



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Issuing Date 03-Apr-2020

Revision Date 03-Apr-2020

Revision Number 1

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

1.1. Product identifier

Product Name World Health Organization Hand Sanitiser Formula (Ethanol-based)

Other information The hand sanitiser is manufactured using only the World Health Organization (WHO) recommended formulation with no deviations in ingredients or percentages.

The compounder does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

This is a personal care product. This SDS contains useful information for the safe handling and proper use of the product for industrial workplace conditions as well as any unintended exposures that might occur with large spills. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to the manufacturer's directions.

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

Recommended use Hand sanitiser

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

Canopus Medical AB
Ideon Science Park
223 63 Lund
Sweden

For further information, please contact

E-mail address manufacturing@canopusmedical.com

1.4. Emergency telephone number

Emergency Telephone 46737165975

Emergency Telephone - §45 - (EC)1272/2008
Europe 112

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Serious eye damage/eye irritation	Category 2 - (H319)
Flammable liquids	Category 2 - (H225)

2.2. Label elements



Signal word

Danger

Hazard statements

H319 - Causes serious eye irritation

H225 - Highly flammable liquid and vapour

Precautionary Statements - EU (§28, 1272/2008)

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

P233 - Keep container tightly closed

P370 + P378 - In case of fire: Use dry chemical, CO₂, water spray or alcohol-resistant foam to extinguish

P403 + P235 - Store in a well-ventilated place. Keep cool

P102 - Keep out of reach of children

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

2.3. Other hazards

May be harmful if inhaled. Causes mild skin irritation. May cause drowsiness or dizziness.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical name	EC No	CAS No	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH registration number
Ethanol	200-578-6	64-17-5	80	Flam. Liq. 2 (H225) Eye Irrit. 2 (H319)	No data available
Water	231-791-2	7732-18-5	18.425	No data available	No data available
Glycerol	200-289-5	56-81-5	1.45	No data available	No data available
Hydrogen peroxide	231-765-0	7722-84-1	0.125	Acute Tox. 4 (H302) Acute Tox. 4 (H332) Skin Corr. 1A (H314) Ox. Liq. 1 (H271)	No data available

Full text of H- and EUH-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice

Show this safety data sheet to the doctor in attendance.

Inhalation

Remove to fresh air.

Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Skin contact	None under normal use conditions. If skin irritation occurs: Get medical advice/attention.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a doctor.
Self-protection of the first aider	Remove all sources of ignition. Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing.

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

Symptoms	May cause redness and tearing of the eyes. Burning sensation. Prolonged contact may cause redness and irritation.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical. Carbon dioxide (CO ₂). Water spray. Alcohol resistant foam.
Unsuitable extinguishing media	None known based on information supplied.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
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5.3. Advice for firefighters

Specific/special fire-fighting measures	Fires need to be assessed to determine appropriate protocols and safety measures for firefighting, including establishing safe zones, extinguishing media to be used, firefighter protection, and actions to control or extinguish the fire.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions	Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Do not touch or walk through spilled material.
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Other information Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Refer to protective measures listed in Sections 7 and 8. Prevent further leakage or spillage if safe to do so. Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapour suppressing foam may be used to reduce vapours. Dyke far ahead of spill to collect run-off water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal.

Methods for cleaning up Take precautionary measures against static discharges. Dam up. Soak up with inert absorbent material. Pick up and transfer to properly labelled containers.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Use personal protection equipment. Avoid breathing vapours or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

General hygiene considerations Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labelled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance with local regulations.

