

Material Safety Data Sheet

BAVARIAN NORDIC

According to Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU

Date of Issue: 05. Feb 2025

Identification of the substance / preparation and company

1.1. Product identification

Product name: Vimkunya (VLP IM Chikungunya vaccine)

Product Family: Vaccine CAS Number: 2986379-37-5

Synonyms:

Chikungunya virus, virus-like-particle formulated with aluminum hydroxide and filled

into syringes (CHIKV VLP)

Drug Product (DP) = syringes of Vimkunya

Unlabeled Drug Product (UDP) = unlabeled syringes of Vimkunya

Assembled Drug Product (ADP) = syringes of Vimkunya with plunger and flange Finished Drug Product (FDP) = syringes of Vimkunya in distribution boxes

1.2. Manufacturer identification

Bavarian Nordic Berna A/S Philip Heymans Alle 3 2900 Hellerup, Danmark

Phone: +45 3326 8383

This information pertains to the occupational use of the product. For patient information, refer to the patient information leaflet as required by legislation on Medicinal Products for Human Use.

2. Hazard identification

Classification No classifications according to 1272/2008EC
Hazard statements No hazard statements according to 1272/2008EC

Other Hazards N/A

3. Composition / information on ingredients

CHIKV VLP is the active pharmaceutical ingredient (API) of the investigative CHIKV VLP vaccine (IND 017998) formulated with aluminum hydroxide. The VLP is none infectious and thus does not represent a biological hazard. The product is an aqueous solution filled into syringes. The chemical components of the solution are given in the table below.

Name	CAS No.	Composition in %	GHS Classification
Potassium phosphate	7778-77-0	0.052	Not classified as
monobasic	1110-11-0	0.032	hazardous
Potassium phosphate dibasic	7758-11-4	0.107	Not classified as
			hazardous
Sodium citrate	6132-04-3	0.735	Not classified as
			hazardous
Sucrose	57-50-1	7.462	Not classified as
			hazardous
Aluminum hydroxide	21645-51-2*	0.037	Not classified as
			hazardous

* CAS-no is for the molecule formula: Al(OH)₃ · H₂O

First aid measures

Inhalation: Avoid inhalation. No data

Avoid contact with skin. In case of accidental contact with skin, clean thoroughly, rinse Skin contact:

skin immediately with plenty of water.

Avoid contact with eyes. In case of accidental contact with eyes, clean thoroughly,

wash eyes immediately with plenty of clean and gently flowing water for at least 15 Eye contact:

minutes and seek medical advice.

Avoid ingestion in occupational settings. In case of accidental ingestion, seek medical Ingestion:

advice.

Fire-fighting measures

Unusual fire or Unknown. Not expected explosion hazards:

Hazardous combustion

products:

Unknown. Not expected

Suitable Extinguishing

media:

Water, foam, CO₂, other chemical extinguishing media

Special firefighting

procedures:

No special requirements

Accidental release measures

Personal precautions Wear lab coat and gloves

Environmental precautions

For large spills, take precautions to prevent entry into

waterways, sewers or surface drainage systems

If contained, pick up mechanically. If the container is leaking, wear protective clothing (gloves, lab coat, eye protection), wash

contaminated surfaces with detergent.

Decontamination

Clean up methods:

procedures:

N/A

Handling and storage

General hygiene measures for the handling of this product are **Handling Precautions:**

> applicable (do not eat, drink, or smoke in work area. Wash hands after use, remove contaminated clothing before

entering eating areas.)

Storage requirements: +2 to +8 °C

Protect against moisture and protect from light

8. Exposure control / personal protection

Exposure controls: Wear laboratory clothing, gloves, and eye protection. Avoid

ingestion and accidental exposure in occupational setting.

Environmental exposure: General advice, do not allow uncontrolled discharge of product

into the environment.

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Denmark

9. Physical and chemical properties

Physical state: Liquid

Appearance: White cloudy solution

Density: not applicable
Solubility in water: Water based

pH: Neutral (pH 6.2 – 8.2 at 20°C)

10. Stability and reactivity

Reactivity No hazardous reactions known.

Stability: Stable under recommended storage conditions

Conditions to avoid: None for normal handling of this product

Hazardous Decomposition

Product:

Not expected

11. Toxicological information

Acute or repeated dose toxicity: not known / not expected Skin corrosion or irritation: not known / not expected Serious Eye Damage/Irritation: not known / not expected Respiratory or Skin Sensitization: not known / not expected **Germ Cell Mutagenicity** not known / not expected Carcinogenicity not known / not expected Reproductive effects not known / not expected Other adverse effects not known / not expected

12. Ecological information

Environmental No data available. Do not discharge into environment. In case

precautions of accident follow release measures (6.1.)

13. Disposal considerations

Product Disposal in agreement with local waste disposal policies and

authorities. Follow all Regional and National regulations.

14. Transport Information

Road Transport (ADR) Not a dangerous good

Marine Transport Not a dangerous good

(IMDG)

Air Transport (IATA) Not a dangerous good

15. Regulatory information

labeling: accordance with 1272/2008EC

Chemical Safety A chemical safety assessment is not required for this

assessment: substance

16. Other information

This information is based on our present state of knowledge. It should therefore not be construed as guaranteeing specific properties of the products described or their suitability for a particular application. This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.