SAFETY DATA SHEET

according to Reg. (EC) No 1907/2006 modified by Reg. (EU) No 2020/878

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

1.1. Product Identifier: **Dr. Peticon Spot on for Cats**

Packaging unit: 5 x 1 ml with PE pipette

1.2. Relevant identified uses: veterinary care product, containing DIMETHICONE (polydimethylsiloxane) used for the treatment of fleas and/or ticks.
DIMETHICONE immobilises the parasites by adhering to their body surface, its controlling effect is achieved by physical, mechanical means and therefore the product is not a biocidal product.

Uses advised against: other than above.

1.3. Details of the supplier of the safety data sheet: Animall Professional Care Kft.
Office: H-2112 Veresegyház, Hársas u. 14., Hungary
Manufacturing plant: H-2376 Hernád, Fő u. 183., Hungary
Phone: +36 20 852 6464
E-mail: info@animall.hu
website: www.animall.hu

1.4. Emergency telephone numbers
Poison Control Centres in EU: https://poisoncentres.echa.europa.eu/appointed-bodies
Slovakia: National Toxicological Information Centre: +421 2 5465 2307
Hungary: Health & Toxicological Information Service: 24 hr service: +36 80 201199

SECTION 2: Hazards identification

2.1. Classification of the mixture: this preparation meets the criteria for classification as hazardous mixture according Reg. (EC) No 1272/2008.

Classification	**Hazard Class**		**Hazard category**[1]
Environmental hazard:	Aquatic Chronic 4	Long-term (chronic) aquatic hazard	4
Physical hazard:	not classified		
Health hazard:	not classified		

2.2. Labels elements
Pictogram: not necessary
Signal word: not necessary
Hazard statement:
H413 May cause long lasting harmful effects to aquatic life.
Precautionary statements
P102 KEEP OUT OF REACH OF CHILDREN.
P103 Read carefully and follow all instructions.
P264 Wash hands thoroughly after handling.

2.3. Other hazards
The product does not contain any substance considered as SVHC (Substances of Very High Concern) and listed on the Candidate List of Substances of Very High Concern for Authorisation published by the European Chemicals Agency (ECHA) see: https://echa.europa.eu/candidate-list-table

Components of the mixture satisfy neither the PBT (persistent, bio-accumulative and toxic), nor the vPvB (very persistent, very toxic) criteria in accordance with Annex XIII of Reg. (EC) No 1907/2006.

Components of the product are not listed in the endocrine disruptor and potential endocrine disruptor databases.

[1] higher number means less hazard

SECTION 3: Composition/information on ingredients

3.1. Substances: not relevant.
3.2. Mixtures: the product is mixture.
Hazardous component of the product which must be listed according to Reg. (EU) No 2020/878:

Hazardous component	Concentration	Hazard class, hazard category, H statement
Polydimethylsiloxane* CAS No: 63148-62-9 EC No: none (polymer)	95%	Aquatic Chronic 4, H413

* Other names: DIMETHICONE in pharmaceutical and cosmetics use; substance has no harmonized EU classification, classification give in the table above is from safety data sheet of the supplier.

The other components of the product are not hazardous, or their concentrations are low enough not to take into consideration in the classification and labelling of the product according to the relevant regulations.
Hazard class, H-statement relates to pure components. Hazard classification of the product is given in Section 2.
Full texts of the H-statement and hazard class, category is listed in Section 16.

SECTION 4: First Aid measures

4.1. Description of first aid measures
General advice: Move victim away from the source of exposure. Never give drink and never induce vomiting if the victim is unconscious or having convulsions.
Inhalation: move to fresh air.
Skin contact: wash hands thoroughly with soap and water after accidental skin contact and also after application the product on dogs.
Eye contact: flush eyes with running water holding the eyelids wide open and moving eyeballs continuously. Remove contact lenses if easy to do and continue rinsing. If symptoms persist, contact an eye physician.
Ingestion: rinse mouth with water, do not induce vomiting, give some water to drink. Consult a physician.

4.2. Most important symptoms and effects, both acute and delayed: significant effect or critical hazard are not known. Over-exposure signs, symptoms: no specific data.

4.3. Indication of any immediate medical attention and special treatment needed: not identified.

Note to the physician: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested.

SECTION 5: Firefighting measures

5.1. Extinguishing media: Use extinguishing media appropriate for surrounding fire.
Consider using of alcohol-resistant foam, carbon dioxide, regular dry chemicals and water spray.
Unsuitable extinguishing media: full water jet

5.2. Special hazard arising from the mixture: hazardous combustion gases carbon monoxide; carbon dioxide and silicon oxides are released upon burning.

5.3. Advice for firefighters: firefighters should wear self-contained breathing apparatus and full protective gear. Keep unprotected persons away. Avoid inhalation of toxic gases and fumes. Extinguishing water must not be discharged into drains. Combustion residues and contaminated extinguishing water should be disposed of in accordance with local regulation, do not allow entering them into drains and water bodies.

