

SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture Oil-based vaccine from PHARMAQ AS (part of Zoetis)
Registration number -
Synonyms Oil adjuvant vaccine from PHARMAQ
Issue date 22-August-2018
Version number 01

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

Identified uses Veterinary vaccine (Fish)
Uses advised against Not for human use

1.3. Details of the supplier of the safety data sheet

Company name: PHARMAQ AS (part of Zoetis)
Office address: Industrivegen 50
Postal address: Skogmo Industriområde
7863
Overhalla, Norge
Phone number: +47 74 28 08 00
Fax number: +47 74 28 08 01
Email: customer.service@pharmaq.no
Website: <http://www.pharmaq.no>

Emergency telephone number: Norway (Giftinformasjonen):+47 22 59 13 00

United Kingdom: 999 or 112
Italy: 112

Additional emergency telephone number: International CHEMTREC (24 hours): +1-703-527-3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Regulation (EC) No 1272/2008 as amended

This mixture does not meet the criteria for classification according to Regulation (EC) 1272/2008 as amended.

Hazard summary Not classified for health hazards. However, occupational exposure to the mixture or substance(s) may cause adverse health effects.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Contains: Antigen, Formaldehyde, Mineral oil and emulsifier, Water for Injection
Hazard pictograms None.
Signal word None.
Hazard statements The mixture does not meet the criteria for classification.

Precautionary statements

Prevention Observe good industrial hygiene practices.
Response Wash hands after handling.
Storage Store away from incompatible materials.
Disposal Dispose of waste and residues in accordance with local authority requirements.

Supplemental label information

EUH208 - Contains Formaldehyde. May produce an allergic reaction.
In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

2.3. Other hazards

Not a PBT or vPvB substance or mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Antigen	*	Not assigned	-	-	
Classification:	-				
Formaldehyde	≤ 0,04	50-00-0 200-001-8	-	605-001-00-5	
Classification:	Acute Tox. 3;H301, Acute Tox. 3;H311, Skin Corr. 1B;H314, Skin Sens. 1;H317, Eye Dam. 1;H318, Acute Tox. 3;H331, STOT SE 3;H335, Muta. 2;H341, Carc. 1B;H350, Aquatic Chronic 2;H411				B,D
Mineral oil and emulsifier	*	Mixture	-	-	
Classification:	-				
Water for Injection	*	7732-18-5 231-791-2	-	-	
Classification:	-				

List of abbreviations and symbols that may be used above

#: This substance has been assigned Union workplace exposure limit(s).

M: M-factor

PBT: persistent, bioaccumulative and toxic substance.

vPvB: very persistent and very bioaccumulative substance.

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition comments *Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret. The full text for all H-statements is displayed in section 16.

SECTION 4: First aid measures

General information

IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance.

4.1. Description of first aid measures

Inhalation

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

In the case of skin contact, immediately wash the skin with plenty of soap and water. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.

Ingestion

Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

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

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

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

Treat symptomatically. Where parenteral oil-adjuvanted vaccine exposure has occurred, the patient should be promptly evaluated for the development of vasospasm and/or compartment syndrome. Persons developing anaphylactic (allergic) reactions must receive immediate medical assistance.

SECTION 5: Firefighting measures

General fire hazards

No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Special fire fighting procedures Move containers from fire area if you can do so without risk.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Local authorities should be advised if significant spillages cannot be contained.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS. In case of spills, beware of slippery floors and surfaces.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up Avoid release to the environment.

Large Spills: Stop the flow of material, if this is without risk. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use.

