According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Footvax Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.06.2024

 3.0
 28.09.2024
 11330109-00005
 Date of first issue: 03.01.2024

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

1.1 Product identifier

Trade name : Footvax Formulation

Other means of identification : Coopers Ovilis Footvax Sheep and Lamb Footrot Vaccine

(51170)

Footvax (A001992)

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

,

Telephone : +1-908-740-4000

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Aspiration hazard, Category 1 H304: May be fatal if swallowed and enters air-

ways.

Long-term (chronic) aquatic hazard, Cat-

egory 4

H413: May cause long lasting harmful effects to aquatic life.

O Label alamanta

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.06.2024

 3.0
 28.09.2024
 11330109-00005
 Date of first issue: 03.01.2024

Hazard pictograms :

Signal word : Danger

Hazard statements : H304 May be fatal if swallowed and enters airways.

H413 May cause long lasting harmful effects to aquatic

life.

Precautionary statements : Prevention:

P273 Avoid release to the environment.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON

CENTER/ doctor.

P331 Do NOT induce vomiting.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Paraffin oil

EUH208 Contains Formaldehyde. May produce an allergic reaction.

## 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.

## **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

## Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Paraffin oil	8012-95-1 232-384-2	Asp. Tox. 1; H304 Aquatic Chronic 4; H413	>= 50 - < 70
Antigen	Not Assigned		>= 20 - < 30
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;	< 0.1

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Footvax Formulation**

Version 3.0	Revision Date: 28.09.2024	SDS Number: 11330109-00005	Date of last issue: 26.06.2024 Date of first issue: 03.01.2024	
Thiom	nersal	54-64-8 200-210-4 080-004-00	H314 Eye Dam. 1; H318 Skin Sens. 1A; H317 Muta. 2; H341 Carc. 1B; H350 STOT SE 3; H335 ———————————————————————————————————	>= 0.0025 - < 0.025

For explanation of abbreviations see section 16.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 28.09.2024 11330109-00005 Date of first issue: 03.01.2024 3.0

#### **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 ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

First Aid responders should pay attention to self-protection. Protection of first-aiders

> 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 : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

Flush eyes with water as a precaution. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

If vomiting occurs have person lean forward.

Call a physician or poison control centre immediately. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May be fatal if swallowed and enters airways.

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

fighting

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

Hazardous combustion prod- : Carbon oxides

4/20

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

ucts

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.
Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Remove undamaged containers from the area in 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 pro-

tective 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.

If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

#### 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 absor-

bent.

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 deter-

mine 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

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation. Advice on safe handling : Avoid inhalation of vapour or mist.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

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. Wash contami-

nated 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 locked up. Keep tightly closed. 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	2 ppm	GB EH40
			2.5 mg/m3	
	Further inform	ner information: Capable of causing cancer and/or heritable		e genetic dam-
	age.			
		STEL	2 ppm	GB EH40
			2.5 mg/m3	
	Further inform	information: Capable of causing cancer and/or heritable genetic date		e genetic dam-
	age.			
		TWA	0.3 ppm	2004/37/EC

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Footvax Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.06.2024

 3.0
 28.09.2024
 11330109-00005
 Date of first issue: 03.01.2024

			0.37 mg/m3	
I	Further inform	ation: Dermal sensit	isation, Carcinogens or muta	igens
I		STEL	0.6 ppm	2004/37/EC
			0.74 mg/m3	
I	Further information: Dermal sensitisation, Carcinogens or mutagens			

## **Derived No Effect Level (DNEL)**

Substance name	End Use	Exposure routes	Potential health effects	Value
Paraffin oil	Workers	Inhalation	Long-term systemic effects	5 mg/m3
	Workers	Inhalation	Short-term exposure	5 mg/m3
	Workers	Inhalation	Long-term local ef- fects	5 mg/m3
	Workers	Inhalation	Acute local effects	5 mg/m3
Formaldehyde	Workers	Inhalation	Long-term systemic effects	9 mg/m3
	Workers	Inhalation	Long-term local ef- fects	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 ef- fects	0.037 mg/cm2
	Consumers	Inhalation	Long-term systemic effects	3.2 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	0.1 mg/m3
	Consumers	Skin contact	Long-term systemic effects	102 mg/kg bw/day
	Consumers	Skin contact	Long-term local ef- fects	0.012 mg/cm2
	Consumers	Ingestion	Long-term systemic effects	4.1 mg/kg bw/day

# **Predicted No Effect Concentration (PNEC)**

Substance name	Environmental Compartment	Value
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.)

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



#### **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

#### 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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

#### 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

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Appearance : oily, liquid

Colour : No data available
Odour : No data available
Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : Not applicable

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : Not applicable

# **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.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.06.2024

 3.0
 28.09.2024
 11330109-00005
 Date of first issue: 03.01.2024

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 toxicological effects

Information on likely routes of:

exposure

: Inhalation Skin contact

Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

Components:

Paraffin oil:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

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

Describe. Expert judgement

Remarks: Based on national or regional regulation.

Acute inhalation toxicity : Acute toxicity estimate: 0.1 mg/l

Exposure time: 4 h

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

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:**

#### Paraffin oil:

Species : Rabbit

Result : No skin irritation

#### 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:**

#### Paraffin oil:

Species : Rabbit

Result : No eye irritation

### Formaldehyde:

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

## Respiratory or skin sensitisation

## Skin sensitisation

Not classified based on available information.

## Respiratory sensitisation

Not classified based on available information.

