

SAFETY DATA SHEET



Atropine Sulfate Formulation

Version 5.0 Revision Date: 14.04.2025 SDS Number: 7665466-00010 Date of last issue: 04.12.2024
Date of first issue: 14.12.2020

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Atropine Sulfate Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin sensitization : Category 1

Reproductive toxicity : Category 2

GHS label elements

Hazard pictograms :

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.
H361 Suspected of damaging fertility or 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 should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

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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

Components

Chemical name	CAS-No.	Concentration (% w/w)
Benzyl alcohol	100-51-6	>= 1 -< 5
Sodium chloride	7647-14-5	>= 1 -< 5
Atropine Sulfate	5908-99-6	>= 0.1 -< 1

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.

In case of eye contact : Thoroughly clean shoes before reuse.
Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

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Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: Carbon oxides Metal oxides Chlorine compounds
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. 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. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	: See Engineering measures under EXPOSURE
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Local/Total ventilation	CONTROLS/PERSONAL PROTECTION section.
Advice on safe handling	<ul style="list-style-type: none">Use only with adequate ventilation.Do not get on skin or clothing.Avoid breathing mist or vapors.Do not swallow.Avoid contact with eyes. <p>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment</p> <p>Take care to prevent spills, waste and minimize release to the environment.</p>
Hygiene measures	<ul style="list-style-type: none">If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.When using do not eat, drink or smoke.Contaminated work clothing should not be allowed out of the workplace.Wash contaminated clothing before re-use. <p>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.</p>
Conditions for safe storage	<ul style="list-style-type: none">Keep in properly labeled containers.Store in accordance with the particular national regulations.
Materials to avoid	<ul style="list-style-type: none">Do not store with the following product types:Strong oxidizing agentsGases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Atropine Sulfate	5908-99-6	TWA	2 µg/m ³ (OEB 4)	
		Further information: Eye		
		Wipe limit	20 µg/100 cm ²	

Engineering measures	<ul style="list-style-type: none">The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.
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All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Essentially no open handling permitted.
Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	: Combined particulates and organic vapor type
Hand protection	
Material	: Chemical-resistant gloves
Remarks	: Consider double gloving.
Eye protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Color	: Translucent-colorless to pale yellow
Odor	: No data available
Odor Threshold	: No data available
pH	: 3.0 - 6.5
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable

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Flammability (liquids)	: 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	: 0.900 - 1.100 g/cm ³
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Autoignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available
Particle characteristics	
Particle size	: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: Can react with strong oxidizing agents.
Conditions to avoid	: None known.
Incompatible materials	: Oxidizing agents
Hazardous decomposition products	: No hazardous decomposition products are known.

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SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

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

Components:

Benzyl alcohol:

Acute oral toxicity : LD50 (Rat): 1,200 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 5.4 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

Sodium chloride:

Acute oral toxicity : LD50 (Rat): 3,550 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 42 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Atropine Sulfate:

Acute oral toxicity : LD50 (Rat): 500 mg/kg
LD50 (Mouse): 75 mg/kg
LD50 (Rabbit): 600 mg/kg
LD50 (Guinea pig): 1,100 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Benzyl alcohol:

Species : Rabbit

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Method : OECD Test Guideline 404
Result : No skin irritation

Sodium chloride:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Benzyl alcohol:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Sodium chloride:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Components:

Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)
Routes of exposure : Skin contact
Species : Humans
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

Sodium chloride:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Benzyl alcohol:

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Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative
Sodium chloride:	
Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Result: positive
	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
	Test Type: Saccharomyces cerevisiae, gene mutation assay (in vitro) Result: positive
	Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro) Result: positive
	Test Type: Chromosome aberration test in vitro Result: positive
	Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo	: Test Type: In vivo micronucleus test Species: Mouse Application Route: Intraperitoneal injection Result: negative
	Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Intraperitoneal injection Result: positive
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen.
Atropine Sulfate:	
Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Germ cell mutagenicity - Assessment	: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity

Not classified based on available information.

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Components:

Benzyl alcohol:

Species	:	Mouse
Application Route	:	Ingestion
Exposure time	:	103 weeks
Method	:	OECD Test Guideline 451
Result	:	negative

Sodium chloride:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative

Atropine Sulfate:

Species	:	Rat
Application Route	:	Intraperitoneal injection
Exposure time	:	28 month(s)
NOAEL	:	2.5 mg/kg bw/day
Result	:	negative

Carcinogenicity - Assessment	:	Weight of evidence does not support classification as a carcinogen
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Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Components:

Benzyl alcohol:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on fetal development	:	Test Type: Embryo-fetal development Species: Mouse Application Route: Ingestion Result: negative

Atropine Sulfate:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Ingestion General Toxicity Parent: LOAEL: 62.5 mg/kg body weight Result: Reduced fertility
		Test Type: Fertility/early embryonic development Species: Rat, female Application Route: Intraperitoneal injection

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General Toxicity Parent: LOAEL: 1 mg/kg body weight
Result: Effect on estrous cycle

Effects on fetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Intravenous injection
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: Abnormalities of the musculoskeletal system.

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

Components:

Atropine Sulfate:

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:

Atropine Sulfate:

Routes of exposure : Inhalation
Target Organs : Eye, Central nervous system
Assessment : Shown to produce significant health effects in animals at concentrations of 50 ppmV/6h/d or less.

Repeated dose toxicity

Components:

Benzyl alcohol:

Species : Rat
NOAEL : 1.072 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 28 Days
Method : OECD Test Guideline 412

Sodium chloride:

Species : Rat
LOAEL : 2,533 mg/kg
Application Route : Ingestion
Exposure time : 2 y

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Species : Rabbit
LOAEL : 59 mg/kg

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Application Route	:	Subcutaneous
Exposure time	:	100 d
Target Organs	:	Central nervous system
Symptoms	:	Convulsions, respiratory depression
Species	:	Rat
LOAEL	:	0.5 mg/kg
Application Route	:	Inhalation
Exposure time	:	21 d
Target Organs	:	Eye
Symptoms	:	Dilatation of the pupil
Species	:	Dog
LOAEL	:	0.5 mg/kg
Application Route	:	Inhalation
Exposure time	:	21 d
Target Organs	:	Eye
Symptoms	:	Dilatation of the pupil

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Atropine Sulfate:

General Information	:	Target Organs: Central nervous system Symptoms: dry mouth, Blurred vision, tachycardia, constipation, central nervous system effects, restlessness, Fatigue, delirium, mental depression
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SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzyl alcohol:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Sodium chloride:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 4,136 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50: > 2,000 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia pulex (Water flea)): 314 mg/l
Exposure time: 21 d

Toxicity to microorganisms : EC10: > 1,000 mg/l

Atropine Sulfate:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 356 mg/l
Exposure time: 48 h

Persistence and degradability

Components:

Benzyl alcohol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Bioaccumulative potential

Components:

Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

Atropine Sulfate:

Partition coefficient: n-octanol/water : log Pow: 1.83

Mobility in soil

No data available

Other adverse effects

No data available

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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 for product as supplied.

Domestic regulation

NOM-002-SCT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Federal Law for the control of chemical precursors, : Not applicable
essential chemical products and machinery for
producing capsules, tablets and pills.

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

DSL : not determined

AICS : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025
Date format : dd.mm.yyyy

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Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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