

Firstmectin Se Selenised Endectocide and Tapewormer for Lambs

Virbac (Australia) Pty Limited

Chemwatch Hazard Alert Code: 2

Chemwatch: 3724409

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

L.GHS.AUS.EN

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

Product Identifier

Product name	Firstmectin Se Selenised Endectocide and Tapewormer for Lambs
Chemical Name	Not Applicable
Synonyms	APVMA No: 56998
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	Use according to manufacturer's directions.
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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. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

ChemWatch Hazard Ratings

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

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

Poisons Schedule	S6
Classification [1]	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Sensitisation (Skin) Category 1, Germ Cell Mutagenicity Category 2, Carcinogenicity Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 1, Acute Toxicity (Oral) Category 4
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.
H317	May cause an allergic skin reaction.
H341	Suspected of causing genetic defects.
H351	Suspected of causing cancer.
H335	May cause respiratory irritation.
H410	Very toxic to aquatic life with long lasting effects.
H302	Harmful if swallowed.

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P261	Avoid breathing mist/vapours/spray.
P264	Wash all exposed external body areas thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P272	Contaminated work clothing should not be allowed out of the workplace.

Precautionary statement(s) Response

P308+P313	IF exposed or concerned: Get medical advice/ attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P330	Rinse mouth.

Precautionary statement(s) Storage

P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

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
55268-74-1	1.35	<u>praziquantel</u>
Not Available		(15g/L)
13410-01-0	0.09	<u>sodium selenate, anhydrous</u>
Not Available		(1g/L)
71751-41-2	0.072	<u>abamectin</u>
Not Available		(0.8g/L)
9005-65-6	10-30	<u>sorbitan monooleate, ethoxylated</u>
Not Available	>60	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	If this product comes in contact with the eyes: ► Wash out immediately with fresh 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.
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	<ul style="list-style-type: none"> Seek medical attention without delay; if pain persists or recurs seek medical attention. 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. Perform CPR if necessary. Transport to hospital, or doctor, without delay.
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 abamectin (avermectins):

Toxicity following accidental ingestion may be minimised by emesis-induction within one half hour of exposure. Since abamectin is thought to bind to glutamate-gated chloride ion channels, it is probably wise to avoid drugs that also interact with other ligand-gated chloride channels, including those that enhance GABA activity in patients with potentially toxic abamectin exposure.

Avoid drugs that enhance GABA activity (barbiturate, benzodiazepines, valproic acid, etc.).

SECTION 5 Firefighting measures**Extinguishing media**

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.

Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.

In such an event consider:

- foam.
- dry chemical powder.
- carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
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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. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area. 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. Equipment should be thoroughly decontaminated after use.
Fire/Explosion Hazard	<p>The emulsion is not combustible under normal conditions. However, it will break down under fire conditions and the hydrocarbon component will burn.</p> <p>Decomposes on heating and produces toxic fumes of: carbon dioxide (CO₂) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.</p>
HAZCHEM	Not Applicable

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"> 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 spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal.
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Major Spills	<p>Moderate hazard.</p> <ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ Stop leak if safe to do so. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Neutralise/decontaminate residue (see Section 13 for specific agent). ▶ Collect solid residues and seal in labelled drums for disposal. ▶ Wash area and prevent runoff into drains. ▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. ▶ If contamination of drains or waterways occurs, advise emergency services.
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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 exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sums. ▶ DO NOT enter confined spaces until atmosphere has been checked. ▶ DO NOT allow material to contact humans, exposed food or food utensils. ▶ 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. Launder contaminated clothing before re-use. ▶ 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 are maintained.
Other information	<ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry, well-ventilated area. ▶ Store away from incompatible materials and foodstuff containers. ▶ Protect containers against physical damage and check regularly for leaks. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none"> ▶ Avoid reaction with oxidising agents ▶ Avoid strong acids, bases.

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	sodium selenate, anhydrous	Selenium compounds (as Se) excluding hydrogen selenide	0.1 mg/m3	Not Available	Not Available	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
sodium selenate, anhydrous	1.4 mg/m3	1.6 mg/m3	2 mg/m3

Ingredient	Original IDLH	Revised IDLH
praziquantel	Not Available	Not Available
sodium selenate, anhydrous	1 mg/m3	Not Available
abamectin	Not Available	Not Available
sorbitan monooleate, ethoxylated	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
abamectin	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.

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Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
sorbitan monooleate, ethoxylated	E	≤ 0.1 ppm
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.</p> <p>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>Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection.</p> <p>An approved self contained breathing apparatus (SCBA) may be required in some situations.</p> <p>Provide adequate ventilation in warehouse or closed storage area. 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 conveyor 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, conveyor loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)
	Within each range the appropriate value depends on:	
	Lower end of the range	Upper end of the range
	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
	2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
	3: Intermittent, low production.	3: High production, heavy use
	4: Large hood or large air mass in motion	4: Small hood-local control only
	<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>	
Personal protection	   	
Eye and face protection	<ul style="list-style-type: none"> ► Safety glasses with side shields. ► Chemical goggles. ► 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] 	
Skin protection	<p>See Hand protection below</p> <ul style="list-style-type: none"> ► Wear chemical protective gloves, e.g. PVC. ► Wear safety footwear or safety gumboots, e.g. Rubber <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 	
Hands/feet protection		

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	<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>
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> Overalls. P.V.C apron. Barrier cream. Skin cleansing cream. Eye wash unit.

