Material Safety Data Sheet

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

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1. Identification of the substance / preparation and company

1.1. Product identification

Product name: Vivotif
Product Family: Vaccine
CAS Number: N/A
Synonyms: Typhoid Vaccine Live Oral Attenuated Salmonella typhi Ty21a

1.2. Manufacturer identification

Bavarian Nordic Berna GmbH
Oberriedstrasse 68
3174 Thörishaus, Switzerland

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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	Risk Group 1 Biological Agent (organism with no or negligible risk)

3. Composition / information on ingredients

Vivotif is a live attenuated vaccine for oral administration. The vaccine contains lyophilized bacteria of the attenuated strain *Salmonella typhi* Ty21a formulated in enteric coated capsules which are then packaged in 3 or 4-capsules blisters for distribution.

Name	**CAS-no / EC-no**	**Composition** (per capsule)	**GHS Classification**
Viable *S. typhi* Ty21a	N/A	at least 2 x 10^9 CFU / Caps	N/A
Non-viable *S. typhi* Ty21a	N/A	5 - 50 x 10^9 bacteria counts (bc)	N/A
Sucrose	57-50-1 / 200-334-9	32 - 64 mg	Not classified as hazardous
Anhydrous Lactose	63-42-3	filled to a total weight of 180 - 200 mg	Not classified as hazardous
Magnesium stearate	557-04-0 / 209-150-3	3.42 - 3.78 mg	Not classified as hazardous

Gelatin Type B	9000-70-8	37.5 – 45.9 mg	Not classified as hazardous
Cellulose, 2-Hydroxypropyl methyl ether, phthalic acid ester	9050-31-1	27 - 33 mg	Not classified as hazardous
Diethyl phthalate	84-66-2	6 – 15 mg	Not classified as hazardous

4. First aid measures

Inhalation: Avoid inhalation. No data

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

Eye contact: 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 minutes and seek medical advice.

Ingestion: Avoid ingestion in occupational settings. In case of accidental ingestion, seek medical advice. Product is a vaccine for oral administration. Up to eight doses of Vivotif did not cause adverse reactions in adult males in over-dosage studies. Vaccine should not be administered to persons with acute febrile illness, acute gastrointestinal illness or persons with a known hypersensitivity to any vaccine component.

5. Fire-fighting measures

Unusual fire or explosion hazards: Unknown. Not expected

Hazardous combustion products: Unknown. Not expected

Suitable Extinguishing media: Water, foam, CO_2, other chemical extinguishing media

Special firefighting procedures: No special requirements

6. 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

Clean up methods: If contained, pick up mechanically. If capsules are broken, wear protective clothing (gloves, lab coat gowning, eye and FFP3 masks with large amounts of spilt material), apply a disinfectant solution (*e.g.*: 1% sodium hypochlorite solution, 70% Ethanol, etc.) and pick up material mechanically.

Decontamination procedures: N/A

7. Handling and storage

Handling Precautions: General hygiene measures for the handling of this product are 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: Observe good microbiological practice. Wear laboratory clothing, gloves, and eye protection. Avoid ingestion and accidental exposure in occupational settings.

Environmental exposure: General advice, do not allow uncontrolled discharge of product into the environment.

9. Physical and chemical properties

Physical state:	Solid
Appearance:	Salmon / white capsules filled with beige powder
Density:	not applicable
Solubility in water:	not applicable
pH:	Neutral (pH 5.0 – 7.5 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 precautions	No data available. Do not discharge into environment. In case 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 (IMDG)	Not a dangerous good
Air Transport (IATA)	Not a dangerous good

15. Regulatory information

EU classification and labeling:	The product does not require a hazard warning label in accordance with 1272/2008EC
Chemical Safety assessment:	A chemical safety assessment is not required for this substance

Vivotif (Typhoid Vaccine Live Oral Attenuated Salmonella typhi Ty21a) is approved by the US Food and Drug Administration for human use as well as the health authorities of Australia, Austria, Belgium, Czech Republic, Germany, Denmark, Spain, Finland, France, Israel, Italy, Korea, Luxembourg, Malaysia. the Netherlands, Norway, New Zealand, Poland, Portugal, Sweden, Slovakia, and the United Kingdom.

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.