SAFETY DATA SHEET

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Tick-Borne Encephalitis Vaccine

Product Code(s) PZ02522
Synonyms Tick-Borne Encephalitis Vaccine
Trade Name: FSME-IMMUN, FSME-IMMUN Jr.; TicoVac
Compound Number PF-06830414
Chemical Family: Not determined

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Vaccine

1.3. Details of the supplier of the safety data sheet

Pfizer Inc
66 Hudson Boulevard East
New York, New York 10001
1-800-879-3477

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

2.2. Label elements

Signal word Not classified

Hazard statements Non-hazardous in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances Not applicable

3.2 Mixtures

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Sucrose (CAS #: 57-50-1)	*	-	200-334-9	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	*	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available
Human albumin (CAS #: 70024-90-7)	*		274-272-6	Not classified as hazardous	Not Listed	No data available	No data available
Aluminum hydroxide (CAS #: 21645-51-2)	*		244-492-7	Not classified as hazardous	Not Listed	No data available	No data available
Disodium phosphate dihydrate (CAS #: 10028-24-7)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Potassium phosphate (CAS #: 7778-77-0)	*	-	231-913-4	Not classified as hazardous	Not Listed	No data available	No data available
Tick-borne encephalitis virus (CAS #: NOT ASSIGNED)	< 1		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Sucrose 57-50-1	29700	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available
Aluminum hydroxide 21645-51-2	5000	No data available	No data available	No data available	No data available
Potassium phosphate 7778-77-0	3200	No data available	0.83	No data available	No data available

Additional information

- Not Assigned
* Proprietary
Non-hazardous ingredients provided for completeness. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation

Remove to fresh air. Seek immediate medical attention/advice.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Skin contact

Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion

Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects

For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians

None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media

Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical

Fine particles (such as mists) may fuel fires/explosions.

Hazardous combustion products

Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling
Restrict access to work area. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Additional controls (based on risk assessment) should be implemented where open handling is required. Use enclosed manufacturing processing strategies. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Vaccine.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits
Refer to available public information for specific member state Occupational Exposure Limits.

Sucrose

ACGIH TLV	10 mg/m³
Bulgaria	10.0 mg/m³
Estonia	10 mg/m³
France	10 mg/m³
Ireland	10 mg/m³ STEL: 20 mg/m³
Latvia	5 mg/m³
Spain	10 mg/m³
OSHA PEL	15 mg/m³ 5 mg/m³ (vacated) TWA: 15 mg/m³ total dust (vacated) TWA: 5 mg/m³ respirable fraction
United Kingdom	TWA: 10 mg/m³ STEL: 20 mg/m³

SODIUM CHLORIDE	
Latvia	5 mg/m³
Russia	MAC: 5 mg/m³
Aluminum hydroxide	
ACGIH TLV	1 mg/m³
Austria	5 mg/m³
	STEL 10 mg/m³
Bulgaria	10.0 mg/m³
	1.5 mg/m³
Czech Republic	10.0 mg/m³
Germany	4 mg/m³
	1.5 mg/m³
Germany	1.25 mg/m³
	10 mg/m³
Ireland	10 mg/m³
	4 mg/m³
	STEL: 30 mg/m³
	STEL: 12 mg/m³
Latvia	6 mg/m³
Poland	2.5 mg/m³
	1.2 mg/m³
Russia	TWA: 6 mg/m³
Slovakia	1.5 mg/m³
	4 mg/m³
	6 mg/m³
Spain	1 mg/m³
Switzerland	3 mg/m³
	10 mg/m³
United Kingdom	TWA: 10 mg/m³
	TWA: 4 mg/m³
Potassium phosphate	
Russia	MAC: 10 mg/m³

Pfizer Occupational Exposure Band (OEB) Statement: The Vaccines Occupational Exposure Band (V-OEB) is a classification that has been assigned to biotechnology-based vaccines and antigen components. Risk assessments should be performed to assess potential exposures and determine appropriate controls.

SODIUM CHLORIDE	
Pfizer Occupational Exposure Band (OEB):	OEB 1 (control exposure to the range of 1000ug/m³ to 3000ug/m³)
Tick-borne encephalitis virus	
Pfizer Occupational Exposure Band (OEB):	V-OEB

8.2. Exposure controls

Engineering controls Release prevention and exposure protection measures should be established for any activities involving this material, as determined by a risk assessment conducted using appropriate Occupational Hygiene Risk Assessment tools. The containment level required for the activity should be based on the conclusions of the risk assessment. Where warranted, engineering controls, such as biosafety cabinets, should be applied as the primary means to control exposures.