7.3. Specific end use(s)

Specific use(s).
Hand sanitiser

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

Chemical name	European Union	United Kingdom	France	Spain	Germany
Ethanol 64-17-5	-	TWA: 1000 ppm TWA: 1920 mg/m ³ STEL: 3000 ppm STEL: 5760 mg/m ³	TWA: 1000 ppm TWA: 1900 mg/m ³ STEL: 5000 ppm STEL: 9500 mg/m ³	STEL: 1000 ppm STEL: 1910 mg/m ³	TWA: 200 ppm TWA: 380 mg/m ³
Glycerol 56-81-5	-	TWA: 10 mg/m ³ STEL: 30 mg/m ³	TWA: 10 mg/m ³	TWA: 10 mg/m ³	TWA: 200 mg/m ³
Hydrogen peroxide 7722-84-1	-	TWA: 1 ppm TWA: 1.4 mg/m ³ STEL: 2 ppm STEL: 2.8 mg/m ³	TWA: 1 ppm TWA: 1.5 mg/m ³	TWA: 1 ppm TWA: 1.4 mg/m ³	-
Chemical name	Italy	Portugal	Netherlands	Finland	Denmark
Ethanol 64-17-5	-	TWA: 1000 ppm	TWA: 260 mg/m ³ STEL: 1900 mg/m ³ H*	TWA: 1000 ppm TWA: 1900 mg/m ³ STEL: 1300 ppm STEL: 2500 mg/m ³	TWA: 1000 ppm TWA: 1900 mg/m ³
Glycerol 56-81-5	-	TWA: 10 mg/m ³	-	TWA: 20 mg/m ³	-
Hydrogen peroxide 7722-84-1	-	TWA: 1 ppm	-	TWA: 1 ppm TWA: 1.4 mg/m ³ STEL: 3 ppm STEL: 4.2 mg/m ³	TWA: 1 ppm TWA: 1.4 mg/m ³
Chemical name	Austria	Switzerland	Poland	Norway	Ireland
Ethanol 64-17-5	TWA: 1000 ppm TWA: 1900 mg/m ³ STEL 2000 ppm STEL 3800 mg/m ³	TWA: 500 ppm TWA: 960 mg/m ³ STEL: 1000 ppm STEL: 1920 mg/m ³	TWA: 1900 mg/m ³	TWA: 500 ppm TWA: 950 mg/m ³ STEL: 625 ppm STEL: 1187.5 mg/m ³	STEL: 1000 ppm
Glycerol 56-81-5	-	TWA: 50 mg/m ³ STEL: 100 mg/m ³	TWA: 10 mg/m ³	-	-
Hydrogen peroxide 7722-84-1	TWA: 1 ppm TWA: 1.4 mg/m ³ STEL 2 ppm STEL 2.8 mg/m ³	TWA: 1 ppm TWA: 1.4 mg/m ³ STEL: 2 ppm STEL: 2.8 mg/m ³	STEL: 0.8 mg/m ³ TWA: 0.4 mg/m ³	TWA: 1 ppm TWA: 1.4 mg/m ³ STEL: 2 ppm STEL: 2.8 mg/m ³	TWA: 1 ppm TWA: 1.5 mg/m ³ STEL: 3 mg/m ³ STEL: 2 ppm

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering controls

Showers
Eyewash stations
Ventilation systems.

Personal protective equipment

Eye/face protection

Tight sealing safety goggles.

Hand protection

Wear suitable gloves.

Skin and body protection

Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.
Antistatic boots.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid
Colour	Colourless
Odour	Alcohol
Odour threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	78.3 °C	
Flash point	17.5 °C	
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapour pressure	No data available	None known
Vapour density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available.	
Oxidising properties	No information available.	

9.2. Other information

VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity None under normal use conditions.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge Yes.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid Heat, flames and sparks.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract. May be harmful if inhaled. May cause drowsiness or dizziness.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.

Skin contact Specific test data for the substance or mixture is not available. Causes mild skin irritation. Prolonged contact may cause redness and irritation.

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms May cause redness and tearing of the eyes. Prolonged contact may cause redness and irritation.