Recommended material(s)**GLOVE SELECTION INDEX**

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

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Material	CPI
BUTYL	A
VITON	A
NATURAL RUBBER	C
NEOPRENE	C
PVA	C

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Respiratory protection

Type A-P 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 P2	-	A-PAPR-AUS / Class 1 P2
up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-PAPR-2 P2 ^

^ - Full-face

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	Liquid; mixes with water.		
Physical state	Liquid	Relative density (Water = 1)	1.11
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

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Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	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"> ▶ 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

Information on toxicological effects

Inhaled	<p>Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial 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>Inhalation hazard is increased at higher temperatures.</p>
Ingestion	<p>Accidental ingestion of the material may be damaging to the health of the individual.</p> <p>Nonionic surfactants may produce localised irritation of the oral or gastrointestinal mucosa and induce vomiting and mild diarrhoea.</p>
Skin Contact	<p>Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.</p> <p>The material may accentuate any pre-existing dermatitis condition.</p> <p>Repeated exposure may cause skin cracking, flaking or drying following normal handling and use.</p> <p>One of the mechanisms of skin irritation caused by surfactants is considered to be denaturation of the proteins of skin. It has also been established that there is a connection between the potential of surfactants to denature protein in vitro and their effect on the skin. Nonionic surfactants do not carry any net charge and, therefore, they can only form hydrophobic bonds with proteins. For this reason, proteins are not deactivated by nonionic surfactants, and proteins with poor solubility are not solubilized by nonionic surfactants.</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.</p> <p>Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
Eye	<p>Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by a temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.</p> <p>Some nonionic surfactants may produce a localised anaesthetic effect on the cornea; this may effectively eliminate the warning discomfort produced by other substances and lead to corneal injury. Irritant effects range from minimal to severe dependent on the nature of the surfactant, its concentration and the duration of contact. Pain and corneal damage represent the most severe manifestation of irritation.</p>
Chronic	<p>On the basis, primarily, of animal experiments, concern has been expressed that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment.</p> <p>Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals.</p> <p>Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance who are likely to become hyper-responsive.</p> <p>Substances than can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing air-way hyper-responsiveness. The latter substances are not classified as asthmagens or respiratory sensitisers.</p> <p>Wherever it is reasonably practicable, exposure to substances that can cause occupational asthma should be prevented. Where this is not possible the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive.</p> <p>Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance.</p>

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Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of appropriate studies using mammalian somatic cells *in vivo*. Such findings are often supported by positive results from *in vitro* mutagenicity studies.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

There is some evidence that human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects.

Prolonged or repeated skin contact may cause degreasing with drying, cracking and dermatitis following.

Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis).

Firstmectin Se Selenised Endectocide and Tapewormer for Lambs	TOXICITY Not Available	IRRITATION Not Available
praziquantel	TOXICITY Oral(Dog) LD50; >200 mg/kg ^[2]	IRRITATION Not Available
sodium selenate, anhydrous	TOXICITY Inhalation(Rat) LC50; >0.052<=0.51 mg/l4h ^[1] Oral(Rat) LD50; 1.6 mg/kg ^[2]	IRRITATION Eye: no adverse effect observed (not irritating) ^[1] Skin: adverse effect observed (irritating) ^[1]
abamectin	TOXICITY dermal (rat) LD50: >330 mg/kg ^[2] Inhalation(Rat) LC50; 1.1 mg/L4h ^[2] Oral(Rat) LD50; 1.5 mg/kg ^[2]	IRRITATION Eye (rabbit): slight * Skin (rabbit): non irritating*
sorbitan monooleate, ethoxylated	TOXICITY Oral(Mammal) LD50; 25000 mg/kg ^[2]	IRRITATION Eye (rabbit): 150 mg - mild Skin (rabbit): - slight
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	