6.4. Reference to other sections For personal protection, see section 8 of the SDS. For waste disposal, see section 13 of the SDS.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with eyes, skin, and clothing. Avoid breathing mist or vapour. Avoid accidental injection. Special care should be taken to avoid accidental self injection and needle stick injury when administering the product. Fish can be slippery. Use non-slip gloves. Wash thoroughly after handling. When using, do not eat, drink or smoke. Wear personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed original container in a well-ventilated place. Store in a cool, dry place out of direct sunlight. @ 2 - 8 °C (36 - 46 °F). Do not freeze. Keep away from heat, sparks and open flame. Use care in handling/storage. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

7.3. Specific end use(s) Not available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

Austria. MAK List, OEL Ordinance (GwV), BGBl. II, no. 184/2001

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	0,6 mg/m ³
	MAK	0,5 ppm 0,6 mg/m ³ 0,5 ppm

Belgium. Exposure Limit Values.

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0,38 mg/m ³	
		0,3 ppm	
Mineral oil, heavy (CAS 8042-47-5)	STEL	10 mg/m ³	Mist.
	TWA	5 mg/m ³	Mist.

Bulgaria. OELs. Regulation No 13 on protection of workers against risks of exposure to chemical agents at work

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2 mg/m ³
	TWA	1 mg/m ³
Mineral oil, heavy (CAS 8042-47-5)	TWA	5 mg/m ³

Croatia. Dangerous Substance Exposure Limit Values in the Workplace (ELVs), Annexes 1 and 2, Narodne Novine, 13/09

Components	Type	Value
Formaldehyde (CAS 50-00-0)	MAC	2,5 mg/m ³
	STEL	2 ppm 2,5 mg/m ³ 2 ppm

Cyprus. OELs. Control of factory atmosphere and dangerous substances in factories regulation, PI 311/73, as amended.

Components	Type	Value
Formaldehyde (CAS 50-00-0)	TWA	3 mg/m ³
		2 ppm

Czech Republic. OELs. Government Decree 361

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	1 mg/m ³	
	TWA	0,5 mg/m ³	
Mineral oil, heavy (CAS 8042-47-5)	Ceiling	10 mg/m ³	Aerosol
	TWA	5 mg/m ³	Aerosol

Denmark. Exposure Limit Values

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	0,4 mg/m ³	
		0,3 ppm	
Mineral oil, heavy (CAS 8042-47-5)	TLV	1 mg/m ³	Mist.

Estonia. OELs. Occupational Exposure Limits of Hazardous Substances. (Annex of Regulation No. 293 of 18 September 2001)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	1,2 mg/m ³
		1 ppm
	TWA	0,6 mg/m ³ 0,5 ppm

Finland. Workplace Exposure Limits

Components	Type	Value
Formaldehyde (CAS 50-00-0)	Ceiling	1,2 mg/m ³
		1 ppm
	TWA	0,37 mg/m ³ 0,3 ppm

France. Threshold Limit Values (VLEP) for Occupational Exposure to Chemicals in France, INRS ED 984

Components	Type	Value
Formaldehyde (CAS 50-00-0)	VLE	1 ppm
	VME	0,5 ppm

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	TWA	0,37 mg/m ³	
		0,3 ppm	
Mineral oil, heavy (CAS 8042-47-5)	TWA	5 mg/m ³	Respirable fraction.

Germany. TRGS 900, Limit Values in the Ambient Air at the Workplace

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	AGW	0,37 mg/m ³	
		0,3 ppm	

Germany. TRGS 900, Limit Values in the Ambient Air at the Workplace

Components	Type	Value	Form
Mineral oil, heavy (CAS 8042-47-5)	AGW	5 mg/m ³	Respirable fraction.

Greece. OELs (Decree No. 90/1999, as amended)

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	2,5 mg/m ³	
	TWA	2 ppm 2,5 mg/m ³	
Mineral oil, heavy (CAS 8042-47-5)	TWA	2 ppm 5 mg/m ³	Mist.

Hungary. OELs. Joint Decree on Chemical Safety of Workplaces

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0,6 mg/m ³	
	TWA	0,6 mg/m ³	
Mineral oil, heavy (CAS 8042-47-5)	Ceiling	5 mg/m ³	Mist.