SECTION 6: Accidental release measures

6.1. Person-related precautionary measures: Keep unauthorised persons away. Do not inhale vapours or sprays. Avoid direct contact. Be aware that there is an increased risk of slipping.
6.2. Environmental precautions: prevent any material for entering drains or water-bodies.

6.3. Methods and material for containment and cleaning up: Collect the spilled material with inert absorbent materials (sand, vermiculite) and place it in a labelled, sealable container for safe disposal in accordance with local regulations.

6.4. Reference to other sections: see Section 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Always read the label and product information before use. Comply with the user's instructions.
Do not use on wounded, abraded, infected or inflamed skin.

7.2. Conditions for safe storage, including any incompatibilities
KEEP OUT of REACH OF CHILDREN.
Keep in original packaging, far away from foodstuff, feed and drinks and any incompatible material (oxidizing agents, acids, alkali).
Recommended temperature for storage:
Store the product at temperature not exceeding 25°C.
Avoid freezing during storage.
Shelf life: best before 2 years from the date of production.

7.3. Specific end use: veterinary care product, containing DIMETHICONE (polydimethylsiloxane) used for the treatment of fleas and/or tick. Users should read label carefully and follow instruction.

SECTION 8: Exposure controls

8.1. Control parameters
Occupational exposure limits: no limit was established for the components of the product.
Polydimethylsiloxane: ADI: 17 mg/kg bw/day (EFSA, 2020)
8.2. Exposure control
Appropriate engineering controls: not necessary.
Hygiene measures
- Do not eat, drink or smoke when handling.
- Wash hands thoroughly after handling

Individual protection measures, such as personal protective equipment
Personal protective equipment
- Hand protection: not necessary.
- Respiratory protection: not necessary.
- Eye protection: not necessary.
- Skin protection: not necessary.

Environmental exposure controls: avoid release into sewers and natural waterways.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Appearance:	clear, homogenous liquid
Colour:	colourless
Odour:	characteristic
Odour threshold:	no data
Melting point/freezing point:	below -50°C
Boiling point/range:	very high, above 200°C
Explosive properties	not explosive
Explosive limits:	not relevant
Flash point:	≥280°C
Auto-ignition temperature:	no data
Decomposition temperature:	> 200°C
pH	not relevant, the product is not aqueous mixture
Kinematic viscosity:	viscous
Solubility in water:	insoluble
Partition coefficient, log $P_{o/w}$:	no data
Vapour pressure:	no data
Relative density/vapour density	< 1

Oxidising properties: not oxidizing

9.2. Other information:

9.2.1. Information with regard to physical hazard classes:

There are no characteristics, test results, experiences which result in classification of the product into physical hazard classes.

9.2.2. Other safety characteristics: none relevant for the safe use of the mixture.

SECTION 10: Stability and reactivity

10.1. Reactivity: not known.

10.2. Chemical stability: stable under normal temperature and normal pressure conditions if it is handled, stored according to Section 7.2.

10.3. Possibility of hazardous reactions: not known.

10.4. Conditions to avoid: high temperature, frost.

10.5. Incompatible materials: strong bases, strong acids, oxidising agents.

10.6. Hazardous decomposition products: no hazardous decomposition products if used properly under normal condition.

SECTION 11: Toxicological information

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

Classification into health hazard classes is not necessary. Polydimethylsiloxane is an inert polymer. It is unlikely that polymers significantly absorb via oral or dermal route. Polydimethylsiloxane is safe as used in cosmetic products according to CIR report, it has skin conditioning and skin protecting function according to CosIng data base.

Acute toxicity (oral, dermal, inhalation): based on available toxicological data and concentration of the components the product is not classified into acute toxicity hazard classes.

Skin corrosion/irritation: based on available data and composition the classification criteria are not met.

Serious eye damage/eye irritation: on the basis of available data and composition the classification criteria are not met.

Respiratory or skin sensitization on the basis of available data and composition the classification criteria are not met.

Germ-cell mutagenicity: on the bases of available data the classification criteria are not met as components of the product are not classified as mutagen substances.

Carcinogenicity: based on available data the classification criteria are not met as components of the product are not classified as carcinogens.

Reproductive toxicity: based on available data the classification criteria are not met as components of the product are not classified as substances having reproductive toxicity.

Specific Target Organ Toxicity – single exposure/STOT SE: based on available data the classification criteria are not met.

Specific Target Organ Toxicity – repeated exposure/STOT RE: based on available data the classification criteria are not met.

Aspiration hazard: not relevant.

11.2. Information on other hazards: not known.

SECTION 12: Ecological information

12.1. Toxicity: according to high polydimethylsiloxane content the product is classified as hazardous mixture to the aquatic environment: Aquatic Chronic - category 4. Polydimethylsiloxane has a very low water solubility, its density is less than 1, it forms film layer on the water surface.
Polydimethylsiloxane is non-volatile and has strong binding affinity to sediments.

