

According to Regulation (EC) No. 1907/2006 (REACH) ChillPhase PCM

10<sup>th</sup> Sept 2018 **Revision Date:** 

Supersedes: 2 Version: 3

IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / **SECTION 1** 

UNDERTAKING

#### PRODUCT IDENTIFIER: 1.1

Product name: ChillPhase

Product Codes: Covers all product codes beginning CP

#### RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED

#### **AGAINST**

Intended Use: For insulated shipping systems, to protect pharmaceutical and biotech products from

extremes of temperature during transportation.

Uses advised against: None given.

Reason why uses advised against: None given.

#### **DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET** 1.3

Supplier: Sonoco ThermoSafe (Trading as Laminar Medica Ltd)

Unit 4.

Tring Industrial Estate,

Icknield Way,

Tring.

Hertfordshire.

**HP23 4JX** 

Telephone number: +44 (0) 1442 828664

Email: thermosaferurop@sonoco.com

#### **EMERGENCY TELEPHONE NUMBER (NOT 24hrs)**

Main UK contact details: +44 (0) 1442 828664

#### SECTION 2 HAZARDS IDENTIFICATION

#### 2.1 **CLASSIFICATION OF SUBSTANCE OR MIXTURE**

2.1.1 Classification according to Regulation (EC) No 1272/2008

Aspiration Toxicity (Category 1) H304

2.1.2 Classification according to EU Directive 67/548/EEC / 1999/45/EC

Xn: R65

2.1.3 Additional Information

For full text of R-phrases and Hazard statements: see **SECTION 16** 

# SONOCO THERMOSAFE

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#### 2.2. LABEL ELEMENTS

After review of the CLP Regulations (for Classification, Labelling and Packaging), which aligns the European Union system of classification, labelling and packaging of chemical substances and mixtures to the Globally Harmonised System (GHS), it has been determined that Hazard labelling is not required for ChillPhase products providing certain criteria are met-

- 1. The product(s) being placed onto the market are defined as an "article with an integral substance not intended to be released during normal and foreseeable use", and are therefore exempt from the labelling and packaging provisions of CLP, unless Article 4(2) applies.
  - 1.1 Article 4(2) states- All substances and mixtures meeting the criteria of one or more of the hazard classes in CLP are considered hazardous. This does not apply to the ChillPhase Products.
- 2. There is no requirement to notify customers about substances in articles unless it relates only to those that are included in the 'candidate list' which are substances of very high concern (SVHCs) and are present in the article above 0.1% and imported into the EU at >1 tonne per annum.
  - 2.1 The active ingredient in ChillPhase bottles, Tetradecane, is currently not included on the REACH candidate list of substances of very high concern.

#### 2.3 OTHER HAZARDS

None detailed.

#### SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

#### 3.1 SUBSTANCES

Description of the substance: Alkane hydrocarbon

Name	CAS No	EC No	REACH Registration No.	% (weight)	Classification according to 67/548/EEC	Classification according to Regulation (EC) No 1278/2008 (CLP)
Tetradecane	629-59-4	211-096-0	01-2119485515-31- XXXX	≤100%	Xn; R65	Asp. Tox Cat 1 (H304)

Please see section 16 for full hazard statements

#### 3.2 MIXTURES

Not Applicable. This product is regulated as a substance.



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#### SECTION 4 FIRST AID MEASURES

#### 4.1 DESCRIPTION OF FIRST AID MEASURES

#### **GENERAL NOTES**

Take off all contaminated clothing immediately.

#### **INHALATION**

Move exposed person to fresh air. Keep person warm and at rest. 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. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing.

#### **SKIN CONTACT**

Flush contaminated skin with plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

#### **EYE CONTACT**

No effects expected. If irritation occurs flush the contaminated eye(s) thoroughly with lukewarm, flowing water for at least 15 minutes, while holding the eyelid(s) open.

#### **INGESTION**

Can enter lungs and cause damage. Do not induce vomiting. Get medical attention. If ingested, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.

#### 4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Acute: Aspiration hazard

**Delayed:** Chemical pneumonitis when aspirated into the lungs

#### 4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

If ingested, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.

#### SECTION 5 FIRE FIGHTING MEASURES

#### 5.1 EXTINGUISHING MEDIA

Suitable Extinguishing Media: Use water fog, carbon dioxide (CO<sub>2</sub>), foam or dry chemical.

