

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

1.1. Product Identifier

Product name	SOLACYL, powder for oral solution
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1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Used in medicine as an analgesic, anti-inflammatory and antipyretic.
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1.3. Details of the supplier of the safety data sheet

Registered company name	Eurovet Animal Health B.V.
Address	Handelsweg 25, 5531 AE Bladel, The Netherlands
Telephone	+31 497 544300
Fax	+31 497 544302

SECTION 2 HAZARDS IDENTIFICATION


2.1. Classification of the substance or mixture

Considered a dangerous substance according to Reg. (EC) No 1272/2008 and its amendments. Not classified as Dangerous Goods for transport purposes.

DSD classification	R37/38	Irritating to respiratory system and skin.
	R41	Risk of serious damage to eyes.
	R22	Harmful if swallowed.

DPD classification	In case of substances classification has been prepared by following DSD (Directive 67/548/EEC) and CLP Regulation (EC) No 1272/2008 regulations
Classification according to regulation (EC) No 1272/2008 [CLP]	Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 2, Serious Eye Damage Category 1, STOT - SE (Resp. Irr.) Category 3

2.2. Label elements

CLP label elements	
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SIGNAL WORD	DANGER
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Hazard statement(s)

H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H335	May cause respiratory irritation

Precautionary statement(s) Prevention

P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P270	Do not eat, drink or smoke when using this product.

Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor/physician/first aider
P321	Specific treatment (see advice on this label).
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.
P302+P352	IF ON SKIN: Wash with plenty of water and soap
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P330	Rinse mouth.
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

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 chemical landfill or if organic to high temperature incineration
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DSD / DPD label elements

Relevant risk statements are found in section 2.1

Indication(s) of danger	Xn
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SAFETY ADVICE

S13	Keep away from food, drink and animal feeding stuffs.
S25	Avoid contact with eyes.
S26	In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
S36	Wear suitable protective clothing.
S37	Wear suitable gloves.
S39	Wear eye/face protection.
S40	To clean the floor and all objects contaminated by this material, use water.
S46	If swallowed, seek medical advice immediately and show this container or label.
S56	Dispose of this material and its container at hazardous or special waste collection point.
S64	If swallowed, rinse mouth with water (only if the person is conscious).

2.3. Other hazards

	Possible respiratory and skin sensitizer.
	Cumulative effects may result following exposure.
	May be harmful to the foetus/ embryo.

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

Contains 1000 mg/g sodium salicylate CAS number 54-21-7.

3.1. Substances

1. CAS No	54-21-7
2. EC No	200-198-0

Classification according to directive 67/548/EEC [DSD]

R37/38, R41, R22

SECTION 4 FIRST AID MEASURES**4.1. Description of first aid measures**

Eye Contact	<p>If this product comes in contact with the eyes:</p> <p>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.</p>
Skin Contact	<p>If skin contact occurs:</p> <p>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.</p>
Inhalation	<p>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.</p>

Ingestion	<p>IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.</p> <p>For advice, contact a Poisons Information Centre or a doctor. Urgent hospital treatment is likely to be needed. In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition. If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the MSDS should be provided. Further action will be the responsibility of the medical specialist. If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the MSDS.</p> <p>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</p> <p>INDUCE vomiting with fingers down the back of the throat, ONLY IF CONSCIOUS. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. NOTE: Wear a protective glove when inducing vomiting by mechanical means.</p>
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SECTION 5 FIREFIGHTING MEASURES

5.1. Extinguishing media

	<ul style="list-style-type: none"> ▸ Water spray or fog. ▸ Foam. ▸ Dry chemical powder. ▸ BCF (where regulations permit).
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5.2. 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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5.3. Advice for firefighters

Fire Fighting	<p>Alert Fire Brigade and tell them location and nature of hazard.</p> <p>Wear breathing apparatus plus protective gloves.</p> <p>Prevent, by any means available, spillage from entering drains or water courses.</p> <ul style="list-style-type: none"> ▸ Use water delivered as a fine spray to control fire and cool adjacent area.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▸ Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions. ▸ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions). ▸ Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.