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ethanol	= 7060 mg/kg (Rat)	-	= 124.7 mg/L (Rat) 4 h
Water	> 90 mL/kg (Rat)	-	-

Glycerol	= 12600 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 570 mg/m ³ (Rat) 1 h
Hydrogen peroxide	= 1518 mg/kg (Rat)	= 9200 mg/kg (Rabbit)	= 2000 mg/m ³ (Rat) 4 h

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitisation	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The environmental impact of this product has not been fully investigated.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethanol	-	LC50: 12.0 - 16.0mL/L (96h, Oncorhynchus mykiss) LC50: >100mg/L (96h, Pimephales promelas) LC50: 13400 - 15100mg/L (96h, Pimephales promelas)	-	LC50: 9268 - 14221mg/L (48h, Daphnia magna) EC50: =2mg/L (48h, Daphnia magna)
Glycerol	-	LC50: 51 - 57mL/L (96h, Oncorhynchus mykiss)	-	-
Hydrogen peroxide	-	LC50: 18 - 56mg/L (96h, Lepomis macrochirus) LC50: =16.4mg/L (96h, Pimephales promelas) LC50: 10.0 - 32.0mg/L (96h, Oncorhynchus mykiss)	-	EC50: 18 - 32mg/L (48h, Daphnia magna)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Ethanol	-0.32
Glycerol	-1.76

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Ethanol	The substance is not PBT / vPvB PBT assessment does not apply
Glycerol	The substance is not PBT / vPvB
Hydrogen peroxide	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture or weld containers.

Waste codes / waste designations according to EWC / AVV According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

SECTION 14: Transport information

IMDG

- 14.1 UN number UN1170
- 14.2 UN proper shipping name ETHANOL SOLUTION
- 14.3 Transport hazard class(es) 3
- 14.4 Packing group II
- Description UN1170, ETHANOL SOLUTION, 3, II, (17.5°C C.C.)
- 14.5 Marine pollutant Not applicable
- 14.6 Special Precautions for Users
- Special Provisions 144
- EmS-No F-E, S-D
- 14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code No information available

RID

14.1 UN number	UN1170
14.2 UN proper shipping name	ETHANOL SOLUTION
14.3 Transport hazard class(es)	3
Labels	3
14.4 Packing group	II
Description	UN1170, ETHANOL SOLUTION, 3, II
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	None
Classification code	F1

ADR

14.1 UN number	UN1170
14.2 UN proper shipping name	ETHANOL SOLUTION
14.3 Transport hazard class(es)	3
Labels	3
14.4 Packing group	II
Description	UN1170, ETHANOL SOLUTION, 3, II, D/E
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	144, 601
Classification code	F1
Tunnel restriction code	(D/E)

IATA

14.1 UN number	UN1170
14.2 UN proper shipping name	Ethanol solution
14.3 Transport hazard class(es)	3
14.4 Packing group	II
Description	UN1170, Ethanol solution, 3, II
14.5 Environmental hazards	Not applicable
14.6 Special Precautions for Users	
Special Provisions	A180, A3, A58
ERG Code	3L Note: None

SECTION 15: Regulatory information

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

National regulations

France

Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
Ethanol 64-17-5	RG 84	-

Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1)

European Union

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

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV). This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII).

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AICS	Contact supplier for inventory compliance status

Legend:

- TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List
- EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
- ENCS** - Japan Existing and New Chemical Substances
- IECSC** - China Inventory of Existing Chemical Substances
- KECL** - Korean Existing and Evaluated Chemical Substances
- PICCS** - Philippines Inventory of Chemicals and Chemical Substances
- AICS** - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

- H225 - Highly flammable liquid and vapour
- H271 - May cause fire or explosion; strong oxidiser
- H302 - Harmful if swallowed
- H314 - Causes severe skin burns and eye damage
- H319 - Causes serious eye irritation
- H332 - Harmful if inhaled

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method

Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method
Flammable liquids	On basis of test data

Key literature references and sources for data used to compile the SDS

U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

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Revision Note Initial Release.

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet