

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Trade name or designation of the mixture

ZOFRAN ORAL SOLUTION

Registration number

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Synonyms

ZOFRAN ORAL SOLUTION 4 MG/5 ML \* ZOFRAN SYRUP 4 MG/5 ML \* ZOFRAN JARABE \* ZOFRAN LOSUNG \* ZOFRAN MIKSTUR \* ZOFRAN MIXTUR \* ZOFRAN SCIROPPO \* ZOFRAN SIROP \* ZOFRAN SIRUP \* ZOFRAN STROOP \* ZOFRAN SYROP \* ZOFRAN XAROPE \* NDC NO 0173-0489-00 \* ONDANSETRON HYDROCHLORIDE DIHYDRATE, FORMULATED PRODUCT

Issue date

22-October-2014

Version number

11

Revision date

22-October-2014

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses

Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Uses advised against

No other uses are advised.

### 1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK

980 Great West Road

Brentford, Middlesex TW8 9GS UK

UK General Information (normal business hours): +44-20-8047-5000

Email Address: [msds@gsk.com](mailto:msds@gsk.com)

Website: [www.gsk.com](http://www.gsk.com)

### 1.4. Emergency telephone number

TRANSPORT EMERGENCIES::

UK In-country toll call: +(44)-870-8200418

International toll call: +1 703 527 3887

available 24 hrs/7 days; multi-language response

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

#### Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### 2.2. Label elements

#### Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### 2.3. Other hazards

Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

## General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
D-SORBITOL	< 45	50-70-4 200-061-5		-	-
<b>Classification:</b>	<b>DSD:</b>	-			
	<b>CLP:</b>	-			
CITRIC ACID ANHYDROUS	< 1	77-92-9 201-069-1		-	-
<b>Classification:</b>	<b>DSD:</b>	Xi;R36			
	<b>CLP:</b>	Eye Irrit. 2;H319			
ONDANSETRON HYDROCHLORIDE DIHYDRATE	< = 0.10	103639-04-9		-	-
<b>Classification:</b>	<b>DSD:</b>	T;R25, Xi;R41, N;R50/53			
	<b>CLP:</b>	Acute Tox. 3;H301, Eye Dam. 1;H318, Aquatic Acute 1;H400, Aquatic Chronic 2;H411			

Other components below reportable levels > 57

## List of abbreviations and symbols that may be used above

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

**Composition comments** The full text for all R- and H-phrases is displayed in section 16.

## SECTION 4: First aid measures

### General information

In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 4.1. Description of first aid measures

#### Inhalation

Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

#### Skin contact

Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.

#### Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

#### Ingestion

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately. Do not induce vomiting without advice from poison control center.

### 4.2. Most important symptoms and effects, both acute and delayed

Direct contact with eyes may cause temporary irritation.

### 4.3. Indication of any immediate medical attention and special treatment needed

No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

## SECTION 5: Firefighting measures

### General fire hazards

No unusual fire or explosion hazards noted.

### 5.1. Extinguishing media

#### Suitable extinguishing media

Water. Foam. Dry chemical powder. Carbon dioxide (CO2).

#### Unsuitable extinguishing media

None known.

### 5.2. Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed.

### 5.3. Advice for firefighters

#### Special protective equipment for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

<b>Special fire fighting procedures</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>SECTION 6: Accidental release measures</b>	
<b>6.1. Personal precautions, protective equipment and emergency procedures</b>	
For non-emergency personnel	Keep unnecessary personnel away. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
<b>6.2. Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>6.3. Methods and material for containment and cleaning up</b>	<p>Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p>
	Never return spills to original containers for re-use.
<b>6.4. Reference to other sections</b>	For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
<b>7.3. Specific end use(s)</b>	Medicinal Product.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

GSK Components	Type	Value
CITRIC ACID ANHYDROUS (CAS 77-92-9)	8 HR TWA	5000 mcg/m3
D-SORBITOL (CAS 50-70-4)	OHC	1
ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9)	OHC	3
	8 HR TWA	30 mcg/m3

**Biological limit values** No biological exposure limits noted for the ingredient(s).

**Recommended monitoring procedures** Follow standard monitoring procedures.

**Derived no-effect level (DNEL)** Not available.

**Predicted no effect concentrations (PNECs)** Not available.

#### Exposure guidelines

### 8.2. Exposure controls

**Appropriate engineering controls** General ventilation normally adequate.

#### Individual protection measures, such as personal protective equipment

**General information** Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

**Eye/face protection** If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Not normally needed.

#### Skin protection

<b>- Hand protection</b>	For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time). Not normally needed.
<b>- Other</b>	Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed.
<b>Respiratory protection</b>	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387). No personal respiratory protective equipment normally required.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>Hygiene measures</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

#### **Environmental exposure controls**

<b>Hazard guidance and control recommendations</b>	Environmental manager must be informed of all major releases.
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## **SECTION 9: Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

#### **Appearance**

<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.

