



# 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 Italia S.P.A.  
Via dei Colatori 12  
Firenze, Sesto Fiorentino, IT 50019  
**Telephone number** : +39-055-4640825  
**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: 800-789-767 (free-phone)  
CHEMTREC: 39024527031 (local)  
**Transportation Emergency telephone number** : CHEMTREC: 800-789-767 (free-phone)  
CHEMTREC: 39024527031 (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<br>CAS: 8042-47-5 | ≥25 - ≤50 | Asp. Tox. 1, H304                                                                              | -                                         | [1]  |
| Sorbitan, (Z)<br>-9-octadecenoate (2:3) | EC: 232-360-1<br>CAS: 8007-43-0 | <10       | Eye Irrit. 2, H319<br><br>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

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.

### 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.

## SECTION 5: Firefighting measures

**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.

**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.

## SECTION 7: Handling and storage

### 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 |
|--------------------------------|-----------------------|
| No exposure limit value known. |                       |

#### 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 <sup>3</sup>  | General population | Systemic |
|                               | DNEL | Long term Dermal     | 93.02 mg/kg bw/day       | General population | Systemic |
|                               | DNEL | Long term Inhalation | 164.56 mg/m <sup>3</sup> | Workers            | Systemic |
|                               | DNEL | Long term Dermal     | 217.05 mg/kg bw/day      | Workers            | Systemic |

#### PNECs

No PNECs available

### 8.2 Exposure controls

**Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

#### Individual protection measures

**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.

## SECTION 8: Exposure controls/personal protection

- 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.
- 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** :

| 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    |          |          |    |        |

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

- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- pH** : Not available.

## SECTION 9: Physical and chemical properties

**Viscosity** : Not available.

**Solubility(ies)** : Not available.

**Solubility in water** : Not available.

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

| Vapour pressure | Ingredient name               | Vapour Pressure at 20°C |       |          | Vapour pressure at 50°C |     |        |
|-----------------|-------------------------------|-------------------------|-------|----------|-------------------------|-----|--------|
|                 |                               | mm Hg                   | kPa   | Method   | mm Hg                   | kPa | Method |
|                 | water                         | 23.8                    | 3.2   |          |                         |     |        |
|                 | White mineral oil (petroleum) | 0.08                    | 0.011 | OECD 104 |                         |     |        |

**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)<br>-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)<br>-9-octadecenoate (2:3) | Eyes - Mild irritant | Rabbit  | -     | 3 mg     | -           |
|                                         | Skin - Mild irritant | Rabbit  | -     | 450 ug   | -           |

## SECTION 11: Toxicological information

**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<br>White mineral oil (petroleum) | ASPIRATION HAZARD - Category 1<br>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

### 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.

## SECTION 11: Toxicological information

### 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<br>Acute LC50 >100 mg/l | Daphnia - Daphnia magna<br>Fish - Oncorhynchus mykiss | 48 hours<br>96 hours |

**Conclusion/Summary** : Not available.

### 12.2 Persistence and degradability

**Conclusion/Summary** : Not available.

### 12.3 Bioaccumulative potential

| Product/ingredient name       | LogP <sub>ow</sub> | BCF | Potential |
|-------------------------------|--------------------|-----|-----------|
| White mineral oil (petroleum) | >6                 | -   | high      |

### 12.4 Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : 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.

**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**

## SECTION 15: Regulatory information

This product is not controlled under the Seveso Directive.

### National regulations

D.Lgs. 152/06 : Not determined.

### **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<br>H319 | May be fatal if swallowed and enters airways.<br>Causes serious eye irritation. |
|--------------|---------------------------------------------------------------------------------|

### Full text of classifications [CLP/GHS]

|                             |                                                                                  |
|-----------------------------|----------------------------------------------------------------------------------|
| Asp. Tox. 1<br>Eye Irrit. 2 | ASPIRATION HAZARD - Category 1<br>SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 |
|-----------------------------|----------------------------------------------------------------------------------|

**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:

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