Environmental exposure controls No information available.

Personal protective equipment Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection	Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
Hand protection	Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
Skin and body protection	Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	If operating and handling conditions result in airborne exposure, wear an appropriate respirator with a protection factor sufficient to control exposures (e.g. particulate cartridge with a full face respirator, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Suspension
Color	Off-white
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

Property	**Values**
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes
No information available

9.2.2. Other safety characteristics
No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity
Reactivity No data available.
10.2. Chemical stability
Stability Stable under normal conditions.
Explosion data
Sensitivity to Mechanical Impact No data available.
Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions
Possibility of hazardous reactions No information available.
10.4. Conditions to avoid
Conditions to avoid Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.

10.5. Incompatible materials
Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products
Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information:	The information included in this section describes the potential hazards of the individual ingredients
Short term	In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.
Known Clinical Effects:	Based on clinical trials in humans, possible adverse effects following exposure to this compound may include: headache, nausea, muscle pain, joint pain, tiredness, malaise, and and injection site reactions.
Acute toxicity	Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.
Skin corrosion/irritation	Based on available data, the classification criteria are not met.
Respiratory or skin sensitization	Based on available data, the classification criteria are not met.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Aspiration hazard	Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)
Sucrose
Rat Oral LD 50 29,700 mg/kg

SODIUM CHLORIDE
Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m^3

Rat Oral LD 50 3 g/kg
Mouse Oral LD 50 4 g/kg
Rabbit Dermal LD 50 > 10 g/kg

Potassium phosphate
Rat Oral LD50 3200 mg/kg
Rabbit Dermal LC50 > 4640 mg/kg

Tick-borne encephalitis virus
Mouse Intramuscular NOEL 0.5 mL
Guinea Pig Intramuscular NOEL 1 mL
Rabbit Intravenous NOEL 0.5 mL/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	-	-
Sucrose	= 29700 mg/kg (Rat)	-	-
SODIUM CHLORIDE	= 3 g/kg (Rat)	> 10000 mg/kg (Rabbit)	> 42 mg/L (Rat) 1 h
Aluminum hydroxide	> 5000 mg/kg (Rat)	-	-
Potassium phosphate	= 3200 mg/kg (Rat)	-	> 0.83 mg/L (Rat) 4 h

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)
SODIUM CHLORIDE
Skin irritation Rabbit Mild
Eye irritation Rabbit Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))
Potassium phosphate
Reproductive & Fertility Rat No route specified 282 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus
Reproductive & Fertility Mouse No route specified 320 mg/kg/day NOAEL No evidence of impaired fertility or harm to the fetus

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)
Potassium phosphate
Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties No information available.

11.2.2. Other information
Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Releases to the environment should be avoided. Environmental properties have not been investigated. Based on available data, the classification criteria are not met.

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply
Aluminum hydroxide	The substance is not PBT / vPvB PBT assessment does not apply
Potassium phosphate	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects
No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number: Not applicable
UN proper shipping name: Not applicable

Transport hazard class(es): Not applicable
Packing group: Not applicable
Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 231-791-2
- **AICS** Present

Sucrose
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 200-334-9
- **AICS** Present

SODIUM CHLORIDE
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 231-598-3
- **AICS** Present

Human albumin
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 274-272-6
- **AICS** Present

Aluminum hydroxide
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 244-492-7
- **AICS** Present

Disodium phosphate dihydrate
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **EINECS** Not Listed
- **AICS** Present
- **Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)** Schedule 5

Potassium phosphate
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed
- **TSCA** Present
- **EINECS** 231-913-4
- **AICS** Present

Tick-borne encephalitis virus
- **CERCLA/SARA Section 313 de minimus %** Not Listed
- **California Proposition 65** Not Listed

EINECS Not Listed

France
Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
SODIUM CHLORIDE 7647-14-5	RG 78	-

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:
This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants
Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009
Not applicable

Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
Sucrose - 57-50-1	Plant protection agent
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment
Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 9 - Physical and Chemical Properties. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

Revision date 10-Jan-2022

Prepared By Pfizer Global Environment, Health, and Safety

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