PRAZIQUANTEL	NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA. * Bayer ADI: 0.02 mg/kg/day NOEL: 20 mg/kg/day
SODIUM SELENATE, ANHYDROUS	Eye effects, general anaesthesia, convulsions, muscle weakness, spasticity, cardiac EKG changes, cyanosis, lung tumours, diarrhoea, impaired liver function tests, leukaemia, specific developmental changes, effects on newborn recorded. The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.
ABAMECTIN	Oral (rat) LD50: 8.7-12.8 mg/kg (14 day) * ADI 0.0001 mg/kg Toxicity Class EPA IV Non-mutagenic in the Ames test ADI: 0.4 mg/day *[Manufacturer] Convulsions recorded. For avermectins: Technical avermectin exhibits high mammalian acute toxicity. In vertebrates, the effects occur via poisoning of the central nervous system (CNS) through reactions at the receptor for the inhibitory neurotransmitter GABA. The avermectins open the GABA _A receptor chloride channel by binding to the GABA recognition site (receptor protein) and act as partial agonists.. Chloride ions then flow into the postsynaptic neuron. This chloride permeability increase can significantly hyperpolarize (make more negative) the membrane potential, which has a dampening effect on nerve impulse firing. There is also a reversible dose-dependent increase in chloride ion permeability in response to very low doses of avermectins. In GABA-insensitive neurons with no inhibitory innervation, the avermectins induce an irreversible increase in chloride ion conductance through interacting with voltage-dependent chloride channels. Avermectin intoxication in mammals begins with hyperexcitability, tremors, and incoordination and later develops into ataxia and coma-like sedation. This is similar to the mode of action of ethanol and barbiturates and benzodiazepine sedatives. However, the avermectins are less specific in their action and can affect a variety of other ligand- and voltage-gated chloride channels. The general safety of the avermectins depends on the presence of an intact P-glycoprotein blood-brain barrier. Avermectin is not considered to be mutagenic and does not sensitise skin. It is not readily absorbed by mammals and the majority of the residue is excreted in the faeces within 2 days. The 24-month rat chronic feeding/ oncogenicity study and 94-week mouse chronic toxicity oncogenicity study were negative for oncogenic potential. The results of a series of developmental toxicity studies (rat, rabbit, mouse) have been evaluated and showed that avermectin B1 produces developmental toxicity (cleft palate) in the CF1 mouse. Toxicology data were also evaluated for the delta-8,9-isomer of avermectin B1 which is a plant photodegrade that can range between 5 and 20 percent of the residue on/in cottonseed. This isomer possesses avermectin-like toxicological activity. It was concluded that the delta 8,9-isomer also produces developmental toxicity (cleft palate) in mice, but not in rats. In addition to avermectin and its delta 8,9-isomer, toxicology data were also evaluated for the "polar degradates" of avermectin, which constitute a large percentage (up to 70%) of the total residue on cottonseed. Review of the toxicology data indicated that these polar degradates do not possess avermectin-like toxicological activity and for this reason need not be included in the tolerance expression for residues on/in cottonseed. Abamectin (a mixture of avermectin isomers) is a reproductive toxin in laboratory animals at doses which are acutely toxic to the mother. In development toxicity studies with abamectin, cleft palates were seen in mice and rabbits and clubbing of the forepaws was seen in rabbits. The no-observed-adverse-effect-level (NOAEL) for maternal and developmental toxicity in rabbits was 1 mg/kg/day. In CF-1 mice, a strain recognised to be particularly sensitive to avermectins, the NOAEL for maternal toxicity was 0.05 mg/kg/day and the NOAEL for malformations was 0.2 mg/kg/day. Studies show that the sensitivity of a subpopulation of CF-1 mice to avermectins is due to the absence of a transmembrane P-glycoprotein, a significant component of the blood-brain interface that normally acts as a non-selective protective barrier in a wide range of species including humans. CF-1 mice are therefore an unlikely candidate for assessing human risk. No evidence of developmental toxicity was seen in oral studies in rats in the absence of maternal toxicity (NOAEL = 1.6 mg/kg/day). In a rat multigenerational reproduction study, pup toxicity and deaths were seen at 0.4 mg/kg/day (NOAEL = 0.12 mg/kg/day). Neonatal rats are not an appropriate model for assessing human risk in humans because (a) rat milk has a greater fat content than human breast milk and abamectin concentrates in fat; (b) on a weight basis, the neonatal rat consumes significantly greater quantities of milk than the newborn human and (c) the blood brain barrier in rodents is formed

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post-natally (as evidenced by low P-glycoprotein levels) while in humans this membrane is formed pre-natally. Ivermectin, a close structural analogue, has been used extensively in the treatment of human onchocerciasis at an oral therapeutic dose of 0.2 mg/kg, without serious drug-related effects. Despite its wide usage in animals and humans, ivermectin does not appear to produce birth defects. Abamectin is non-mutagenic in the Ames test and the micronucleus test. Dietary carcinogenicity studies in mice and rats showed negative results. In a 14-week oral study in monkeys no effects were seen at 0.2, 0.5 or 1.0 mg/kg/day; emesis was seen at 2.0 mg/kg/day; delayed pupillary obstruction at 6 and 8 mg/kg/day and mydriasis at 12 mg/kg/day. In chronic oral toxicity, abamectin produced decreased body weight gain in mice (no-observed-adverse-effect-level (NOAEL) = 1.5 mg/kg/day); tremors in rats (NOAEL = 1.5 mg/kg/day), weight loss, tremors, mydriasis, liver and gall bladder changes and death in dogs (NOAEL = 0.25 mg/kg/day); and emesis, mydriasis and sedation in monkeys (NOAEL = 1 mg/kg/day).

