

Section 1. Identification

GHS product identifier : Forte VII
Product code : 124000000797
Other means of identification : AV6737

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

Identified uses : Animal vaccine.
Uses advised against : None known.

Company Name : Elanco US Inc.
2500 Innovation Way
Greenfield IN, US 46140
Telephone number : 1-877 Elanco1 (1-877-352-6261)
Emergency telephone number : Elanco Product Technical Support / Human or Animal Exposure Reporting:
1-888-545-5973
Email : elanco_sds@elancoah.com
Transportation Emergency telephone number : CHEMTREC: 1-800-424-9300
(Outside U.S. CHEMTREC International: 00 1-703-527-3887)

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : ASPIRATION HAZARD - Category 1

GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H304 - May be fatal if swallowed and enters airways.

Precautionary statements

Prevention : Not applicable.

Response : P301 + P310, P331 - IF SWALLOWED: Immediately call a POISON CENTER or doctor. Do NOT induce vomiting.

Storage : P405 - Store locked up.

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Supplemental label elements : None known.

Hazards not otherwise classified : None known.

Other hazards : Accidental injection may cause local swelling, irritation or necrosis at the injection site.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
White mineral oil (petroleum)	≥25 - ≤50	8042-47-5
Sorbitan, (Z)-9-octadecenoate (2:3)	<10	8007-43-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Get medical attention immediately. Call a poison center or physician. Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Aspiration hazard if swallowed. Can enter lungs and cause damage. Do not induce vomiting. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : May be fatal if swallowed and enters airways.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : Adverse symptoms may include the following:
nausea or vomiting

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : To the Doctor: This product contains mineral oil. Accidental injection with this oil-based product, even in small quantities, can cause intense swelling which may, for example, result in ischaemic necrosis and the loss of a digit. Expert PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Section 4. First aid measures

- Specific treatments** : In case of accidental self-injection of oil emulsion vaccines, get medical attention immediately.
- SEEK IMMEDIATE MEDICAL TREATMENT at nearest Hospital Emergency Room even if only a very small amount is injected, as failure to treat may result in the mineral oil adjuvant causing sterile abscess and/or loss of affected finger or thumb. If pain persists for more than 12 hours after medical examination, seek additional medical advice.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media** : None known.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Section 6. Accidental release measures

- Large spill** : Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not swallow. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

<u>Ingredient name</u>	<u>Exposure limits</u>
White mineral oil (petroleum)	OSHA PEL (United States, 5/2018). [Oil mist, mineral] TWA: 5 mg/m ³ 8 hours. ACGIH TLV (United States, 1/2022). [Mineral Oil, pure, highly and severely refined] TWA: 5 mg/m ³ 8 hours. Form: Inhalable fraction NIOSH REL (United States, 10/2020). [OIL MIST MINERAL] TWA: 5 mg/m ³ 10 hours. Form: Mist STEL: 10 mg/m ³ 15 minutes. Form: Mist
Sorbitan, (Z)-9-octadecenoate (2:3)	None.

Biological exposure indices

No exposure indices known.

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Section 8. Exposure controls/personal protection

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Liquid.
- Color** : Brown. / Gray.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point/freezing point** : Not available.
- Boiling point, initial boiling point, and boiling range** : Not available.
- Flash point** :

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
Sorbitan monooleate, ethoxylated	>93	>199.4	ISO 2719			
White mineral oil (petroleum)	>112	>233.6				
Sorbitan, (Z) -9-octadecenoate (2:3)	225	437				

- Evaporation rate** : Not available.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not available.

Section 9. Physical and chemical properties and safety characteristics

Vapor pressure	:	Ingredient name	Vapor Pressure at 20°C			Vapor pressure at 50°C		
			mm Hg	kPa	Method	mm Hg	kPa	Method
		White mineral oil (petroleum)	0.08	0.011	OECD 104			

Relative vapor density : Not available.

Relative density : Not available.

Solubility(ies) : Not available.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not applicable.

Auto-ignition temperature	:	Ingredient name	°C	°F	Method
		White mineral oil (petroleum)	325 to 355	617 to 671	ASTM E 659

Decomposition temperature : Not available.

Viscosity : Not available.

Flow time (ISO 2431) : Not available.

Particle characteristics

Median particle size : Not applicable.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : No specific data.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
White mineral oil (petroleum)	LD50 Oral	Rat	>5000 mg/kg	-
Sorbitan, (Z) -9-octadecenoate (2:3)	LD50 Oral	Rat	>39.8 g/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Sorbitan, (Z) -9-octadecenoate (2:3)	Eyes - Mild irritant	Rabbit	-	3 mg	-
	Skin - Mild irritant	Rabbit	-	450 ug	-

Sensitization

Section 11. Toxicological information

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name	OSHA	IARC	NTP
White mineral oil (petroleum)	-	3	-

Reproductive toxicity

Product/ingredient name	Maternal toxicity	Fertility	Development toxin	Species	Dose	Exposure
White mineral oil (petroleum)	-	Negative	-	Rat	Oral: >4350 mg/ kg NOAEL	-

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Name	Result
Forte VII White mineral oil (petroleum)	ASPIRATION HAZARD - Category 1 ASPIRATION HAZARD - Category 1

Information on the likely routes of exposure : Not available.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : May be fatal if swallowed and enters airways.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : Adverse symptoms may include the following:
nausea or vomiting

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Long term exposure

Section 11. Toxicological information

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : No known significant effects or critical hazards.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
White mineral oil (petroleum)	Acute LC50 >100 mg/l	Daphnia - Daphnia magna	48 hours
	Acute LC50 >100 mg/l	Fish - Oncorhynchus mykiss	96 hours

Persistence and degradability

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
White mineral oil (petroleum)	>6	-	high

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

Section 14. Transport information

	DOT Classification	TDG Classification	Mexico Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-	-
Transport hazard class(es)	-	-	-	-	-
Packing group	-	-	-	-	-
Environmental hazards	No.	No.	No.	No.	No.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : ASPIRATION HAZARD - Category 1

Composition/information on ingredients

Name	%	Classification
White mineral oil (petroleum)	≥25 - ≤50	ASPIRATION HAZARD - Category 1
Sorbitan, (Z)-9-octadecenoate (2:3)	<10	EYE IRRITATION - Category 2B

State regulations

Massachusetts : The following components are listed: OIL MIST, MINERAL

New York : None of the components are listed.

Section 15. Regulatory information

- New Jersey** : None of the components are listed.
Pennsylvania : None of the components are listed.
California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

Inventory list

- United States** : Not determined.

Section 16. Other information

History

Date of issue/Date of revision : 3/23/2023

Date of previous issue : No previous validation

Version : 0.01

Key to abbreviations

- : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
SGG = Segregation Group
UN = United Nations

References : Not available.

✔ Indicates information that has changed from previously issued version.

Notice to reader

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Elanco Animal Health
0011+1-877-352-6261
0011+1-800-428-4441