

Safety Data Sheet

legal basis:

Commission regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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

1.1. Product identifier

Trade name:	ORTHOSOL Ligno
Identifier:	Contains: Formic acid, Propionic acid
Product code:	714277
UFI Code:	P9G2-G00N-000H-5CS5
Composition for label/Other name(s)	COMPLEMENTARY FEED., Composition: Feed materials: Dextrose., Propylene glycol., Feed additives: Preservatives: Formic acid (1a236)., (including sodium formate 1k237i). - 262 g/kg, Propionic acid 1k280. - 125 g/kg, Acetic acid 1a260 - 56 g/kg, Binder: Sodium lignosulphonate E565., Flavorings: : Benzoic acid 2b08021. - 5 000 g/kg,

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

Identified uses

Uses:

Complementary feed.

Uses advised against:

other than named above

1.3. Details of the supplier of the safety data sheet

Name and address:

 Orthovit BV
 Sint Antoniusstraat 7B
 6095 AK Baexem
 Nederland
 Phone: +31 475 2981
 orthovitbv@gmail.com

Phone number:

e-mail address for a competent person responsible for the safety data sheet:

1.4. Emergency telephone number

998 or 112, or contact with the nearest local Fire Department

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

General hazards

This product is classified as hazardous according to current regulations

Health hazards

Skin Corr. 1B	Skin corrosion, Category 1B	H314 Causes severe skin burns and eye damage
Eye Dam. 1	Serious eye damage, Category 1	H318 Causes serious eye damage
STOT SE 3	Specific target organ toxicity — single exposure, Category 3	H335 May cause respiratory irritation

Physical hazards

not applicable

Environmental hazards

not applicable

2.2. Label elements

Hazard pictograms:



Signal Word:

Danger

Hazard statements:

H314 Causes severe skin burns and eye damage

EUH Phrases

EUH071 Corrosive to the respiratory tract

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/ spray.

P264c Wash hands and parts of the body in contact with the product thoroughly after handling

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor/...

P405 Store locked up.

P271 Use only outdoors or in a well-ventilated area.

2.3.Other hazards

Causes acidification of surface water and soil

There is no evidence of endocrine disrupting properties.

SECTION 3:Composition/information on ingredients
3.2.Mixtures

Concentration value	Substance	CAS	EC	Index number	Hazard class	Specific concentration limits, the M-factors, ATE
>= 5 - < 10 %	Formic acid	64-18-6	200-579-1	607-001-00-0	Flam. Liq. 3 H226 Acute Tox. 4 H302 Acute Tox. 3 H331 Skin Corr. 1A H314 Eye Dam. 1 H318 EUH071	Skin Corr.1A, H314 >= 90 % Skin Corr.1B, H314 >= 10 - < 90 % Skin Irrit.2, H315 >= 2 - < 10 % Eye Irrit.2, H319 >= 2 - < 10 %
< 15 %	Propionic acid	79-09-4	201-176-3	607-089-00-0	Skin Corr. 1B H314 Flam. Liq. 3 H226 STOT SE 3 H335 Eye Dam. 1 H318	Skin Corr.1B, H314 >= 25 % Eye Irrit.2, H319 >= 10 - < 25 % Skin Irrit.2, H315 >= 10 - < 25 % STOT SE 3, H335 >= 10 %
< 10 %	Acetic acid	64-19-7	200-580-7	607-002-00-6	Skin Corr. 1B H314 Flam. Liq. 3 H226 Eye Dam. 1 H318	Skin Corr.1A, H314 >= 90 % Skin Corr.1B, H314 >= 25 - < 90 % Eye Irrit.2, H319 >= 10 - < 25 % Skin Irrit.2, H315 >= 10 - < 25 %

Remarks

See Section 16 for the full text of the H statements

SECTION 4:First aid measures
4.1.Description of first aid measures
Inhalation

Remove from exposure, lie down. Lie the victim down in the position comfortable for breathing. Protect against heat loss. In case of dyspnea qualified personnel should give oxygen. Ensure medical assistance.

Skin contact

Take off all contaminated clothing immediately. Wash off immediately with plenty of water for at least 15 minutes. Immediately ensure medical aid. Burns must be treated by a physician.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses. Protect unharmed eye. Immediately ensure medical aid. Avoid strong stream of water due to the risk of damage to the cornea.

Ingestion

If swallowed, Immediately rinse mouth with water. If conscious, give the victim plenty of water to drink. Do NOT induce vomiting. Immediately ensure a physician aid.