Polyoxyethylene sorbitan monooleate (TW80) is widely used as an emulsifier or solubilizer in a variety of foods, cosmetics and other commercial products. In addition, TW80 in water has been used as a vehicle for the delivery of other chemical agents to pregnant laboratory animals by the oral route of administration (eg. by gavage or in the drinking water). Based upon the large population of pregnant women potentially exposed to TW80, and because of its use as a vehicle in laboratory animal studies, TW80 was evaluated for potential developmental toxicity. Timed-mated Sprague-Dawley-derived (CD®) rats (25 per group) were exposed to 0, 500 or 5000 mg/kg/day of TW80. Aqueous solutions were delivered by gavage in a volume of 5 ml/kg of body weight on gestational days (gd) 6 through 15. At termination (gd 20), the uterus was removed and examined to determine pregnancy status, and to evaluate the number of resorptions, and dead or live foetuses. Dead or live foetuses were weighed, and live foetuses were examined for external, visceral and skeletal defects. All treated females survived to scheduled necropsy and 19-23 pregnancies per group were confirmed. No dose-related signs of toxicity were observed for individual animals during the in-life phase of the study or at scheduled necropsy. Average maternal body weight (gd 0, 3, 6, 9, 12, 15, 18, or 20) did not differ among treatment groups, nor was there a treatment related change in maternal weight gain during treatment or gestation (absolute or corrected). There were no treatment-related effects upon the following maternal organ weights: gravid weight (absolute), kidney weight (absolute or relative), and heart weight (absolute or relative). Relative maternal liver weight (% body weight on gd 20 or % corrected body weight) was elevated in both TW80 groups and absolute liver weight was elevated at 500 mg/kg/day. Maternal food intake was comparable across groups during the pre- and post-treatment periods, but was decreased by 14% during the first 3 days of treatment at 5000 mg/kg/day relative to the vehicle control group. Maternal relative water intake was comparable among treatment groups throughout gestation. No differences among groups were noted for the number of corpora lutea per dam, the number of implantation sites per dam or the percent preimplantation loss per litter. No adverse effects were noted on the growth, viability or morphological development of the conceptuses. In conclusion, the maternal LOAEL was 500 mg/kg/day (based upon an increase in maternal relative liver weight). No definitive adverse effects of TW80 upon prenatal development were noted in this study. Thus, the developmental NOAEL was greater than 5000 mg/kg/day. Exposure to the material may result in a possible risk of irreversible effects. The material may produce mutagenic effects in man. This concern is raised, generally, on the basis of appropriate studies using mammalian somatic cells in vivo. Such findings are often supported by positive results from in vitro mutagenicity studies.

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.

The Cosmetic Ingredient Review (CIR) Expert Panel concluded that listed polysorbates are safe in cosmetics when formulated to be non-irritating. This conclusion supersedes the conclusion reached in the 1984, 2000, and 2001 CIR safety assessments. This safety assessment combines polysorbates reviewed in 3 previous safety assessments with other polysorbates that have not been reviewed by the CIR Panel into a group of 80 polyethoxylated sorbitan or sorbitol esters of fatty acid.

Following oral administration of polysorbate 20 to rats, ester bonds of polysorbates are hydrolyzed within the digestive tract by pancreatic lipase.²⁴ Free fatty acids were absorbed from the digestive tract and oxidized and excreted, mainly as carbon dioxide in exhaled breath. No migration of the polyoxyethylene sorbitan into the thymus lymph nodes has been demonstrated. No sex difference has been detected in the disposition of polysorbates in rats. Following oral ingestion of polysorbate 20 in humans, 90% or more of the administered substance was excreted in the feces as metabolites, with the polyoxyethylene sorbitan structure maintained, and 2%-3% of these metabolites were excreted in the urine.

The Panel considered the data available to characterize the potential for polysorbates to cause systemic toxicity, irritation, sensitization, reproductive and developmental toxicity, and genotoxicity. They noted the lack of systemic toxicity at low and moderate doses in several acute and repeated-dose oral exposure studies, and low toxicity at high doses; little or no irritation or sensitization in multiple tests of dermal and ocular exposure; the absence of genotoxicity in multiple Ames tests and chromosome aberration tests, and minimal irritation and lack of sensitization in tests of dermal exposure at concentration of use. The Panel recognizes that there are data gaps regarding use and concentration of these ingredients. However, the overall information available on the types of products in which these ingredients are used, concentrations of use and the similar pattern of use raise no safety concerns. The Panel note that polysorbate 20, polysorbate 65, and polysorbate 80 were shown to enhance dermal drug absorption. The Panel cautions that care should be taken in formulating cosmetic products that may contain these ingredients in combination with any ingredients whose safety was based on their lack of dermal absorption, or when dermal absorption was a concern. Especially, care should be taken when creating formulations intended for use on infants.