#### Components:

#### 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 hu-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

mans

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

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- As-

sessment

Positive result(s) from in vivo mammalian somatic cell muta-

genicity tests.

Thiomersal:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mammalian spermatogonial chromosome aberra-

tion test (in vivo) Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Formaldehyde:

Species : Rat

Application Route : inhalation (gas)
Exposure time : 28 Months
Result : positive

Carcinogenicity - Assess-

ment

: Sufficient evidence of carcinogenicity in animal experiments

Thiomersal:

Species : Rat Exposure time : 1 Years

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.06.2024

 3.0
 28.09.2024
 11330109-00005
 Date of first issue: 03.01.2024

Result : negative

## Reproductive toxicity

Not classified based on available information.

## **Components:**

## Formaldehyde:

Effects on foetal development Test Type: Embryo-foetal development

Species: Rat

Application Route: inhalation (gas)

Result: negative

#### Thiomersal:

Effects on foetal develop-

Species: Rat

ment

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on sexual function and fertil-

ity, and/or on development, based on animal experiments

#### STOT - single exposure

Not classified based on available information.

#### **Components:**

## 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, Gastrointes-

tinal tract, Kidney

Assessment : Causes damage to organs through prolonged or repeated

exposure.

## Repeated dose toxicity

#### **Components:**

#### Paraffin oil:

Species: Rat, femaleLOAEL: 161 mg/kgApplication Route: IngestionExposure time: 90 Days

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

Thiomersal:

Species Rat

LOAEL >= 0.5 mg/kgApplication Route Ingestion

Remarks Based on data from similar materials

**Aspiration toxicity** 

May be fatal if swallowed and enters airways.

**Components:** 

Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

## **SECTION 12: Ecological information**

#### 12.1 Toxicity

#### **Components:**

Paraffin oil:

Toxicity to fish : LL50 (Scophthalmus maximus (turbot)): > 100 mg/l

Exposure time: 96 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

aquatic invertebrates

Toxicity to daphnia and other : EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l

Exposure time: 48 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

: EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Formaldehyde:

Toxicity to fish : LC50 (Morone saxatilis (striped bass)): 6.7 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia pulex (Water flea)): 5.8 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic : ErC50 (Desmodesmus subspicatus (green algae)): 4.89 mg/l

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

plants 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 (Chron-

ic 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 tox- :

icity)

10

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic 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:**

Formaldehyde:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 99 % Exposure time: 28 d

Method: OECD Test Guideline 301A

## 12.3 Bioaccumulative potential

#### **Components:**

Paraffin oil:

Partition coefficient: n- : log Pow: > 4

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

octanol/water Remarks: Calculation

Formaldehyde:

Partition coefficient: n- : log Pow: 0.35

octanol/water 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 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

This substance/mixture does not contain components consid-

ered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

**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.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

**SECTION 14: Transport information** 

14.1 UN 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

16 / 20

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.06.2024
3.0	28.09.2024	11330109-00005	Date of first issue: 03.01.2024

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 Transport in bulk according to Annex II of Marpol and the IBC Code

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)

UK REACH List of restrictions (Annex 17)

UK REACH List of restrictions (Annex 17) : Conditions of restriction for the following entries should be considered:

Number on list 3

Number on list 18: Thiomersal

Number on list 72: Formaldehyde

Substance(s) or mixture(s) are listed

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

Version Revision Date: SDS Number: Date of last issue: 26.06.2024 3.0 28.09.2024 11330109-00005 Date of first issue: 03.01.2024

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.

Not applicable

Not applicable

Not applicable

Not applicable

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained : Not applicable

Regulation (EU) 2019/1021 as amended for Great Brit-

ain)

Regulation (EC) on substances that deplete the ozone

layer

UK REACH List of substances subject to authorisation

(Annex XIV)

GB Export and import of hazardous chemicals - Prior

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Not applicable

## Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

#### 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.

H304 : May be fatal if swallowed and enters airways.

H310 : Fatal in contact with skin.
H311 : Toxic in contact with skin.

H314 : Causes severe skin burns and eye damage.

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



#### **Footvax Formulation**

Version 3.0	Revision Date: 28.09.2024	SDS Number: 11330109-00005	Date of last issue: 26.06.2024 Date of first issue: 03.01.2024
H317 H318 H330 H335 H341 H350 H360 H372		<ul> <li>Causes serior</li> <li>Fatal if inhale</li> <li>May cause re</li> <li>Suspected of</li> <li>May cause ca</li> <li>May damage</li> <li>Causes dama exposure.</li> <li>Very toxic to a</li> </ul>	equatic life.
H410 H413		<ul><li>Very toxic to aquatic life with long lasting effects.</li><li>May cause long lasting harmful effects to aquatic life.</li></ul>	

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard Aquatic Chronic : Long-term (chronic) aquatic hazard

Asp. Tox. : Aspiration hazard Carc. Carcinogenicity Eve Dam. Serious eve damage Flam. Gas Flammable gases Germ cell mutagenicity Muta. 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

GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

2004/37/EC / STEL : Short term exposure limit 2004/37/EC / TWA : Long term exposure limit

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (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 - Interna-

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Footvax Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 26.06.2024

 3.0
 28.09.2024
 11330109-00005
 Date of first issue: 03.01.2024

tional 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; 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 Agen-

cy, http://echa.europa.eu/

#### Classification of the mixture:

#### Classification procedure:

Asp. Tox. 1 H304 Calculation method Aquatic Chronic 4 H413 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.

GB / EN