NOEC (Daphnia magna (Water flea)): 6,000 mg/l Exposure time: 48 h EC50 (Daphnia magna (Water flea)): 13,100 mg/l Exposure time: 48 h Test Type: static test Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): > 1,000 mg/l Exposure time: 72 h Method: DIN 38412
Toxicity to microorganisms	:	EC50 (Bacteria): 12,300 - 17,500 mg/l Exposure time: 5 min

Test Type: static test

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:

Formamide, N,N-dimethyl-:

Biodegradability : aerobic
Result: Readily biodegradable.
Biodegradation: 100 %
Exposure time: 21 d
Method: OECD Test Guideline 301E

Biochemical Oxygen Demand (BOD) : 900 mg/g
Incubation time: 5 d

Bioaccumulative potential

Components:

Albumins, blood serum:

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

Formamide, N,N-dimethyl-:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 0.3 - 1.2
Exposure time: 56 d
Temperature: 77 °F / 25 °C
Concentration: 0.002 mg/l
Method: OECD Test Guideline 305C
Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : log Pow: -0.85 (77 °F / 25 °C)

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).

Components:

Formamide, N,N-dimethyl-:

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation

49 CFR
Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

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 : Reproductive toxicity
Respiratory or skin sensitization

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

Formamide, N,N-dimethyl-	68-12-2	>= 0.1 - < 1 %

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know

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

Pennsylvania Right To Know

non hazardous compounds (liquid)	Not Assigned
Urine from human origin	Not Assigned
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

California Prop. 65

WARNING: This product can expose you to chemicals including Formamide, N,N-dimethyl-, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

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

AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. non hazardous compounds (liquid) Urine from human origin oxycodone
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

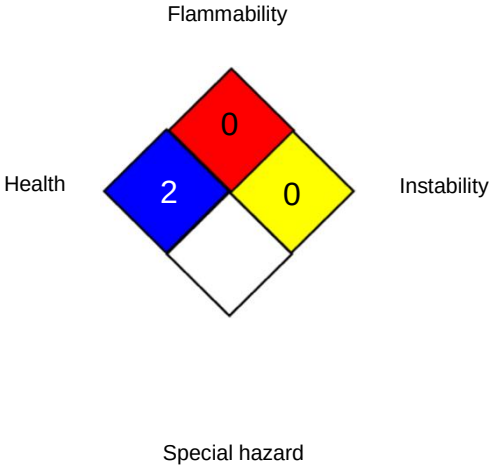
TSCA list

No substances are subject to a Significant New Use Rule.

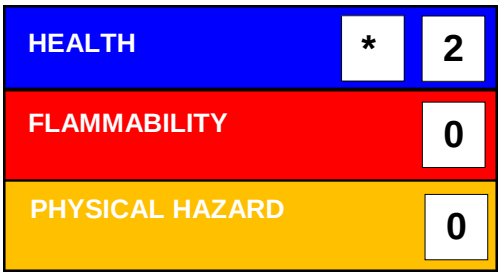
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

NFPA 704:



HMIS® IV:



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

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI	:	ACGIH - Biological Exposure Indices (BEI)
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
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
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of

Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 04-13-2022

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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