

Cortavance Cutaneous Spray Solution for Dogs (Virbac Cortavance Cutaneous Spray Solution for Dogs)

Virbac (Australia) Pty Limited

Chemwatch Hazard Alert Code: 2

Chemwatch: 23-0231

Version No: 4.1.16.10

Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

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L.GHS.AUS.EN

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

Product Identifier

Product name	Cortavance Cutaneous Spray Solution for Dogs (Virbac Cortavance Cutaneous Spray Solution for Dogs)
Chemical Name	Not Applicable
Synonyms	Not Available
Proper shipping name	1-METHOXY-2-PROPANOL
Chemical formula	Not Applicable
Other means of identification	Not Available

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

Relevant identified uses	Veterinary product used to treat dogs for skin conditions.
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Details of the supplier of the safety data sheet

Registered company name	Virbac (Australia) Pty Limited
Address	361 Horsley Road Milperra NSW 2214 Australia
Telephone	1800 242 100
Fax	+61 2 9772 9773
Website	au.virbac.com
Email	au_customerservice@virbac.com.au

Emergency telephone number

Association / Organisation	Poisons Information Centre
Emergency telephone numbers	13 11 26
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

Classification of the substance or mixture

HAZARDOUS CHEMICAL. DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.


ChemWatch Hazard Ratings

	Min	Max
Flammability	2	
Toxicity	1	
Body Contact	2	
Reactivity	1	
Chronic	0	

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

Poisons Schedule	S4
Classification [1]	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Specific Target Organ Toxicity - Single Exposure (Narcotic Effects) Category 3, Flammable Liquids Category 3
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

Label elements

Hazard pictogram(s)	
Signal word	Warning

Hazard statement(s)

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H315	Causes skin irritation.
H319	Causes serious eye irritation.
H336	May cause drowsiness or dizziness.
H226	Flammable liquid and vapour.

Precautionary statement(s) Prevention

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P271	Use only outdoors or in a well-ventilated area.
P240	Ground and bond container and receiving equipment.
P241	Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.
P242	Use non-sparking tools.
P243	Take action to prevent static discharges.
P261	Avoid breathing mist/vapours/spray.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P264	Wash all exposed external body areas thoroughly after handling.

Precautionary statement(s) Response

P370+P378	In case of fire: Use alcohol resistant foam or fine spray/water fog to extinguish.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

Precautionary statement(s) Storage

P403+P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
108-65-6	>80	propylene glycol monomethyl ether - mixture of isomers
74050-20-7	0.062-0.065	hydrocortisone aceponate
Not Available		(0.584mg/ml)
Not Available	balance	other secret ingredients determined not to be hazardous
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available	

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Immediately hold eyelids apart and flush the eye continuously with running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▶ Transport to hospital or doctor without delay. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes or combustion products are inhaled remove from contaminated area. ▶ Lay patient down. Keep warm and rested. ▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▶ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained.

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	<ul style="list-style-type: none"> Perform CPR if necessary. ▶ Transport to hospital, or doctor.
Ingestion	<ul style="list-style-type: none"> ▶ For advice, contact a Poisons Information Centre or a doctor at once. ▶ Urgent hospital treatment is likely to be needed. ▶ If swallowed do NOT induce vomiting. ▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▶ Observe the patient carefully. ▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▶ Transport to hospital or doctor without delay.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

For corticosteroid overdose:

- The adverse effects of corticosteroids are almost always due to their use in excess of physiological requirements. Symptomatic treatment is called for. Where possible the dose should be withdrawn or reduced. Acute renal insufficiency should be treated with intravenous hydrocortisone sodium succinate with infusions of 0.9% dextrose. *MARTINDALE, The Extra Pharmacopoeia, 29th Ed.*
- Patients or individuals exposed regularly in an occupational setting, should be evaluated periodically for evidence of HPA axis suppression. The evaluation may be performed by using the ACTH stimulation, A.M. plasma cortisol and urinary free cortisol tests. If HPA axis suppression is confirmed the individual should be removed from exposure. Recovery of the HPA axis function is generally prompt upon exposure cessation. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur, requiring supplemental systemic corticosteroids.
- Corticosteroid overdose is usually treated by restoring fluid and electrolyte balance. Prognosis is good unless there are life-threatening symptoms, which is usually infrequent
- In case of severe symptoms that include high body temperature, increased blood pressure, abnormal heart rhythms and heart attack, stroke, or coma, the outlook can be guarded
- Nevertheless, the prognosis is dependent on the amount of drug consumed, time between overdose and treatment, severity of the symptoms, as well as general health status of the patient
- In general, overdoses are common situations in the emergency departments. A majority of the cases are often not fatal, when appropriate treatment is given.
- The management of psychiatric symptoms due to administration of corticosteroids includes the reduction of the dose or treatment discontinuation. The patient can be treated with medications normally used in patients with psychiatric or neurological disorders. Mood-stabilizing drugs, such as lithium and valproic acid, are able to control the symptoms caused by corticosteroids. Carbamazepine, inducing steroids metabolism, reduces their neurotoxic effects; atypical antipsychotics, such as olanzapine and fluoxetine (SSRI), are active on this symptoms. The effect of anti-depressive drugs are different, i.e., tricyclic antidepressants could lead to a significant worsening of symptoms, while a selective serotonin reuptake inhibitors, such as fluoxetine,[37] may improve symptoms of depression during corticosteroid therapy as well as phenytoin, lamotrigine, risperidone, quetiapine, and gabapentin.

