

Material Safety Data Sheet

Japanese Encephalitis Virus (JEV) Vaccine Inactivated

Effective Date: 01 June 2009

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: IXIARO®/JESPECT®
Synonyms: Japanese Encephalitis Vaccine, Inactivated, Adsorbed
Manufacturer: Valneva Scotland Ltd
Address: Oakbank Park Road
Livingston, United Kingdom
EH53 OTG
Product Type: Biological
Chemical Formula: N/A.
CAS Number: Unassigned
Customer Service Contact:
+44 (0) 1506 446600 (UK and Europe)
+1 (301) 556-4500 Weekdays 8:00am-5:30pm ET (USA)
+1 (301) 263-4051 All other times (USA)

2. COMPOSITION/INFORMATION ON INGREDIENTS

HAZARDOUS INGREDIENTS:

The IXIARO vaccine consists of inactivated attenuated JE virus suspension formulated in PBS, sucrose and 0.1% Alum and supplied packaged in a pre-filled glass syringe. The vaccine can be supplied with or without a separate needle.

A hazard evaluation (Risk Assessment) of the above product has been carried out in accordance with OSHA's hazard communication standard [29 CFR 1910.1200(d)]. It has been determined that the product ingredients do not pose a physical or health hazard at the percentages present in the formulation based on the guidelines set by OSHA's Hazard Communication Standard. Therefore, as of this date, we are not required under OSHA Federal Regulations to distribute a Material Safety Data Sheet for these products within the USA. However to provide material safety data for shipments of IXIARO to all other countries worldwide a MSDS is provided.

For further information concerning product safety, refer to the IXIARO Full Prescribing Information.

3. HAZARDS IDENTIFICATION POTENTIAL HEALTH EFFECTS

Handling this product in its final form presents minimal risk from occupational exposure.

IXIARO contains protamine sulphate, a fish protein compound known to cause hypersensitivity reaction in some individuals.

4. FIRST AID MEASURES

EYES:

Immediately flush eyes with large amounts of water for at least 15 minutes. Obtain medical attention.

SKIN:

Wash skin thoroughly with soap and water. Remove contaminated clothing from site of contact. Contact a physician if irritation develops.

INGESTION:

Obtain medical attention immediately.

INHALATION:

Obtain medical attention immediately.

INJECTION:

In case of accidental injection, remove needle from injection site. Wash and disinfect area. Obtain medical attention immediately. While the vaccine is not considered to be a human pathogen, medical attention should be sought to address the risk of trauma-associated infection or allergic reactions.

5. FIRE FIGHTING MEASURES FLAMMABLE PROPERTIES

FIRE AND EXPLOSION HAZARDS:

This product is classified as non-flammable although the packaging is combustible.

EXTINGUISHING MEDIA:

Water is recommended for fires involving packaging.

HAZARDOUS COMBUSTION PRODUCTS:

Toxic, corrosive or flammable thermal decomposition products are expected from the product packaging when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

Wear protective clothing and equipment consistent with the degree of hazard. Collect and place in a suitable, properly labeled container for recovery or disposal.

For large spills, take precautions to prevent entry into waterways, sewers or surface drainage systems.

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7. HANDLING AND STORAGE

HANDLING PRECAUTIONS:

No special control measures are required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:	N/A.
EYE/FACE PROTECTION:	Normal accepted work practices.
SKIN PROTECTION:	Normal accepted work practices.
RESPIRATORY PROTECTION:	Normal accepted work practices.
OTHER/GENERAL PROTECTION:	None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE:	Particulate liquid formulation in a glass syringe.
PHYSICAL STATE:	Aqueous suspension which might separate.

10. STABILITY AND REACTIVITY

STABILITY:	Stable at recommended storage conditions of 2 – 8°C.
CONDITIONS TO AVOID (STABILITY):	Storage below 0°C, DO NOT FREEZE.

11. TOXICOLOGICAL INFORMATION

EYE EFFECTS:	Irritation is not expected following direct contact.
SKIN EFFECTS:	Irritation is not expected following direct contact.
ORAL EFFECTS:	Not expected to be toxic following ingestion.
INHALATION EFFECTS:	Irritation is not expected following inhalation.
EFFECTS OF OVEREXPOSURE:	N/A.

12. ECOLOGICAL INFORMATION

No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

13. DISPOSAL CONSIDERATIONS

PRODUCT/CONTAINER DISPOSAL:

Empty containers and unused contents should be incinerated. The disposal method for rejected products/ returned goods must ensure that they cannot be re-sold or re-used.

14. TRANSPORT INFORMATION

The MSDS should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product are not restricted. It has no known significant hazards requiring special packaging or labeling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

N/A.

16. OTHER INFORMATION

Licensed product for human use.

DISCLAIMER OF EXPRESSED AND IMPLIED WARRANTIES

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Valneva Scotland Ltd.
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