



SAFETY DATA SHEET

AceSedate 2 mg/mL

Issued: 18 June 2018

Version: 01

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

1.1 Product identification

Product Name: AceSedate 2 mg/ml solution for injection for dogs and cats

Product code: TBD

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

Relevant identified uses: Veterinary medicine. Solution for Injection used as Anaesthetic premedication, Tranquilisation aid and Sedative.

Uses advised against: For Animal use only – Not for use in humans.

Reason why uses advised against: The safety of the veterinary medicinal product has not been established in humans.

1.3 Details of the Supplier of the Safety Data Sheet

Supplier: JUROX (UK) Private Limited Company
Street:/P.O. Box: Second Floor, Richmond House, 105 High Street,
Postcode / City: Crawley, West Sussex RH10 1DD,
Country: UK
Telephone: +44 1293 510 681
E-mail (competent person): info@jurox.co.uk
National contact: richard.beckwith@jurox.co.uk

1.4 Emergency telephone number

Please contact: 01293 510681
Opening hours: 24 hours a day, 365 days a year
Other comments: Language(s) of the phone service: English

Section 2: HAZARDS IDENTIFICATION

2.1 Classification according to regulation (EC) No 1272/2008 [CLP]

Non-Hazardous.

2.2 Label elements

None.

2.3 Other hazards

Acepromazine is an antipsychotic drug. It affects a number of receptors in the brain. Side effects include sedation, drowsiness, confusion, apathy and depression, increased production of saliva, increased susceptibility to seizures, constipation, low blood pressure on standing up, heartbeat disturbances high prolactin levels (causing unwanted milk production, breast development in males, loss of periods in women, loss of sex drive and impotence), weight gain (especially with the atypical agents), extremely low white cell count, tardive dyskinesia (involuntary repetitive writhing movements), akathisia (restlessness), and worsening of psychiatric symptoms.

Section 3: COMPOSITION / INFORMATION ON ACTIVE INGREDIENTS

3.1 Substances

This product is a mixture. Health hazard information is based on its components.

3.2 Mixtures

1. CAS No. 2. EC No. 3. Index No. 4. REACH No.	% w/w	NAME	HAZARD (according to regulation (EC) No 1272/2008 [CLP])
1. 108-95-2 2. 203-632-7 3. 604-001-00-2 4. 01-2119471329-32-XXXX	0-1 %	Phenol	Acute Toxicity (Oral) Category 3 - H301, Acute Toxicity (Dermal) Category 3 - H311, Acute Toxicity (Inhalation) Category 3 - H331, Skin orrosion/Irritation Category 1B - H314, Germ cell mutagenicity Category 2 - H341, Specific target organ toxicity - repeated exposure Category 2 - H373
1. 3598-37-6 2. 222-748-9 3. Not Available 4. Not Available	0-1%	Acepromazine maleate	Acute Toxicity (Oral) Category 4 [H302]
1. Not Available 2. Not Available 3. Not Available 4. Not Available	>60%	Other non-hazardous ingredients	Not applicable

Section 4: FIRST AID MEASURES

4.1 Description of first aid measures

General Information:	Consult the National Poisons Information Service (dial 111) or a doctor immediately in every case of suspected chemical poisoning. DO NOT DRIVE as sedation may occur. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.
Following eye contact:	If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. If eye irritation persists, get medical advice/attention.
Following skin contact:	If skin contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention.
Following ingestion:	If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. Seek medical assistance.
Following injection:	Treat as for needle stick injury. Wash the wound thoroughly with soap and water or use a waterless cleanser or antiseptic if water is unavailable. Apply a dressing as necessary and apply pressure through the dressing if bleeding is still occurring. Do not squeeze or rub the injury site. Dispose of the needle in a suitable sharps container and seek medical advice/attention. Show the product label and this SDS to the doctor.
Following inhalation:	If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen and seek medical assistance immediately.
Self-protection of the first aider:	Protective glasses or goggles are recommended when handling bulk quantities of this product. When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and Effects of Exposure: Cardiac dysrhythmia and most important sedation may occur following rapid intravenous injection. Transient dose-dependent hypotension may occur in cases of accidental overdose.

4.3 Indication of any immediate medical attention and special treatment needed

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Treat symptomatically. Patients should be managed with intensive symptomatic and supportive therapy with particular attention being paid to the maintenance of oxygenation, respiratory, cardiovascular and renal functions.

Section 5: FIRE-FIGHTING MEASURES (BULK PRODUCT)**5.1 Extinguishing media**

Suitable extinguishing media: Use extinguishing media suitable for surrounding area.

Unsuitable extinguishing media: There is no restriction on the type of extinguisher which may be used.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products: If involved in a fire, may emit noxious or irritating fumes.

5.3 Advice for firefighters

Flammability: Not combustible. Not considered to be a significant fire risk, however containers may burn.

Protective equipment: Wear breathing apparatus plus protective gloves in the event of a fire.

Section 6: ACCIDENTAL RELEASE MEASURES (Large spills)**6.1 Personal precautions, protective equipment and emergency procedures****6.1.1 For non-emergency personnel**

Protective equipment: See Section 8.