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

no data available

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

no data available

SECTION 5:Firefighting measures
5.1.Extinguishing media

Suitable extinguishing media

extinguishing powder, foam, water spray jet, carbon dioxide (CO₂)

5.2.Special hazards arising from the substance or mixture

Fire may produce: carbon monoxide, carbon dioxide (CO₂)

5.3.Advice for firefighters

Containers exposed to fire or high temperature cool by spraying water from a safe distance. Prevent fire extinguishing water from contaminating surface water or the ground water system.

Wear self-contained breathing apparatus and full protective clothing.

SECTION 6:Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Ensure adequate ventilation. Avoid contact with released product. Avoid skin, eyes and clothing contamination. Avoid breathing vapour/fog/aerosol.

6.2. Environmental precautions

Do not allow contact with soil, surface or ground water. If the product contaminates rivers and lakes or drains inform respective authorities.

6.3. Methods and material for containment and cleaning up

Collect with a sorption material. Pick up and transfer to properly labelled containers. Transfer for disposal.

Large spills should be collected mechanically (remove by pumping) for disposal.

6.4. Reference to other sections

More information about suitable personal protective equipment is given in section 8.

Dispose of in accordance with the recommendations given in Section 13.

SECTION 7:Handling and storage

7.1.Precautions for safe handling

Avoid eyes and skin contamination. Do not breathe vapours/mist/aerosol. Do not empty into drains. Ensure suitable ventilation. Smoking, eating and drinking should be prohibited in the application area. Wash hands after handling the product. Remove and wash contaminated clothing before re-use.

7.2.Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Store in a dark place. Store at ambient temperature. Protect from direct sunlight.

Store away from incompatible materials (see section 10 of MSDS).

7.3.Specific end use(s)

See section 1.2.

SECTION 8:Exposure controls/personal protection

8.1.Control parameters

DNEL value

Formic acid	DNEL value	workers	inhalation	Long term	Local effects	9,5 mg/m ³
	DNEL value	workers	inhalation	Long term	Systemic effects	9,5 mg/m ³
	DNEL value	consumers	inhalation	Short term	Local effects	9,5 mg/m ³
	DNEL value	consumers	inhalation	Short term	Systemic effects	9,5 mg/m ³
	DNEL value	consumers	inhalation	Short term	Local effects	3 mg/m ³
	DNEL value	consumers	inhalation	Short term	Systemic effects	3 mg/m ³

Propionic acid	DNEL value	for workers	inhalation	Short-term exposure	Systemic effects	62 mg/m ³
	DNEL value	for workers	inhalation	Short-term exposure	Local effects	62 mg/m ³
	DNEL value	for workers	inhalation	Long-term exposure	Systemic effects	31 mg/m ³
	DNEL value	for workers	inhalation	Long-term exposure	Local effects	31 mg/m ³
	DNEL value	for workers	dermal	Long-term exposure	Systemic effects	132 mg/kg
	DNEL value	for workers	dermal	Long-term exposure	Local effects	0,26 mg/cm ²

Acetic acid	DNEL value	for workers	by inhalation	Short-term exposure	Local effects	25 mg/m ³
	DNEL value	for workers	by inhalation	Long-term exposure	Local effects	25 mg/m ³

PNEC value

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Formic acid	PNEC value	Fresh water	2 mg/l
	PNEC value	Marine water	0,2 mg/l
	PNEC value	Intermittent releases	1 mg/l
	PNEC value	Sewage treatment plant (STP)	7,2 mg/l
	PNEC value	Sediment (Fresh water)	13,4 mg/kg
	PNEC value	Sediment (Marine water)	1,34 mg/kg
	PNEC value	Soil	1,5 mg/kg

Propionic acid	PNEC value	Fresh water	0,5 mg/l
	PNEC value	Sewage treatment plant (STP)	5 mg/l
	PNEC value	Soil	0,1258 mg/kg
	PNEC value	Sediment (Marine water)	0,186 mg/kg
	PNEC value	Sediment (Fresh water)	1,86 mg/kg
	PNEC value	Intermittent releases	5 mg/l
	PNEC value	Marine water	0,05 mg/l

Acetic acid	PNEC value	Water	3,058 mg/l
	PNEC value	Soil	0,478 mg/kg
	PNEC value	Sewage treatment plant (STP)	0,85 mg/l

Occupational exposure limits

Formic acid	NDS	5 mg/m ³
	NDSCH	15 mg/m ³

Propionic acid	NDS	30 mg/m ³
	NDSCH	45 mg/m ³

Acetic acid	NDS	25 mg/m ³
	NDSCH	50 mg/m ³
	NDS	10 ppm
	NDSCH	20 ppm

Comments

Poland. OELs - Regulation of the Minister of Family, Labour and Social Policy, of 12 June 2018; Journal of Laws 2018, item 1286 as amended.