Iceland. OELs. Regulation 154/1999 on occupational exposure limits

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	1,2 mg/m ³	
	TWA	1 ppm 0,4 mg/m ³ 0,3 ppm	
Mineral oil, heavy (CAS 8042-47-5)	TWA	1 mg/m ³	Mist.

Ireland. Occupational Exposure Limits

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0,4 ppm	
	TWA	0,2 ppm	
Mineral oil, heavy (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.

Italy. Occupational Exposure Limits

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0,3 ppm	
	TWA	0,1 ppm	
Mineral oil, heavy (CAS 8042-47-5)	TWA	5 mg/m ³	Inhalable fraction.

Latvia. OELs. Occupational exposure limit values of chemical substances in work environment

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	TWA	0,5 mg/m ³	

Lithuania. OELs. Limit Values for Chemical Substances, General Requirements

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	1 mg/m ³	
	TWA	1,2 ppm 0,6 mg/m ³ 0,5 ppm	
Mineral oil, heavy (CAS 8042-47-5)	STEL	3 mg/m ³	Fume and mist.
	TWA	1 mg/m ³	Fume and mist.

Netherlands. OELs (binding)

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0,5 mg/m ³	

Netherlands. OELs (binding)

Components	Type	Value	Form
Mineral oil, heavy (CAS 8042-47-5)	TWA	0,15 mg/m3	Mist.
	TWA	5 mg/m3	

Norway. Administrative Norms for Contaminants in the Workplace

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	1,2 mg/m3	
	TLV	1 ppm	
Mineral oil, heavy (CAS 8042-47-5)	TLV	0,6 mg/m3	Mist.
	TLV	0,5 ppm	
		1 mg/m3	

Poland. MACs. Regulation regarding maximum permissible concentrations and intensities of harmful factors in the work environment, Annex 1

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	1 mg/m3	
	TWA	0,5 mg/m3	
Mineral oil, heavy (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable fraction.
	TWA	5 mg/m3	

Portugal. VLEs. Norm on occupational exposure to chemical agents (NP 1796)

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	0,3 ppm	
Mineral oil, heavy (CAS 8042-47-5)	STEL	10 mg/m3	Aerosol
	TWA	5 mg/m3	Aerosol

Romania. OELs. Protection of workers from exposure to chemical agents at the workplace

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	3 mg/m3	
	TWA	2 ppm	
Mineral oil, heavy (CAS 8042-47-5)	STEL	1,2 mg/m3	
	STEL	1 ppm	
	STEL	10 mg/m3	
	TWA	5 mg/m3	

Slovakia. OELs. Regulation No. 300/2007 concerning protection of health in work with chemical agents

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0,74 mg/m3	
	TWA	0,6 ppm	
	TWA	0,37 mg/m3	
Mineral oil, heavy (CAS 8042-47-5)	STEL	0,3 ppm	Fume and mist.
	STEL	3 mg/m3	
	TWA	15 ppm	
	TWA	1 mg/m3	
		5 ppm	Fume and mist.
		5 ppm	Fume and mist.

Slovenia. OELs. Regulations concerning protection of workers against risks due to exposure to chemicals while working (Official Gazette of the Republic of Slovenia)

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	TWA	0,62 mg/m3	
	TWA	0,5 ppm	

Spain. Carcinogens and Mutagens with Limit Values (Table 2)

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	TWA	0,37 mg/m3	
	TWA	0,3 ppm	

Spain. Occupational Exposure Limits

Components	Type	Value	Form
Mineral oil, heavy (CAS 8042-47-5)	STEL	10 mg/m3	Mist.
	TWA	5 mg/m3	Mist.

Sweden. OELs. Work Environment Authority (AV), Occupational Exposure Limit Values (AFS 2015:7)

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	Ceiling	0,74 mg/m3	
	TWA	0,6 ppm	
		0,37 mg/m3	
Mineral oil, heavy (CAS 8042-47-5)	STEL	3 mg/m3	Mist.
	TWA	1 mg/m3	Mist.