#### **Upper/lower flammability or explosive limits**

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.

<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.

#### **Solubility(ies)**

<b>Solubility (water)</b>	Not available.
<b>Solubility (other)</b>	Not available.

<b>Partition coefficient (n-octanol/water)</b>	Not available.
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<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.

<b>9.2. Other information</b>	No relevant additional information available.
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## **SECTION 10: Stability and reactivity**

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.

<b>10.4. Conditions to avoid</b>	Contact with incompatible materials.
<b>10.5. Incompatible materials</b>	Strong oxidising agents.
<b>10.6. Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## SECTION 11: Toxicological information

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Symptoms</b>	Direct contact with eyes may cause temporary irritation.

### 11.1. Information on toxicological effects

Components	Species	Test results
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	3000 mg/kg
D-SORBITOL (CAS 50-70-4)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	15.9 g/kg
ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	100 - 150 mg/kg
<b>Chronic</b>		
<i>Oral</i>		
LD	Rat	> 36 mg/kg/day
LOEL	Dog	1 mg/kg/day, 52 weeks
NOAEL	Rat	1 mg/kg/day, 18 months

\* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation** Due to partial or complete lack of data the classification is not possible.

### Corrosivity

ONDANSETRON HYDROCHLORIDE DIHYDRATE 50 %, formulated in soft paraffin.  
Result: Non-irritant  
Species: Guinea pig

### Irritation Corrosion - Skin: P.I.I. value

CITRIC ACID ANHYDROUS OECD 404  
Result: Mild to moderate irritant.  
Species: Rabbit

**Serious eye damage/eye irritation** Due to partial or complete lack of data the classification is not possible.

### Eye

CITRIC ACID ANHYDROUS Acute ocular irritation; OECD 405  
Result: Severe Irritant  
Species: Rabbit

ONDANSETRON HYDROCHLORIDE DIHYDRATE OECD 405  
Result: Severe Irritant  
Species: Rabbit

**Respiratory sensitisation** Due to partial or complete lack of data the classification is not possible.

**Skin sensitisation** Due to partial or complete lack of data the classification is not possible.

### Sensitisation

ONDANSETRON HYDROCHLORIDE DIHYDRATE Split adjuvant assay  
Result: negative  
Species: Guinea pig

**Germ cell mutagenicity**

Due to partial or complete lack of data the classification is not possible.

**Mutagenicity**

ONDANSETRON HYDROCHLORIDE DIHYDRATE

Ames

Result: negative

Chromosomal Aberration Assay In Vitro

Result: positive

HPRT gene mutation in human lymphocytes

Result: negative

Micronucleus test

Result: negative

Species: Mouse

V79 Cell Mutagenicity Assay

Result: negative

**Carcinogenicity**

ONDANSETRON HYDROCHLORIDE DIHYDRATE

Carcinogenic effects are not expected as a result of occupational exposure.

ICH S1B

Result: negative

Species: Mouse

ICH S1B

Result: negative

Species: Rat

**Reproductive toxicity**

Due to partial or complete lack of data the classification is not possible.

**Reproductivity**

ONDANSETRON HYDROCHLORIDE DIHYDRATE

Embryofetal Development

Result: No effect

Species: Rabbit

Embryofetal Development

Result: No effect

Species: Rat

Fertility

Result: No effect

Species: Rat

Pre- and Post-natal development

Result: negative

Species: Rat

**Specific target organ toxicity - single exposure**

Due to partial or complete lack of data the classification is not possible.

**Specific target organ toxicity - repeated exposure**

Due to partial or complete lack of data the classification is not possible.

**Aspiration hazard**

Due to partial or complete lack of data the classification is not possible.

**Mixture versus substance information**

No information available.

**Other information**

Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

**SECTION 12: Ecological information****12.1. Toxicity**

Not expected to be harmful to aquatic organisms.

**Components****Species****Test results**

CITRIC ACID ANHYDROUS (CAS 77-92-9)

**Aquatic****Acute**

Algae

NOEC

Green algae (Scenedesmus quadricauda)

425 mg/l, 8 days Static Test

Crustacea

EC50

Water flea (Daphnia magna)

120 mg/l, 72 hours Static test

Fish

EC50

Bluegill sunfish (Adult Lepomis macrochirus)

1516 mg/l, 96 hours Static test

Golden ide/orfe (Adult Leuciscus idus)

440 - 760 mg/l, 96 hours Static test

ONDANSETRON HYDROCHLORIDE DIHYDRATE (CAS 103639-04-9)

**Aquatic****Acute**

Activated Sludge Respiration

IC50

Residential sludge

&gt; 1000 mg/l, 3 hours OECD 209

Algae

EC50

Green algae (Selenastrum capricornutum)

