SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Nobilis Salenvac Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.0	28.09.2024	7522681-00010	Date of first issue: 13.11.2020

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

1.1 Product identifier

Trade name : Nobilis Salenvac Formulation

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

Use of the Sub-stance/Mixture : Veterinary medicine

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements : **Prevention:**

P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

Maleic acid
Formaldehyde

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Antigen	Not Assigned		4 - <= 12
Maleic acid	110-16-7 203-742-5 607-095-00-3	Acute Tox. 4; H302 Acute Tox. 4; H312 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Sens. 1; H317 STOT SE 3; H335 --- specific concentration limit Skin Sens. 1; H317 >= 0.1 %	0.23

		Acute toxicity estimate Acute oral toxicity: 500 mg/kg Acute dermal toxicity: 1,560 mg/kg	
Formaldehyde	50-00-0 200-001-8 605-001-00-5 01-2119488953-20	Flam. Gas 1B; H221 Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Sens. 1A; H317 Muta. 2; H341 Carc. 1B; H350 STOT SE 3; H335 --- specific concentration limit Skin Corr. 1B; H314 >= 25 % Skin Irrit. 2; H315 5 - < 25 % Eye Irrit. 2; H319 5 - < 25 % STOT SE 3; H335 >= 5 % Skin Sens. 1A; H317 >= 0.2 % --- Acute toxicity estimate Acute oral toxicity: 100 mg/kg Acute inhalation toxicity (gas): 100 ppm Acute dermal toxicity: 270 mg/kg	<= 0.025
Thiomersal	54-64-8 200-210-4 080-004-00-7	Acute Tox. 2; H300 Acute Tox. 2; H330 Acute Tox. 1; H310 Repr. 1B; H360 STOT RE 1; H372 (Central nervous system, Cardiovascular system, Gastrointestinal tract, Kidney) Aquatic Acute 1; H400	<= 0.013

			Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 10 specific concentration limit STOT RE 2; H373 >= 0.1 % Acute toxicity estimate Acute oral toxicity: 10 mg/kg Acute inhalation toxicity (dust/mist): 0.1 mg/l Acute dermal toxicity: 10 mg/kg	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks	:	May cause an allergic skin reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment	:	Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.
Avoid breathing mist or vapours.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Formaldehyde	50-00-0	TWA	0.3 ppm 0.37 mg/m3	2004/37/EC
	Further information: Dermal sensitisation, Carcinogens or mutagens			
		STEL	0.6 ppm 0.74 mg/m3	2004/37/EC
	Further information: Dermal sensitisation, Carcinogens or mutagens			
		OELV - 8 hrs (TWA)	0.3 ppm 0.37 mg/m3	IE OEL
	Further information: Chemical agents which following exposure may cause sensitisation of the respiratory tract and lead to asthma, rhinitis or extrinsic allergic alveolitis, Carc 1B - Substances presumed to have carcinogenic potential for humans			
		OELV - 15 min (STEL)	0.6 ppm 0.738 mg/m3	IE OEL
	Further information: Chemical agents which following exposure may cause sensitisation of the respiratory tract and lead to asthma, rhinitis or extrinsic allergic alveolitis, Carc 1B - Substances presumed to have carcinogenic potential for humans			
Thiomersal	54-64-8	OELV - 8 hrs (TWA)	0.01 mg/m3 (Mercury)	IE OEL
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			
		OELV - 15 min (STEL)	0.03 mg/m3 (Mercury)	IE OEL
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

Substance name	End Use	Exposure routes	Potential health effects	Value
Maleic acid	Workers	Inhalation	Long-term systemic	3 mg/m3

