

Express® FP 5 lyophilisate

Version 1.0 Revision Date: 04/11/2023 SDS Number: 000000059542 Date of last issue: -
Date of first issue: 04/11/2023

SECTION 1. IDENTIFICATION

Product name : Express® FP 5 lyophilisate

Synonyms : Express® FP 5-VL5 lyophilisate; Express® FP 5-VL5 HB lyophilisate; Express® FP 10 lyophilisate; Express® FP 5-HS lyophilisate; Express® FP 5/Somnugen lyophilisate; Express® FP 10-HS lyophilisate; Express® FP 10/Somnugen lyophilisate; Express® 10-HS lyophilisate; Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus Vaccine, Modified Live Virus. USDA Code 1181.24 with: Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza 3-Respiratory Syncytial Virus, Modified Live Virus

Manufacturer or supplier's details

Company name of supplier : Boehringer Ing. Pharma GmbH & Co.KG

Address : Binger Straße 173
Ingelheim 55216
Germany

Telephone : +498007790900

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

Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887
German Emergency Telephone number: +49800 1817059

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Safety Data Sheet only for the professional user., For veterinary use only, Refer to the product insert for complete instructions on usage

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

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

Express® FP 5 lyophilisate

Version Revision Date: SDS Number: Date of last issue: -
1.0 04/11/2023 000000059542 Date of first issue: 04/11/2023

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).

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
sucrose	57-50-1	>= 50 - < 70

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.
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)

Express® FP 5 lyophilisate

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	04/11/2023	000000059542	Date of first issue: 04/11/2023

- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
- Hazardous combustion products : Carbon oxides
- 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.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : 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.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
- Conditions for safe storage : Refer to the product insert for instructions on storage.
- 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	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL

Express® FP 5 lyophilisate

Version 1.0 Revision Date: 04/11/2023 SDS Number: 000000059542 Date of last issue: -
Date of first issue: 04/11/2023

		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0

Engineering measures : Local exhaust

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.
Do not breathe dust.
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 warranty 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

Express® FP 5 lyophilisate

Version 1.0 Revision Date: 04/11/2023 SDS Number: 000000059542 Date of last issue: -
Date of first issue: 04/11/2023

Appearance : lyophilised cake

Colour : white, opaque

Odour : No data available

pH : 6.5 - 7.0
(as a suspension)

Melting point/range : No data available

Boiling point/boiling range : Not applicable

Flash point : Not applicable

Flammability (solid, gas) : 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 : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Bulk density : No data available

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 : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : Not tested

Express® FP 5 lyophilisate

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	04/11/2023	000000059542	Date of first issue: 04/11/2023

Oxidizing properties	:	No data available
Particle size	:	No data available

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.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method

Components:**sucrose:**

Acute oral toxicity	:	LD50 (Rat): 29,700 mg/kg
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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Express® FP 5 lyophilisate

Version Revision Date: SDS Number: Date of last issue: -
1.0 04/11/2023 000000059542 Date of first issue: 04/11/2023

Components:

sucrose:

Genotoxicity in vitro : Test Type: Mammalian cell gene mutation assay
Result: negative

Carcinogenicity

Not classified based on available information.

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.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

Components:

sucrose:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Components:

sucrose:

Partition coefficient: n- : log Pow: -3.27
octanol/water

Mobility in soil

No data available

Express® FP 5 lyophilisate

Version 1.0 Revision Date: 04/11/2023 SDS Number: 000000059542 Date of last issue: -
Date of first issue: 04/11/2023

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.
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

Special precautions for user

Not applicable

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

Listed substances in the product are at low enough levels to not be expected to exceed the 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

Express® FP 5 lyophilisate

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	04/11/2023	000000059542	Date of first issue: 04/11/2023

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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

potassium hydroxide	1310-58-3	>= 0.1 - < 1 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

potassium hydroxide	1310-58-3	>= 0.1 - < 1 %
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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**

sucrose	57-50-1
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Pennsylvania Right To Know

sucrose	57-50-1
Gelatins	9000-70-8
potassium hydroxide	1310-58-3

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 Neomycin, sulfate (salt), 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.

California Permissible Exposure Limits for Chemical Contaminants

sucrose	57-50-1
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The components of this product are reported in the following inventories:

TCSI : On the inventory, or in compliance with the inventory

TSCA : All substances listed as active on the TSCA inventory

Express® FP 5 lyophilisate

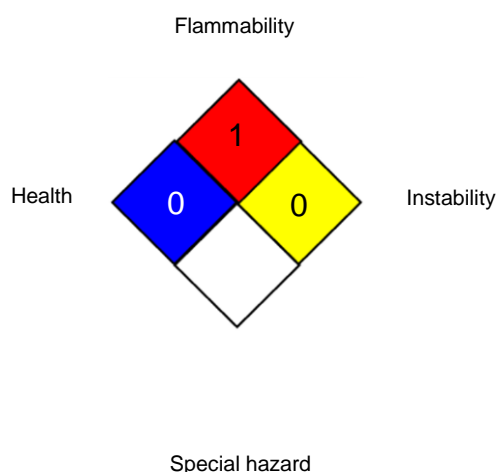
Version 1.0 Revision Date: 04/11/2023 SDS Number: 000000059542 Date of last issue: -
Date of first issue: 04/11/2023

AIIC : Not in compliance with the inventory
 DSL : All components of this product are on the Canadian DSL
 ENCS : Not in compliance with the inventory
 ISHL : Not in compliance with the inventory
 KECI : On the inventory, or in compliance with the inventory
 PICCS : On the inventory, or in compliance with the inventory
 IECSC : On the inventory, or in compliance with the inventory
 NZIoC : On the inventory, or in compliance with the inventory
 TECI : 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.

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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 NIOSH REL : USA. NIOSH Recommended Exposure Limits
 OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated)

Express® FP 5 lyophilisate

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	04/11/2023	000000059542	Date of first issue: 04/11/2023

OSHA Z-1	:	values) USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIIC - 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; (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; TECI - Thailand Existing Chemicals 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

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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

Revision Date : 04/11/2023

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

SAFETY DATA SHEET



Express® FP 5 lyophilisate

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	04/11/2023	000000059542	Date of first issue: 04/11/2023

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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