



SAFETY DATA SHEET

Pentium Forte Plus

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name : Pentium Forte Plus
Product code : 124000000484
Product description : Not available.
Other means of identification : AV6755; PFP

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

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

1.3 Details of the supplier of the safety data sheet

Elanco Nederland B.V.
Van Deventerlaan 31
Utrecht, NL 3528 AG

Telephone number : Not Available
e-mail address of person responsible for this SDS : elanco_sds@elancoah.com

1.4 Emergency telephone number

Supplier or Manufacturer

Supplier Emergency telephone number : CHEMTREC: 31-858880596 (local)
Transportation Emergency telephone number : CHEMTREC: 31-858880596 (local)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Asp. Tox. 1, H304

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

Ingredients of unknown toxicity : 21.2 percent of the mixture consists of component(s) of unknown acute oral toxicity
21.2 percent of the mixture consists of component(s) of unknown acute dermal toxicity
21.2 percent of the mixture consists of component(s) of unknown acute inhalation toxicity

Ingredients of unknown ecotoxicity : Contains 21.2% of components with unknown hazards to the aquatic environment

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

SECTION 2: Hazards identification

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

: Not applicable.

Disposal

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

Supplemental label elements

: Not applicable.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

: Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant fastenings

: Not applicable.

Tactile warning of danger

: Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other hazards which do not result in classification

: None known.

Other hazards

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

: Mixture

Product/ingredient name	Identifiers	%	Classification	Specific Conc. Limits, M-factors and ATEs	Type
White mineral oil (petroleum)	EC: 232-455-8 CAS: 8042-47-5	≥25 - ≤50	Asp. Tox. 1, H304	-	[1] [2]
Sorbitan, (Z) -9-octadecenoate (2:3)	EC: 232-360-1 CAS: 8007-43-0	<10	Eye Irrit. 2, H319 See Section 16 for the full text of the H statements declared above.	-	[1]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

SECTION 3: Composition/information on ingredients

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

SECTION 4: First aid measures

4.1 Description of 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.
- 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.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

- 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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

SECTION 5: Firefighting measures

5.2 Special hazards arising from the substance or mixture

- Hazards from the substance or mixture** : In a fire or if heated, a pressure increase will occur and the container may burst.
- Hazardous combustion products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

5.3 Advice for firefighters

- 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. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 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 spilt material. Avoid breathing vapour or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialised 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".

6.2 Environmental precautions

- : Avoid dispersal of spilt 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).

6.3 Methods and material 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.
- Large spill** : Stop leak if without risk. Move containers from spill area. Approach the 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. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilt product.

6.4 Reference to other sections

- : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 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 vapour 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.

SECTION 7: Handling and storage

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.

7.2 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 unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations : Not available.

Industrial sector specific solutions : Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
White mineral oil (petroleum)	Ministry of Social Affairs and Employment, Legal limit values (Netherlands, 7/2021). [mineral oils] OEL, 8-h TWA: 5 mg/m ³ 8 hours. Form: Mist

Biological exposure indices

None known.

Recommended monitoring procedures : Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Product/ingredient name	Type	Exposure	Value	Population	Effects
White mineral oil (petroleum)	DNEL	Long term Oral	25 mg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	34.78 mg/m ³	General population	Systemic
	DNEL	Long term Dermal	93.02 mg/kg bw/day	General population	Systemic
	DNEL	Long term Inhalation	164.56 mg/m ³	Workers	Systemic
	DNEL	Long term Dermal	217.05 mg/kg bw/day	Workers	Systemic

PNECs

No PNECs available

8.2 Exposure controls

SECTION 8: Exposure controls/personal protection

Appropriate engineering controls	: Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
<u>Individual protection measures</u>	
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.
<u>Skin protection</u>	
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.
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.

SECTION 9: Physical and chemical properties

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

9.1 Information on basic physical and chemical properties

Appearance

Physical state	: Liquid.
Colour	: Brown. Grey.
Odour	: Not available.
Odour threshold	: Not available.
Melting point/freezing point	: Not available.
Initial boiling point and boiling range	: Not available.
Flammability	: Not available.
Lower and upper explosion limit	: Not available.
Flash point	:

SECTION 9: Physical and chemical properties

	Ingredient name	Closed cup			Open cup		
		°C	°F	Method	°C	°F	Method
Auto-ignition temperature	Sorbitan monooleate, ethoxylated	>93	>199.4	ISO 2719			
	White mineral oil (petroleum)	>112	>233.6				
	Sorbitan, (Z) -9-octadecenoate (2:3)	225	437				
	Ingredient name	°C		°F	Method		
	White mineral oil (petroleum)	325 to 355		617 to 671	ASTM E 659		
Decomposition temperature	: Not available.						
pH	: Not available.						
Viscosity	: Not available.						
Solubility(ies)	: Not available.						
Solubility in water	: Not available.						
Partition coefficient: n-octanol/ water	: Not applicable.						
Vapour pressure		Vapour Pressure at 20°C			Vapour pressure at 50°C		
	Ingredient name	mm Hg	kPa	Method	mm Hg	kPa	Method
	water	23.8	3.2	OECD 104			
	White mineral oil (petroleum)	0.08	0.011				
Evaporation rate	: Not available.						
Relative density	: Not available.						
Vapour density	: Not available.						
Explosive properties	: Not available.						
Oxidising properties	: Not available.						
Particle characteristics							
Median particle size	: Not applicable.						

SECTION 10: Stability and reactivity

10.1 Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	: The product is stable.
10.3 Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	: No specific data.
10.5 Incompatible materials	: No specific data.
10.6 Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 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	-

Conclusion/Summary : Not available.

Acute toxicity estimates

N/A

Irritation/Corrosion

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

Conclusion/Summary : Not available.

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Product/ingredient name	Result
Pentium Forte Plus White mineral oil (petroleum)	ASPIRATION HAZARD - Category 1 ASPIRATION HAZARD - Category 1

Information on 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

SECTION 11: Toxicological information

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

Conclusion/Summary : 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.

11.2 Information on other hazards

11.2.1 Endocrine disrupting properties

Not available.

11.2.2 Other information

Not available.

SECTION 12: Ecological information

12.1 Toxicity

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

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

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

12.4 Mobility in soil

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

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Endocrine disrupting properties

Not available.

12.7 Other adverse effects

No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised 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.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : 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 spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number or ID number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments : Not available.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

SECTION 15: Regulatory information

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Other EU regulations

Industrial emissions (integrated pollution prevention and control) - Air : Not listed

Industrial emissions (integrated pollution prevention and control) - Water : Not listed

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Persistent Organic Pollutants

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

National regulations

Water Discharge Policy (ABM) : A(4) Low hazard for aquatic organisms, may have long-term hazardous effects in aquatic environment. Decontamination effort: A

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms

: ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
SGG = Segregation Group
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Asp. Tox. 1, H304	Expert judgment

Full text of abbreviated H statements

H304 H319	May be fatal if swallowed and enters airways. Causes serious eye irritation.
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Full text of classifications [CLP/GHS]

Asp. Tox. 1 Eye Irrit. 2	ASPIRATION HAZARD - Category 1 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
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SECTION 16: Other information

Date of issue/ Date of revision : 11/15/2022

Date of previous issue : 8/5/2022

Version : 0.04

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:

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