SECTION 6 ACCIDENTAL RELEASE MEASURES

6.3. Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▸ Clean up waste regularly and abnormal spills immediately. ▸ Avoid breathing dust and contact with skin and eyes. ▸ Wear protective clothing, gloves, safety glasses and dust respirator. ▸ Use dry clean up procedures and avoid generating dust.
Major Spills	<p>Moderate hazard.</p> <p>CAUTION: Advise personnel in area.</p>

SECTION 7 HANDLING AND STORAGE

7.1. 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 sumps.
Other information	<ul style="list-style-type: none"> ▸ Store in original containers. ▸ Keep containers securely sealed. ▸ Store in a cool, dry area protected from environmental extremes. ▸ Store away from incompatible materials and foodstuff containers.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▸ Glass container is suitable for laboratory quantities ▸ Polyethylene or polypropylene container. ▸ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<ul style="list-style-type: none"> ▸ Avoid strong acids, bases. ▸ Avoid reaction with oxidising agents

Special precautions to be taken by the person administering the veterinary medicinal product to animals:


People with known hypersensitivity to sodium salicylate or related substances (e.g. aspirin) should avoid contact with the veterinary medicinal product. Irritation of the skin, eye, and respiratory tract might occur. During preparation and mixing of the product, direct contact with the skin and eyes and inhalation of the powder should be avoided. It is recommended to wear gloves, safety glasses, and a dust mask.

SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

EMERGENCY LIMITS

Ingredient	TEEL-0	TEEL-1	TEEL-2	TEEL-3
Natriumsalicylaat	40(ppm)	100(ppm)	500(ppm)	500(ppm)

8.2. Exposure controls

8.2.2. Personal protection	
Eye and face protection	<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: Chemical goggles. Face shield.</p>
Hand protection	<p>NOTE: 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>
Other protection	<p>For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.</p>

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Odourless white crystals or powder with an unpleasant sweetish saline taste; mixes with water (1;1). Soluble alcohol and glycerol. Becomes pink on long exposure to air.
Physical state	Divided Solid
Initial boiling point and boiling range (°C)	300
Solubility in water (g/L)	Miscible
Molecular weight (g/mol)	160.11

SECTION 10 STABILITY AND REACTIVITY

10.2. Chemical stability	<p>Presence of incompatible materials.</p> <ul style="list-style-type: none"> ▸ Product is considered stable. ▸ Hazardous polymerisation will not occur.
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SECTION 11 TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Inhaled	Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial number of individuals, following inhalation.
Ingestion	<p>Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual.</p> <p>Large oral doses of salicylates may cause mild burning pain in the throat, stomach and usually prompt vomiting. Several hours may elapse before the development of deep and rapid breathing, lassitude, anorexia, nausea, vomiting, thirst and occasional diarrhoea. Common derivatives of salicylic acid produce substantially the same toxic syndrome, ("salicylism").</p>
Skin Contact	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.
Eye	When applied to the eye(s) of animals, the material produces severe ocular lesions which are present twenty-four hours or more after instillation.

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Chronic	Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. Limited evidence shows that inhalation of the material is capable of inducing a sensitisation reaction in a significant number of individuals at a greater frequency than would be expected from the response of a normal population. Pulmonary sensitisation, resulting in hyperactive airway dysfunction and pulmonary allergy may be accompanied by fatigue, malaise and aching.
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Sodium salicylate	TOXICITY	IRRITATION
	Intraperitoneal (rat) LD50: 542 mg/kg	
	Oral (rat) LD50: 1200 mg/kg	
	Subcutaneous (rat) LD50: 980 mg/kg	

* Value obtained from manufacturer's MSDS
unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances

Acute Toxicity	Acute Toxicity (Oral) Category 4
Skin Irritation/Corrosion	Skin Corrosion/Irritation Category 2
Serious Eye Damage/Irritation	Serious Eye Damage Category 1
STOT - Single Exposure	STOT - SE (Resp. Irr.) Category 3

CMR STATUS

SECTION 12 ECOLOGICAL INFORMATION

12.1. Toxicity

DO NOT discharge into sewer or waterways.

SECTION 13 DISPOSAL CONSIDERATIONS

- Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. A Hierarchy of Controls seems to be common - the user should investigate:
 - Reduction.
 - 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.
 - 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 licenced to accept chemical and / or pharmaceutical wastes or incineration in a licenced apparatus (after admixture with suitable combustible material).
 - Observe all label safeguards until containers are cleaned and destroyed.
- According to the European Waste Catalogue, Waste Codes are not product specific but application specific. Waste Codes should be assigned by the User based on the application in which the product is used.

Product / Packaging disposal	Containers may still present a chemical hazard/ danger when empty.
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SECTION 14 TRANSPORT INFORMATION

Labels Required

HAZCHEM	Not Applicable
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NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: ADR, ICAO-IATA / DGR, IMDG-Code / GGVSee, ADN

SECTION 15 REGULATORY INFORMATION

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

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : 67/548/EEC, 1999/45/EC, 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Regulation (EU) No 453/2010, Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008 and their amendments.

SECTION 16 OTHER INFORMATION

The (M)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.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 16 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms

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