Switzerland. SUVA Grenzwerte am Arbeitsplatz

Components	Type	Value	Form
Formaldehyde (CAS 50-00-0)	STEL	0,74 mg/m3	
	TWA	0,6 ppm	
		0,37 mg/m3	
Mineral oil, heavy (CAS 8042-47-5)	TWA	5 mg/m3	Inhalable dust.

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Formaldehyde (CAS 50-00-0)	STEL	2,5 mg/m3
	TWA	2 ppm
		2,5 mg/m3
		2 ppm

Biological limit values No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures Follow standard monitoring procedures.

Derived no effect levels (DNELs) Not available.

Predicted no effect concentrations (PNECs) Not available.

Exposure guidelines**Slovenia. OELs. Regulations concerning protection of workers against risks due to exposure to chemicals while working (Official Gazette of the Republic of Slovenia)**

Formaldehyde (CAS 50-00-0)

Can be absorbed through the skin.

8.2. Exposure controls

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. CEN: European Committee for Standardization (Comité Européen de Normalisation).

Eye/face protection If contact is likely, safety glasses with side shields are recommended. (Ref: EN 166).

Skin protection

- Hand protection Wear appropriate chemical resistant gloves. Neoprene, butyl rubber, nitrile or Viton gloves are recommended. Non-slip gloves. (Ref: BS-EN 374, BS-EN 420).

- Other Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. (Ref: EN 143).

Thermal hazards	Not applicable.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.
Environmental exposure controls	Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Emulsion.
Physical state	Liquid.
Form	Liquid.
Colour	White - Cream.
Odour	Odourless.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials. Sunlight. Do not allow material to freeze.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	No hazardous decomposition products are known.

SECTION 11: Toxicological information

General information	Occupational exposure to the substance or mixture may cause adverse effects.
Information on likely routes of exposure	
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Prolonged skin contact may cause temporary irritation. Frequent or prolonged contact may defat and dry the skin, leading to discomfort and dermatitis. In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

Formaldehyde Species: Rabbit
Severity: Moderate Severe

Eye contact Direct contact with eyes may cause temporary irritation.

Formaldehyde Species: Rabbit
Severity: Severe

Ingestion May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. In the event of accidental injection, an allergic reaction may occur. Signs and symptoms might include skin rash, itching, redness or swelling. Respiratory reactions may be characterized by rhinitis, sneezing, scratchy throat, oral mucosal edema, laryngeal mucosal edema, coughing, shortness of breath, wheezing, and chest pain. Asthma like reactions occur with acute exposures in sensitized patients. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

11.1. Information on toxicological effects

Acute toxicity In the event of accidental injection, an allergic reaction may occur. This product is an oil-adjuvanted suspension. Oil-adjuvant containing products may cause severe vasospasm following accidental injection.

Components	Species	Test results
Formaldehyde (CAS 50-00-0)		
Acute		
Oral		
LD50	Rat	800 mg/kg 100 mg/kg
Chronic		
Inhalation		
LOAEL	Mouse	15 ppm, 2 years Tumours
	Rat	15 ppm, 9 days Respiratory system 6 ppm, 2 years Tumours

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Based on available data, the classification criteria are not met.

Eye contact
Formaldehyde Species: Rabbit
Severity: Severe

Respiratory sensitisation Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur.

Skin sensitisation Based on available data, the classification criteria are not met. In the event of accidental injection, an allergic reaction may occur. This product contains formaldehyde which is considered to be a skin sensitizer.

