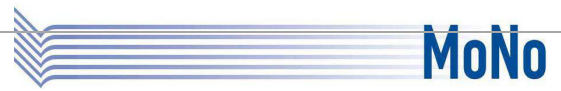


Material Safety Data Sheet



According to regulation (EC) No. 1907/2006 (changed by regulation (EU) No. 453/2010)
For information only for medical devices

ULTRASTOP version 05.2023 (replacing version 03.2019)
ULTRASTOP pro med. version 05.2023

Section 1. Identification of the substance/mixture and the company/undertaking

1.1. Product identifier

Product name ULTRASTOP

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

Anti-fogging agent for medical use

1.3. Details of the supplier of the safety data sheet

MoNo chem-pharm Produkte GmbH

Leystraße 129
A-1200 Wien

Tel.: +43-1-330 06 71-0
Fax: +43-1-330 06 71-38
Email: msds@mono.co.at

1.4. Emergency telephone number

+43-1-406 43 43
(Toxicology information center, 24/7)

Section 2. Hazards Identification

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No. 1272/2008:

H225: Highly flammable liquid and vapour



H319: Causes serious eye irritation

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2.2. Label elements

Hazard pictograms	 GHS02	 GHS07
Signal word	Danger	Warning
<u>Hazard statements</u>	H225: Highly flammable liquid and vapour	H319: Causes serious eye irritation
<u>Precautionary statements</u>	<p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P233: Keep container tightly closed.</p> <p>P240: Ground/bond container and receiving equipment.</p> <p>P241: Use explosion-proof electrical/ventilating/lighting equipment</p> <p>P242: Use only non-sparking tools.</p> <p>P243: Take precautionary measures against static discharge.</p> <p>P280: Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>P303 + P361 + P353: If on skin remove/take off immediately all contaminated clothing, rinse skin with water/shower.</p> <p>P370 + P378: in case of fire use water spray jet, foam (alcohol resistant), carbon dioxide or dry chemicals for extinction.</p> <p>P310: Immediately call a POISON CENTER or doctor/physician.</p> <p>P403 + P235: Store in a well ventilated place. Keep cool.</p> <p>P501 Dispose of contents/container according national and local regulations.</p>	

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2.3. Other hazards

None known

Section 3. Composition/information on ingredients

3.1. Substances

Not applicable.

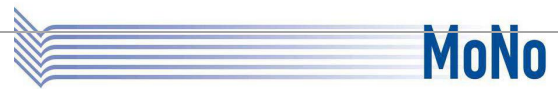
3.2. Mixture

This product is a mixture of surface-active substances in an ethanol-water-matrix. The substances relevant for classification according to Regulation (EG) 1272/2008 are listed below:

Hazardous component:	Ethanol
EC-No.:	200-578-6
Index-No.:	603-002-00-5
CAS-No.:	64-17-5
REACH-Registration number.:	01-2119457610-43
Concentration:	Approx. 77%
Classification according to regulation (EC) No. 1272/2008:	Flammable liquide, Category 2, H225; Eye irritation, Category 2, H319;

Hazardous component:	Tensides
EC-No.:	n.a./ mixture
Index-No.:	n.a./ mixture
CAS-No.:	n.a./ mixture
REACH-Registration number.:	n.a./ mixture
Concentration:	Below 5% w/w

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Classification according to regulation (EC) No. 1272/2008:	Causes skin irritation, category 2, H315 Causes eye irritation, category 1, H318. May be harmful for water organisms, with long term effect., category 4, H413
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Section 4. First-aid measures

4.1. Description of first-aid measures

After inhalation

Move injured person from the hazardous area to the fresh air under self protection.
Keep injured person calm, protect from hypothermia.
Let the patient inhale oxygen if breathing is difficult.
When the patient is unconscious but the breathing is stable, move into lateral position.
Get medical attention.

In case of skin contact

Remove contaminated clothing under self protection.
Clean contaminated skin with water and soap.
After contamination of large areas or continuing irritation get medical attention.

After eye contact

Rinse the eye under running water with the eyelids wide open for 10 minutes under protection of the uninjured eye.
If irritation persists get medical attention.

After swallowing

After accidental ingestion of technical ethanol: rinse mouth, spit out liquid.
If patient is conscious – immediately let him drink plenty of water.
Get medical attention.

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

Irritant effects (e.g. conjunktivitis, dermatitis).

At very high concentrations: respiratory paralysis, dizziness, narcosis, inebriation, euphoria, nausea, vomiting.
Degreasing effect with formation of brittle and cracked skin.

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

No information available.

