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Section 1. Identification

GHS product identifier : Voriconazole for Injection

Other means of identification: Not available. **Product type** : Powder.

Relevant identified uses of the substance or mixture and uses advised against

Product use : Pharmaceuticals. (For intended use only.)

Observe technical data sheet/instructions for use.

Specific Treatments: Antifungal.

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.

8700 W. Bryn Mawr, Suite 600S

Chicago, IL 60631

Telephone: 224-443-4617 www.meithealpharma.com

e-mail address of person responsible for this SDS

info@meithealpharma.com

Emergency telephone number (with hours of operation)

: 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard

(29 CFR 1910.1200).

Classification of the COMBUSTIBLE DUSTS substance or mixture

H302 ACUTE TOXICITY (oral) - Category 4 H317 SKIN SENSITIZATION - Category 1 H351 **CARCINOGENICITY - Category 2**

H361 **TOXIC TO REPRODUCTION - Category 2**

H373 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) -

Category 2

GHS label elements

Hazard pictograms





Signal word : Warning



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Section 2. Hazards identification

Hazard statements

: H302 - Harmful if swallowed.

H317 - May cause an allergic skin reaction.

H351 - Suspected of causing cancer.

H361 - Suspected of damaging fertility or the unborn child.

H373 - May cause damage to organs through prolonged or repeated exposure.

May form combustible dust concentrations in air.

Precautionary statements

Prevention

: P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P280 - Wear protective gloves, protective clothing and eye or face protection.

P260 - Do not breathe dust or mist.

P270 - Do not eat, drink or smoke when using this product.

P264 - Wash thoroughly after handling.

P272 - Contaminated work clothing must not be allowed out of the workplace.

Response : P308 + P313 - IF exposed or concerned: Get medical advice or attention.

P301 + P312, P330 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel

unwell. Rinse mouth.

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

P333 + P313 - If skin irritation or rash occurs: Get medical advice or attention.

P363 - Wash contaminated clothing before reuse.

Storage : P405 - Store locked up.

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national

and international regulations.

Supplemental label

elements

: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames

and other ignition sources. No smoking. Prevent dust accumulation.

Hazards not otherwise

classified

: None known.

Section 3. Composition/information on ingredients

Substance/mixture

: Mixture

Other means of identification

: Not available.

Ingredient name	Other names	%	Identifiers
.betaCyclodextrin, sulfobutyl ethers, sodium salts	-	≥90	CAS: 182410-00-0
voriconazole	-	≤10	CAS: 137234-62-9

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.



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Section 4. First aid measures

Description of necessary first aid measures

Eye contact: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower

eyelids. Check for and remove any contact lenses. Continue to rinse for at least $10\,$

minutes. Get medical attention.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not

breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway.

Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may

need to be kept under medical surveillance for 48 hours.

Skin contact: Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash

contaminated clothing thoroughly with water before removing it, or wear gloves.

Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean

shoes thoroughly before reuse.

Ingestion: Wash out mouth with water. Remove dentures if any. If material has been swallowed

and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If

unconscious, place in recovery position and get medical attention immediately. Maintain

an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact: Exposure to airborne concentrations above statutory or recommended exposure limits

may cause irritation of the eyes.

Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits

may cause irritation of the nose, throat and lungs.

Skin contact: May cause an allergic skin reaction.

Ingestion: Harmful if swallowed.

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:

irritation redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

reduced fetal weight increase in fetal deaths skeletal malformations



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Section 4. First aid measures

Skin contact: Adverse symptoms may include the following:

irritation redness

reduced fetal weight increase in fetal deaths skeletal malformations

Ingestion : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The

exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments: No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It may be

dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing

media

: Use dry chemical powder.

Unsuitable extinguishing

media

: Do not use water jet.

Specific hazards arising from the chemical

Hazardous thermal decomposition products

: May form explosible dust-air mixture if dispersed.

: Decomposition products may include the following materials:

carbon dioxide carbon monoxide nitrogen oxides sulfur oxides

halogenated compounds metal oxide/oxides

Special protective actions for fire-fighters

: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.



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Section 5. Fire-fighting measures

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders: If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For nonemergency personnel".

Environmental precautions

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill

: Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill

: Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor.

Section 7. Handling and storage

Precautions for safe handling

Protective measures

: Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Avoid exposure - obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not breathe dust. Do not ingest. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take



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Section 7. Handling and storage

precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene

Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
.betaCyclodextrin, sulfobutyl ethers, sodium salts	None.
voriconazole	None.

Appropriate engineering controls

: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

Environmental exposure controls

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.



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Section 8. Exposure controls/personal protection

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles.

Skin protection

Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state : Solid. [Lyophilized/Powder.]

: White to off-white. Color : Not available. Odor : Not available. Odor threshold

Ha : 5.5 to 7 [Conc. (% w/w): 1%]

Melting point Not available. **Boiling point or initial** boiling point and boiling

: Not available.

range

: Not applicable. Flash point **Evaporation rate** : Not available. : Not available. **Flammability** Lower and upper explosion : Not applicable.

limit/flammability limit

: Not available. Vapor pressure : Not applicable. Relative vapor density



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Section 9. Physical and chemical properties

Relative density

: Not available.

Density

1.0654 to 1.0702 g/cm³ [25°C (77°F)]

Solubility(ies)

Media Result cold water Very slightly soluble hot water Very slightly soluble

Miscible with water

: No.