Unsuitable Extinguishing Media: Do not use a direct water jet.



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#### 5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

No specific hazards.

Hazardous Combustion Products: Smoke, Fume, Incomplete combustion products, Oxides of carbon

#### **ADVICE FOR FIRE FIGHTERS** 5.3

#### Fire Fighting Instructions:

Evacuate area. Prevent run-off from fire control or dilution from entering streams, sewers or drinking water supply. Fire-fighters should use standard protective equipment and in enclosed spaces, selfcontained breathing apparatus (SCBA). Use water spray to cool fire exposed surfaces and to protect personnel.

Flammability Properties: Combustible. Hazardous material.

Flash Point (Method): 115 °C, 239 °F; DIN 51758

Upper/Lower Flammable Limits: No data available

Autoignition Temperature: No data available

#### **SECTION 6 ACCIDENTAL RELEASE MEASURES**

#### PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES 6.1

#### 6.1.1 For non-emergency personnel

Protective equipment: Slip hazard. Use suitable protective equipment.

Emergency procedure: Avoid contact with spilled material. Warn or evacuate occupants in surrounding and downwind areas if required, due to toxicity or flammability of the material. Stop leak if you can do so without risk. Do not touch or walk through spilled material. Vapour-suppressing foam may be used to reduce vapour. Isolate and dike to confine the spill and absorb with a non-combustible absorbent. Vacuum, shovel or pump waste into a drum and label contents for disposal. Repeat if necessary.

#### 6.1.2 For emergency responders

Respiratory protection: half-face or full-face respirator with filter(s) for organic vapour and, when applicable, Self Contained Breathing Apparatus (SCBA) can be used depending on the size of spill and potential level of exposure. Gloves recommended.

Small spills (<5L): Normal antistatic work clothes are usually adequate.

Large spills (>5L): Full body suit of chemical resistant, antistatic material is recommended.



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#### 6.2 ENVIRONMENTAL PRECAUTIONS

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

#### 6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

6.3.1 For containment:

Dyke far ahead of liquid spill for later recovery and disposal.

6.3.2 For cleaning up:

Collect with non-combustible absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust) and place in container for disposal according to local/ national regulation (see section 13).

6.3.3 Other information: N/A

#### 6.4 REFERENCE TO OTHER SECTIONS

See Sections 8 and 13.

#### SECTION 7 HANDLING AND STORAGE

#### 7.1 PRECAUTIONS FOR SAFE HANDLING

Avoid contact with skin. Material can accumulate static charges which may cause an electrical spark (ignition source). Handle in accordance with good industrial hygiene and safety practice. Wash hands and exposed skin immediately after handling.

#### 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep container closed. Handle containers with care. Open slowly in order to control possible pressure release. Store in a cool, well-ventilated area.

#### 7.3 SPECIFIC END USES:

None detailed.

#### SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

#### 8.1 CONTROL PARAMETERS

This substance does not currently have an occupational exposure limit.

#### 8.2 EXPOSURE CONTROLS

#### 8.2.1 Appropriate engineering controls

Ensure adequate ventilation in work area(s).



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

In case of insufficient ventilation wear suitable respiratory equipment. Guidance on suitable respiratory protective equipment and eye protection is provided in HSE Booklet HS(G)53: "The Selection, Use and Maintenance of Respiratory Protective Equipment - A Practical Guide". Gloves are recommended. Check with glove manufacturer for specific advice. Wash after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment. Ensure that eyewash stations and safety showers are close to the workstation location.

#### 8.2.3 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.

#### SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

(a) Physical State: Blue liquid(b) Odour: Hydrocarbons

(c) Odour Threshold: No data available(d) pH: No data available

(e) Melting Point: 5.5 °C, 42 °F

(f) Boiling Point/ Boiling Range: 252 – 254 °C, 486 – 489 °C
 (g) Flash Point: 115 °C, 239 °F; DIN 51758

(h) Evaporation Rate: No data available
(i) Flammability (Solid, Gas): No data available
(j) Upper explosion limit: No data available
Lower explosion limit: No data available

(k) Vapour Pressure: No data available

(I) Vapour Density (Air = 1): No data available

(m) Density: 0.762 g/cm3 @ 20 °C, 68 °F

(n) Water solubility: Insoluble

(o) Partition coefficient (n-Octanol/Water Partition Coefficient) (log Kow): No data available

(p) Auto ignition Temperature: No data available(g) Decomposition Temperature: No data available



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(r) Viscosity: 2.1 cSt @ 40 °C, 104 °F

(s) Explosive Properties: No data available

(t) Oxidising Properties: No data available

#### 9.2 OTHER INFORMATION

No data available

#### SECTION 10 STABILITY AND REACTIVITY

#### **10.1 REACTIVITY**

Stable under ambient storage conditions

#### 10.2 CHEMICAL STABILITY

Product is stable under normal conditions.