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Section 5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media:

water spray, foam (alcohol resistant), carbon dioxide, dry chemicals or spray (water)

Unsuitable extinguishing media:

Do not use a full water jet to suppress the spread of the fire.

5.2. Special hazards arising from the substance or mixture

Vapours are heavier than air and may spread along floors.

Forms explosive mixtures with air at ambient temperatures.

Development of hazardous combustion gases or vapours possible in the event of fire: carbon monoxide, carbon dioxide.

5.3. Advice for fire fighters

In the event of fire, wear self-contained breathing apparatus.

Avoid skin contact by wearing suitable protective equipment and maintaining a safe distance.

Cool endangered container from a safe distance with water spray.

Capture escaping vapours with water.

Watch for flashbacks.

Prevent penetration of extinguishing water into surface water, ground water and soil.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not breathe vapours or Aerosols.

Avoid skin contact by wearing suitable protective equipment and maintaining a safe distance.

Protective Equipment see section 8.2.

6.2. Environmental precautions

Do not let product enter drains.

6.3. Methods and materials for containment and cleaning up

Large amounts: pump down product

Remains: isolate leaked material with neutralizing and non-flammable absorbent and collect in appropriate container for disposal according to local regulation.

Small amounts (up to 1L):

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Pick up with large amount of water, dispose the water over sewage system.

Only use non-sparking tools in the hazardous area.

6.4. Reference to other sections

Information for safe handling see section 7.

Information on personal protective equipment see section 8.

Information on disposal considerations see section 13.

Section 7. Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid development of vapours and aerosols.
Provide well workplace ventilation / exhaustion
Don't breath in vapours / aerosols.

Advice on protection against fire and explosion

Keep away from open flames hot surfaces, heat sources, electrical devices, sparks and other sources of ignition.
No smoking.
No hot works.

Take precautionary measures against static discharge.
Provide sufficient electrical grounding.
Use only non-sparking tools..



Handle emptied containers carefully. When vapours ignite it might explode.
It must be prevented that vapours may enter adjacent rooms with possible ignition sources.

Measures to prevent vapours and aerosols

Keep container tightly closed.
Avoid spraying.

Advice on protecting the environment

Do not let product enter drains.
Information on disposal considerations see section 13.

Hygiene measures

Observe usual hygiene measures for the handling of chemical substances, especially wash hands with water and soap after working with the product.
Use moisturizing skin care products.
No eating or drinking while using the product.



7.2. Conditions for safe storage, including any incompatibilities

7.2.1. Storage conditions

Don't store above room temperature, protect from light.

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7.2.2. Requirements on storage rooms and containers

No storage in:

entrances, exits, passages,
staircases,
buffer rooms and locks,
in attics, shafts, channels and poorly-ventilated shaft-like yards, in
work spaces, sanitary facilities, shop windows and show cases, on
or under stairs, ramps, catwalks, pedestals and platforms,
in ventilation- and air-conditioning-control centers, electrical operating rooms, engine rooms, fire panels etc.
on escape routes, at emergency exits, emergency stairs, emergency ladders;

Containers:

Don't use food containers – danger of confusion!
Containers must be clearly and permanently marked.
If possible keep in original container.
Keep container tightly closed and store in drip pans.
Keep container in well-ventilated place.
Store away from ignition and heat sources.

Requirements on protection against explosion:

Take precautionary measures against static discharge.
Provide sufficient electrical grounding.
The design of equipment and electrical equipment must be carried out in accordance with the classification
which results from the explosion protection document to be prepared in accordance with §5 VEXAT.

Joint storage:

According TRGS 510 the product is storage class 3 (flammable liquid).
Only substances of the same storage class should be stored together.

The **joint storage** with the following substances is **prohibited**:

- medicines, food and feeding stuff including additives.
- gases
- other explosive substances of storage class 4.1A
- flammable solids or desensitized substances of storage class 4.1B
- pyrophoric substances
- substances which emit flammable gases when they come into contact with water
- strong oxidizing substances of storage class 5.1A
- ammonium nitrate and its preparations
- organic peroxides and self-reactive substances
- non-combustible, acute toxic substances of storage class 6.1B

The **joint storage** with the following substances is **only allowed under certain conditions** (for details see TRGS 510):

- oxidizing substances of storage class 5.1S
- non-combustible toxic or chronic substances of storage class 6.1D
- combustible solids of storage class 11

The substance should not be stored together with substances that may cause dangerous chemical reactions.

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7.3. Specific end use(s)

Anti-fogging agent for medical use (medical device).
Follow the instructions.