The beginning of the appearance of symptoms induced by corticosteroids is variable. They may arise in the first phases of treatment, during, or even at the end of therapy. In most cases (86%), they occur within the first 5 days of treatment. The analysis of several studies leads to an average of 11.5 days after the beginning of corticosteroid treatment to the onset of psychiatric symptoms] 89% of patients develop symptoms in the first six weeks, 62% within two weeks, and 39% in the first week. The duration of the neuropsychiatric effects is highly variable and depends on the severity, treatment discontinuation, and by other drug therapies.

Risk factors

Side effects of psychiatric type have been reported following different routes of administration, e.g., intra-articular injection, epidural, topical, and systemic.

Psychiatric side effects due to corticosteroids appear to be dose dependent; they occur in 1.3% of the cases when the dose is less than 40 mg daily and reaches 18.4% for doses of 80 mg daily.

It is not entirely clear whether gender affects the ability to manifest psychiatric symptoms, but some studies suggest that women are more prone.

Other studies show that 73% of the paediatric population receiving steroid therapy develops hyperactivity, irritability, insomnia as well as showing deficits of attention and memory, especially those under 10 years of age and/or high doses of the drug.

Miriam Ciriaco, et al Journal ListJ Pharmacol Pharmacother.v.4(Suppl1); 2013 Dec
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3853679/>

SECTION 5 Firefighting measures

Extinguishing media

- ▶ Water spray or fog.
- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ If safe, switch off electrical equipment until vapour fire hazard removed. ▶ Use water delivered as a fine spray to control fire and cool adjacent area. ▶ Avoid spraying water onto liquid pools. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Liquid and vapour are flammable. ▶ Moderate fire hazard when exposed to heat or flame. ▶ Vapour forms an explosive mixture with air. ▶ Moderate explosion hazard when exposed to heat or flame. ▶ Vapour may travel a considerable distance to source of ignition. ▶ Heating may cause expansion or decomposition leading to violent rupture of containers. ▶ On combustion, may emit toxic fumes of carbon monoxide (CO). <p>Combustion products include: carbon dioxide (CO₂) carbon monoxide (CO) nitrogen oxides (NO_x)</p>

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	other pyrolysis products typical of burning organic material.
HAZCHEM	*2Y

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▶ Remove all ignition sources. ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment. ▶ Contain and absorb small quantities with vermiculite or other absorbent material. ▶ Wipe up. ▶ Collect residues in a flammable waste container.
Major Spills	<ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ Consider evacuation (or protect in place). ▶ No smoking, naked lights or ignition sources. ▶ Increase ventilation. ▶ Stop leak if safe to do so. ▶ Water spray or fog may be used to disperse /absorb vapour. ▶ Contain spill with sand, earth or vermiculite. ▶ Use only spark-free shovels and explosion proof equipment. ▶ Collect recoverable product into labelled containers for recycling. ▶ Absorb remaining product with sand, earth or vermiculite. ▶ Collect solid residues and seal in labelled drums for disposal. ▶ Wash area and prevent runoff into drains. ▶ If contamination of drains or waterways occurs, advise emergency services.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of overexposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps. ▶ DO NOT enter confined spaces until atmosphere has been checked. ▶ Avoid smoking, naked lights or ignition sources. ▶ Avoid generation of static electricity. ▶ DO NOT use plastic buckets. ▶ Earth all lines and equipment. ▶ Use spark-free tools when handling. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ Keep containers securely sealed when not in use. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. ▶ Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. ▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions. ▶ DO NOT allow clothing wet with material to stay in contact with skin
Other information	<ul style="list-style-type: none"> ▶ Store in original containers in approved flammable liquid storage area. ▶ Store away from incompatible materials in a cool, dry, well-ventilated area. ▶ DO NOT store in pits, depressions, basements or areas where vapours may be trapped. ▶ No smoking, naked lights, heat or ignition sources. ▶ Storage areas should be clearly identified, well illuminated, clear of obstruction and accessible only to trained and authorised personnel - adequate security must be provided so that unauthorised personnel do not have access. ▶ Store according to applicable regulations for flammable materials for storage tanks, containers, piping, buildings, rooms, cabinets, allowable quantities and minimum storage distances. ▶ Use non-sparking ventilation systems, approved explosion proof equipment and intrinsically safe electrical systems. ▶ Have appropriate extinguishing capability in storage area (e.g. portable fire extinguishers - dry chemical, foam or carbon dioxide) and flammable gas detectors. ▶ Keep adsorbents for leaks and spills readily available. ▶ Protect containers against physical damage and check regularly for leaks. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. <p>In addition, for tank storages (where appropriate):</p> <ul style="list-style-type: none"> ▶ Store in grounded, properly designed and approved vessels and away from incompatible materials. ▶ For bulk storages, consider use of floating roof or nitrogen blanketed vessels; where venting to atmosphere is possible, equip storage tank vents with flame arrestors; inspect tank vents during winter conditions for vapour/ ice build-up. ▶ Storage tanks should be above ground and diked to hold entire contents.