#### 10.3 POSSIBILITY OF HAZARDOUS REACTIONS

No dangerous reactions known during recommended use.

#### 10.4 CONDITIONS TO AVOID

Avoid heat, sparks, open flames and other ignition sources.

#### 10.5 INCOMPATIBLE MATERIALS

Strong oxidising materials

#### 10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Material does not decompose at ambient temperatures. In case of fire hazardous decomposition products may be produced such as carbon oxides.

#### SECTION 11 TOXICOLOGICAL INFORMATION

#### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity:

#### Oral toxicity:

Method	Similar to OECD 401 (pre-GLP)	Similar to OECD 401 (pre-GLP)
Read Across substance	No	No
Species	Rat	Rat
Routes of exposure	Oral: gavage	Oral: gavage
Endpoint	LD50 (no mortality observed)	LD50 (no mortality observed)
Dose	15g/kg bw	5000 mg/kg bw



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Exposure time 14 days 14 days
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### **Inhalation toxicity:**

Method	Similar to OECD 403 (pre-GLP)	Similar to OECD 403 (pre-GLP)
Read Across substance	No	No
Species	Rat	Rat
Routes of exposure	Inhalation: vapour	Inhalation: vapour
Endpoint	LC50 (no mortality observed)	LC50 (no mortality observed)
Dose	1369 ppm	> 9300 mg/m <sup>3</sup>
Exposure time	8 hr	4 hr

### **Dermal toxicity:**

Method	Standard acute method (OECD Guideline 402)	Standard acute method (OECD Guideline 402)
Read Across substance	No	No
Species	Rabbit	Rabbit
Routes of exposure	Occlusive	Occlusive
Endpoint	LD50 (no mortality observed)	LD50 (no mortality observed)
Effective Dose	> 5000 mg/kg bw	≥ 3160 mg/kg bw
Exposure time	24hr	14 days

#### Skin irritation/ corrosion:

Method	Acute Dermal Irritation / Corrosion (OECD Guideline 404)	Acute Dermal Irritation / Corrosion (OECD Guideline 404)
Read Across substance	No	No
Species	Rabbit	Rabbit
Routes of exposure	Semi occlusive	Semi occlusive
Dose	0.5 ml (neat)	Neat
Result	Fully reversible	Non irritating
Exposure time	14 days	7 days

### Serious eye damage/ irritation:

Method	Acute Eye Irritation / Corrosion (OECD Guideline 405)	Acute Eye Irritation / Corrosion (OECD Guideline 405)
Read Across substance	No	No
Species	Rabbit	Rabbit
Routes of exposure	Eye	Eye
Dose	0.1 ml	0.1 ml
Result	No inflammation or damage, slight irritation	Not an eye irritant
Exposure time	72 hr	72 hr

### Respiratory or skin sensitisation:

Method	Skin Sensitisation (OECD Guideline 406)	Skin Sensitisation (OECD Guideline 406)
Read Across substance	No	No
Species	Guinea pig	Guinea pig
Routes of exposure	intradermal and epicutaneous	intradermal and epicutaneous



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Dose	1% w/v sensitisation 50% w/v topical induction	5% w/v sensitisation 50% w/v topical induction
Result	Not sensitising	Not sensitising
Exposure time	48hr after challenge	48hr after challenge

### Germ cell mutagenicity:

Method	Bacterial Reverse Mutation Assay (OECD Guideline 471)	In vitro Mammalian Cell Gene Mutation Test (OECD Guideline 476)
Read Across substance	No	No
Species	S. typhimurium TA 102	Chinese hamster lung fibroblasts (V79)
Dose	0, 41.2, 123.5, 310.4, 1111.1, 3333.3, 10000 μg/plate	without S9: 0.1, 0.3, 0.6, 1, 2, 3 μg/ml with S9: 100, 500, 1000, 5000 μg/ml
Genotoxicity Result	Negative	Negative with and without metabolic activation

