

Asenapine Formulation

Version 3.4 Revision Date: 10.10.2020 SDS Number: 690799-00011 Date of last issue: 13.09.2019
Date of first issue: 19.05.2016

Section 1: Identification

Product name : Asenapine Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Section 2: Hazard identification**GHS Classification**

Acute toxicity (Oral) : Category 3

Acute toxicity (Inhalation) : Category 4

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure (Oral) : Category 1 (Central nervous system, Cardio-vascular system)

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Central nervous system)

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H301 Toxic if swallowed.
H332 Harmful if inhaled.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H370 Causes damage to organs (Central nervous system, Cardio-vascular system) if swallowed.
H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

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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 dust.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P271 Use only outdoors or in a well-ventilated area.
 P281 Use personal protective equipment as required.

Response:
 P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. Rinse mouth.
 P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
 P307 + P311 IF exposed: Call a POISON CENTER or doctor/ physician.

Storage:
 P405 Store locked up.

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

Other hazards which do not result in classification

Dust contact with the eyes can lead to mechanical irritation.
 Contact with dust can cause mechanical irritation or drying of the skin.
 May form explosive dust-air mixture during processing, handling or other means.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate	85650-56-2	>= 30 -< 60

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.
 If not breathing, give artificial respiration.
 If breathing is difficult, give oxygen.
 Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.

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- In case of eye contact : Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- If swallowed : If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.
If swallowed, DO NOT induce vomiting.
Call a physician or poison control centre immediately.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Toxic if swallowed.
Harmful if inhaled.
Suspected of damaging fertility. Suspected of damaging the unborn child.
Causes damage to organs if swallowed.
Causes damage to organs through prolonged or repeated exposure if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
- Protection of first-aiders : Dust contact with the eyes can lead to mechanical irritation.
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.
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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 : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
- 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
- Hazchem Code : 2X
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Section 6: Accidental release measures

- Personal precautions, protective equipment and emergency measures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal pro-

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- Conditions for safe storage : industrial hygiene monitoring, medical surveillance and the use of administrative controls.
Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Explosives

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate	85650-56-2	TWA	1 µg/m ³ (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm ²	Internal

- Engineering measures** : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).
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.

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 : Particulates 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, dis-

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posable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance	:	powder
Colour	:	white to off-white
Odour	:	odourless
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, kinematic	:	Not applicable

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Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : No data available

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

Section 11: Toxicological information

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Toxic if swallowed.
Harmful if inhaled.

Product:

Acute oral toxicity : Acute toxicity estimate: 238.4 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 1.08 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:**trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Acute oral toxicity : LD50 (Rat): 110 - 178 mg/kg
LD50 (Dog): > 200 mg/kg
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 0.5 - 2 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist

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Acute toxicity (other routes of administration) : LD50 (Rat): > 200 mg/kg
Application Route: Intravenous
Target Organs: Central nervous system
Remarks: No mortality observed at this dose.

Skin corrosion/irritation

Not classified based on available information.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Remarks : No data available

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Species : Guinea pig
Result : Not a skin sensitizer.

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

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

Test Type: Mouse Lymphoma
Result: negative

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Test Type: sister chromatid exchange assay
Result: negative

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Application Route: Oral
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Species : Mouse
Application Route : Subcutaneous
Exposure time : 89 - 98 weeks
Result : negative

Species : Rat
Application Route : Subcutaneous
Exposure time : 100 - 106 weeks
Result : negative

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:**trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:**

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Fertility: LOAEL: 1.0 mg/kg body weight
Symptoms: Reduced maternal body weight gain, Reduced offspring weight gain, Effects on fertility, Effects on F1 offspring
Result: Embryotoxic effects and adverse effects on the offspring were detected.

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 30 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects

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Test Type: Embryo-foetal development
 Species: Rabbit
 Application Route: Intravenous injection
 Developmental Toxicity: NOAEL: 0.626 mg/kg body weight
 Result: No teratogenic effects

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

STOT - single exposure

Causes damage to organs (Central nervous system, Cardio-vascular system) if swallowed.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Exposure routes : Oral
 Target Organs : Central nervous system, Cardio-vascular system
 Assessment : Causes damage to organs.

STOT - repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Exposure routes : Ingestion
 Target Organs : Central nervous system
 Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:**

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Species : Rat
 LOAEL : 0.6 mg/kg
 Application Route : Oral
 Exposure time : 52 Weeks
 Target Organs : Central nervous system
 Symptoms : constriction of pupils

Species : Rat
 LOAEL : 0.1 mg/kg
 Application Route : Intravenous
 Exposure time : 14 Weeks
 Symptoms : constriction of pupils, Lachrymation

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Species	:	Rat
LOAEL	:	0.5 mg/kg
Application Route	:	Subcutaneous
Exposure time	:	13 Weeks
Target Organs	:	Central nervous system

Species	:	Dog
LOAEL	:	> 1.25 mg/kg
Application Route	:	Oral
Exposure time	:	13 - 52 Weeks
Target Organs	:	Central nervous system
Symptoms	:	constriction of pupils, Tremors, Irritability

Aspiration toxicity

Not classified based on available information.

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Not applicable

Experience with human exposure**Components:**

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Ingestion	:	Symptoms: restlessness, Drowsiness, Dizziness, decrease in heart rate, hypotension
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Section 12: Ecological information**Ecotoxicity****Components:**

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Toxicity to fish	:	LC50 (Cyprinus carpio (Carp)): 0.53 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
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Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0.27 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
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	:	NOEC (Pseudokirchneriella subcapitata (green algae)): 0.084 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
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Toxicity to fish (Chronic tox-	:	NOEC (Pimephales promelas (fathead minnow)): 0.04 mg/l
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icity) Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.00086 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: 37 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 10 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Persistence and degradability

No data available

Bioaccumulative potential

Components:

trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 2,424

Partition coefficient: n-octanol/water : log Pow: 4.9

Mobility in soil

No data available

Other adverse effects

No data available

Section 13: Disposal considerations

Disposal methods

Waste from residues : 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

UN number : UN 2811
Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S.
(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)
Class : 6.1

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Packing group : III
Labels : 6.1

IATA-DGR

UN/ID No. : UN 2811
Proper shipping name : Toxic solid, organic, n.o.s.
(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)

Class : 6.1
Packing group : III
Labels : Toxic
Packing instruction (cargo aircraft) : 677
Packing instruction (passenger aircraft) : 670

IMDG-Code

UN number : UN 2811
Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S.
(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)

Class : 6.1
Packing group : III
Labels : 6.1
EmS Code : F-A, S-A
Marine pollutant : yes

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

Not applicable for product as supplied.

National Regulations**NZS 5433**

UN number : UN 2811
Proper shipping name : TOXIC SOLID, ORGANIC, N.O.S.
(trans-5-Chloro-2,3,3a,12b-tetrahydro-2-methyl-1H-dibenz[2,3:6,7]oxepino[4,5-c]pyrrole maleate)

Class : 6.1
Packing group : III
Labels : 6.1
Hazchem Code : 2X

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information**Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

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HSW Controls

Certified handler certificate not required.
 Tracking hazardous substance not required.
 Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

Section 16: Other information**Further information**

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

Date format : dd.mm.yyyy

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; KECl - 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;

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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.

NZ / EN