12.2. Persistence and degradability: polydimethylsiloxane can degrade in soil abiotically to form smaller polymers, ultimate degradation products are silica, carbon dioxide and water.

12.3. Bio-accumulative potential: due to being polymer polydimethylsiloxane is unlikely to bioconcentrate, it is unable to pass through or be absorbed by biological membranes.

12.4. Mobility in soil: polydimethylsiloxane sorbs to soil, and break down slowly, abiotically.

12.5. Result of PBT and vPvB assessment: polydimethylsiloxane is not considered PBT, vPvB substance.

12.6. Endocrine disrupting properties: components of the product are not listed in the available lists and databases of endocrine disruptors and suspected endocrine disruptors.

12.7. Other adverse effects: not known.

SECTION 13: Disposal consideration

13.1. Waste treatment methods:
If it is possible avoid or at least minimize waste generation.
Chemical and its waste and packaging must be disposed of in compliance with state and local regulations and Dir. (EC) No. 2008/98.

Do not empty waste into drains, rivers, watercourses, ponds, standing waters, natural waterways.
Waste and packaging of the product can be handled as household waste.

SECTION 14: Transport information

According to the international transport (ADR/RID, IMDG and ICAO/IATA) regulations the product is not dangerous goods.

14.1. UN-number: not applicable.

14.2. UN proper shipping name: not applicable.

14.3. Transport hazard class(es): not applicable.

14.4. Packing group: not applicable.

14.5. Environmental hazards: not applicable.

14.6. Special precautions for user: not applicable.

14.7. Maritime transport in bulk according to IMO instruments: not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations, legislations specific for the mixture

The product does not contain any components listed in Annex XVII of REACH.

The product contains no SVHC and no SVHC candidate substance.

Relevant European Acts

Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and its modifications

Regulation (EC) No 1272/2008 and of the European Parliament and of the Council on Classification, labelling and packaging of substances and mixtures and its modifications

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work and its five amendments

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste

Pertinent websites

https://www.cir-safety.org/sites/default/files/Methicones.pdf

Linear Polymethylsiloxanes (CAS No. 63148-62-9) 2nd Ed. JACC No. 55; ECETOC – European Centre For Ecotoxicology and Toxicology of Chemicals.

http://www.ecetoc.org/wp-content/uploads/2014/08/JACC-055-Linear-Polydimethylsiloxanes-CAS-No.-63148-62-9-Second-Edition.pdf

https://www.cir-safety.org/sites/default/files/Methicones.pdf
Safety Assessment of Dimethicone, Methicone, and Substituted Methicone Polymers, as Used in Cosmetics, 2019.

15.2. Chemical Safety assessment: not available.

SECTION 16: Other information

The information contained in the Safety Data Sheet is true and correct to our best knowledge at the date of issue; it is intended as a guide for safe use, handling, disposal, storage and transportation.

Manufacturer and distributor do not assume any warranty or responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected to the handling, storage, use or disposal of the product because conditions of application, handling, storage, use or disposal of the product is beyond their control.

Classification of the product: the product is classified by calculation methods in accordance with the Reg. (EC) No 1272/2008.

Training recommendation: in the annual occupational safety training workers should be informed about the hazards of handling chemicals and the general safety and health protection measures.

SAFETY DATA SHEET SHOULD ALWAYS BE AVAILABLE FOR WORKERS AT HAND.

H-statements, hazard classes, codes for the pure substance(s), acronyms in SDS:
Abbreviations of hazard classes (numbers after abbreviations mean the hazard category within the class, higher numbers mean less hazard):
Aquatic Chronic: hazardous to the aquatic environment, chronic hazard
H413 May cause long lasting harmful effects to aquatic life

ADI Acceptable Daily Intake - maximum amount of a chemical substance that can be ingested on a daily basis over a lifetime without health risk.
ADR European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS Chemical Abstract Service, number for the identification of chemical substances.
CIR Cosmetic Ingredient Review; https://www.cir-safety.org/
CLP Classification, Labelling and Packaging
CosIng Database for information on cosmetic substances and ingredients
ECHA European Chemicals Agency
EFSA European Food Safety Authority
IATA International Air Transport Association
ICAO International Civil Aviation Organization Technical Instruction for the Safe Transport of Dangerous Goods by Air
IMDG International Maritime Dangerous Goods Code
IMO International Maritime Organization
PBT Persistent, bio accumulative and toxic
REACH Registration, Evaluation, Authorisation and Restriction of Chemicals
RID Accord Européen Relatif au Transport International des Marchandises Dangereuses par Route
SVHC Substances of Very High Concern
vPvB Very persistent and very bio accumulative

History: safety data sheet is issued on 30 January 2023 based on the manufacturer's data, supersedes the previous versions, the purpose of the modification is to comply with the Reg. (EU) No 2020/878.