Biological limit values comments

not available

Recommended monitoring procedures

Regulation of the Minister of Health on tests and measurements applicable for hazardous substances and other adverse factors which are present in the workplace, of 2 February 2011 (Journal of Laws No33, item 166).

8.2.Exposure controls

Appropriate engineering controls

Provide adequate ventilation.

Individual protection measures

Respiratory protection

Combined acidic gas/vapour and organic vapour type

Eye /face protection

Safety goggles

Skin and hand protection

Safety gloves Nitril rubber gloves Break through time >= 30 min Layer thickness 0,38mm

Other protection equipment

acid-resistant protective clothing

Reference to regulations

Individual protection measures should satisfy the requirements specified in the Regulation (EU) 2016/425 of the European Parliament and of the Council on basic requirements for personal protective equipment, of 9 March 2016.

General advice

Do not eat, drink or smoke when using this product. Wash hands before every break and at the end of workday. Avoid eyes and skin contamination. Avoid inhaling of vapors/gases/mist/aerosols.

Environ. exposure controls

Prevent entry into drains, waterways, sewers and soil.

SECTION 9:Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	liquid
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ORTHOSOL Ligno

Colour:	brown		
Odour threshold:			
Odour:	pungent	No data available.	
Melting point/freezing point:	no data available		
Boiling point or initial boiling point and boiling range:	no data available		
Flammability:	Not flammable product.		
Lower and upper explosion limit:	no data available		
Flash point:	Not applicable.		
Auto-ignition temperature:	no data available		
Decomposition temperature:	no data available		
pH:	ca. 3,9	5 % solution	
Kinematic viscosity:	no data available		
Solubility:	no data available		
Partition coefficient: n-octanol/water (log value):	Not applicable.		
Vapour pressure:	no data available		
Density and/or relative density:	Density	ca. 1,238 g/cm ³	20 °C
Relative vapour density:	no data available		
Particle characteristics:	not applicable		

9.2. Other information

Information with regard to physical hazard classes:	no data available
Other safety characteristics:	no data available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reacts with: Bases.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Reacts exothermically on exposure to: Bases.
Gives off hydrogen by reaction with metals.

10.4. Conditions to avoid

Exposure to sunlight.

10.5. Incompatible materials

Strong bases. Nitrates. Peroxides. Metals.

10.6. Hazardous decomposition products

Fire may produce: Carbon oxides. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity

Propionic acid	LD50	3 500 - 5 160 mg/kg	Rat		
Formic acid	LD50	730 mg/kg	Rat	OECD Test Guideline 401	

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Acetic acid	LD50	3 310 mg/kg	Rat		for 100% substance
Product	Acute toxicity estimate ATE	ca. 9 125 mg/kg			Classification criteria are not met

Acute dermal toxicity

Propionic acid	LD50	496 mg/kg	Rabbit		
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Acute inhalation toxicity

Propionic acid	LC50	> 5 mg/l	4 h		
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Formic acid	LC50	7,85 mg/l	4 h	Rat	
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Acetic acid	LC50	40 mg/l	4 h		
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Product	Acute toxicity estimate ATE	ca. 98 mg/l			Classification criteria are not met
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Acute toxicity - other exposure routes

No data available.

Skin corrosion/irritation

Causes severe skin burns, based on information on ingredients

Serious eye damage/irritation

Causes serious eye damage, based on information on ingredients

Respiratory sensitisation

No sensitizing effect known., based on information on ingredients

Skin sensitisation

No sensitizing effect known., based on information on ingredients

Germ cell mutagenicity

Summary

Based on available data, the classification criteria are not met.

Carcinogenicity

Summary

Based on available data, the classification criteria are not met.

Reproductive toxicity

Summary

Based on available data, the classification criteria are not met.

STOT-single exposure

Summary

May cause respiratory irritation
(based on information on ingredients)

STOT-repeated exposure

Summary

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Information on likely routes of exposure

Inhalation.
Skin contact.
Eye contact.
Ingestion.

Symptoms related to the physical, chemical and toxicological characteristics

no data available

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

burns
serious eyes damage
Corrosive to the respiratory tract.