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Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Glass container is suitable for laboratory quantities ▶ Packing as supplied by manufacturer. ▶ Plastic containers may only be used if approved for flammable liquid. ▶ Check that containers are clearly labelled and free from leaks. ▶ For low viscosity materials (i) : Drums and jerry cans must be of the non-removable head type. (ii) : Where a can is to be used as an inner package, the can must have a screwed enclosure. ▶ For materials with a viscosity of at least 2680 cSt. (23 deg. C) ▶ For manufactured product having a viscosity of at least 250 cSt. (23 deg. C) ▶ Manufactured product that requires stirring before use and having a viscosity of at least 20 cSt (25 deg. C): (i) Removable head packaging; (ii) Cans with friction closures and (iii) low pressure tubes and cartridges may be used. ▶ Where combination packages are used, and the inner packages are of glass, there must be sufficient inert cushioning material in contact with inner and outer packages ▶ In addition, where inner packagings are glass and contain liquids of packing group I there must be sufficient inert absorbent to absorb any spillage, unless the outer packaging is a close fitting moulded plastic box and the substances are not incompatible with the plastic.
Storage incompatibility	<ul style="list-style-type: none"> ▶ Avoid reaction with oxidising agents

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	propylene glycol monomethyl ether - mixture of isomers	Propylene glycol monomethyl ether	100 ppm / 369 mg/m3	553 mg/m3 / 150 ppm	Not Available	Not Available
Australia Exposure Standards	propylene glycol monomethyl ether - mixture of isomers	1-Methoxy-2-propanol acetate	50 ppm / 274 mg/m3	548 mg/m3 / 100 ppm	Not Available	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
propylene glycol monomethyl ether - mixture of isomers	100 ppm	160 ppm	660 ppm
propylene glycol monomethyl ether - mixture of isomers	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
propylene glycol monomethyl ether - mixture of isomers	Not Available	Not Available
hydrocortisone aceponate	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
hydrocortisone aceponate	E	≤ 0.01 mg/m ³


Notes: Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

MATERIAL DATA

Exposure controls

Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>For flammable liquids and flammable gases, local exhaust ventilation or a process enclosure ventilation system may be required. Ventilation equipment should be explosion-resistant.</p> <p>Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p>	
	Type of Contaminant:	Air Speed:
	solvent, vapours, degreasing etc., evaporating from tank (in still air).	0.25-0.5 m/s (50-100 f/min.)
	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
	Within each range the appropriate value depends on:	
	Lower end of the range	Upper end of the range

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	<p>1: Room air currents minimal or favourable to capture</p> <p>2: Contaminants of low toxicity or of nuisance value only.</p> <p>3: Intermittent, low production.</p> <p>4: Large hood or large air mass in motion</p>	<p>1: Disturbing room air currents</p> <p>2: Contaminants of high toxicity</p> <p>3: High production, heavy use</p> <p>4: Small hood-local control only</p> <p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.</p>
<p>Personal protection</p>		
<p>Eye and face protection</p>	<p>When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:</p> <ul style="list-style-type: none"> ▶ Chemical goggles. ▶ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes. ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent] 	
<p>Skin protection</p>	<p>See Hand protection below</p>	
<p>Hands/feet protection</p>	<p>NOTE:</p> <ul style="list-style-type: none"> ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. <p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p> <p>Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:</p> <ul style="list-style-type: none"> · frequency and duration of contact, · chemical resistance of glove material, · glove thickness and · dexterity <p>Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).</p> <ul style="list-style-type: none"> · When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. · When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. · Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use. · Contaminated gloves should be replaced. <p>As defined in ASTM F-739-96 in any application, gloves are rated as:</p> <ul style="list-style-type: none"> · Excellent when breakthrough time > 480 min · Good when breakthrough time > 20 min · Fair when breakthrough time < 20 min · Poor when glove material degrades <p>For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.</p> <p>It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.</p> <p>Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers' technical data should always be taken into account to ensure selection of the most appropriate glove for the task.</p> <p>Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:</p> <ul style="list-style-type: none"> · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of. · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential <p>Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p> <ul style="list-style-type: none"> ▶ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. ▶ Double gloving should be considered. ▶ PVC gloves. ▶ Change gloves frequently and when contaminated, punctured or torn. ▶ Wash hands immediately after removing gloves. ▶ Protective shoe covers. [AS/NZS 2210] ▶ Head covering. ▶ Neoprene gloves 	
<p>Body protection</p>	<p>See Other protection below</p>	
<p>Other protection</p>	<ul style="list-style-type: none"> ▶ Overalls. ▶ PVC Apron. ▶ PVC protective suit may be required if exposure severe. 	

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- ▶ Eyewash unit.
- ▶ Ensure there is ready access to a safety shower.
- ▶ Some plastic personal protective equipment (PPE) (e.g. gloves, aprons, overshoes) are not recommended as they may produce static electricity.
- ▶ For large scale or continuous use wear tight-weave non-static clothing (no metallic fasteners, cuffs or pockets).
- ▶ Non sparking safety or conductive footwear should be considered. Conductive footwear describes a boot or shoe with a sole made from a conductive compound chemically bound to the bottom components, for permanent control to electrically ground the foot and shall dissipate static electricity from the body to reduce the possibility of ignition of volatile compounds. Electrical resistance must range between 0 to 500,000 ohms. Conductive shoes should be stored in lockers close to the room in which they are worn. Personnel who have been issued conductive footwear should not wear them from their place of work to their homes and return.

