

# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Ketamine (10%) Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Skin corrosion/irritation : Category 2

Serious eye damage/eye irri-

tation

Category 2B

Reproductive toxicity : Category 2

Specific target organ toxicity - :

repeated exposure (Dermal)

Category 2 (Kidney, Liver, Brain)

**GHS** label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H315 + H320 Causes skin and eye irritation.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs (Kidney, Liver, Brain) through prolonged or repeated exposure in contact with skin.



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.
P332 + P313 If skin irritation occurs: Get medical advice/ atten-

P337 + P313 If eye irritation persists: Get medical advice/ at-

tention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

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

# **Additional Labelling**

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 10 %

### Other hazards which do not result in classification

None known.

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Ketamine hydrochloride	1867-66-9	>= 10 - < 20	-

### 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical



# **Ketamine (10%) Formulation**

Date of last issue: 2024/04/06 Version Revision Date: SDS Number: 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

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 plenty of water

for at least 15 minutes while removing contaminated clothing

and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of contact, immediately flush eyes with plenty of water In case of eye contact

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. Causes skin and eye irritation.

Most important symptoms and effects, both acute and

delayed

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure in contact with skin.

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).

Treat symptomatically and supportively. Notes to physician

### 5. FIREFIGHTING 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 Chlorine compounds Nitrogen oxides (NOx)

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

Evacuate area.

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### 7. HANDLING AND STORAGE

# Handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation Advice on safe handling Use only with adequate ventilation.

Do not get on skin or clothing.

Do not breathe mist or vapours.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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

environment.

Avoidance of contact

Hygiene measures

Oxidizing agents

: 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.



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

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.

**Storage** 

Conditions for safe storage : Keep in properly labelled containers.

Store locked up.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / Permissible concentration	Basis		
Ketamine hydrochloride	1867-66-9	TWA	10 μg/m3 (OEB 3)	Internal		
	Further information: Skin					
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal		

**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 con-

tainment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type
Hand protection

: Particulates type

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.



# **Ketamine (10%) Formulation**

Date of last issue: 2024/04/06 Version **Revision Date:** SDS Number: 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state liquid

Colour No data available

Odour No data available

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit /

Lower flammability limit

No data available

Flash point No data available

Decomposition temperature No data available

pΗ No data available

No data available Evaporation rate

Auto-ignition temperature No data available

Viscosity

No data available Viscosity, kinematic

Solubility(ies)

Water solubility soluble



# **Ketamine (10%) Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure No data available

Density and / or relative density

Relative density No data available

No data available Density

Relative vapour density 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

### 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

Can react with strong oxidizing agents.

Conditions to avoid None known. Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of: Inhalation

exposure 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



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

### **Components:**

### **Ketamine hydrochloride:**

Acute oral toxicity : LD50 (Rat): 447 mg/kg

LD50 (Mouse): 617 mg/kg

Acute toxicity (other routes of :

administration)

LD50 (Rat): 59 mg/kg

**Application Route: Intravenous** 

LD50 (Mouse): 59 mg/kg

Application Route: Intramuscular

LD50 (Mouse): 356 mg/kg Application Route: Intramuscular

LD50 (Guinea pig): 361 mg/kg Application Route: Intramuscular

LD50 (Rat): 224 mg/kg

Application Route: Intraperitoneal

#### Skin corrosion/irritation

Causes skin irritation.

### **Components:**

### Ketamine hydrochloride:

Species : Rabbit Result : irritating

### Serious eye damage/eye irritation

Causes eye irritation.

### **Components:**

### Ketamine hydrochloride:

Species : Rabbit Result : irritating

## Respiratory or skin sensitisation

## Skin sensitisation

Not classified based on available information.

# Respiratory sensitisation

Not classified based on available information.

### Germ cell mutagenicity

Not classified based on available information.



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Suspected of damaging the unborn child.

### **Components:**

### Ketamine hydrochloride:

Effects on foetal develop- : Test Type: Development

ment Species: Rat

Application Route: Intramuscular
Developmental Toxicity: NOAEL: 120 mg/kg body weight

Target Organs: Kidney, Liver, Heart

Result: No teratogenic effects

Test Type: Development

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: LOAEL: 20 mg/kg body weight

Symptoms: Skeletal and visceral variations
Result: Effects on prenatal and postnatal growth.

Test Type: Development

Species: Rat

Application Route: Intramuscular

Symptoms: Skeletal and visceral variations Result: Effects on prenatal and postnatal growth.