0.87 mg/l, 72 hours Measured, OECD 201

Components		Species	Test results
	NOEC	Green algae ( <i>Selenastrum capricornutum</i> )	0.31 mg/l, 72 hours Static test
Crustacea	EC50	Water flea ( <i>Daphnia pulex</i> )	28 mg/l, 48 hours Static test, TAD 4.08
	NOEC	Water flea ( <i>Daphnia pulex</i> )	16 mg/l, 48 hours Static test
Fish	EC50	Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	6.5 mg/l, 96 hours Static test, OECD 203
	NOEC	Rainbow trout (Adult <i>Oncorhynchus mykiss</i> )	2.6 mg/l, 96 hours Measured
<i>Chronic</i> Crustacea	EC50	Water flea ( <i>Ceriodaphnia dubia</i> )	1.4 mg/l, 8 days Static renewal test, EPA 1002
	LOEC	Water flea ( <i>Ceriodaphnia dubia</i> )	1 mg/l, 8 days
	NOEC	Water flea ( <i>Ceriodaphnia dubia</i> )	0.32 mg/l, 8 days

\* Estimates for product may be based on additional component data not shown.

## 12.2. Persistence and degradability

### Photolysis

#### UV/visible spectrum wavelength

ONDANSETRON HYDROCHLORIDE DIHYDRATE 305 nm, pH 5-9

### Hydrolysis

#### Half-life (Hydrolysis-neutral)

ONDANSETRON HYDROCHLORIDE DIHYDRATE > 1 years

### Biodegradability

#### Percent degradation (Aerobic biodegradation-inherent)

CITRIC ACID ANHYDROUS 98 %, 2 days Modified Zahn-Wellens, Activated sludge  
ONDANSETRON HYDROCHLORIDE DIHYDRATE 18.9 %, 28 days Semi-continuous activated sludge (SCAS), Activated sludge

#### Percent degradation (Aerobic biodegradation-soil)

ONDANSETRON HYDROCHLORIDE DIHYDRATE 20.3 - 99.9 %, 64 days, Soil

## 12.3. Bioaccumulative potential

### Partition coefficient

#### n-octanol/water (log Kow)

D-SORBITOL -2.2  
ONDANSETRON HYDROCHLORIDE DIHYDRATE 0.995

### Bioconcentration factor (BCF)

D-SORBITOL 1 Estimated

## 12.4. Mobility in soil

### Adsorption

#### Sludge/biomass distribution coefficient - log Kd

ONDANSETRON HYDROCHLORIDE DIHYDRATE 3.95 - 4.23 Calculated

#### Soil/sediment sorption - log Koc

D-SORBITOL 0.3 Estimated  
ONDANSETRON HYDROCHLORIDE DIHYDRATE 4.22 - 4.51 Measured

### Mobility in general

### Volatility

#### Henry's law

CITRIC ACID ANHYDROUS < 0 atm m^3/mol Calculated, 25 °C  
D-SORBITOL 0 atm m^3/mol Estimated

### Distribution

#### Octanol/water distribution coefficient log DOW

ONDANSETRON HYDROCHLORIDE DIHYDRATE 0.23, pH 5  
0.99, pH 7  
1.26, pH 9

## 12.5. Results of PBT and vPvB assessment

Not available.

## 12.6. Other adverse effects

Not available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Residual waste</b>	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
<b>EU waste code</b>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.
<b>Special precautions</b>	Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

### ADR

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**      MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

## SECTION 15: Regulatory information

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

#### EU regulations

##### **Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I**

Not listed.

##### **Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**

Not listed.

##### **Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**

Not listed.

##### **Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**

Not listed.

##### **Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**

Not listed.

##### **Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**

Not listed.

##### **Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**

Not listed.

##### **Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry**

Not listed.

##### **Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA**

Not listed.

#### Authorisations

##### **Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**

Not listed.

#### Restrictions on use

##### **Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**

Not listed.

##### **Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work**

Not listed.

##### **Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding**

Not listed.

## Other EU regulations

**Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**

Not listed.

**Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**

Not listed.

**Directive 94/33/EC on the protection of young people at work**

Not listed.

## Other regulations

### National regulations

### 15.2. Chemical safety assessment

The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

Follow national regulation for work with chemical agents.

No Chemical Safety Assessment has been carried out.

## SECTION 16: Other information

### List of abbreviations

Not available.

### References

GSK Hazard Determination

### Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

### Full text of any statements or R-phrases and H-statements under Sections 2 to 15

R25 Toxic if swallowed.

R36 Irritating to eyes.

R41 Risk of serious damage to eyes.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

H301 Toxic if swallowed.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

May form combustible dust concentrations in air.

### Revision information

Product and Company Identification: Product and Company Identification

Composition / Information on Ingredients: Undisclosed Ingredient Statement

Physical & Chemical Properties:

Ecological Information: Ecotoxicity

Transport Information: Agency Name and Packaging Type/Transport Mode Selection

Regulatory Information: United States

Material Attributes & Uses; Experimental Data: Material Uses

Follow training instructions when handling this material.

### Training information

### Disclaimer

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.