Personal precautions: For large spills: Ventilate area. Clear area of excess personnel.

Emergency procedure:

For small spills: Wash area well with excess water.

For large spills: Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Wash spill site after pick-up complete. Dispose of waste safely according to local regulations.

For individual vials: Dispose of any unused veterinary medicinal product or empty containers in accordance with label directions.

6.1.2 For emergency responders

Protective equipment: See Section 8.

Personal precautions: For large spills: Ventilate area.

Emergency procedure:

For small spills: Wash area well with excess water.

For large spills: Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Wash spill site after pick-up complete. Dispose of waste safely according to local regulations.

For individual vials: Dispose of any unused veterinary medicinal product or empty containers in accordance with label directions.

6.2 Environmental precautions

Spillage: Prevent spillage from entering drains or waterways.

6.3 Methods and material for containment and cleaning up**6.3.1 Containment techniques:** See Section 6.1.**6.3.2 Clean-up procedures**

Decontamination procedure: Water can be used for clean-up and decontamination operations. No specific decontamination or detoxification procedures have been identified for this substance.

6.4 Reference to other sections

See Section 8 for Personal Protection and Section 13 for Disposal Considerations.

Section 7: HANDLING AND STORAGE**7.1 Precautions for safe handling**

Protective measures: The product should be handled with care to avoid exposure. Avoid contact with skin, eyes and inhalation of vapours. Take care to avoid accidental self-injection. Use personal protective equipment as required.

Measures to prevent fire: Keep the product away from combustibles.
Measures to prevent aerosol and dust generation: Not applicable.
Measures to protect the environment: Prevent spillage from entering drains or waterways.
Advice on general occupational hygiene: Do not eat, drink or smoke when handling this product.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions: Do not store above 30°C. Keep out of the sight and reach of children. Protect from light. Do not freeze. Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton.

Packaging materials: Store product in original packaging.

Requirements for storage rooms and vessels: Keep storage area free from debris, wastes and combustibles.

7.3 Specific end use(s)

See Section 1.2. Use individual vials according to label directions. Always read the label before use. See label for further information on handling and storage.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

8.1 Control parameters

Derived No Effect Level (DNEL): Not available.

Predicted No Effect Level (PNEC): Not available.

Occupational Exposure Limits (OEL):

Source	INGREDIENT	TWA	STEL
UK Workplace Exposure Limits (WELs)	Phenol	2 ppm / 7.8 mg/m ³	16 mg/m ³ / 4 ppm

8.2 Exposure controls

8.2.1 Appropriate engineering controls:

Engineering Controls: Use only in a well-ventilated area. Make sure that the work environment remains clean and that vapours and mists are minimised.

8.2.2 Individual protection measures, such as personal protective equipment:

Protective Equipment:

Eye Protection: Protective glasses or goggles are recommended when handling bulk quantities of this product.

Skin Protection: When handling bulk product, prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory Protection: Not required for the normal use of this product.

Other: For the bulk product, overalls, PVC apron or protective suit. Have eyewash unit at hand. Ensure there is ready access to a safety shower.

Thermal Hazards: Not available.

8.2.3 Environmental exposure controls: See Section 12.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

(a) APPEARANCE: Pale yellow solution	(h) EVAPORATION RATE: Not available	(o) PARTITION CO-EFFICIENT (n-octanol / water): Not available
(b) ODOUR: Not available	(i) FLAMMABILITY (SOLID, GAS): Not applicable	(p) AUTO-IGNITION TEMPERATURE (°C): Not applicable
(c) ODOUR THRESHOLD: Not available	(j) UPPER / LOWER EXPLOSIVE LIMITS (%): Not applicable	(q) DECOMPOSITION TEMPERATURE: Not available
(d) pH: 4.5 – 5.5	(k) VAPOUR PRESSURE (kPa): Not available	(r) VISCOSITY (cSt): Not available

(e) MELTING POINT / FREEZING POINT (°C): Not available.	(l) VAPOUR DENSITY (Air = 1): Not available	(s) EXPLOSIVE PROPERTIES: Not available
(f) INITIAL BOILING POINT AND BOILING RANGE (°C): Not available	(m) RELATIVE DENSITY (Water = 1): 1	(t) OXIDISING PROPERTIES: Not available
(g) FLASH POINT (°C): Not combustible	(n) SOLUBILITY IN WATER (g/L): Miscible	

Section 10: STABILITY AND REACTIVITY

10.1 Reactivity

This product is unlikely to react or polymerise under normal storage conditions.

10.2 Chemical stability

When stored appropriately this product should show no significant degradation before the date of expiry on the container.

10.3 Possibility of hazardous reactions

Unlikely under normal storage conditions.

10.4 Conditions to avoid

Protect this product from light.

10.5 Incompatible materials

Oxidising agents.

10.6 Hazardous decomposition products.

No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute Toxicity:

Ingestion: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route.

Acepromazine maleate: Oral (rat) LD₅₀: 400 mg/kg

Phenol: Oral (rat) LD₅₀: 317 mg/kg

Inhalation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route.

Phenol: Inhalation (rat) LC₅₀: 0.316 mg/l/4H

Dermal: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

Injection: Avoid needle stick injury.