Section 8. Exposure controls/personal protection

8.1. Control parameters

Ethanol (CAS-No. 64-17-5)

MAK-Wert (maximum workplace concentration) according to Grenzwerteverordnung 2011:

TMW (day average value): 1.000ppm / 1.900mg/m³

KZW (short time value): 2.000ppm / 3.800mg/m³ 3x per shift for 60 minutes

DNEL (Derived No Effect Level):

950mg/m³ via inhalation

343mg/kg body weight / day via absorption through the skin

PNEC (Predicted No Effect Concentration):

freshwater: 0,96mg/L

saltwater: 0,79mg/L

Hazardous incident ordinance:

threshold: 10t

8.2. Exposure controls

8.2.1. Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Ensure good ventilation. This can be achieved by local exhaust or general exhaust air.

8.2.2. Individual protection measures

eye- / facial protection






Sufficient eye protection must be worn.

At least use goggles with side shields.

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<p>hand protection</p> 	<p><u>gloves – full contact (break through time \geq 8 hours):</u> butylrubber (0,5mm) fluororubber (0,4mm)</p> <p><u>gloves – contact with spray (break through time \geq 2 hours):</u> polychloroprene (0,5mm)</p> <p>Not suitable due to degradation, strong swelling or low break through time are the following materials: natural latex, nitrile rubber, polyvinyl chloride.</p> <p>The time specification are approximate values from measurements at 22°C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt contact the manufacturer. At an approx. 1.5 times larger/smaller layer thickness, the respective break-through time is doubled/halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be regarded as guiding value.</p>
<p>skin protection</p> 	<p>Wear an apron or labcoat. Use flame retardant, antistatic protective clothing. The protective clothing should be solvent-resistant.</p>
<p>respiratory protection</p> 	<p>In exceptional circumstances wearing respiratory protection is indicated (e.g. unintentional release of the product in large amounts). Observe limits of wearing-time. <u>respirator:</u> gasfilter type A, color code brown.</p> <p>At concentrations above the limit of the filter units, at oxygen-levels below 17% or in unclear conditions a self-contained breathing apparatus has to be used.</p>

8.2.3. Environmental exposure controls

see section 6 and 7.

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Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

appearance: - physical state - color	liquid colorless
odour:	alcohol-like
odour threshold:	80ppm
pH:	7,0 (20°C, 10g/L)
melting point:	-114°C
boiling point:	78°C
flash point:	<21°C
evaporation rate: (proportional to diethyl ether)	8,3
flammability (solid, gas):	not applicable
explosion limits: - lower explosion limit - upper explosion limit	4 Vol % 20 Vol %
vapour pressure:	58,0 hPa (20°C), 104 hPa (30°C), 178 hPa (40°C), 293 hPa (50°C)
relative vapour density:	not tested
density:	0,865 g/cm ³
solubility:	completely miscible with water
partition coefficient (n-Octanol/Wasser): - log Kow:	-0,3 (recommended value of the LOG KOW database)
auto-ignition temperature:	430°C
decomposition temperature:	>= 700°C

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decomposition products:	methane, ethane, ethene, ethine, formaldehyde, acetaldehyde, ether, benzene
viscosity:	not tested
explosive properties:	product is not explosive, but the formation of explosive vapour/air mixtures is possible.
oxidising properties:	not applicable

9.2. Other data

none

Section 10. Stability and reactivity

10.1. Reactivity

flammable

10.2. Chemical stability

The product is chemically stable under standard ambient conditions (room temperature).

10.3. Possibility of hazardous reactions

When used as intended no hazardous reactions are expected.

10.4. Conditions to avoid

Temperatures above 9°C favor the transition of the liquid into the vapour phase and the formation of explosive atmospheres.

Keep away from heat sources (e.g. hot surfaces), sparks and open flames.

10.5. Incompatible materials

alkali metals
ammonia
oxidizing agents
peroxides

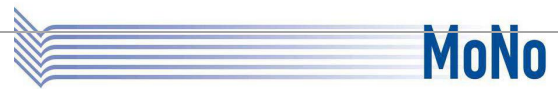
10.6. Hazardous decomposition products

Development of hazardous combustion gases or vapours possible in the event of fire: carbon monoxide, carbon dioxide.

Section 11. Toxicological information

11.1. Information on toxicological effects

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11.1.1. Acute toxicity

Ethanol (EG-No.: 200-578-6; CAS-No.: 64-17-5; REACH Registration number.: 01-2119457610-43)

LC50 (inhalation, rat): 124,7mg/L/4h (ECHA)

LD50 (oral, rat): 10.470mg/kg bodyweight (ethanol 95% (ECHA))

11.1.2. Skin corrosion/irritation

No skin corrosion/irritation

Repeated or prolonged exposure may cause skin irritation and dermatitis due to the degreasing properties of the product.

