

SAFETY DATA SHEET

Pentium Forte Plus

Section 1. Identification

Product identifier	: Pentium Forte Plus
Product code	: 12400000484
Other means of identification	: AV6755; PFP
Relevant identified uses	s of the substance or mixture and uses advised against

Identified uses	: Animal vaccine.
Uses advised against	: None known.
Company Name	: Elanco Canada Ltd. 37 McCarville Street, Charlottetown, PE, C1E 2A7
Telephone number	: Not Available
Emergency telephone number	: CHEMTREC International: 00 1 703-527-3887 (24 hours)
Email	: elanco_sds@elancoah.com
Transportation Emergency telephone number	: CANUTEC (24 HR) 1-613-996-6666

Section 2. Hazard identification

Classification of the substance or mixture	: ASPIRATION HAZARD - Category 1
	Percentage of the mixture consisting of ingredient(s) of unknown acute oral toxicity: 21.2%
	Percentage of the mixture consisting of ingredient(s) of unknown acute dermal toxicity: 21.2%
	Percentage of the mixture consisting of ingredient(s) of unknown acute inhalation toxicity: 21.2%
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.

Section 2. Hazard identification

Other hazards

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

Section 3. Composition/information on ingredients

Ingredient name	Synonyms	% (w/w)	CAS number
White mineral oil (petroleum)	White mineral oil, petroleum; White spirits; Mineral oil; Paraffin oil; White mineral oil; Paraffinum liquidum; OILS, WHITE MINERAL, PETROLEUM; petroleum mineral oil	≥30 - ≤60	8042-47-5
Sorbitan, (Z)-9-octadecenoate (2:3)	Sorbitan, (9Z)-9-octadecenoate (2:3); Sorbitan sequioleate; Sorbitan sesquioleate; Sorbitan, sesquioleate; serbitan sesquioleate; Sorbitan, monohexadecanoate; Sorbitan aliphatic-carboxylate; Sorbitan (Z) -9-octadecenoate (2:3); Sorbitan ester	≥5 - ≤10	8007-43-0

Ranges if listed above for hazardous ingredient(s) are prescribed ranges. The actual concentration(s) or actual concentration range(s) are being withheld as a trade secret.

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.		

Section 4. First-aid measures

dection 4. I inst-and measures			
Skin contact	: No known significant effects or critical hazards.		
Ingestion	: May be fatal if swallowed and enters airways.		
Over-exposure signs/sym	<u>ptoms</u>		
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 me	dical 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.		
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, prote	ctive 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 c	ontainment 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.
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

Section 8. Exposure controls/personal protection

Ingredient name	Exposure limits
White mineral oil (petroleum)	CA British Columbia Provincial (Canada, 3/2022). [Oil mist - mineral, severely refined] TWA: 1 mg/m ³ 8 hours. CA Alberta Provincial (Canada, 6/2018). [Oil] 8 hrs OEL: 5 mg/m ³ 8 hours. Form: Mist 15 min OEL: 10 mg/m ³ 15 minutes. Form: Mist CA Quebec Provincial (Canada, 6/2021). [Mineral oil (mist)] TWAEV: 5 mg/m ³ 8 hours. Form: mist STEV: 10 mg/m ³ 15 minutes. Form: mist

Biological exposure indices

None 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 measu	res
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	1	Brown. Gray.
Odor	1	Not available.
Odor threshold	1	Not available.
рН	1	Not available.
Melting point/freezing point	1	Not available.
Boiling point, initial boiling point, and boiling range	1	Not available.

Flash point	:		Closed cu		l cup			Open cup	
		Ingredient name	°C	°F	Meth	nod	°C	°F	Method
		Sorbitan monooleate, ethoxylated	>93	>199.4					
		White mineral oil (petroleum)	>112	>233.6	ISO 2	719			
		Sorbitan, (Z) -9-octadecenoate (2:3)	225	437					
Evaporation rate	:	Not available.		•				-	
Flammability	:	Not available.							
Lower and upper explosion limit/flammability limit	:	Not available.							
Vapor pressure	:		Vapo	r Press	ure at 2	20°C	Va	por press	ure at 50°C
		Ingredient name	mm Hg	kPa	Meth	nod	mm Hg	kPa	Method
		water	23.8	3.2					
		White mineral oil (petroleum)	0.08	0.011	OECE	0 104			
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 (petrole	eum)	325 to	355	617 to 6	671	ASTM E 659	
Decomposition temperature	:	Not available.				<u>I</u>			

Viscosity Flow time (ISO 2431) <u>Particle characteristics</u> Median particle size

- : Not available.
- : Not available.

: 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) Sorbitan, (Z) -9-octadecenoate (2:3)	LD50 Oral LD50 Oral	Rat Rat	>5000 mg/kg >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

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Classification

Product/ingredient name	IARC	NTP	ACGIH
White mineral oil (petroleum)	3	-	A4

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Section 11. To	oxicological inform	nation
Product/ingredient r	name	Result
Pentium Forte Plus White mineral oil (pet	roleum)	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	Мау	be fatal if swallowed and enters airways.
Symptoms related to the physical	<u>cal, c</u>	hemical and toxicological characteristics
Eye contact	No :	specific data.
Inhalation	No :	specific data.
Skin contact	No :	specific data.
Ingestion	Adv	erse symptoms may include the following:

stion	: Adverse symptoms may include the following	:
	nausea or vomiting	

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

<u>Short term exposure</u>	
Potential immediate effects	: Not available.
Potential delayed effects	: Not available.
<u>Long term exposure</u>	
Potential immediate effects	: Not available.
Potential delayed effects	: Not available.
Potential chronic health effe	<u>cts</u>
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)		Daphnia - Daphnia magna Fish - Oncorhynchus mykiss	48 hours 96 hours

Persistence and degradability **Bioaccumulative potential**

Version :0.07

Section 12. Ecological information					
Product/ingredient name	LogPow	BCF	Potential		
White mineral oil (petroleum)	>6	-	high		
Mobility in soil	•				

Soil/water partition coefficient (Koc)	: 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

	TDG Classification	DOT Classification	IMDG	ΙΑΤΑ	
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.	
UN proper shipping name	-	-	-	-	
Transport hazard class(es)	-	-	-	-	
Packing group	-	-	-	-	
Environmental hazards	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 : Not available. to IMO instruments

Section 15. Regulatory information

: None of the components are listed.
: None of the components are listed.
: Not determined.

Section 16. Other information

<u>History</u>	
Date of issue/Date of revision	: 11/15/2022
Date of previous issue	: 8/1/2022
Version	: 0.07
Key to abbreviations	: ATE = Acute Toxicity Estimate BCF = Bioconcentration Factor GHS = Globally Harmonized System of Classification and Labelling of Chemicals HPR = Hazardous Products Regulations IATA = International Air Transport Association IBC = Internediate 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

Procedure used to derive the classification

Classification	Justification
ASPIRATION HAZARD - Category 1	Expert judgment

References

: Not available.

✓ Indicates information that has changed from previously issued version.

Notice to reader

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For additional information contact: Elanco Animal Health 0011+1-877-352-6261 0011+1-800-428-4441