Partition coefficient: n-

octanol/water

: Not applicable.

Auto-ignition temperature Decomposition temperature : Not applicable.

: Not available. : Not available.

Viscosity

SADT

: Dynamic (room temperature): Not available. Kinematic (room temperature): Not available.

Kinematic (40°C (104°F)): Not available.

Flow time (ISO 2431)

: Not available.

Particle characteristics

Median particle size

: Not available.

Other information

Physical/chemical properties comments : No additional information.

Section 10. Stability and reactivity

Reactivity

: No specific test data related to reactivity available for this product or its ingredients.

Chemical stability

: The product is stable.

Possibility of hazardous reactions

: Under normal conditions of storage and use, hazardous reactions will not occur. Under normal conditions of storage and use, hazardous polymerization will not occur.

Conditions to avoid

: Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation.

Incompatible materials

: Reactive or incompatible with the following materials: oxidizing materials



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Section 10. Stability and reactivity

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Not available.

Irritation/Corrosion

Not available.

Sensitization

Not available.

Mutagenicity

Conclusion/Summary: Not available.

Carcinogenicity

Conclusion/Summary: Not available.

Reproductive toxicity

Conclusion/Summary: Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Name	3.3	Route of exposure	Target organs
voriconazole	Category 2	-	-

Aspiration hazard

Not available.

Information on the likely routes of exposure

: Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

Eye contact: Exposure to airborne concentrations above statutory or recommended exposure limits

may cause irritation of the eyes.

Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits

may cause irritation of the nose, throat and lungs.

Skin contact: May cause an allergic skin reaction.

Ingestion : Harmful if swallowed.



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Section 11. Toxicological information

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact: Adverse symptoms may include the following:

irritation redness

Inhalation : Adverse symptoms may include the following:

respiratory tract irritation

coughing

reduced fetal weight increase in fetal deaths skeletal malformations

Skin contact: Adverse symptoms may include the following:

irritation redness

reduced fetal weight increase in fetal deaths skeletal malformations

Ingestion : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Long term exposure

Potential immediate : Not available.

effects

Potential delayed effects : Not available.

Potential chronic health effects

General: May cause damage to organs through prolonged or repeated exposure. Repeated or

prolonged inhalation of dust may lead to chronic respiratory irritation. Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity: Suspected of causing cancer. Risk of cancer depends on duration and level of exposure.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity: Suspected of damaging fertility or the unborn child.

Numerical measures of toxicity

Acute toxicity estimates



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Section 11. Toxicological information

Product/ingredient name	Oral (mg/ kg)	(mg/kg)	(gases)	(vapors)	Inhalation (dusts and mists) (mg/ I)
Voriconazole for Injection voriconazole	1700.7 100		N/A N/A	N/A N/A	N/A N/A

Section 12. Ecological information

Toxicity

Conclusion/Summary: Not available.

Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.



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Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	- 0,	-
Environmental hazards	No.	No.	No.

Additional information

Special precautions for user : Transport within user's premises: always transport in closed containers that are

upright and secure. Ensure that persons transporting the product know what to do in the

event of an accident or spillage.

Transport in bulk according

to IMO instruments

: Not available.

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112

(b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602

Class I Substances

: Not listed

Clean Air Act Section 602

Class II Substances

: Not listed

DEA List I Chemicals (Precursor Chemicals)

: Not listed

DEA List II Chemicals (Essential Chemicals)

: Not listed

SARA 302/304

Composition/information on ingredients

No products were found.



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Section 15. Regulatory information

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : COMBUSTIBLE DUSTS

ACUTE TOXICITY (oral) - Category 4 SKIN SENSITIZATION - Category 1 CARCINOGENICITY - Category 2

TOXIC TO REPRODUCTION - Category 2

SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

Composition/information on ingredients

Name	%	Classification
.betaCyclodextrin, sulfobutyl ethers, sodium salts	≥90	SKIN SENSITIZATION - Category 1
voriconazole	≤10	ACUTE TOXICITY (oral) - Category 3 CARCINOGENICITY - Category 2 TOXIC TO REPRODUCTION - Category 2 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

SARA 313

Not applicable.

State regulations

Massachusetts: None of the components are listed.New York: None of the components are listed.New Jersey: None of the components are listed.Pennsylvania: None of the components are listed.

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.



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Section 16. Other information

Hazardous Material Information System (U.S.A.)



Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.)



Procedure used to derive the classification

Classification	Justification
COMBUSTIBLE DUSTS ACUTE TOXICITY (oral) - Category 4 SKIN SENSITIZATION - Category 1 CARCINOGENICITY - Category 2	On basis of test data Calculation method Calculation method Calculation method
TOXIC TO REPRODUCTION - Category 2 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2	Calculation method Calculation method

History

Date of issue/Date of

revision

: 06/06/2024

Date of previous issue

: 06/06/2022

Version

2.0

Prepared by

: Sphera Solutions

Key to abbreviations

: ATE = Acute Toxicity Estimate

AMP = Acceptable maximum peak above the acceptable ceiling concentration for an

8-hr shift

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as

modified by the Protocol of 1978. ("Marpol" = marine pollution)



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Section 16. Other information

N/A = Not available UN = United Nations

References : HCS (U.S.A.)- Hazard Communication Standard

International transport regulations

V Indicates information that has changed from previously issued version. **I**

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.