

Section 1. Identification

Product identifier : Elanco AH0323 Oestradiol Compudose 200; Elanco AH0343 Oestradiol Compudose 400; Elanco AH0351 Oestradiol Compudose 100

Product code : 124000000210

Other means of identification : 033636 Formulation; AH0320; AH0323; AH0327; AH0340; AH0343; AH0347; AH0351; AH0370; AH0373; AH0918; AH0919; Compudose 100; Compudose 200; Compudose 400; Controlled Release Implant; Elanco AH0323 Oestradiol Compudose 200; Elanco AH0343 Oestradiol Compudose 400; Elanco AH0351 Oestradiol Compudose 100; Encore; Estra-1,3,5(10)-triene-3,17-diol (17beta)-; Estradiol Implants; QA330A; Shur-Gain; SI6480; UC5190; UC5199

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

Identified uses : Veterinary pharmaceutical.

Uses advised against : None known.

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Section 2. Hazard(s) identification

Classification of the substance or mixture : CARCINOGENICITY - Category 1
REPRODUCTIVE TOXICITY - Category 1
REPRODUCTIVE TOXICITY - Effects on or via lactation
SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Percentage of the mixture consisting of ingredient(s) of unknown hazards to the aquatic environment: 95%

GHS label elements

Hazard pictograms :



Signal word : DANGER

Hazard statements : H350 - May cause cancer.
H360 - May damage fertility or the unborn child.
H362 - May cause harm to breast-fed children.
H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements

Section 2. Hazard(s) identification

- Prevention** : P201 - Obtain special instructions before use.
P281 - Use personal protective equipment as required.
P273 - Avoid release to the environment.
P263 - Avoid contact during pregnancy or while nursing.
P270 - Do not eat, drink or smoke when using this product.
- Response** : P391 - Collect spillage.
P308 + P313 - IF exposed or concerned: Get medical advice or attention.
- Storage** : P405 - Store locked up.
- Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
- Supplemental label elements** : Not applicable.

Other hazards which do not result in classification : None known.

Section 3. Composition and ingredient information

Substance/mixture : Mixture

| Ingredient name | % (w/w) | CAS number |
|-------------------------------|---------|------------|
| estradiol | ≤10 | 50-28-2 |
| estradiol benzoate | ≤5 | 50-50-0 |
| oxytetracycline hydrochloride | ≤0.3 | 2058-46-0 |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.

Section 4. First aid measures

- Skin contact** : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
Inhalation : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations
Skin contact : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations
Ingestion : Adverse symptoms may include the following:
reduced foetal weight
increase in foetal deaths
skeletal malformations

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments : No specific treatment.
Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Firefighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : This material is very toxic to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities. Collect spillage.

Methods and material for containment and cleaning up

Small spill : Move containers from spill area. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill : Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Avoid contact during pregnancy or while nursing. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid release to the environment. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls and personal protection

Control parameters

Occupational exposure limits

| Ingredient name | Exposure limits |
|-----------------|-----------------|
| None. | |

- Appropriate engineering controls** : If user operations generate dust, fumes, gas, vapour or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties and safety characteristics

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

- Physical state** : Solid.
- Colour** : Yellow. [Light]
- Odour** : Odourless.
- Odour threshold** : Not available.
- pH** : Not available.

Section 9. Physical and chemical properties and safety characteristics

| | |
|--|---|
| Melting point/freezing point | : Not available. |
| Boiling point, initial boiling point, and boiling range | : Not available. |
| Flash point | : Not applicable. |
| Evaporation rate | : Not available. |
| Flammability | : Not available. |
| Lower and upper explosion limit/flammability limit | : Not applicable. |
| Vapour pressure | : Not available. |
| Relative vapour density | : Not applicable. |
| Relative density | : Not available. |
| Solubility | : Insoluble in the following materials: cold water and hot water. |
| Solubility in water | : Not available. |
| Partition coefficient: n-octanol/water | : Not applicable. |
| Auto-ignition temperature | : Not applicable. |
| Decomposition temperature | : Not available. |
| Viscosity | : Not applicable. |
| Flow time (ISO 2431) | : Not available. |
| Particle characteristics | |
| Median particle size | : Not available. |