### Carcinogenicity:

Method	Combined Chronic Toxicity / Carcinogenicity Studies (OECD Guideline 453)	Combined Chronic Toxicity / Carcinogenicity Studies (OECD Guideline 453)
Read Across substance	No	No
Species	Mouse	Rat
Routes of exposure	Inhalation/ vapour	Inhalation/ vapour
Dose	0, 550, 1100, or 2200 mg/m <sup>3</sup>	25, 100, or 400 ppm
Result	NOAEC ≥2200 mg/m³ males NOAEC ≥1100 mg/m³ females	NOAEC ≥400 ppm females
Exposure Time	6hr per day, 5days/ week for 105 weeks	6hr per day, 5days/ week for 105 weeks

#### Reproductive toxicity:

Method	Reproduction / Developmental Toxicity Screening Test (OECD Guideline 421)
Read Across substance	No
Species Rat	
Routes of exposure	Inhalation/ vapour
Dose 100 or 400 ppm	
Result NOAEC ≥ 300 ppm	

#### Summary of evaluation of the CMR properties:

Not considered to be a carcinogenic, mutagenic, or reproductive toxicant.

STOT-single exposure: No data available.

STOT-repeated exposure: No data available

Aspiration hazard: No data available on substance. Similar hydrocarbons have known aspiration



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hazards and so Tetradecane is considered an aspiration hazard on the basis of similar chemical substances.

Other information: No data available.

#### SECTION 12 ECOLOGICAL INFORMATION

The information given is based on data available for substances detailed in section 3.2 unless otherwise specified.

#### 12.1. TOXICITY

### Acute (short-term) toxicity:

#### Fish:

Method	Fish Acute Toxicity Test (OECD Guideline 203)	Fish Acute Toxicity Test (OECD Guideline 203)	
Read Across substance	Hydrocarbons, C11-C14, containing n-alkanes, isoalkanes, and cyclics, with <2% aromatics	Hydrocarbons, C11-C14, containing n-alkanes, isoalkanes, and cyclics, with <2% aromatics	
Species	Rainbow Trout (Oncorhynchus mykiss)	Rainbow Trout (Oncorhynchus mykiss)	
Routes of exposure	In water	In water	
Endpoint	LL50	LL50	
Effective Dose	> 1000 mg/L	50.9 mg/L	
Exposure time	96 hr	96 hr	

#### Crustacea:

No data available

#### Algae/ aquatic plants:

Method	ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with Skeletonema costatum and Phaeodactylum tricornutum)	Alga, Growth Inhibition Test (OECD Guideline 201)
Substance	Hydrocarbons, C11-C14, containing n-alkanes, isoalkanes, and cyclics, with <2% aromatics	Hydrocarbons, C11-C14, containing n-alkanes, isoalkanes, and cyclics, with <2% aromatics
Species	Skeletonema costatum	Pseudokirchnerella subcapitata
Routes of exposure	in saltwater	In water
Endpoint	EL90	NOELR
Effect Concentration	> 100137 mg/L	1000 mg/l
Exposure time	72 hr	72 hr

Other organisms: No data available

#### Chronic (long-term) toxicity:



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#### Fish:

Method	QSAR Petrox computer modelling	
Read Across	No	
substance	INO	
Species	N/A computer model; juvenile fish	
Routes of exposure	N/A computer modelling	
Endpoint	NOELR	
Effective Dose	> 1000 mg/L	
Exposure time	28 days	

<u>Crustacea:</u> No data available Algae/ aquatic plants: No data available

#### Other organism:

Method	QSAR Petrox computer modelling	
Read Across	No	
substance	INO	
Species	Daphnia magna	
Routes of exposure	N/A computer modelling	
Endpoint	NOELR	
Effective Dose	> 1000 mg/L	
Exposure time	21 days	

#### 12.2 PERSISTENCE AND DEGRADABILITY

Abiotic Degradation: Considered to be readily biodegradable

<u>Physical- and photo-chemical elimination:</u> Substances present are not expected to be majorly photolytic

Biodegradation: The substances in this product are expected to be biodegradable

#### 12.3 BIOACCUMULATIVE POTENTIAL

Partition coefficient n-octanol/ water (log Kow at 25°C): No data available

Bio concentration factor (BCF): 962.9 l/kg (calculated)

#### 12.4 MOBILITY IN SOIL

Known or predicted distribution to environmental compartments: Not expected to partition to sediment and wastewater solids.