			effects	
	Workers	Inhalation	Acute systemic effects	3 mg/m3
	Workers	Inhalation	Long-term local effects	3 mg/m3
	Workers	Inhalation	Acute local effects	3 mg/m3
Formaldehyde	Workers	Inhalation	Long-term systemic effects	9 mg/m3
	Workers	Inhalation	Long-term local effects	0.375 mg/m3
	Workers	Inhalation	Acute local effects	0.75 mg/m3
	Workers	Skin contact	Long-term systemic effects	240 mg/kg bw/day
	Workers	Skin contact	Long-term local effects	0.037 mg/cm2
	Consumers	Inhalation	Long-term systemic effects	3.2 mg/m3
	Consumers	Inhalation	Long-term local effects	0.1 mg/m3
	Consumers	Skin contact	Long-term systemic effects	102 mg/kg bw/day
	Consumers	Skin contact	Long-term local effects	0.012 mg/cm2
	Consumers	Ingestion	Long-term systemic effects	4.1 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Maleic acid	Fresh water	0.1 mg/l
	Freshwater - intermittent	0.428 mg/l
	Marine water	0.01 mg/l
	Sewage treatment plant	44.6 mg/l
	Fresh water sediment	0.334 mg/kg dry weight (d.w.)
	Marine sediment	0.033 mg/kg dry weight (d.w.)
	Soil	0.042 mg/kg dry weight (d.w.)
Formaldehyde	Fresh water	0.44 mg/l
	Freshwater - intermittent	4.44 mg/l
	Marine water	0.44 mg/l
	Sewage treatment plant	0.19 mg/l
	Fresh water sediment	2.3 mg/kg dry weight (d.w.)
	Marine sediment	2.3 mg/kg dry weight (d.w.)
	Soil	0.2 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

Personal protective equipment

Eye/face protection	:	Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Hand protection		
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	suspension
Colour	:	cream
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	6.6 - 7.0
Viscosity		
Viscosity, kinematic	:	Not applicable
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	No data available
Vapour pressure	:	Not applicable
Relative density	:	ca. 1
Density	:	ca. 1 g/cm³ similar to water
Relative vapour density	:	Not applicable
Particle characteristics		
Particle size	:	No data available

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

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

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Maleic acid:

Acute oral toxicity	:	LD50 (Rat): > 300 - 2,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rabbit): 1,560 mg/kg

Formaldehyde:

Acute oral toxicity	:	Acute toxicity estimate: 100 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation.
Acute inhalation toxicity	:	Acute toxicity estimate (Rat): 100 ppm Exposure time: 4 h Test atmosphere: gas Method: Expert judgement
Acute dermal toxicity	:	LD50 (Rabbit): 270 mg/kg

Thiomersal:

Acute oral toxicity	:	LD50 (Rat): 75 mg/kg Acute toxicity estimate: 10 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation.
Acute inhalation toxicity	:	Acute toxicity estimate: 0.1 mg/l Exposure time: 4 h Test atmosphere: dust/mist

		Method: Expert judgement Remarks: Based on national or regional regulation.
Acute dermal toxicity	:	Acute toxicity estimate: 10 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation.

Skin corrosion/irritation

Not classified based on available information.

Components:

Maleic acid:

Species	:	in vitro membrane barrier
Method	:	OECD Test Guideline 435
Result	:	Corrosive after 3 minutes to 1 hour of exposure

Formaldehyde:

Result	:	Corrosive after 3 minutes to 1 hour of exposure
Remarks	:	Based on national or regional regulation.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Maleic acid:

Result	:	Irreversible effects on the eye
Remarks	:	Based on skin corrosivity.

Formaldehyde:

Result	:	Irreversible effects on the eye
Remarks	:	Based on skin corrosivity.

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

Maleic acid:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	positive

Assessment	:	Probability or evidence of skin sensitisation in humans

Formaldehyde:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Species	:	Humans
Result	:	positive
Assessment	:	Probability or evidence of high skin sensitisation rate in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Maleic acid:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative

Formaldehyde:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: positive Test Type: In vitro mammalian cell gene mutation test Result: positive Test Type: Chromosome aberration test in vitro Result: positive
Genotoxicity in vivo	:	Test Type: In vivo mammalian alkaline comet assay Species: Mouse Application Route: Inhalation Result: positive
Germ cell mutagenicity- Assessment	:	Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Thiomersal:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
Genotoxicity in vivo	:	Test Type: Mammalian spermatogonial chromosome aberration test (in vivo) Species: Mouse

Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Maleic acid:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	2 Years
Result	:	negative
Remarks	:	Based on data from similar materials

Formaldehyde:

Species	:	Rat
Application Route	:	inhalation (gas)
Exposure time	:	28 Months
Result	:	positive
Carcinogenicity - Assessment	:	Sufficient evidence of carcinogenicity in animal experiments

Thiomersal:

Species	:	Rat
Exposure time	:	1 Years
Result	:	negative

Reproductive toxicity

Not classified based on available information.

