

1. Product and company identification:

Product identification:

Oil adjuvant vaccines from PHARMAQ

Product Use:

Injectable Fish Vaccine (for veterinary use only)

Manufacturer/Supplier: PHARMAQ AS
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For any information, please contact the local representative of the marketing authorization holder. See package leaflet for contact information.

2. Composition/information of ingredients:

Ingredients:

Formaldehyde inactivated bacterial and/or viral antigens, oil, emulsifiers and water.

3. Hazards identification:

Occupational hazards:

This product contains mineral oil and antigens. Accidental self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

Repeated self-injections may aggravate effects or cause anaphylactic shock.

Pregnant women and people with immune suppression should not perform vaccination.

Environmental hazards:

Low

4. First aid measures:

Self injection:

Seek prompt medical advice even if only a very small amount is injected and take the package insert with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.



It is recommended that vaccinators have adrenaline available at the workplace in case of anaphylactic shock

Skin contact:

As a precaution wash well with water. Seek medical attention if irritation or other symptoms occur.

Eye contact:

As a precaution rinse well with water. Seek medical attention if irritation or other symptoms occur.

Ingestion:

Not expected to be harmful if swallowed, but as a precaution do not induce vomiting and seek medical attention.

5. Fire fighting measures:

Extinguishing media:

Use water fog, foam, dry chemical or carbon dioxide (CO₂) to extinguish flames.

Fire fighting procedures:

Due to the content of mineral oil this material can catch fire, however it is very difficult to ignite. For fires involving this material, do not enter any enclosed or confined fire space without proper protective equipment, including self-contained breathing apparatus

6. Accidental release measures:

Personal precautions:

No special measures required.

Environmental precautions:

Do not flush into surface water or sanitary sewage system.

Methods for cleaning up:

Clean up promptly by sweeping or by using an absorbent. Dispose in a manner consistent with local and national regulations.

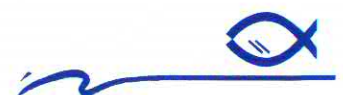
7. Handling and storage:

Handling:

Ensure that the method of restraint, handling and administration e.g. by the use of guarded needles (such as a protecting device attached to the syringe providing a shield against the tip of the needle) minimizes the risk of self-injection. The anaesthetized fish are wet and slippery, and the vaccinators should wear wet cotton gloves to be able to hold the fish.

Storage:

Store and transport at 2- 8°C. Do not freeze. Protect from light. Do not use after the expiry date stated on the label. Keep out of reach from children.



8. Exposure controls and personal protection:

See 7

9. Physical and chemical properties:

Appearance:

White to cream-coloured homogenous emulsion when shaken. No continuous water phase visible on bottom of the container when observed at rest.

pH:

Not applicable

Odor:

No characteristic smell

Physical state:

Water-in-oil emulsion

Flammability:

Not tested

10. Stability and reactivity:

Stable:

Yes

Materials to avoid:

None

Hazardous decomposition products:

None expected

11. Toxicological information:

Self-injection:

It is well known that manual administration of injection vaccines to fish gives risk of accidental self-injection for the vaccinators. Accidental self-injection may cause health effects, but the overall risk for serious health effect is low. Following an accidental self-injection with vaccine, usually an inflammatory reaction in the injected finger is seen, occasionally spreading to the hand. More seldom a "flu" like syndrome with fever, muscle aches and general malaise are experienced, probably caused by the endotoxins in the vaccine.

The largest risk appears after repeated self-injections. This can lead to allergy against the vaccine. If an allergic person is exposed to self-injection, he/she could run the risk of anaphylactic shock.

This is a rare and dangerous health situation. Without prompt and correct medical treatment it can be fatal.



Acute oral effects:

The product is not tested, but it is not expected to be harmful if swallowed. However, as a precaution do not induce vomiting and seek medical attention.

12. Ecological information:

Environmental fate:

The mineral oil in the vaccine is considered inherently but not readily biodegradable.

Ecotoxicity:

The toxicity of the mineral oil to aquatic organisms other than intended use in fish has not been evaluated. Consequently, this material should be kept out of sewage and drainage systems and the contact with all bodies of water should be minimized.

13. Disposal considerations:

Waste disposal:

Dispose of in accordance with local and national regulations.

Container disposal:

Dispose of in accordance with local and national regulations.

14. Transport information:

Transport over land (ADR):

Not regulated

Transport over land (RID):

Not regulated

Sea transport (IMDG):

Not regulated

Air transport (ICAO/IATA):

Not regulated

15. Regulatory Information:

R-Phrases:

None

S-Phrases:

S37: Wear suitable gloves.



16. Other information

Note:

The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