To address the possible presence of 1,4-dioxane and ethylene oxide impurities in these ingredients, the Panel stressed that the cosmetics industry should continue to use the necessary procedures to limit these impurities from the PEG ingredients before blending them into cosmetic formulations. The Panel expressed concern about pesticide residues and heavy metals that may be present in botanical (ie, coconut-derived) ingredients. They stressed that the cosmetics industry should continue to use current good manufacturing practices (cGMPs) to limit impurities. Data from the 1984 safety assessment suggested that polysorbates caused a slight enhancement of tumor development caused by 7,12-dimethyl-benz[a]anthracene (DMBA) and N-methyl-N'-nitro-N-nitrosoguanidine (MNNG); however, the data were not consistent. For other compounds, the tumorigenic properties of 3-methyl-cholanthrene (MCA) and 3,4-benz[a]pyrene (BP) were not enhanced by polysorbates. Since the tumor enhancement effects were inconsistent and depended on the simultaneous exposure to strong chemical carcinogens, which are not present in cosmetics, the Panel felt that the weak tumor enhancement effects were not relevant to cosmetic formulations. Because some studies showed minimal irritation at concentrations that are used in cosmetics, the Panel cautioned that products containing these ingredients should be formulated to be non-irritating. It was noted that at the time of the 2001 safety assessment on sorbeth beeswaxes, the Panel had recommended that

cosmetic formulations containing PEGs not be used on damaged skin because of the possibility of renal toxicity when PEGs were applied to severely damaged skin, such as in burn patients. Since then, PEGs have been re-reviewed and the additional data demonstrated minimal dermal penetration of low-molecular weight PEGs. The amount of PEGs that would penetrate the stratum corneum barrier, even if damaged, from the use of cosmetics was well below the level of renal toxicity. Therefore, the Panel has removed the caveat that PEGs should not be used on damaged skin. The Panel strongly asserted that it is inappropriate to apply cosmetic products containing high concentrations of PEGs to individuals exhibiting barrier skin disruption through both the stratum corneum and the epidermis.

The Panel discussed the issue of incidental inhalation exposure from spray products, including aerosol and pump hair sprays, spray deodorants, spray body and hand products, and spray moisturizing products. The limited acute exposure data available from 1 new inhalation study and 1 historical tracheal study suggest little potential for respiratory effects at relevant doses. These ingredients are reportedly used at concentrations up to 4% in cosmetic products that may be aerosolized. The Panel noted that 95%-99% of droplets/particles would not be respirable to any appreciable amount.

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Coupled with the small actual exposure in the breathing zone and the concentrations at which the ingredients are used, the available information indicates that incidental inhalation would not be a significant route of exposure that might lead to local respiratory or systemic effects.

Safety Assessment of Polysorbates as Used in Cosmetic July 2015
http://www.cir-safety.org/sites/default/files/PSorba_062015_FR_0.pdf

For sorbitan esters, ethoxylated (syn: polyoxyethylene sorbitan esters):

Some of the early short-term studies with these polyoxyethylene sorbitan esters in rats and hamsters showed deleterious effects. Subsequent work suggests that these were largely due to diarrhoea resulting from a large amount of unabsorbed polyglycol, possibly aggravated in some experiments by the use of an unsuitable basal diet. Since that time there has been considerable improvement in testing procedures, and more extensive long-term studies have been carried out. It seems reasonable therefore to base the evaluation of these substances on the levels causing no adverse effects indicated by the results of the more recent investigations.

The significance of the local tumours which were produced by injection has been discussed at the meeting of the Scientific Group (1966). No increase in tumour incidence has followed the oral intake of polyoxyethylene sorbitan esters. Furthermore, large doses of the oleate and stearate have been well tolerated by human subjects.

Polyoxyethylene (20) sorbitan monoester of lauric, oleic, palmitic and stearic acid and triester of stearic acid
 Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. Techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53.

Polyethers, for example, ethoxylated surfactants and polyethylene glycols, are highly susceptible towards air oxidation as the ether oxygens will stabilize intermediary radicals involved. Investigations of a chemically well-defined alcohol (pentaethylene glycol mono-n-dodecyl ether) ethoxylate, showed that polyethers form complex mixtures of oxidation products when exposed to air.

Sensitization studies in guinea pigs revealed that the pure nonoxidized surfactant itself is nonsensitizing but that many of the investigated oxidation products are sensitizers. Two hydroperoxides were identified in the oxidation mixture, but only one (16-hydroperoxy-3,6,9,12,15-pentaoxaheptacosan-1-ol) was stable enough to be isolated. It was found to be a strong sensitizer in LLNA (local lymph node assay for detection of sensitization capacity). The formation of other hydroperoxides was indicated by the detection of their corresponding aldehydes in the oxidation mixture.

On the basis of the lower irritancy, nonionic surfactants are often preferred to ionic surfactants in topical products. However, their susceptibility towards autoxidation also increases the irritation. Because of their irritating effect, it is difficult to diagnose ACD to these compounds by patch testing.

Allergic Contact Dermatitis—Formation, Structural Requirements, and Reactivity of Skin Sensitizers.

Ann-Therese Karlberg et al; Chem. Res. Toxicol. 2008;21:53-69

Polyethylene glycols (PEGs) have a wide variety of PEG-derived mixtures due to their readily linkable terminal primary hydroxyl groups in combination with many possible compounds and complexes such as ethers, fatty acids, castor oils, amines, propylene glycols, among other derivatives. PEGs and their derivatives are broadly utilized in cosmetic products as surfactants, emulsifiers, cleansing agents, humectants, and skin conditioners.