Acepromazine maleate: Intravenous (rat) LD₅₀: 95mg/kg

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin irritant.

Serious Eye Damage / Irritation: Based on available data for the ingredients, the mixture is not considered to be an eye irritant.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin sensitiser or respiratory sensitiser.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic. However, there has been some concern that antipsychotic drugs can cause mutations but there is not enough data to make an assessment.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic. However, there has been some concern that there is an increase in the incidence of breast and pancreas cancer which may be common adverse effects of antipsychotic dopamine antagonists but there is no enough data to make an assessment.

Reproductive Toxicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant. There is some evidence from animal studies that there is a possibility that repeated exposure to antipsychotic drugs may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother.

Specific Target Organ Toxicity (STOT): Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure.

Specific Target Organ Toxicity (STOT): Repeated exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after repeat exposure.

Aspiration Hazard: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard.

Section 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an ecotoxic.

<i>Fish:</i>	Acepromazine maleate: Phenol:	No data. LC ₅₀ (96 hr): 0.00175 mg/L BCF(24 hr)L: 60 mg/L
<i>Crustacea:</i>	Acepromazine maleate: Phenol:	No data. EC ₅₀ (48 hr): 3.1 mg/L NOEC (144 HR): 0.01 mg/L
<i>Algae or other aquatic plants:</i>	Phenol:	EC ₅₀ (96 hr): 0.0611 mg/L

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Phenol	LOW (Half-life = 10 days)	LOW (Half-life = 0.95 days)

12.3 Bioaccumulative potential

Ingredient	Bioaccumulation
Phenol	LOW (BCF = 17.5)

12.4 Mobility in soil

Ingredient	Mobility
Phenol	LOW (KOC = 268)

12.5 Results of PBT and vPvB assessment

No data is available on the product.

12.6 Other adverse effects

No data is available on the product.

Section 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

13.1.1 Product / Packaging disposal: Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with the label instructions and local regulations and procedures.

13.1.2 Waste treatment options: Not Available.

13.1.3 Sewage disposal options: Not Available.

Section 14: TRANSPORT INFORMATION

The product is not regulated for transport of Dangerous Goods (by land, sea or air).

14.1 UN number

Not applicable.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Class: Not applicable; Subrisk: Not applicable.

14.4 Packing Group

Not applicable.

14.5 Environmental hazards

Not applicable. The product is not a marine pollutant.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

Section 15: REGULATORY INFORMATION**15.1 Safety, health and environmental regulations / legislation specific for the substance or mixture**

Acepromazine maleate(3598-37-6) is found on the following regulatory lists

- European Customs Inventory of Chemical Substances ECICS (English).
- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English).

Phenol (108-95-2) is found on the following regulatory lists

- *EU Consolidated List of Indicative Occupational Exposure Limit Values (IOELVs).*
- *EU REACH Regulation (EC) No 1907/2006 - Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.*
- *European Customs Inventory of Chemical Substances ECICS (English).*

15.2 Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

Section 16: OTHER INFORMATION**Abbreviations and acronyms**

BCF	BioConcentration Factors.
CLP	The CLP Regulation (for "Classification, Labelling and Packaging") is a European Union regulation from 2008 which aligns the European Union system of classification, labelling and packaging of chemical substances and mixtures to the Globally Harmonised System (GHS).
EC	European Commission.
EC ₅₀	The median effect concentration, being a statistically derived concentration of a substance that can be expected to cause an adverse reaction in 50% of organisms or a 50% reduction in growth or in the growth rate of organisms.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
HAZCHEM Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
KOC	Soil/water partition coefficient.
LC ₅₀	The median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of animals.
LD ₅₀	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
Log-KOW	The logarithm of the KOW (Octanol Water Partition Coefficient). The KOW is the ratio of a compound's concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium.
NOEC	No Observed Effect Concentration.
POM-V	Prescription Only Medicine – Veterinarian (UK).
pH	Partial pressure of Hydrogen.
PVC	Polyvinyl chloride.
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals. This is the key chemical control regulation in the European Union.
SDS	Safety Data Sheet.
STEL	Short Term Exposure Limit.
TWA	Time Weighted Average.
UN	United Nations.
UN Number	Number identifying a hazardous substance, assigned by the United Nations Committee of Experts on the Transport of Dangerous Goods.
VPO	Veterinary Practitioner Only.
UK	United Kingdom.
WEL	Workplace Exposure Limit.

Full text of Hazard Statements referred to under section 3

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H314	Causes severe skin burns and eye damage.
H341	Suspected of causing genetic defects.
H373	May cause damage to organs through prolonged or repeated exposure.
H302	Harmful if swallowed.



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References

1. ChemID Plus (A Toxnet Database) <https://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
2. EPA New Zealand Chemical Classification and Information Database (CCID) <http://www.epa.govt.nz/search-databases/Pages/HSNO-CCID.aspx>
3. Hazardous Substances Data Bank (HSDB)(A Toxnet Database) <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>

This Version Issued: 18 June 2018

Supersedes: This is the first SDS for the product.

Disclaimer

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END OF SDS