

VAXXITEK® HVT+IBD+ILT, solution for injection

Version	Revision Date:	SDS Number:	Date of last issue: 09/08/2021
2.1	09/08/2021	000000057021	Date of first issue: 07/30/2021

SECTION 1. IDENTIFICATION

Product name : VAXXITEK® HVT+IBD+ILT, solution for injection

Synonyms : Live recombinant Vacchine with: Bursal Disease – Infectious Laryngotracheitis – Marek’s Disease Vaccine, Serotype 3, Live recombinant Marek’s Disease Vector (ARG 1, HRG 1) USDA Code 1J81.R0

Manufacturer or supplier's details

Company name of supplier : Boehringer Ingelheim AH USA

Address : Satellite Blvd Ste 500 3239
Duluth GA 30096
USA

Telephone : (678) 638-3000

Prepared by : EHS-Services@Boehringer-Ingelheim.com

Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887
US Emergency Telephone number: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Safety Data Sheet only for the professional user.

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

The pharmacological effect of the medicament has to be considered (see package leaflet).
In case the product is handled, stored or shipped with dry ice or liquid nitrogen, please consider the respective SDS.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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Chemical nature : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Dimethyl sulfoxide	67-68-5	>= 1 - < 5

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
(show the package insert where possible).
First Aid responders should pay attention to self-protection and use the recommended protective clothing
Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
- If inhaled : Move to fresh air.
- In case of skin contact : Wash off immediately with plenty of water.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.
- If swallowed : Rinse mouth.
Drink plenty of water.
- Most important symptoms and effects, both acute and delayed : No information available.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Dry chemical
Foam
Carbon dioxide (CO₂)
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Product itself is non-combustible; fire extinguishing method of surrounding areas must be considered.

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Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment.
Ensure adequate ventilation.
High risk of slipping due to leakage/spillage of product.

Environmental precautions : Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders).
Pick up and transfer to properly labelled containers.
Clean with disinfectants.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No special protective measures against fire required.
The product is not flammable.

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.

Conditions for safe storage : No special storage conditions required.

Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Observe joint storage prohibition.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION
Components with workplace control parameters

Components	Basis	Category	Values	Remarks
Penicillin G sodium 69-57-8	BIEL	3A	20 µg/m ³	
	BIPC	1b		

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Abbreviations:

BIEL = Boehringer Ingelheim Exposure Limit (internal value)
 BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)
 BIPC = Boehringer Ingelheim Pregnancy Category
 BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.

Components	Basis	Category	Values	Remarks
Streptomycin sulfate 3810-74-0	BIEL	3A	83 µg/m ³	
	BIPC	3		

Abbreviations:

BIEL = Boehringer Ingelheim Exposure Limit (internal value)
 BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)
 BIPC = Boehringer Ingelheim Pregnancy Category
 BIPC 3: There is evidence in animals and/or humans or the mechanism of actions indicates that the compound has the potential to cause harm to the unborn. Harm to the unborn can occur even if exposure does not exceed the BIEL value.

Engineering measures : Local exhaust
Emergency sprinkling nozzle

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Nitrile rubber

Remarks : The break through time depends amongst other things on the material, the thickness and the type of glove and therefore has to be measured for each case.

Eye protection : Safety glasses with side-shields
(Not necessary when using full face mask)

Skin and body protection : Laboratory: laboratory coat; Factory: disposable Overall.

Protective measures : Handle in accordance with good industrial hygiene and safety practice.
Avoid contact with skin, eyes and clothing.
Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warran-

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ty given by the manufacturer for the safe function.

Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	light orange, light pink
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	Not applicable
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	Not applicable

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Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not tested

Oxidizing properties : No data available

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : No data available

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Components:**Dimethyl sulfoxide:**

Acute oral toxicity : LD50 (Rat): 28,500 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC0 (Rat): > 5.33 mg/l
Exposure time: 4 h
Method: OECD Test Guideline 403

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Acute dermal toxicity : LD50 (Rat): 40,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Dimethyl sulfoxide:**

Species : Rabbit
Method : OECD Test Guideline 404
Result : Mild skin irritant

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Dimethyl sulfoxide:**

Species : Rabbit
Result : Mild eye irritant
Method : OECD Test Guideline 405

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Dimethyl sulfoxide:**

Test Type : Maximisation Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : Does not cause skin sensitisation.