<u>Surface tension:</u> No data available

<u>Adsorption/ Desorption:</u> No data available

#### 12.5 RESULTS OF PBT AND vPvB ASSESSMENT

Not a PBT or vPvB substance

#### 12.6 OTHER ADVERSE EFFECTS



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No adverse effects are expected.

#### 12.7 ADDITIONAL INFORMATION

N/A

#### SECTION 13 DISPOSAL CONSIDERATIONS

#### 13.1 WASTE TREATMENT METHODS

Dispose of waste and residues in accordance with local authority requirements.

Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site. This substance is suitable for disposal by supervised incineration at very high temperatures to prevent formation of undesirable combustion products by a specialist company.

European Waste Code: 08 XX XX

#### **SECTION 14 TRANSPORT INFORMATION**

**14.1 – 14.6** This product is not regulated for carriage according to ADR/RID/ADN, IMDG, ICAO-TI/IATA-DGR

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code - Not applicable

#### SECTION 15 REGULATORY INFORMATION

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

This substance is classified and labelled under European Regulation (EC) No 1272/2008 The CLP Regulations. Classification under Chemicals (Hazard Information & Packaging for supply) Regulations – CHIP 4 (2009) is also provided (includes both EU Directive 67/548/EEC Dangerous Substances Directive (DSD) and 1999/45/EC Dangerous Preparations Directive (DPD).

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

#### 15.2 CHEMICAL SAFETY ASSESSMENT

No Chemical Safety Assessment has been carried out by the supplier.

#### SECTION 16 OTHER INFORMATION

#### List of abbreviations and acronyms:

μ Micro

ADN European provisions concerning the international carriage of dangerous goods by inland waterways

ADNR European Agreement Concerning the International Carriage of Dangerous Goods by Inland

Waterways

ADR European Agreement Concerning the International Carriage of Dangerous Goods by Road

bw body weight



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CAS Chemical Abstracts Service

CHIP Chemical (Hazard Information and Packaging) Regulations

CLP Classification Packaging and Labelling

CMR Carcinogenic, Mutagenic or toxic to Reproduction

DPD Dangerous Preparations Directive
DSD Dangerous Substances Directive
EC European Commission/ Communities
EEC European Economic Community

EL Effective loading rate
EU European Union

g grams

GLP Good Laboratory Practice

hr hour

HSE Health and Safety Executive

IATA International Air Transport Association

IBC International bulk container

IMDG International Maritime Dangerous Goods Code ISO International Organization for Standardization

kg kilogram I litre

LC Lethal Concentration

LD Lethal Dose

LL Lethal loading rate

m³ cubic metre
mg milligram
ml millilitre
mm millimetre
N/A Not Applicable

NOAEC No Observed Adverse Effect Concentration

NOELR No Observable Effect Loading Rate

OECD The Organisation for Economic Co-operation and Development

PBT Persistent, Bioaccumulative and Toxic chemicals

ppm Parts per million

REACH Registration Evaluation and Authorisation of Chemicals

RID Reglements Internationales Relatif au Transport des Marchandises Dangereuses par Chemin de Fer

STOT Specific target organ toxicity

Tox Toxicity

vPvB Very Persistent and Very Bioacccumulative substances

#### Hazard abbreviations, statements and phrases

Xn Harmful

R65 Harmful: may cause lung damage if swallowed. H304 May be fatal if swallowed and enters airways.



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#### References

ECHA European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>
HSE Health and Safety Executive, <a href="http://www.hse.gov.uk/">http://www.hse.gov.uk/</a>

TOXNET Databases on toxicology, hazardous chemicals, environmental health, and toxic releases,

http://toxnet.nlm.nih.gov/

#### **Revisions**

April 2018: Second issue

#### Recommended uses and restrictions:

The data and advice given apply when the product is sold for the stated application(s).

#### **Further information:**

Above information corresponds to present knowledge and experience and should only be used as a guide. It is not a guarantee that no errors or incomplete data may be contained.