PEGs and PEG derivatives were generally regulated as safe for use in cosmetics, with the conditions that impurities and by-products, such as ethylene oxides and 1,4-dioxane, which are known carcinogenic materials, should be removed before they are mixed in cosmetic formulations. Most PEGs are commonly available commercially as mixtures of different oligomer sizes in broadly- or narrowly-defined molecular weight (MW) ranges. For instance, PEG-10,000 typically designates a mixture of PEG molecules ($n = 195$ to 265) having an average MW of 10,000. PEG is also known as polyethylene oxide (PEO) or polyoxyethylene (POE), with the three names being chemical synonyms. However, PEGs mainly refer to oligomers and polymers with molecular masses below 20,000 g/mol, while PEOs are polymers with molecular masses above 20,000 g/mol, and POEs are polymers of any molecular mass. Relatively small molecular weight PEGs are produced by the chemical reaction between ethylene oxide and water or ethylene glycol (or other ethylene glycol oligomers), as catalyzed by acidic or basic catalysts. To produce PEO or high-molecular weight PEGs, synthesis is performed by suspension polymerization. It is necessary to hold the growing polymer chain in solution during the course of the poly-condensation process. The reaction is catalyzed by magnesium-, aluminum-, or calcium-organoelement compounds. To prevent coagulation of polymer chains in the solution, chelating additives such as dimethylglyoxime are used

Safety Evaluation of Polyethyene Glycol (PEG) Compounds for Cosmetic Use: Toxicol Res 2015; 31:105-136 The Korean Society of Toxicology <http://doi.org/10.5487/TR.2015.31.2.105>

For Group D aliphatic esters: (sorbitan fatty esters)

Sorbitan fatty acid esters are mono-, di-, and triesters of fatty acids and sorbitol-derived hexitol anhydrides.

Sorbitan fatty acid esters were relatively nontoxic via ingestion in acute and long-term studies. They were generally minimal to mild skin irritants in animal studies, except that sorbitan isostearate applied to the skin was a moderate irritant in one rabbit study and when injected intradermally caused mild to severe irritation in guinea pigs. Sorbitan fatty acid esters did not sensitise guinea pigs. The fatty acid component, tested alone, typically caused only slight irritation and sensitisation, and was not photosensitising. Sorbitan fatty acid esters were not ocular irritants. Fatty acids are normal components of diet for which no data were available concerning reproductive or developmental toxicity, but Sorbitol had no adverse effects on the reproduction of CD rats during a multigeneration feeding study and was not a reproductive toxin at doses of 3000 to 7000 mg/kg/day for 2 years. Overall these esters and their corresponding fatty acids were not mutagenic, but sorbitan oleate was reported to reduce DNA repair following ultraviolet radiation exposure in human lymphocytes in culture. Sorbitan laurate and sorbitan trioleate were cocarcinogens in one mouse study, but sorbitan trioleate and sorbitan oleate were not tumour promoters in another study. In clinical tests, Sorbitan fatty acid esters were generally minimal to mild skin irritants and were nonsensitizing, but sorbitan sesquioleate did produce an allergic reaction in fewer than 1% of patients with suspected contact dermatitis and addition of sorbitan sesquioleate to the components of a fragrance mix used in patch testing increased both irritant and allergic reactions to the fragrance mix. Careful consideration was made of the data on the cocarcinogenesis of sorbitan laurate and sorbitan trioleate, but the high exposure levels, high frequency of exposure, and absence of a dose-response led to the conclusion that there was not a cocarcinogenesis risk with the use of these ingredients in cosmetic formulations. Accordingly, these ingredients were considered safe for use in cosmetic formulations under the present practices of use.

Final report on the safety assessment of sorbitan caprylate, sorbitan cocoate, sorbitan diisostearate, sorbitan dioleate, sorbitan distearate, sorbitan isostearate, sorbitan olivate, sorbitan sesquisostearate, sorbitan sesquistearate, and sorbitan triisostearate Lanigan et al Int J. Toxicol 2002, pp 93-112

According to a classification scheme described by the American Chemistry Council' Aliphatic Esters Panel, Group D substances are esters of monoacids, mainly common fatty acids, and sorbitan (which is derived from sorbitol - a natural carbohydrate sweetener). The fatty acids include lauric, stearic, oleic acids and coca fatty acids (mainly lauric and myristic acids). The hydroxy group in the sorbitan represents the alcohol portion of the ester linkage. The Group D esters are carbohydrate-derived esters since the ester linkage is connected to the hydroxy group(s) of sorbitan. They may have single ester linkages (i.e., sorbitan monoester) or may have multiple ester linkages, as in the case of sorbitan sesquioleate and sorbitan trioleate. Multiple ester linkages with long-chain fatty acids increase lipophilicity and also tend to diminish water solubility. The sorbitan esters are non-ionic surfactant-active agents that typically find use as emulsifiers, stabilizers, and thickeners in foods, cosmetics and medical products.