Respiratory protection

Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS / Class 1	-	A-PAPR-AUS / Class 1
up to 50 x ES	Air-line*	-	-
up to 100 x ES	-	A-3	-
100+ x ES	-	Air-line**	-

* - Continuous-flow; ** - Continuous-flow or positive pressure demand

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- ▶ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Clear colourless or slightly yellow flammable liquid with characteristic odour of ether; mixes with water.		
Physical state	Liquid	Relative density (Water = 1)	0.90-0.94
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	115-125 approx.	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	33	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Flammable.	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Presence of elevated temperatures. ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Cortavance Cutaneous Spray Solution for Dogs (Virbac Cortavance Cutaneous Spray Solution for Dogs)

Information on toxicological effects

Inhaled	<p>Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by narcosis, reduced alertness, loss of reflexes, lack of coordination and vertigo.</p> <p>Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual.</p> <p>Limited evidence or practical experience suggests that the material may produce irritation of the respiratory system, in a significant number of individuals, following inhalation. In contrast to most organs, the lung is able to respond to a chemical insult by first removing or neutralising the irritant and then repairing the damage. The repair process, which initially evolved to protect mammalian lungs from foreign matter and antigens, may however, produce further lung damage resulting in the impairment of gas exchange, the primary function of the lungs. Respiratory tract irritation often results in an inflammatory response involving the recruitment and activation of many cell types, mainly derived from the vascular system.</p> <p>Systemic absorption of aerosols containing corticosteroids may produce adrenal insufficiency and collapse.</p> <p>Inhalation hazard is increased at higher temperatures.</p> <p>The odour of for propylene glycol <u>monomethyl</u> ether (PGME) becomes objectionable at 100 ppm and intolerable with anaesthetic effects at 1000 ppm. High vapour concentrations (above 1000 ppm) are intolerable due to severe eye, nose and throat irritation. Odour is transiently objectionable above 100 ppm. Obvious sedation, increased liver weights and reduced specific gravity of the urine were found in animals subject to concentrations of 3000 ppm PGME.</p> <p>Inhalation may produce central nervous system depression. High concentrations of the beta-isomer produced slight growth depression and slight liver change and lung effects in rats and mice.</p>
Ingestion	<p>Accidental ingestion of the material may be damaging to the health of the individual.</p> <p>Corticosteroids (glucocorticoids) affect carbohydrate, protein and fat metabolism, the cardiovascular system, kidney, skeletal muscle, the nervous system and other organs and tissues. Other adverse systemic effects include effects on blood chemistry, atrophy of the adrenal cortex, spleen, thymus and lymph nodes, swelling of hepatocytes (liver cells), liver enlargement, diminished thyroid activity, hypocellularity of the marrow, bone resorption, skeletal changes and muscle wasting. The corticosteroids may also modify the ability of the body's immune system to react to diverse stimuli; this may lead to the reactivation of latent tuberculosis, enhance the effect of secondary eye infections produced by fungi or viruses or mask certain signs of infection. Hypersensitivity reactions may result. Large doses of corticosteroids may produce an excessive action on electrolyte balance, inhibit gluconeogenesis, delay wound healing and tissue repair and may inhibit the secretion of corticotrophin by the anterior lobe of the pituitary gland. Disturbances in electrolyte balance result in the retention of sodium and water, with oedema and hypertension, and the excretion of potassium with the possible development of hypokalaemic alkalosis. Cardiac failure may occur in extreme cases. The synthetic corticosteroids generally produce a lesser effect on electrolyte balance than those that occur naturally (mineralocorticoids are the exception).</p> <p>High blood glucose levels (hyperglycaemia), often concurrent with the presence of sugar in the urine, may also result following corticosteroid exposure. Other adverse effects produced by high doses of corticosteroids include those typical of hyperactivity of the adrenal cortex including a moon-shaped face, sometimes with hirsutism, buffalo hump, flushing, increased bruising, striae, and acne, and sometimes full-blown Cushing's syndrome. Cushing's syndrome describes redistribution of fat, often with great obesity, muscular weakness, skeletal weakness, high blood pressure and the characteristic rounded or "moon" face. Symptoms are usually reversed on withdrawal of treatment. Other adverse states include amenorrhoea, hyperhidrosis, mental and neurological disturbance, intracranial hypertension, acute pancreatitis, and aseptic necrosis of the bone. Increases in the coagulability of the blood may result in thrombo-embolic complications. An increased susceptibility to infection arising from delayed wound healing may be masked due to the anti-inflammatory, antipyretic and analgesic properties exhibited by the corticosteroids.</p> <p>Patients may also exhibit increased susceptibility to other infections including sepsis, fungal and viral infection due to the immunosuppressive effects of the corticosteroids; Candida infections of the mouth, for example, are not uncommon. Corticosteroid exposure may produce psychic derangements including euphoria, insomnia, mood swings, personality changes, and severe depression to frank psychotic tendencies. Emotional instability or psychotic tendencies may be aggravated by intake. The adverse effects of corticosteroids may be exaggerated in individuals with non-specific ulcerative colitis, diverticulitis, ulcers, renal insufficiency, hypertension, osteoporosis, myasthenia gravis, hypothyroidism or cirrhosis. Prolonged exposure may produce posterior subcapsular cataracts and glaucoma, with possible damage to the optic nerve.</p> <p>Propylene glycol <u>monomethyl</u> ether (PGME) has low oral hazard. Ingestion of large amounts of PGME may cause headache, nausea, vomiting, diarrhoea, light-headedness, drowsiness, incoordination, possible unconsciousness. Death may result from anaesthesia.</p> <p>A single oral dose of the beta-isomer produced central nervous system depression with dyspnea, somnolence, ataxia, and respiratory arrest in test animals. Repeated doses caused profound central nervous system depression, minor kidney injury and liver enlargement in rats.</p>
Skin Contact	<p>The material is not thought to be a skin irritant (i.e. is unlikely to produce irritant dermatitis as described in EC Directives using animal models). Temporary discomfort, however, may result from prolonged dermal exposures. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.</p> <p>Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.</p> <p>Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. These may be more likely to occur with occlusive use, prolonged use, or use of higher potency corticosteroids. Some local adverse reactions may be irreversible. Topically applied corticosteroids may be absorbed in sufficient quantity to produce systemic effects, especially when applied under occlusive conditions or to broken skin. Application to the skin may result in collagen loss and subcutaneous atrophy and local hypopigmentation of deeply pigmented skin. A marked hypopigmentation may appear on the skin of the fingers. Sensitive individuals may experience burning, itching and dryness. Dermal exposure to corticosteroids may produce a non-allergic dermatitis characterised by moderate to severe erythema, acne and oedema. Symptoms may appear after several days of low or no exposure; lesions may resemble "sun-burn" and peeling (exfoliation) may be present.</p> <p>Systemic absorption may produce adrenal suppression and collapse as well as other symptoms consistent with corticosteroid exposure. These include a reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for corticosteroid insufficiency after withdrawal of treatment, manifestations of Cushing's syndrome, hyperglycaemia and glucosuria. Dermal irritation has been noted with certain topically applied corticosteroids. Allergic contact dermatitis is usually diagnosed by observing a failure to heal rather than noting the clinical exacerbation which occurs with most topical allergens not containing corticosteroids. Such observations are corroborated with appropriate diagnostic patch testing.</p> <p>Toxic amounts of for propylene glycol <u>monomethyl</u> ether (PGME) may be absorbed through the skin following extensive prolonged contact ; this may result in drowsiness. Constant contact with the beta-isomer, on the skin of rabbits, for several weeks caused very mild, simple irritation.</p> <p>Dose rates of 10 mg/kg produced incomplete anaesthesia, depression, and slight increase in kidney weights in test animals.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
Eye	<p>It has either been demonstrated or it is expected that when the material is applied to the eye(s) of animals, it produces severe ocular lesions which are present twenty-four hours or more after instillation.</p> <p>When applied to the eye corticosteroids may produce corneal ulcers, raised intraocular pressure, and reduced visual function - systemic application has produced posterior subcapsular cataract.</p> <p>The vapour when concentrated has pronounced eye irritation effects and this gives some warning of high vapour concentrations. If eye irritation occurs seek to reduce exposure with available control measures, or evacuate area.</p>
Chronic	<p>Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.</p> <p>There exists limited evidence that shows that skin contact with the material is capable either of inducing a sensitisation reaction in a significant number of individuals, and/or of producing positive response in experimental animals.</p> <p>Chronic exposure to corticosteroids (glucocorticoids) may produce pituitary-adrenal suppression, Cushing's syndrome (redistribution of body fat</p>