Components:

Maleic acid:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Ingestion Result: negative Remarks: Based on data from similar materials

Formaldehyde:

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: inhalation (gas)

Result: negative

Thiomersal:

Effects on foetal development	:	Species: Rat Application Route: Ingestion Result: positive Remarks: Based on data from similar materials
Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments

STOT - single exposure

Not classified based on available information.

Components:

Maleic acid:

Assessment	:	May cause respiratory irritation.
Remarks	:	Based on national or regional regulation.

Formaldehyde:

Assessment	:	May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

Thiomersal:

Target Organs	:	Central nervous system, Cardio-vascular system, Gastrointestinal tract, Kidney
Assessment	:	Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Thiomersal:

Species	:	Rat
LOAEL	:	>= 0.5 mg/kg
Application Route	:	Ingestion
Remarks	:	Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Maleic acid:

Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): > 10 - 100 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 42.81 mg/l Exposure time: 48 h Test substance: Neutralised product Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	ErC50 (Pseudokirchneriella subcapitata (green algae)): 74.35 mg/l Exposure time: 72 h Test substance: Neutralised product Method: OECD Test Guideline 201 EC10 (Pseudokirchneriella subcapitata (green algae)): 11.8 mg/l Exposure time: 72 h Test substance: Neutralised product Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC10 (Pseudomonas putida): 44.6 mg/l Exposure time: 18 h Test substance: Neutralised product Method: DIN 38 412 Part 8
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: > 1 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Remarks: Based on data from similar materials

Formaldehyde:

Toxicity to fish	:	LC50 (Morone saxatilis (striped bass)): 6.7 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia pulex (Water flea)): 5.8 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Desmodesmus subspicatus (green algae)): 4.89 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to microorganisms	:	EC50 (activated sludge): 19 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 1.04 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

Thiomersal:

Toxicity to fish	:	LC50 (Poecilia reticulata (guppy)): > 0.01 - 0.1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 0.01 - 0.1 mg/l Exposure time: 48 h Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: > 0.001 - 0.01 mg/l Exposure time: 21 d Species: Daphnia sp. (water flea) Remarks: Based on data from similar materials
M-Factor (Chronic aquatic toxicity)	:	10

12.2 Persistence and degradability

Components:

Maleic acid:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 97 % Exposure time: 28 d Method: OECD Test Guideline 301B

Formaldehyde:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 99 % Exposure time: 28 d Method: OECD Test Guideline 301A

12.3 Bioaccumulative potential

Components:

Maleic acid:

Partition coefficient: n-octanol/water	:	log Pow: -1.3

Formaldehyde:

Partition coefficient: n-octanol/water	:	log Pow: 0.35 Remarks: Calculation

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging	:	Do not dispose of waste into sewer. Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID number

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.2 UN proper shipping name

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

14.4 Packing group

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:
Number on list 3

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Number on list 18: Thiomersal

Number on list 72: Formaldehyde

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Number on list 77: Formaldehyde

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations,

where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H221	:	Flammable gas.
H300	:	Fatal if swallowed.
H301	:	Toxic if swallowed.
H302	:	Harmful if swallowed.
H310	:	Fatal in contact with skin.
H311	:	Toxic in contact with skin.
H312	:	Harmful in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H317	:	May cause an allergic skin reaction.
H318	:	Causes serious eye damage.
H330	:	Fatal if inhaled.
H335	:	May cause respiratory irritation.
H341	:	Suspected of causing genetic defects.
H350	:	May cause cancer.
H360	:	May damage fertility or the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Carc.	:	Carcinogenicity
Eye Dam.	:	Serious eye damage
Flam. Gas	:	Flammable gases
Muta.	:	Germ cell mutagenicity
Repr.	:	Reproductive toxicity
Skin Corr.	:	Skin corrosion
Skin Sens.	:	Skin sensitisation

STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
2004/37/EC	:	Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
IE OEL	:	Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
2004/37/EC / STEL	:	Short term exposure limit
2004/37/EC / TWA	:	Long term exposure limit
IE OEL / OELV - 8 hrs (TWA)	:	Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL)	:	Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet	:	Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification of the mixture:		**Classification procedure:**
Skin Sens. 1	H317	Calculation method

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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