Acute toxicity: Sorbitan esters do not represent a toxicological concern since they are derived from naturally occurring materials and the parent esters are ultimately metabolised back to these same natural constituents: namely, sorbitan and common fatty acids, both of which have low orders of toxicity. The oral LD₅₀ in rats ranged from >2.9 g/kg to >39.8 g/kg. Numerous sorbitan esters have been studied by acute oral and dermal administration. Results from these studies support the general conclusion that sorbitan fatty acid esters have low orders of acute toxicity. Repeated Dose Toxicity: A large number of subchronic oral and dermal studies and chronic oral feeding studies have been carried out for sorbitan monolaurate, sorbitan monostearate and sorbitan monooleate. For sorbitan monostearate, no adverse effects were reported in rats fed 5% concentrations of the test substance in the diet for 6 weeks. The NOAEL was estimated to be 5% or approximately 2500 mg/kg/day. In 2-year feeding studies at 5, 10 and 20% in the diet rats tolerated sorbitan monostearate with no adverse effects. However, at 20%, there was a small but significant decrease on growth rate in male rats. Hence, the NOAEL was 10% in the diet or approximately 5000 mg/kg/day in rats, based on these findings. In a 80-week dietary study in mice, no adverse effects were observed for sorbitan monostearate at 2% concentration in the diet and the NOAEL was 2% or approximately 2600 mg/kg/day. Subchronic studies have also been carried out with sorbitan, fatty acids C6-10, tetraester (CAS 228573-47-5). Oral gavage studies for 28 days at dose levels up to 1000 mg/kg/day resulted in no systemic toxicity. Therefore, the NOAEL was 1000 mg/kg/day for this tetraester.

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Since the sesquioleate and trioleate of sorbitan are merely multiple ester homologs of sorbitan monooleate, they would be expected to show similar effects, given their structural similarities and potential to be metabolised to the monooleate.

Sensitisation: Sorbitan fatty acid esters were generally minimal to mild skin irritants and were nonsensitising, but sorbitan sesquioleate did produce an allergic reaction in fewer than 1% of patients with suspected contact dermatitis and addition of sorbitan sesquioleate to the components of a fragrance mix used in patch testing increased both irritant and allergic reactions to the fragrance mix.

Reproductive and developmental toxicity: Limited reproductive toxicity data have been reported for the sorbitan esters. In a 2-year feeding studies in rats with sorbitan monostearate, there were no effects on gestation and fertility at any dose level (0, 5, 10 and 20% in the diet) but survival of the newborn animals and maternal lactation were slightly diminished at the 20% level. Sorbitol was also studied indirectly as part of a mixture of hydrogenated starch hydrolysates (HSH) which contained about 7% sorbitol as part of the polyhydric alcohol mixture. The HSH mixture was investigated as part of a two-year ingestion study, a multigeneration reproduction study and a teratology study. At concentrations of 18% in drinking water (3000-7000 mg/kg/day), HSH did not produce reproductive or developmental effects. These results indicate that sorbitol does not cause reproductive/ developmental toxicity in animals. Given these findings and the low order of toxicity of natural fatty acids, it seems unlikely that sorbitan esters would present reproductive and developmental toxicity concerns.

Genotoxicity: Sorbitan monostearate (CAS 1338-41-6) was found to be negative in the Ames assay. In addition, the non-HPV substance, sorbitan fatty acid C6-10 tetraester (CAS 228573-47-5), did not cause any mutagenic effects in the *Salmonella* *in vitro* test. These substances bridge the low and high carbon range of most of the sorbitan esters and the chemistry of the sorbitan esters (i.e., sorbitan/ sorbitol, natural fatty acids) does not suggest the likelihood that the sorbitan esters are electrophilic or reactive in nature. Thus, it is not likely that the substances in Group D cause mutagenic effects.

Sorbitan monostearate did not transform primary Syrian golden hamster embryo cells. As discussed above for point mutation, the chemistry of the sorbitan esters does not suggest the likelihood that these substances, or their constituent substructures (i.e., sorbitol, fatty acids) are reactive or electrophilic in nature.

Carcinogenicity: Overall these esters and their corresponding fatty acids were not mutagenic, but sorbitan oleate was reported to reduce DNA repair following ultraviolet radiation exposure in human lymphocytes in culture. sorbitan laurate and sorbitan trioleate were cocarcinogens in one mouse study, but sorbitan trioleate and sorbitan oleate were not tumour promoters in another study.

WARNING: This substance has been classified by the IARC as Group 1: **CARCINOGENIC TO HUMANS.**

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.

ABAMECTIN & SORBITAN MONOOLEATE, ETHOXYLATED

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**

	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
praziquantel	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	1h	Fish	40mg/l	4
sodium selenate, anhydrous	LC50	96h	Fish	22.17-38.51mg/l	4
	Endpoint	Test Duration (hr)	Species	Value	Source
abamectin	EC50	48h	Crustacea	0.52-0.63mg/l	4
	LC50	96h	Fish	2.1-2.7mg/l	4
	NOEC(ECx)	4320h	Fish	<0.005mg/l	2
	EC50	96h	Algae or other aquatic plants	12mg/l	4
sorbitan monooleate, ethoxylated	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50(ECx)	48h	Crustacea	<0.001mg/l	4
	EC50	72h	Algae or other aquatic plants	4.4mg/l	4
	LC50	96h	Fish	0.002-0.006mg/L	4
	EC50	48h	Crustacea	<0.001mg/l	4
	EC50	96h	Algae or other aquatic plants	7.31mg/l	4

Legend:

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

Continued...