Cortavance Cutaneous Spray Solution for Dogs (Virbac Cortavance Cutaneous Spray Solution for Dogs)

to the face -"moon-face" - and to the back of the neck and trunk), increased susceptibility to infections (through suppression of inflammatory response), osteoporosis, cataracts, glaucoma with possible damage to the optic nerve, mental symptoms, hyperglycaemia (high blood sugar) and glycosuria (glucose in the urine), muscular weakness and fatigue, acne, menstrual disorders and peptic ulcers.

Repeated intake of the corticosteroids may produce metabolic effects resulting in the mobilisation of calcium and phosphorus leading to osteoporosis, spontaneous fracture, nitrogen depletion and hyperglycaemia which may accentuate or precipitate diabetic states. Inhibition of corticotrophin secretion may produce atrophy of the adrenal cortex and, if treatment is prolonged, acute adrenal insufficiency. Growth retardation of children may also occur.

There have been reports of joint damage following intra-articular injection of corticosteroids (specifically hydrocortisone) into load-bearing joints.

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Glucocorticoids have been shown to be teratogenic in laboratory studies, when administered systemically at relatively low doses; however, there are no systematic studies which demonstrate an association between congenital malformations and therapeutic use of steroid hormones. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

Systemically administered corticosteroids appear in human milk and may suppress growth, interfere with endogenous corticosteroid production or produce other undesirable effects.

Repeated oral doses of 3 g/kg for propylene glycol monomethyl ether (PGME) produced minor changes in the liver and kidneys in rats. Repeated doses on the skin over a 90-day period resulted in absorption and anaesthetic death at 7-10 ml/kg/day. Mild narcosis was observed after topical application of 2-4 ml/kg/day.

Administration of 2% PGME in drinking water ad libitum to males for 25 days did not elicit significant changes in testes or seminal vesicle and coagulating gland weights or in peripheral leukocyte counts. No significant testicular toxicity was found in rats or rabbits that were exposed at up to 3000 PGME, 6 hours/day, 5 days/week for 13 weeks. Oral and parenteral administration to pregnant rabbits, mice and rats did not induce congenital malformations at concentrations up to 1800 mg/kg/day.

In a study on the teratogenic potential of the acetate of the beta-isomer (2-methoxy-1-propyl acetate), a significant increase in the number of litters with abnormal rats and rabbits was found after inhalation exposure by the mothers to 2700 ppm or 550 ppm, respectively, on days 6 to 15, or 6 to 18 of gestation. The rabbit inhalation no-observed-adverse effect concentration was 145 ppm. A similar embryotoxicity profile was seen after inhalation of 2-methoxy-1-propanol (beta-PGMA). In contrast to the alpha-isomer, beta-PGMA is oxidised in rats to 2-methoxypropionic acid. Male dogs exposed to the beta-isomer, developed numerous spermiothages in epididymi. Administration of high doses of the beta-isomer to rats, by gavage, caused delayed ossification of the skull of rat foetus.

