according to the Hazardous Products Regulations



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SECTION 1. IDENTIFICATION

Product name : Acetyl Methionine Formulation

Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.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 in accordance with the Hazardous Products Regulations

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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
N-Acetyl-DL- methionine	2-Acetamido-4- (methylsulfa- nyl)butanoic acid	1115-47-5	>= 10 - < 30 *
Nicotinamide	3- Pyridinecarbox- amide	98-92-0	>= 1 - < 5 *
Caffeine	1H-Purine-2,6- dione, 3,7- dihydro-1,3,7- trimethyl-	58-08-2	>= 1 - < 5 *
Pyridoxine Hydrochlo- ride	3,4- Pyridinedi- methanol, 5- hydroxy-6- methyl-, hydro-	58-56-0	>= 0.1 - < 1 *

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chloride

Actual concentration or concentration range is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.

Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

None known.

Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

Protection of first-aiders : No special precautions are necessary for first aid responders. 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

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulfur oxides

Chlorine compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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

Wear self-contained breathing apparatus for firefighting if

necessary.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Follow safe handling advice (see section 7) and personal

according to the Hazardous Products Regulations



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tive equipment and emergency procedures

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

il barriara

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

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

Use only with adequate ventilation.

Advice on safe handling

Handle in accordance with good industrial hygiene and safety

practice, based on the results of the workplace exposure

assessment

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage

Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
N-Acetyl-DL-methionine	1115-47-5	TWA	2000 μg/m3 (OEB 1)	Internal
Pyridoxine Hydrochloride	58-56-0	TWA	OEB 3 (>= 10 <	Internal

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| 100 μg/m3)

Engineering measures : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face

containment devices).
Minimize open handling.

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 Hand protection Combined particulates and organic vapor type

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.

Hygiene measures : 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. Wash contaminated clothing before re-use.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : Colorless to pale yellow

Odor : characteristic

according to the Hazardous Products Regulations



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Odor Threshold : No data available

pH : 3.30 - 4.30

Melting point/freezing point : No data available

Initial boiling point and boiling

range

99 °C

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

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 : 1.03 - 1.09

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No

: 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

according to the Hazardous Products Regulations



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SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

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: > 2,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

Components:

N-Acetyl-DL-methionine:

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

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5.25 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

Nicotinamide:

Acute oral toxicity : LD50 (Rat): > 2,500 mg/kg

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

Acute inhalation toxicity : LC50 (Rat): > 3.8 mg/l

Exposure time: 4 h

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Test atmosphere: dust/mist

Method: OECD Test Guideline 436

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

Caffeine:

Acute oral toxicity : LD50 (Rat): 367.7 mg/kg

Acute inhalation toxicity : LC50 (Rat): 4.94 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

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

Assessment: The substance or mixture has no acute dermal

toxicity

Pyridoxine Hydrochloride:

Acute oral toxicity : LD50 (Rat): 4,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

N-Acetyl-DL-methionine:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Nicotinamide:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Caffeine:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Pyridoxine Hydrochloride:

Species : Rabbit

Result : No skin irritation

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Serious eye damage/eye irritation

Not classified based on available information.

Components:

Nicotinamide:

Species : Rabbit

Result : Irritation to eyes, reversing within 7 days

Method : OECD Test Guideline 405

Caffeine:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Pyridoxine Hydrochloride:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

N-Acetyl-DL-methionine:

Test Type : Buehler Test Routes of exposure : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials

Nicotinamide:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Caffeine:

Test Type : Local lymph node assay (LLNA)

Routes of exposure : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

according to the Hazardous Products Regulations



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Pyridoxine Hydrochloride:

Test Type : Maximization Test Routes of exposure : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

N-Acetyl-DL-methionine:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Remarks: Based on data from similar materials

Nicotinamide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection Method: OECD Test Guideline 474

Result: negative

Caffeine:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: positive

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Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Mouse

Application Route: Ingestion

Result: negative

Pyridoxine Hydrochloride:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Caffeine:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

Nicotinamide:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Ingestion

Method: OECD Test Guideline 414

Result: negative

Caffeine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Pyridoxine Hydrochloride:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

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STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

N-Acetyl-DL-methionine:

Species Rat

NOAEL > 100 mg/kg Application Route Ingestion 90 Days Exposure time

OECD Test Guideline 408 Method

Remarks Based on data from similar materials

Nicotinamide:

Species Rat NOAEL 215 mg/kg Application Route Ingestion Exposure time 28 Days

Method **OECD Test Guideline 407**

Caffeine:

Species Rat, male NOAEL 151 mg/kg LOAEL 271.9 mg/kg Application Route : Ingestion Exposure time 90 Days

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

N-Acetyl-DL-methionine:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

according to the Hazardous Products Regulations



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Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Nicotinamide:

Toxicity to fish LC50 (Poecilia reticulata (guppy)): > 1,000 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l

Exposure time: 24 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Desmodesmus subspicatus (green algae)): > 1,000

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 560 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudomonas putida): 4,235 mg/l Toxicity to microorganisms

Exposure time: 18 h

Method: OECD Test Guideline 209

Caffeine:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 87 mg/l

> Exposure time: 96 h Method: DIN 38412

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 182 mg/l

Exposure time: 48 h Method: DIN 38412

Toxicity to algae/aquatic

plants

: ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Desmodesmus subspicatus (green algae)): > 100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : EC10 (Pseudomonas putida): 1,530 mg/l

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Exposure time: 17 h

Method: DIN 38 412 Part 8

Pyridoxine Hydrochloride:

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

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Persistence and degradability

Components:

N-Acetyl-DL-methionine:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Nicotinamide:

Result: Readily biodegradable. Biodegradability

Biodegradation: 95 % Exposure time: 28 d

Method: OECD Test Guideline 301E

Caffeine:

Biodegradability Result: Readily biodegradable.

Remarks: Based on data from similar materials

Pyridoxine Hydrochloride:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 94 % Exposure time: 28 d

Method: OECD Test Guideline 301E

Bioaccumulative potential

Components:

N-Acetyl-DL-methionine:

Partition coefficient: n-: log Pow: -0.313

octanol/water Remarks: Calculation

Nicotinamide:

Partition coefficient: nlog Pow: -0.38

octanol/water

Caffeine:

Partition coefficient: n-

octanol/water

log Pow: -0.091

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Pyridoxine Hydrochloride:

Partition coefficient: n-

octanol/water

log Pow: 4.32

Mobility in soil

No data available

Other adverse effects

No data available

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

TDG

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

AICS : not determined

DSL : not determined

IECSC : not determined

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SECTION 16. OTHER INFORMATION

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 Agen-

cy, http://echa.europa.eu/

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

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific

according to the Hazardous Products Regulations



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context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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