11.1.3. Serious eye damage/eye irritation

causes serious eye irritation

Triggers a burning/stinging pain on the eye in case of direct contact.

On the mucous membranes of the eyes redness and superficial lesions are possible which are rapidly reversible.

11.1.4. Respiratory or skin sensitisation

no known sensitising effect

11.1.5. Chronic toxicity

Repeated or prolonged exposure may cause skin irritation and dermatitis due to the degreasing properties of the product

Allergic skinreactions (dermatitis, urticaria) are possible in individual cases.

NOAEL oral, rat: 10ml/kg bodyweight (16,25% ethanol) – (ECHA)

LOAEL oral, ratt: 4ml/kg bodyweight (100% ethanol) – (ECHA)

NOAEC inhalation, rat: 2,65mg/L air – (ECHA)

LOAEC inhalation, rat: 13,3mg/L air – (ECHA)

11.1.6. Carcinogenicity

no data available

11.1.7. Mutagenicity

no data available

11.1.8. Reproductive toxicity

no data available

11.2. Additional information

See below

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Section 12. Ecological information

12.1. Toxicity

WGK 1 – slightly hazardous to water

PNEC (Predicted No Effect Concentration):

freshwater: 0,96mg/L or 2,75mg/L with periodic release – (ECHA)

saltwater: 0,79mg/L – (ECHA)

sewage plant: 580mg/L – (ECHA)

LC50 fish (96h): 11.000mg/L (median value GESTIS)

LC50 crustacean (48h): 9.280mg/L (median value GESTIS)

EC50 crustacean (48h): 9.950mg/L (median value GESTIS)

12.2. Persistence and degradability

Ethanol is easily biodegradable (>70%, 5d; OECD 301 D)

12.3. Bioaccumulative potential

Ethanol has low potential for bioaccumulation (log Kow3), therefore no testing necessary – (ECHA).

12.4. Mobility in soil

Ethanol is highly water-soluble -> high mobility

12.5. Results of PBT and vPvB assessment

no data available

12.6. Endocrine disrupting properties

no data available

12.7. Other adverse effects

no data available

Section 13. Disposal considerations

13.1. Waste treatment methods

Product residues must be disposed of in compliance with the relevant national and regional regulations.

Keep chemicals in original container and do not mix with other waste.

Must not be disposed of together with household waste.

Do not empty into drains.

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13.2. Treatment of contaminated packaging

Packages that can't be cleaned must be treated like the product.

Must be disposed of in compliance with the relevant national and regional regulations.

13.3. Waste code number according to Abfallverzeichnis-Verordnung

55351 – Ethanol; gefährlicher Abfall

Section 14. Transport information

14.1. UN number:

UN 1170

14.2. UN proper shipping name:

Ethanol (Ethylalcohol)

14.3. Transport hazard class(es):

ADR/RID: 3; IMDG: 3; IATA: 3 (flammable liquids)

14.4. Packaging group:

ADR/RID: 2; IMDG: 2; IATA: 2

14.5. Environmental hazards:

ADR/RID: no; IMDG: sea water hazard: no; IATA: no

14.6. Special precautions for user:

Classification code: F1

Special regulations: 144 ADR, RID, ADN, IMDG

601 ADR, RID, ADN

A3, A59, A180 ICAO

Limited quantity (LQ): 1L

Optional quantity: E2

Transport category: 2 ADR/RID

Hazard number: 33 ADR/RID

Tunnel restriction code: D/E ADR/RID

EmS: F-E, S-D IMDG

Bulk transport in accordance with Annex II of MARPOL 73/78 and IBC code: not applicable IMDG

IATA Packing Instructions – Passenger: 363 ICAO

IATA maximum quantity – passenger: 5L ICAO

IATA Packing Instructions – Cargo: 364 ICAO

IATA maximum quantity – Cargo: 60L ICAO

Passenger LQ: Y341 ICAO

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Section 15. Regulatory information

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

15.1.1. EU regulations

Regulation (EC) No. 1907/2006 (REACH)
Regulation (EC) No. 1272/2008 (CLP-VO)

15.1.2. National legislation (Austria)

Verordnung brennbare Flüssigkeiten (VbF)
Chemikaliengesetz (ChemG)
Grenzwerteverordnung (GKV)
Abfallverzeichnis-Verordnung

15.2. Chemical safety assessment

For this product a chemical safety assessment was not carried out.