Whilst alpha-PGMA undergoes hepatic O-demethylation as the principal pathway, the beta-isomer is detoxified by alcohol/ aldehyde dehydrogenase. Commercial PGME contains low concentrations of the beta-isomer.

Studies with some glycol ethers (principally the monoethylene glycols) and their esters indicate reproductive changes, testicular atrophy, infertility and kidney function changes. The metabolic acetic acid derivatives of glycol ethers (alkoxyacetic acids), not the ether itself, have been found to be the proximal reproductive toxin in animals. The potency of these metabolites decreases significantly as the chain length of the ether increases. Consequently glycol ethers with longer substituents (e.g diethylene glycols, triethylene glycols) have not generally been associated with reproductive effects. One of the most sensitive indicators of toxic effects observed from many of the glycol ethers is an increase in the erythrocytic osmotic fragility in rats which produces haemolytic anaemia. This appears to be related to the development of haemoglobinuria (blood in the urine) at higher exposure levels or as a result of chronic exposure.

Glycol ethers based on propylene oxides, propylene glycol ethers, dipropylene glycol ethers and tripropylene glycol ethers are mainly available, commercially, as alpha-isomers (because of thermodynamic considerations); these are incapable of forming alkoxyacetic or alkoxypropionic acids as metabolites and therefore do not produce erythrocyte fragility unless contaminated by ethylene glycol ethers or to a significant degree by the beta-isomer. beta-isomers are able to form the alkoxypropionic acids and these are linked to teratogenic effects (and possibly haemolytic effects).

Cortavance Cutaneous Spray Solution for Dogs (Virbac Cortavance Cutaneous Spray Solution for Dogs)	TOXICITY	IRRITATION
	Not Available	Not Available
propylene glycol monomethyl ether - mixture of isomers	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Eye (rabbit) 230 mg mild
	Oral(Rat) LD50; 5155 mg/kg ^[1]	Eye (rabbit) 500 mg/24 h. - mild
		Eye: no adverse effect observed (not irritating) ^[1]
		Skin (rabbit) 500 mg open - mild
		Skin: no adverse effect observed (not irritating) ^[1]
hydrocortisone aceponate	TOXICITY	IRRITATION
	Not Available	Not Available
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

NOTE: Exposure of pregnant rats and rabbits to the substance did not give rise to teratogenic effects at concentrations up to 3000 ppm. Fetotoxic effects were seen in rats but not in rabbits at this concentration; maternal toxicity was noted in both species.

Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance.

Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.

for propylene glycol ethers (PGEs):

Typical propylene glycol ethers include propylene glycol n-butyl ether (PnB); dipropylene glycol n-butyl ether (DPnB); dipropylene glycol methyl ether acetate (DPMA); tripropylene glycol methyl ether (TPM).

Testing of a wide variety of propylene glycol ethers Testing of a wide variety of propylene glycol ethers has shown that propylene glycol-based ethers are less toxic than some ethers of the ethylene series. The common toxicities associated with the lower molecular weight homologues of the ethylene series, such as adverse effects on reproductive organs, the developing embryo and fetus, blood (haemolytic effects), or thymus, are not seen with the commercial-grade propylene glycol ethers. In the ethylene series, metabolism of the terminal hydroxyl group produces an alkoxyacetic acid. The reproductive and developmental toxicities of the lower molecular weight homologues in the ethylene series are due specifically to the formation of methoxyacetic and ethoxyacetic acids.

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Longer chain length homologues in the ethylene series are not associated with the reproductive toxicity but can cause haemolysis in sensitive species, also through formation of an alkoxyacetic acid. The predominant alpha isomer of all the PGEs (thermodynamically favored during manufacture of PGEs) is a secondary alcohol incapable of forming an alkoxypropionic acid. In contrast beta-isomers are able to form the alkoxypropionic acids and these are linked to teratogenic effects (and possibly haemolytic effects). This alpha isomer comprises greater than 95% of the isomeric mixture in the commercial product.

Because the alpha isomer cannot form an alkoxypropionic acid, this is the most likely reason for the lack of toxicity shown by the PGEs as distinct from the lower molecular weight ethylene glycol ethers. More importantly, however, very extensive empirical test data show that this class of commercial-grade glycol ether presents a low toxicity hazard. PGEs, whether mono, di- or tripropylene glycol-based (and no matter what the alcohol group), show a very similar pattern of low to non-detectable toxicity of any type at doses or exposure levels greatly exceeding those showing pronounced effects from the ethylene series. One of the primary metabolites of the propylene glycol ethers is propylene glycol, which is of low toxicity and completely metabolised in the body.

As a class, the propylene glycol ethers are rapidly absorbed and distributed throughout the body when introduced by inhalation or oral exposure. Dermal absorption is somewhat slower but subsequent distribution is rapid. Most excretion for PGEs is via the urine and expired air. A small portion is excreted in the faeces.

As a group PGEs exhibits low acute toxicity by the oral, dermal, and inhalation routes. Rat oral LD50s range from >3,000 mg/kg (PnB) to >5,000 mg/kg (DPMA). Dermal LD50s are all > 2,000 mg/kg (PnB, & DPnB; where no deaths occurred), and ranging up to >15,000 mg/kg (TPM). Inhalation LC50 values were higher than 5,000 mg/m3 for DPMA (4-hour exposure), and TPM (1-hour exposure). For DPnB the 4-hour LC50 is >2,040 mg/m3. For PnB, the 4-hour LC50 was >651 ppm (>3,412 mg/m3), representing the highest practically attainable vapor level. No deaths occurred at these concentrations. PnB and TPM are moderately irritating to eyes while the remaining category members are only slightly irritating to nonirritating. PnB is moderately irritating to skin while the remaining category members are slightly to non-irritating. None are skin sensitizers.