Test Type: Development

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: LOAEL: 60 mg/kg body weight

Symptoms: Skeletal and visceral variations Result: Effects on prenatal and postnatal growth.

Test Type: Development

Species: Monkey

Application Route: Intramuscular

Target Organs: Brain

Result: Effects on prenatal and postnatal growth.

Reproductive toxicity - As-

sessment

: Suspected of damaging the unborn child.

# STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs (Kidney, Liver, Brain) through prolonged or repeated exposure in contact with skin.



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

### **Components:**

# **Ketamine hydrochloride:**

Exposure routes : Skin contact
Target Organs : Kidney, Liver, Brain

Assessment : May cause damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

# **Components:**

### **Ketamine hydrochloride:**

Species : Mouse
LOAEL : 30 mg/kg
Application Route : Intraperitoneal
Exposure time : 3 Months

Target Organs : Kidney, Liver, Bladder

Remarks : Significant toxicity observed in testing

Species : Mouse
LOAEL : 30 mg/kg
Application Route : Intraperitoneal
Exposure time : 6 Months

Target Organs : Kidney, Liver, Bladder

Remarks : Significant toxicity observed in testing

Species : Mouse
LOAEL : 30 mg/kg
Application Route : Intraperitoneal
Exposure time : 28 Weeks
Target Organs : Kidney

Remarks : Significant toxicity observed in testing

Species : Mouse
LOAEL : 30 mg/kg
Application Route : Intraperitoneal
Exposure time : 30 Days
Target Organs : Brain, Liver

Remarks : Significant toxicity observed in testing

Species : Monkey
LOAEL : 1 mg/kg
Application Route : Intraperitoneal
Exposure time : 6 Months
Target Organs : Brain

Remarks : Significant toxicity observed in testing

### **Aspiration toxicity**

Not classified based on available information.



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

### **Experience with human exposure**

### **Components:**

### Ketamine hydrochloride:

Ingestion Symptoms: The most common side effects are:, central nerv-

ous system effects, hypertension, Dizziness, Headache, Nau-

sea, Drowsiness

### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

### **Components:**

### Ketamine hydrochloride:

### **Ecotoxicology Assessment**

Acute aquatic toxicity Toxic effects cannot be excluded

Chronic aquatic toxicity Toxic effects cannot be excluded

### Persistence and degradability

No data available

### Bioaccumulative potential

### **Components:**

### Ketamine hydrochloride:

Partition coefficient: n-

: log Pow: 2.18 octanol/water

Mobility in soil

No data available

### Hazardous to the ozone layer

Not applicable

## Other adverse effects

No data available

# 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

#### 14. TRANSPORT INFORMATION

### **International Regulations**

**UNRTDG** 

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

**IMDG-Code** 

**UN** number Not applicable Not applicable Proper shipping name Not applicable Class : Not applicable Subsidiary risk : Not applicable Packing group Labels Not applicable **EmS Code** Not applicable Marine pollutant Not applicable

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

Not applicable for product as supplied.

# **National Regulations**

Refer to section 15 for specific national regulation.

### Special precautions for user

Not applicable

# 15. REGULATORY INFORMATION

### **Related Regulations**

### **Fire Service Law**

Not applicable to dangerous materials / designated flammables.



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

### **Industrial Safety and Health Law**

### **Harmful Substances Prohibited from Manufacture**

Not applicable

### **Harmful Substances Required Permission for Manufacture**

Not applicable

### **Substances Prevented From Impairment of Health**

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

### **Substances Subject to be Notified Names**

Not applicable

### **Substances Subject to be Indicated Names**

Not applicable

# Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

# Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

### Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

### Ordinance on Prevention of Lead Poisoning

Not applicable

### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

# Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

### **Poisonous and Deleterious Substances Control Law**

Not applicable



# **Ketamine (10%) Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

**High Pressure Gas Safety Act** 

Not applicable

**Explosive Control Law** 

Not applicable

**Vessel Safety Law** 

Not regulated as a dangerous good

**Aviation Law** 

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act** 

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 16. OTHER INFORMATION

**Further information** 

Sources of key data used to : compile the Safety Data

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Sheet cv. 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.

Internal technical data, data from raw material SDSs, OECD

Date format : yyyy/mm/dd

Full text of other abbreviations



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Version Revision Date: SDS Number: Date of last issue: 2024/04/06 7.0 2024/09/28 3976792-00013 Date of first issue: 2019/02/14

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

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 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.

JP / EN