Section 10. Stability and reactivity

| | |
|---|--|
| Reactivity | : No specific test data related to reactivity available for this product or its ingredients. |
| Chemical stability | : The product is stable. |
| Possibility of hazardous reactions | : Under normal conditions of storage and use, hazardous reactions will not occur. |
| Conditions to avoid | : No specific data. |
| Incompatible materials | : No specific data. |
| Hazardous decomposition products | : Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

| Product/ingredient name | Result | Species | Dose | Exposure |
|-------------------------------|-----------|---------|------------|----------|
| oxytetracycline hydrochloride | LD50 Oral | Rat | 6696 mg/kg | - |

Irritation/Corrosion

Not available.

Sensitisation

Not available.

Mutagenicity

Section 11. Toxicological information

Not available.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Not available.

Potential acute health effects

| | |
|---------------------|---|
| Eye contact | : No known significant effects or critical hazards. |
| Inhalation | : No known significant effects or critical hazards. |
| Skin contact | : No known significant effects or critical hazards. |
| Ingestion | : No known significant effects or critical hazards. |

Symptoms related to the physical, chemical and toxicological characteristics

| | |
|---------------------|---|
| Eye contact | : No specific data. |
| Inhalation | : Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations |
| Skin contact | : Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations |
| Ingestion | : Adverse symptoms may include the following: reduced foetal weight increase in foetal deaths skeletal malformations |

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

| | |
|------------------------------------|------------------|
| Potential immediate effects | : Not available. |
| Potential delayed effects | : Not available. |

Long term exposure

| | |
|------------------------------------|------------------|
| Potential immediate effects | : Not available. |
| Potential delayed effects | : Not available. |

Potential chronic health effects

Not available.

| | |
|----------------|---|
| General | : No known significant effects or critical hazards. |
|----------------|---|

Section 11. Toxicological information

| | |
|------------------------------|---|
| Carcinogenicity | : May cause cancer. Risk of cancer depends on duration and level of exposure. |
| Mutagenicity | : No known significant effects or critical hazards. |
| Reproductive toxicity | : May damage fertility or the unborn child. May cause harm to breast-fed children. |

Numerical measures of toxicity

Acute toxicity estimates

| Product/ingredient name | Oral (mg/kg) | Dermal (mg/kg) | Inhalation (gases) (ppm) | Inhalation (vapours) (mg/l) | Inhalation (dusts and mists) (mg/l) |
|-------------------------------|--------------|----------------|--------------------------|-----------------------------|-------------------------------------|
| oxytetracycline hydrochloride | 6696 | N/A | N/A | N/A | N/A |

Section 12. Ecological information

Toxicity

| Product/ingredient name | Result | Species | Exposure |
|----------------------------------|---|---|---------------------|
| Compudose estradiol | LC50 1493.938598633 mg/l | Fish | 96 hours |
| | Acute EC50 >3.1 mg/l | Algae | 72 hours |
| | Acute EC50 2.04 mg/l Fresh water | Daphnia - Daphnia magna - Neonate | 48 hours |
| | Acute LC50 1.69 mg/l Marine water | Crustaceans - Americamysis bahia - Larvae | 48 hours |
| | Acute LC50 2 ng/L Fresh water | Fish - Oryzias latipes - Sexually mature | 96 hours |
| | Chronic NOEC 0.523 mg/l | Algae - Pseudokirchnerella subcapitata | 72 hours |
| | Chronic NOEC 6 µg/l Fresh water | Crustaceans - Eurytemora affinis - Nauplii | 21 days |
| | Chronic NOEC 0.2 mg/l Chronic NOEC 0.42 ng/L Fresh water | Daphnia - Daphnia magna Fish - Oncorhynchus mykiss - Sexually mature | 48 hours 50 days |
| estradiol benzoate | Acute EC50 >3.1 mg/l | Algae | 72 hours |
| | Acute EC50 2.87 mg/l | Daphnia - Daphnia magna | 48 hours |
| | Chronic LC50 0.000002 mg/l | Fish - Oryzias latipes | 96 hours |
| | Chronic NOEC 0.523 mg/l | Algae - Pseudokirchnerella subcapitata | 72 hours |
| oxytetracycline hydrochloride | Chronic NOEC 0.2 mg/l | Daphnia - Daphnia magna | 48 hours |
| | Acute EC50 0.342 mg/l Fresh water | Algae - Pseudokirchneriella subcapitata | 72 hours |
| | Acute EC50 3.1 mg/l Fresh water | Algae - Pseudokirchneriella subcapitata - Exponential growth phase | 96 hours |
| | Acute EC50 114 mg/l Fresh water | Daphnia - Daphnia magna - Neonate | 48 hours |
| | Acute LC50 805.99 mg/l Marine water | Crustaceans - Artemia parthenogenetica - Nauplii | 48 hours |
| | Acute LC50 75000 µg/l Fresh water | Fish - Morone saxatilis - Fingerling | 96 hours |
| | Chronic NOEC 0.183 mg/l Fresh water | Algae - Pseudokirchneriella subcapitata | 72 hours |
| | Chronic NOEC 3.08 mg/l Fresh water | Daphnia - Daphnia magna - Neonate | 21 days |
| Chronic NOEC 50 mg/l Fresh water | Fish - Oryzias latipes - Embryo | 100 days | |