In repeated dose studies ranging in duration from 2 to 13 weeks, few adverse effects were found even at high exposure levels and effects that did occur were mild in nature. By the oral route of administration, NOAELs of 350 mg/kg-d (PnB – 13 wk) and 450 mg/kg-d (DPnB – 13 wk) were observed for liver and kidney weight increases (without accompanying histopathology). LOAELs for these two chemicals were 1000 mg/kg-d (highest dose tested).

Dermal repeated-dose toxicity tests have been performed for many PGEs. For PnB, no effects were seen in a 13-wk study at doses as high as 1,000 mg/kg-d. A dose of 273 mg/kg-d constituted a LOAEL (increased organ weights without histopathology) in a 13-week dermal study for DPnB. For TPM, increased kidney weights (no histopathology) and transiently decreased body weights were found at a dose of 2,895 mg/kg-d in a 90-day study in rabbits. By inhalation, no effects were observed in 2-week studies in rats at the highest tested concentrations of 3244 mg/m3 (600 ppm) for PnB and 2,010 mg/m3 (260 ppm) for DPnB. TPM caused increased liver weights without histopathology by inhalation in a 2-week study at a LOAEL of 360 mg/m3 (43 ppm). In this study, the highest tested TPM concentration, 1010 mg/m3 (120 ppm), also caused increased liver weights without accompanying histopathology. Although no repeated-dose studies are available for the oral route for TPM, or for any route for DPMA, it is anticipated that these chemicals would behave similarly to other category members.

One and two-generation reproductive toxicity testing has been conducted in mice, rats, and rabbits via the oral or inhalation routes of exposure on PM and PMA. In an inhalation rat study using PM, the NOAEL for parental toxicity is 300 ppm (1106 mg/m3) with decreases in body and organ weights occurring at the LOAEL of 1000 ppm (3686 mg/m3). For offspring toxicity the NOAEL is 1000 ppm (3686 mg/m3), with decreased body weights occurring at 3000 ppm (11058 mg/m3). For PMA, the NOAEL for parental and offspring toxicity is 1000 mg/kg/d. In a two generation gavage study in rats. No adverse effects were found on reproductive organs, fertility rates, or other indices commonly monitored in such studies. In addition, there is no evidence from histopathological data from repeated-dose studies for the category members that would indicate that these chemicals would pose a reproductive hazard to human health.

In developmental toxicity studies many PGEs have been tested by various routes of exposure and in various species at significant exposure levels and show no frank developmental effects. Due to the rapid hydrolysis of DPMA to DPM, DPMA would not be expected to show teratogenic effects. At high doses where maternal toxicity occurs (e.g., significant body weight loss), an increased incidence of some anomalies such as delayed skeletal ossification or increased 13th ribs, have been reported. Commercially available PGEs showed no teratogenicity.

The weight of the evidence indicates that propylene glycol ethers are not likely to be genotoxic. *In vitro*, negative results have been seen in a number of assays for PnB, DPnB, DPMA and TPM. Positive results were only seen in 3 out of 5 chromosome aberration assays in mammalian cells with DPnB. However, negative results were seen in a mouse micronucleus assay with DPnB and PM. Thus, there is no evidence to suggest these PGEs would be genotoxic *in vivo*. In a 2-year bioassay on PM, there were no statistically significant increases in tumors in rats and mice. The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.

HYDROCORTISONE ACEPONATE	Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).
PROPYLENE GLYCOL MONOMETHYL ETHER - MIXTURE OF ISOMERS & HYDROCORTISONE ACEPONATE	No significant acute toxicological data identified in literature search.

Acute Toxicity	✗	Carcinogenicity	✗
Skin Irritation/Corrosion	✓	Reproductivity	✗
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✗
Mutagenicity	✗	Aspiration Hazard	✗

Legend: ✗ – Data either not available or does not fill the criteria for classification
✓ – Data available to make classification

SECTION 12 Ecological information

Toxicity

Cortavance Cutaneous Spray Solution for Dogs (Virbac Cortavance Cutaneous Spray Solution for Dogs)	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

propylene glycol monomethyl ether - mixture of isomers	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	>1000mg/l	2
	LC50	96h	Fish	>100mg/l	2

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	EC50	48h	Crustacea	373mg/l	2
	NOEC(ECx)	336h	Fish	47.5mg/l	2
	EC50	96h	Algae or other aquatic plants	>1000mg/l	2
hydrocortisone aceponate	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend: <i>Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data</i>					

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
propylene glycol monomethyl ether - mixture of isomers	LOW (Half-life = 56 days)	LOW (Half-life = 1.7 days)

Bioaccumulative potential

Ingredient	Bioaccumulation
propylene glycol monomethyl ether - mixture of isomers	LOW (BCF = 2)

Mobility in soil

Ingredient	Mobility
propylene glycol monomethyl ether - mixture of isomers	HIGH (KOC = 1)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	<p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.</p> <ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ Recycle wherever possible. ▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. ▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or Incineration in a licensed apparatus (after admixture with suitable combustible material). ▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
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SECTION 14 Transport information

Labels Required

	
Marine Pollutant	NO
HAZCHEM	*2Y

Land transport (ADG)

UN number	3092
UN proper shipping name	1-METHOXY-2-PROPANOL
Transport hazard class(es)	Class 3
	Subrisk Not Applicable