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Method : OECD Test Guideline 429
Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Not classified based on available information.

Components:**Dimethyl sulfoxide:**

Genotoxicity in vitro : Test Type: Ames test
Test system: Salmonella typhimurium
Result: negative

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Test Type: sister chromatid exchange assay
Test system: Chinese hamster ovary cells
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: negative

Genotoxicity in vivo : Species: Rat (male and female)
Method: OECD Test Guideline 474
Result: negative

Carcinogenicity

Not classified based on available information.

Components:**Dimethyl sulfoxide:**

Remarks : No data available

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Not classified based on available information.

Components:**Dimethyl sulfoxide:**

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Not classified based on available information.

Components:**Dimethyl sulfoxide:**

Remarks : No data available

STOT - repeated exposure

Not classified based on available information.

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Components:**Dimethyl sulfoxide:**

Remarks : No data available

Repeated dose toxicity**Components:****Dimethyl sulfoxide:**

Species	: Rat, male and female
NOAEL	: 3,300 mg/kg
LOAEL	: 9,900 mg/kg
Application Route	: Oral
Exposure time	: 18 month

Species	: Monkey, male and female
NOAEL	: 8,910 mg/kg
LOAEL	: 990 mg/kg
Exposure time	: 18 month

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Dimethyl sulfoxide:**

Toxicity to fish	: LC50 (Danio rerio (zebra fish)): > 25,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 24,600 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): 17,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to fish (Chronic toxicity)	: Remarks: No data available
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: Remarks: No data available
Toxicity to microorganisms	: EC50 (activated sludge): 10 - 100 mg/l

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Exposure time: 0.5 h
Method: ISO 8192

Persistence and degradability**Components:****Dimethyl sulfoxide:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Stability in water : Hydrolysis: at 30 °C (0.12 - 1.2 h)
Remarks: Hydrolyses readily.

Bioaccumulative potential**Components:****Dimethyl sulfoxide:**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: -1.35

Mobility in soil**Components:****Dimethyl sulfoxide:**

Distribution among environmental compartments : Remarks: No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App. A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.

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Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION**International Regulations****IATA-DGR**

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

Dimethyl sulfoxide	67-68-5	>= 1 - < 5 %
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Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations
Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water	7732-18-5
Dimethyl sulfoxide	67-68-5

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Prop. 65

WARNING: This product can expose you to chemicals including streptomycin sulphate, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

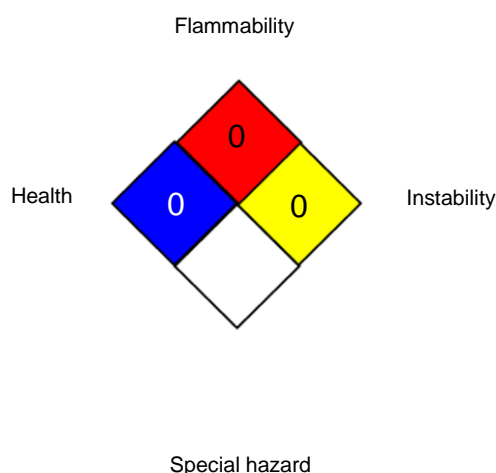
The components of this product are reported in the following inventories:

TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. amphotericin B
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	On the inventory, or in compliance with the inventory
NZIoC	:	Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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SECTION 16. OTHER INFORMATION
Further information
NFPA 704:

HMIS® IV:

HEALTH	/	0
FLAMMABILITY	1	
PHYSICAL HAZARD	0	

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances

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es; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Revision Date : 09/08/2021

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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