Section 16. Other information

complete revision and adaption of the material safety data sheet according to applicable guidelines

abbreviations:

ADN (*Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure*, english: European Agreement on the Transport of Dangerous Goods by Inland Waterways)

ADR (*Accord européen relatif au transport international des marchandises Dangereuses par Route*, english: European Agreement Concerning the International Carriage of Dangerous Goods by Road)

BGBl (*Bundesgesetzblatt*, english: Federal Law Gazette)

CAS (*Chemical Abstract Service*)

CLP (*Classification, Labelling and Packaging of Chemicals*)

DNEL (*Derived No Effect Level*)

EC (*European Community*)

EC50 (*Effective Concentration 50%*)

ECHA (*European Chemicals Agency*)

GHS (*Globally Harmonized System of Classification and Labelling of Chemicals*)

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IATA (*International Air Transport Association*)

ICAO (*International Civil Aviation Organization*)

IMDG (*International Maritime Code for Dangerous Goods*)

KZW (*Kurzzeitwert*, english: short time value)

LC50 (*Lethal Concentration 50%*)

LD50 (*Lethal Dose 50%*)

LOAEC (*Lowest Observed Adverse Effect Concentration*)

LOAEL (*Lowest Observed Adverse Effect Level*)

MAK-Wert (*Maximale Arbeitsplatzkonzentration*, english: maximum workplace concentration)

NOAEC (*No Observed Adverse Effect Concentration*)

NOAEL (*No Observed Adverse Effect Level*)

OECD (*Organisation for Economic Co-Operation and Development*)

PBT (*persistent, bioaccumulative, toxic*)

PNEC (*Predicted No Effect Concentration*)

RID (*Règlement concernant le transport international ferroviaire de marchandises Dangereuses*, english: Regulation concerning the Carriage of Dangerous Goods by Rail)

TMW (*Tagesmittelwert*, english: day average value)

TRGS (*Technische Richtlinie Gefahrstoffe*, english: Technical Rules for Hazardous Substances)

UN (*United Nations*)

vPvB (*very persistent, very bioaccumulative*)

WGK (*Wassergefährdungsklasse*, english: water hazard class)

H-Statements:

H225: Highly flammable liquid and vapour

H319: Causes serious eye irritation

P- Statements:

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

P233: Keep container tightly closed.

P240: Ground/bond container and receiving equipment.

P241: Use explosion-proof electrical/ventilating/lighting equipment according the explosion protection document that has to be prepared in accordance with §5 VEXAT (austrian regulation).

P242: Use only non-sparking tools.

P243: Take precautionary measures against static discharge.

P264: Wash hands thoroughly after handling.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

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P303 + P361 + P353: If on skin remove/take off immediately all contaminated clothing, rinse skin with water/shower.

P305 + P351 + P338 + P337 + P313: If in eyes rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: get medical advice/attention.

P370 + P378: In case of fire: use water spray, foam (alcohol resistant), carbon dioxide, dry chemicals or spray (water) for extinction.

P403 + P235: Store in a well-ventilated place. Keep container tightly closed.

P501: Dispose of contents/container according national and local regulations.

Data origin:

Regulation (EC) No. 1907/2006 (REACH)

Regulation (EC) No. 1272/2008 (CLP-VO)

BGBl Nr 240/1991 – Verordnung brennbare Flüssigkeiten (VbF) – austrian legislation

BGBl. I Nr. 53/1997 – Chemikaliengesetz (ChemG) – austrian legislation

BGBl II Nr 253/2001 – Grenzwertverordnung 2011 (GKV) – austrian legislation

BGBl II Nr 570/2003 – Abfallverzeichnis-Verordnung – austrian legislation

GESTIS-Stoffdatenbank (german substance database):

www.dguv.de/ifa/stoffdatenbank

ECHA (European Chemicals Agency):

<https://echa.europa.eu/de/registration-dossier/-/registered-dossier/16105/1>

<https://echa.europa.eu/de/information-on-chemicals/registered-substances>

TRGS 510 – Lagerung von Gefahrstoffen in ortsbeweglichen Behältern

Herbert F. Bender (2013) Das Gefahrstoffbuch, Wiley-VCH, Weinheim

SDB Merck "Ethanol absolut"

SDB Iwotec "Fluid Extra"

Further information:

The information given in this safety data sheet corresponds to our best knowledge of our findings on the date of issue.

The information is intended to provide guidance on the safe handling of the product mentioned in this safety data sheet during storage, processing, transport and disposal.

The details are not transferable to other products.

Insofar as the product is mixed or processed with other materials, or subjected to other processing, the information in this safety data sheet, unless expressly stated otherwise, can not be transferred to the material produced in this way.