Cortavance Cutaneous Spray Solution for Dogs (Virbac Cortavance Cutaneous Spray Solution for Dogs)

Packing group	III	
Environmental hazard	Not Applicable	
Special precautions for user	Special provisions	Not Applicable
	Limited quantity	5 L

Air transport (ICAO-IATA / DGR)

UN number	3092	
UN proper shipping name	1-Methoxy-2-propanol	
Transport hazard class(es)	ICAO/IATA Class	3
	ICAO / IATA Subrisk	Not Applicable
	ERG Code	3L
Packing group	III	
Environmental hazard	Not Applicable	
Special precautions for user	Special provisions	Not Applicable
	Cargo Only Packing Instructions	366
	Cargo Only Maximum Qty / Pack	220 L
	Passenger and Cargo Packing Instructions	355
	Passenger and Cargo Maximum Qty / Pack	60 L
	Passenger and Cargo Limited Quantity Packing Instructions	Y344
	Passenger and Cargo Limited Maximum Qty / Pack	10 L

Sea transport (IMDG-Code / GGVSee)

UN number	3092	
UN proper shipping name	1-METHOXY-2-PROPANOL	
Transport hazard class(es)	IMDG Class	3
	IMDG Subrisk	Not Applicable
Packing group	III	
Environmental hazard	Not Applicable	
Special precautions for user	EMS Number	F-E , S-D
	Special provisions	Not Applicable
	Limited Quantities	5 L

Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
propylene glycol monomethyl ether - mixture of isomers	Not Available
hydrocortisone aceponate	Not Available

Transport in bulk in accordance with the ICG Code

Product name	Ship Type
propylene glycol monomethyl ether - mixture of isomers	Not Available
hydrocortisone aceponate	Not Available

SECTION 15 Regulatory information

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

propylene glycol monomethyl ether - mixture of isomers is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals	Chemical Footprint Project - Chemicals of High Concern List
Australian Inventory of Industrial Chemicals (AIIC)	

hydrocortisone aceponate is found on the following regulatory lists

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 3	Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4
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National Inventory Status

National Inventory	Status

Continued...

Cortavance Cutaneous Spray Solution for Dogs (Virbac Cortavance Cutaneous Spray Solution for Dogs)

National Inventory	Status
Australia - AIC / Australia Non-Industrial Use	No (hydrocortisone aceponate)
Canada - DSL	No (hydrocortisone aceponate)
Canada - NDSL	No (hydrocortisone aceponate)
China - IECSC	No (hydrocortisone aceponate)
Europe - EINEC / ELINCS / NLP	No (hydrocortisone aceponate)
Japan - ENCS	No (hydrocortisone aceponate)
Korea - KECI	No (hydrocortisone aceponate)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (hydrocortisone aceponate)
USA - TSCA	No (hydrocortisone aceponate)
Taiwan - TCSI	No (hydrocortisone aceponate)
Mexico - INSQ	Yes
Vietnam - NCI	No (hydrocortisone aceponate)
Russia - FBEPH	No (hydrocortisone aceponate)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	11/01/2019
Initial Date	11/01/2009

SDS Version Summary

Version	Date of Update	Sections Updated
3.1.1.1	01/24/2017	Acute Health (eye), Acute Health (inhaled), Acute Health (skin), Acute Health (swallowed), Appearance, Chronic Health, Classification, Environmental, Fire Fighter (fire/explosion hazard), First Aid (eye), First Aid (swallowed), Handling Procedure, Personal Protection (Respirator), Personal Protection (eye), Personal Protection (hands/feet), Physical Properties, Storage (storage incompatibility), Storage (suitable container), Toxicity and Irritation (Other)
4.1.1.1	11/01/2019	One-off system update. NOTE: This may or may not change the GHS classification
4.1.2.1	04/26/2021	Regulation Change
4.1.3.1	05/03/2021	Regulation Change
4.1.4.1	05/06/2021	Regulation Change
4.1.5.1	05/10/2021	Regulation Change
4.1.5.2	05/30/2021	Template Change
4.1.5.3	06/04/2021	Template Change
4.1.5.4	06/05/2021	Template Change
4.1.6.4	06/07/2021	Regulation Change
4.1.6.5	06/09/2021	Template Change
4.1.6.6	06/11/2021	Template Change
4.1.6.7	06/15/2021	Template Change
4.1.7.7	06/17/2021	Regulation Change
4.1.8.7	06/21/2021	Regulation Change
4.1.8.8	07/05/2021	Template Change
4.1.9.8	07/14/2021	Regulation Change
4.1.10.8	07/19/2021	Regulation Change
4.1.10.9	08/01/2021	Template Change
4.1.11.9	08/02/2021	Regulation Change
4.1.12.9	08/05/2021	Regulation Change
4.1.13.9	08/09/2021	Regulation Change
4.1.14.9	08/23/2021	Regulation Change
4.1.15.9	08/26/2021	Regulation Change
4.1.15.10	08/29/2021	Template Change
4.1.16.10	08/30/2021	Regulation Change

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Cortavance Cutaneous Spray Solution for Dogs (Virbac Cortavance Cutaneous Spray Solution for Dogs)

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit
IDLH: Immediately Dangerous to Life or Health Concentrations
ES: Exposure Standard
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
AIIC: Australian Inventory of Industrial Chemicals
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
NLP: No-Longer Polymers
ENCS: Existing and New Chemical Substances Inventory
KECI: Korea Existing Chemicals Inventory
NZIoC: New Zealand Inventory of Chemicals
PICCS: Philippine Inventory of Chemicals and Chemical Substances
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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