Persistence and degradability

Bioaccumulative potential

Section 12. Ecological information

| Product/ingredient name | LogP _{ow} | BCF | Potential |
|-------------------------|--------------------|-----|-----------|
| estradiol | 4.01 | - | high |
| estradiol benzoate | 4.01 | - | high |

Mobility in soil

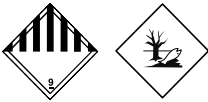
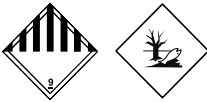
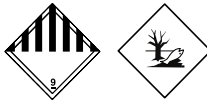

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

| | ADG | ADR/RID | IMDG | IATA |
|-----------------------------------|--|--|---|--|
| UN number | UN3077 | UN3077 | UN3077 | UN3077 |
| UN proper shipping name | Environmentally hazardous substance, solid, n.o.s. (estradiol) | Environmentally hazardous substance, solid, n.o.s. (estradiol) | Environmentally hazardous substance, solid, n.o.s. (estradiol) | Environmentally hazardous substance, solid, n.o.s. (estradiol) |
| Transport hazard class(es) | 9  | 9  | 9  | 9  |
| Packing group | III | III | III | III |
| Environmental hazards | Yes. | Yes. | Yes. | Yes. |

Additional information

ADG : The product is not regulated as a dangerous good when transported by road or rail in either an IBC, or in other container types if ≤500 kg. This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

ADR/RID : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

IMDG : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8.

IATA : This product is not regulated as a dangerous good when transported in sizes of ≤5 L or ≤5 kg, provided the packagings meet the general provisions of 5.0.2.4.1, 5.0.2.6.1.1 and 5.0.2.8.

Section 14. Transport information

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

National regulations

Standard for the Uniform Scheduling of Medicines and Poisons

5

Model Work Health and Safety Regulations - Scheduled Substances

No listed substance

APVMA Approval Number : 46230; 36799; 36789

Inventory list

Australia : Not determined.

Section 16. Any other relevant information

History

Date of issue/Date of revision : 8/6/2022

Date of previous issue : 8/2/2022

Version : 0.03

Key to abbreviations : ADG = Australian Dangerous Goods
ADR = The European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
SGG = Segregation Group
SUSMP = Standard Uniform Schedule of Medicine and Poisons
UN = United Nations

Procedure used to derive the classification

| Classification | Justification |
|---|--------------------|
| CARCINOGENICITY - Category 1 | Calculation method |
| REPRODUCTIVE TOXICITY - Category 1 | Calculation method |
| REPRODUCTIVE TOXICITY - Effects on or via lactation | Calculation method |
| SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1 | Calculation method |
| LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1 | Calculation method |

References : Not available.

Indicates information that has changed from previously issued version.

Notice to reader

Section 16. Any other relevant information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANT ABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

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