11.2. Information on other hazards

Endocrine disrupting properties

There is no evidence of endocrine disrupting properties.

Other information

no data available

SECTION 12: Ecological information
12.1. Toxicity

Formic acid	Toxicity to fish	LC50	130 mg/l	96 h	Brachydanio rerio	ISO 7346	Based on test data for structurally similar materials.
	Acute toxicity to aquatic invertebrates	EC50	365 mg/l	48 h	Daphnia magna (Water flea)	OECD Test Guideline 202	Based on test data for structurally similar materials.
	Toxicity to algae	EC50	1 240 mg/l	72 h	Selenastrum capricornutum	OECD Test Guideline 201	Based on test data for structurally similar materials.
	Toxicity to bacteria	EC10	72 mg/l	13 days			
	Chronic toxicity to aquatic invertebrates		>= 100 mg/l	21 days	Daphnia magna (Water flea)	OECD Test Guideline 211	
	Respiration inhibition of activated sludge	EC20	> 1 000 mg/l				
Propionic acid	Toxicity to fish	LC50	> 10 000 mg/l	96 h	Leuciscus idus (Golden orfe)	DIN 38412	
	Toxicity to aquatic invertebrates	EC50	> 500 mg/l	48 h	Daphnia magna (Water flea)	84/449/EEC, C.2, static	
	Toxicity to aquatic plants	EC50	> 500 mg/l	72 h	Scenedesmus subspicatus	OECD Test Guideline 201	Biomass
	Toxicity to microorganisms	EC20	500 - 1 040 mg/l	30 min	activated sludge, domestic	DIN EN ISO 8192	
Acetic acid	Toxicity to fish	LC50	410 mg/l		Leuciscus idus (Golden orfe)		anhydrous substance
	Toxicity to daphnia	LC50	47 mg/l	24 h	Daphnia magna (Water flea)		anhydrous substance
	Toxicity to bacteria	EC50	2 850 mg/l		Pseudomonas putida		anhydrous substance
	Toxicity to protozoa	EC5	78 mg/l		Entosiphon sulcatum		anhydrous substance

12.2. Persistence and degradability
Summary

no data available

12.3. Bioaccumulative potential
Summary

no data available

12.4. Mobility in soil
Summary

no data available

12.5. Results of PBT and vPvB assessment

no data available

12.6. Endocrine disrupting properties

There is no evidence of endocrine disrupting properties.

12.7. Other adverse effects

Do not allow the product to reach sewage system or ground or surface waters.

SECTION 13: Disposal considerations
13.1. Waste treatment methods

Comply with below named regulations:

ORTHOSOL Ligno

Waste Disposal Law, of 14 December 2012 (Journal of Laws 2013, item 21), with further amendments.

Law on packages and spent packages, of 13 June 2013 (Journal of Laws 2013, item 888) as amended.

Regulation of the Minister of Climate of 2 January 2020 on a catalog of waste (Journal of Laws 2020, item 10).

Waste code: 16 03 05* Organic wastes containing dangerous substances.

Dispose of in accordance with current legislation concerning Waste disposal. Waste packaging should be recycled. Packaging that can not be cleaned, should be disposed of like the product.

SECTION 14:Transport information

14.1. UN number or ID number

Transport type	UN Number
ADR	3265
RID	N/A
IMDG	N/A
ICAO	N/A
ADN	N/A

14.2. UN proper shipping name

Transport type	UN proper shipping name
ADR	3265 Corrosive liquid, acidic, organic, n.o.s. (contains: Formic acid)
RID	not available
IMDG	not available
ICAO	not available
ADN	not available

14.3. Transport hazard class(es)

Transport type	Transport hazard class:	Classification code:	Hazard identification number:	Tunnel restriction code:	Labels numbers:
ADR	8	C3	80	E	8
RID	not available				
IMDG	not available				
ICAO	not available				
ADN	not available				



14.4. Packing group

Transport type	Packing group:
ADR	II
RID	not available
IMDG	not available
ICAO	not available
ADN	not available

14.5. Environmental hazards

The product does not pose a hazard to the environment in accordance with the criteria of the UN Model Regulations.

