

Material Safety Data Sheet

Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution for dogs and cats

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s): Recicort 1.77 mg/ml + 17.7 mg/ml ear drops, solution for dogs and cats
Product code(s): XVD 313 (20 ml bottle)

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

Relevant identified uses: Veterinary medicinal product
Uses advised against: Not for human use. Refer to the product information leaflet
Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name: Animalcare Limited
Address: 10 Great Northway
 York Business Park
 Nether Poppleton
 York
 YO26 6RB
 United Kingdom

1.4 Emergency telephone number

Daytime: +44 (0) 1904 487687

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms: Not applicable
Signal word: Not applicable
Hazard statements: Not applicable
Precautionary statements: Not applicable
Supplemental information: May be harmful by inhalation, ingestion, or skin absorption. May cause eye, skin, or respiratory system irritation

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC) None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>% [weight]</i>
Triamcinolone acetonide	[58786-99-5]	0.1766%
Salicylic acid	[121-54-0]	1.766%
Benzalkonium chloride	[77-92-9]	Proprietary
Ethanol 96%	[6132-04-3]	Proprietary
Purified water	[7789-20-0]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately
Skin:	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more information on health effects and symptoms

4.3 Indication of any immediate medical attention and special treatment needed

No specific measures identified. Seek medical advice if required

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment (CO ₂ , extinguishing powder, foam, or water)
Unsuitable extinguishing media:	None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:	Not flammable or combustible
Hazardous combustion products:	Formation of toxic gases is possible during heating or fire

5.3 Advice for fire-fighters

Special protective equipment for firefighters:	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus
Further information:	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Personnel involved in clean-up should wear appropriate personal protective equipment (See section 8). Minimize exposure

Advice 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

6.2 Environmental precautions

Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release

6.3 Methods and material for containment and cleaning up

Large spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel

Small spills: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly

6.4 Reference to other sections

See Section 1 for emergency contact information

See section 8 for personal protection

See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing

Hygiene measures: None identified

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep out of reach of children. Keep in the original packaging

Storage temperature: Store as directed by product packaging

Further information on storage conditions: Protect from direct incidence of light

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit: No data available.

8.2 Exposure controls

Engineering measures: Not applicable

Individual protection measures:

Hygiene measures: No specific measures identified

Eye/face protection: Wear safety glasses or goggles if eye contact is possible

Skin/body protection: Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible

Hand protection:	Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible
Respiratory protection:	None required if airborne concentrations are maintained below the exposure limit listed in Exposure Limit Information. Use certified respiratory protection equipment meeting EU requirements (89/656/EEC, 89/686/EEC), or equivalent, when respiratory risks cannot be avoided or sufficiently limited by technical means of collective protection or by measures, methods or procedures of work organization.
Environmental exposure controls:	Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Liquid
Colour:	Colourless
Odour:	Ethanol
Odour threshold:	No data available
pH:	No data available
Density:	No data available
Melting point:	No data available
Boiling point:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability:	No data available
Water solubility:	No data available
Partition coefficient:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Explosive properties:	No data available
Oxidizing properties:	The substance or mixture is not classified as oxidizing

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

None Known

10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Triamcinolone acetonide LD ₅₀ 2168 mg/kg (mouse, oral) Triamcinolone acetonide LD ₅₀ 1451 mg/kg (rat, oral)
Chronic toxicity:	No data available
Skin irritation/sensitization:	No data available
Reproductive toxicity:	No data available
Carcinogenicity:	None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA
Mutagenicity:	No data available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15: REGULATORY INFORMATION

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

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

End of document