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

Mutagenicity
Formaldehyde In Vitro Bacterial Mutagenicity (Ames)
Result: positive
Species: Bacteria

In Vitro Chromosome Aberration
Result: positive
Species: Rodent

In Vitro Sister Chromatid Exchange
Result: positive
Species: Rodent

Mutagenicity
Formaldehyde

In Vivo Chromosome Aberration
Result: positive
Species: Not specified

Carcinogenicity

Based on available data, the classification criteria are not met. Contains a substance which may cause cancer by inhalation. No known carcinogens are present at greater than 0.1%.

Hungary. 26/2000 EüM Ordinance on protection against and preventing risk relating to exposure to carcinogens at work (as amended)

Formaldehyde (CAS 50-00-0)

IARC Monographs. Overall Evaluation of Carcinogenicity

Formaldehyde (CAS 50-00-0)

1 Carcinogenic to humans.

Slovenia. OELs. Regulations concerning protection of workers against risks due to exposure to chemicals while working (Official Gazette of the Republic of Slovenia)

Formaldehyde (CAS 50-00-0)

Carcinogenic, Category 2.

Reproductive toxicity

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

Developmental effects

Formaldehyde

185 mg/kg/day Embryo / Fetal Development, Not teratogenic
Maternal toxicity
Species: Mouse
Organ: Oral

40 ppm Embryo / Fetal Development, Not Teratogenic
Maternal Toxicity
Species: Rat
Organ: Inhalation

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Due to partial or complete lack of data the classification is not possible.

Mixture versus substance information

No information available

Other information

Allergic reactions are possible. The antigens included in this product are non-infectious. All have been prepared from killed or inactivated preparations of microorganisms.

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met for hazardous to the aquatic environment. The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Avoid release to the environment.

Components

Species

Test results

Formaldehyde (CAS 50-00-0)

Aquatic

Crustacea

EC50

Water flea (*Daphnia pulex*)

4,3 - 7,8 mg/l, 48 hours

Fish

LC50

Striped bass (*Morone saxatilis*)

10,302 - 16,743 mg/l, 96 hours

12.2. Persistence and degradability

No data is available on the degradability of this product.

12.3. Bioaccumulative potential

No data available.

Bioconcentration factor (BCF)

Not available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Not a PBT or vPvB substance or mixture.

12.6. Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

12.7. Additional information

Estonia Dangerous substances in groundwater Data

Formaldehyde (CAS 50-00-0)

Pesticides (total) 0,5 UG/L
Pesticides (total) 5 UG/L

Estonia Dangerous substances in soil Data

Formaldehyde (CAS 50-00-0)

Synthetic pesticides (total of active substances) 0,5 mg/kg

Synthetic pesticides (total of active substances) 20 mg/kg

Synthetic pesticides (total of active substances) 5 mg/kg

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

14.1. - 14.6.: Not regulated as dangerous goods.

RID

14.1. - 14.6.: Not regulated as dangerous goods.

ADN

14.1. - 14.6.: Not regulated as dangerous goods.

IATA

14.1. - 14.6.: Not regulated as dangerous goods.

IMDG

14.1. - 14.6.: Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code Not established.

SECTION 15: Regulatory information

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

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I and II, as amended

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 1 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 2 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex I, Part 3 as amended

Not listed.

Regulation (EU) No. 649/2012 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry, as amended

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(10) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Formaldehyde (CAS 50-00-0)

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work, as amended.

Formaldehyde (CAS 50-00-0)

Other EU regulations

Directive 2012/18/EU on major accident hazards involving dangerous substances, as amended

Formaldehyde (CAS 50-00-0)

Other regulations

The product is classified and labelled in accordance with Regulation (EC) 1272/2008 (CLP Regulation) as amended. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006, as amended.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References

Not available.

Information on evaluation method leading to the classification of mixture

The data contained in this SDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature. The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.

Full text of any H-statements not written out in full under Sections 2 to 15

H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H341 Suspected of causing genetic defects.
H350 May cause cancer.
H411 Toxic to aquatic life with long lasting effects.

Revision information

None.

Training information

Follow training instructions when handling this material.

Disclaimer

Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.