14.6. Special precautions for user

not available

14.7. Maritime transport in bulk according to IMO instruments

not available

SECTION 15:Regulatory information

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

ACT of 25 February 2011 on the chemical substances and their mixtures, with further amendments.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)

15.2. Chemical safety assessment

not applicable

SECTION 16: Other information**Changes of previous version**

Section 2 Section 8 Section 11

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

STOT RE - Specific target organ toxicity — repeated exposure
Asp. Tox. - Aspiration hazard
Aquatic Acute - Hazardous to the aquatic environment - Acute
Aquatic Chronic - Hazardous to the aquatic environment - Chronic
Ozone - Hazardous for the ozone layer
Lact. - Effects on or via lactation
NDS - Maximum permissible exposure level/concentration
NDSCH - Maximum short-term exposure level/concentration
NDSP - Maximum permissible ceiling exposure level/concentration
vPvB (Substance) very persistent and very bioaccumulating
PBT (Substance) persistent, bioaccumulating and toxic
PNEC – Predicted No Effect Concentration
DNEL – Derived No Effect Level
LD50 - Lethal dose 50; dose/amount of a substance which kills 50 % of the test population
LC50 - Lethal concentration; concentration of a substance which kills 50 % of the test population
LOEC - Lowest Observed Effect Concentration
NOEL No Observed Effect Level
NOEC - No Observed Effect Concentration
ECX - Effective concentration; concentration of a substance which produces X % effect response
ADR – Agreement Concerning the International Carriage of Dangerous Goods by Road
ADN – Agreement Concerning the International Carriage of Dangerous Goods by Inland Waters
RID – Regulations Concerning the International Carriage of Dangerous Goods by Rail
IMDG – International Maritime Dangerous Goods Code
ICAO/IATA – International Civil Aviation Organization/International Air Transport Association
UVCB - Substances of Unknown or Variable composition, Complex reaction products or Biological materials
Expl. - Explosive
Flam. Gas - Flammable gas
Flam. Aerosol - Flammable aerosol
Ox. Gas - Oxidising gas
Press. Gas - Gases under pressure
Flam. Liq. - Flammable liquid
Flam. Sol. - Flammable solid
Self-react. - Self-reactive substance or mixture
Pyr. Liq. - Pyrophoric liquid
Pyr. Sol. - Pyrophoric solid
Self-heat. - Self-heating substance or mixture
Water-react. - Substance or mixture which in contact with water emits flammable gas
Ox. Liq. - Oxidising liquid
Ox. Sol. - Oxidising solid
Org. Perox. - Organic peroxide
Met. Corr. - Substance or mixture corrosive to metals
Acute Tox. - Acute toxicity
Skin Corr. - Skin corrosion
Skin Irrit. - Skin irritation
Resp. Sens. - Respiratory sensitization
Skin Sens. - Skin sensitization
Muta. - Germ cell mutagenicity
Carc. - Carcinogenicity
Repr. - Reproductive toxicity, Category 1A
STOT SE - Specific target organ toxicity — single exposure

Key literature references and sources for data

This safety data sheet has been prepared based on the MSDS provided by the manufacturer or / and internet databases and current regulations.

Advice on any training appropriate for workers to ensure protection of human health and the environment

People involved in the handling of the product should be trained in the handling, safety and hygiene. The staff / drivers should be trained and obtain proper certification in accordance with the requirements of ADR.

List of relevant hazard statements and/or precautionary statements

EUH071 Corrosive to the respiratory tract

H226 Flammable liquid and vapour

H302 Harmful if swallowed

H314 Causes severe skin burns and eye damage

H318 Causes serious eye damage

H331 Toxic if inhaled

H335 May cause respiratory irritation

not applicable

P261 Avoid breathing dust/fume/gas/mist/vapours/ spray.

P264c Wash hands and parts of the body in contact with the product thoroughly after handling

P271 Use only outdoors or in a well-ventilated area.

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

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310 Immediately call a POISON CENTER/doctor/...

P405 Store locked up.

Other Information

Product contain sodium lignosulphonate which causes a significant reduction in the acidity of the others components of the mixture (Companies Borregaard patent).

This safety data sheet is prepared to provide downstream users information about product.

Calculation method was used for classification to hazard of acute toxicity.

Producer/importer did not register the substance(s) under Reach (EC 1907/2006). Certain non- food/feed/pharma uses may however need a registration.

It is in the responsibility of the downstream user to comply with REACH regulation in this respect.

Exposure scenarios are not required.

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product in terms of safety requirements.

These data can not be considered in any case describe the product (as product specification).

The information contained in this safety data sheet refer to the product in the form in which it is delivered

Conditions of use and suitability of the product for specific applications remain under user control

It is the user's responsibility to insure proper health, safety and other necessary information

Appropriate warnings and safe-handling procedures should be provided to handlers and users.