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Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.**Persistence and degradability**

Ingredient	Persistence: Water/Soil	Persistence: Air
sodium selenate, anhydrous	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
sodium selenate, anhydrous	LOW (LogKOW = -3.1818)

Mobility in soil

Ingredient	Mobility
sodium selenate, anhydrous	LOW (KOC = 48.64)

SECTION 13 Disposal considerations**Waste treatment methods**

Product / Packaging disposal	<ul style="list-style-type: none"> ► Containers may still present a chemical hazard/ danger when empty. ► Return to supplier for reuse/ recycling if possible. <p>Otherwise:</p> <ul style="list-style-type: none"> ► If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. ► Where possible retain label warnings and SDS and observe all notices pertaining to the product. <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.

SECTION 14 Transport information**Labels Required**

Marine Pollutant	
HAZCHEM	Not Applicable

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS**Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS****Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS****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
praziquantel	Not Available
sodium selenate, anhydrous	Not Available
abamectin	Not Available
sorbitan monooleate, ethoxylated	Not Available

Continued...

Firstmectin Se Selenised Endectocide and Tapewormer for Lambs

Transport in bulk in accordance with the ICG Code

Product name	Ship Type
praziquantel	Not Available
sodium selenate, anhydrous	Not Available
abamectin	Not Available
sorbitan monooleate, ethoxylated	Not Available

SECTION 15 Regulatory information

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

praziquantel is found on the following regulatory lists

Australia Chemicals with non-industrial uses removed from the Australian Inventory of Chemical Substances (old Inventory)

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

sodium selenate, anhydrous is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

Australian Inventory of Industrial Chemicals (AIIC)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

abamectin is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals

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

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 7

Chemical Footprint Project - Chemicals of High Concern List

sorbitan monooleate, ethoxylated is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (abamectin)
Canada - DSL	No (praziquantel; abamectin)
Canada - NDSL	No (praziquantel; sodium selenate, anhydrous; abamectin; sorbitan monooleate, ethoxylated)
China - IECSC	No (abamectin)
Europe - EINEC / ELINCS / NLP	No (abamectin)
Japan - ENCS	No (praziquantel; abamectin)
Korea - KECL	No (praziquantel)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (abamectin)
USA - TSCA	No (praziquantel; abamectin)
Taiwan - TCSI	Yes
Mexico - INSQ	No (praziquantel)
Vietnam - NCI	Yes
Russia - FBEPH	No (sodium selenate, anhydrous; abamectin)
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	05/11/2016

SDS Version Summary

Version	Date of Update	Sections Updated
2.1.1.1	05/11/2016	Acute Health (eye), Acute Health (inhaled), Acute Health (skin), Acute Health (swallowed), Advice to Doctor, Appearance, Chronic Health, Classification, Disposal, Engineering Control, Environmental, Fire Fighter (extinguishing media), Fire Fighter (fire/explosion hazard), Fire Fighter (fire fighting), Fire Fighter (fire incompatibility), First Aid (eye), First Aid (inhaled), First Aid (skin), First Aid (swallowed), Handling Procedure, Ingredients, Instability Condition, Personal Protection (other), Personal Protection (Respirator), Personal Protection (eye), Personal Protection (hands/feet), Physical Properties, Spills (major), Spills (minor), Storage (storage incompatibility), Storage (storage requirement), Storage (suitable container), Transport, Use
3.1.1.1	11/01/2019	One-off system update. NOTE: This may or may not change the GHS classification
3.1.2.1	04/26/2021	Regulation Change
3.1.3.1	05/03/2021	Regulation Change
3.1.4.1	05/06/2021	Regulation Change
3.1.5.1	05/10/2021	Regulation Change

Continued...

Firstmectin Se Selenised Endectocide and Tapewormer for Lambs

Version	Date of Update	Sections Updated
3.1.5.2	05/30/2021	Template Change
3.1.5.3	06/04/2021	Template Change
3.1.5.4	06/05/2021	Template Change
3.1.6.4	06/07/2021	Regulation Change
3.1.6.5	06/09/2021	Template Change
3.1.6.6	06/11/2021	Template Change
3.1.6.7	06/15/2021	Template Change
3.1.7.7	06/17/2021	Regulation Change
3.1.8.7	06/21/2021	Regulation Change
3.1.8.8	07/05/2021	Template Change
3.1.9.8	07/14/2021	Regulation Change
3.1.10.8	07/19/2021	Regulation Change
3.1.10.9	08/01/2021	Template Change
3.1.11.9	08/02/2021	Regulation Change
3.1.12.9	08/05/2021	Regulation Change
3.1.13.9	08/09/2021	Regulation Change
3.1.14.9	08/23/2021	Regulation Change
3.1.15.9	08/26/2021	Regulation Change
3.1.15.10	08/29/2021	Template Change
3.1.16.10	08/30/2021	Regulation Change
3.1.17.10	09/06/2021	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.

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
 KECl: 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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