

Fentadon

GHS Safety Data Sheet (Conforms to Regulation (EC) No 1907/2006, Article 31.)

Issue Date: 4-Mar-2012

Version No: 3.1.1.1

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Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Fentadon

PRODUCT USE

Used according to manufacturer's directions.

Adverse effects on the foetus cannot be excluded. Pregnant women should avoid handling the product. In case of breastfeeding women being accidentally exposed, breastfeeding is discouraged for 24 hours, as fentanyl may transfer to breast milk.

SUPPLIER

Company: Eurovet Animal Health BV

Address: Handelsweg 25

5531 AE Bladel

Netherlands

Telephone: +31 497 544 300

Fax: +31 497 544 302

Section 2 - HAZARDS IDENTIFICATION

GHS Classification

STOT - RE Category 2



EMERGENCY OVERVIEW

HAZARD

WARNING

H373 May cause damage to organs through prolonged or repeated exposure.

PRECAUTIONARY STATEMENTS

Prevention

Code

P260

Phrase

Do not breathe dust/fume/gas/mist/vapours/spray.

Response

Code

P314

Phrase

Get medical advice/attention if you feel unwell.

Disposal

Code

P501

Phrase

Dispose of contents/container to ...

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

Composition:

Contains per ml solution:

50 microgram fentanyl (equivalent to 78.5 microgram fentanyl citrate), CAS RN 990-73-8 and excipients propyl paraben, CAS RN 94-13-3 and methyl paraben, CAS RN 99-76-3

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Section 4 - FIRST AID MEASURES

SWALLOWED

- 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.

EYE

- 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.
 - 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

- If skin contact occurs:
 - Quickly but gently, wipe material off skin with a dry, clean cloth.
 - Immediately remove all contaminated clothing, including footwear.
 - Wash skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre.
 - Transport to hospital, or doctor.
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation may occur.

INHALED

- If fumes or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

NOTES TO PHYSICIAN

Treat symptomatically for a narcotic analgesic.

A vigorous program of symptomatic and supportive therapy has saved many victims of poisoning.

GOSSELIN et al: Clinical Toxicology of Commercial Products.

Treat symptomatically.

Fentanyl is an opioid whose toxicity may cause clinical effects including respiratory depression or apnoea, sedation, hypotension and coma. When respiratory depression occurs controlled ventilation should be installed. Administration of the opioid antagonist naloxone to reverse the symptoms is recommended.

Section 5 - FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

FIRE FIGHTING

- 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.

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FIRE/EXPLOSION HAZARD

- Non combustible.
- Not considered a significant fire risk, however containers may burn.
- May emit poisonous fumes.
- May emit corrosive fumes.

FIRE INCOMPATIBILITY

- None known.

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- 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.

MAJOR SPILLS

Moderate hazard.

- 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.

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

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- DO NOT allow clothing wet with material to stay in contact with skin.
- 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.
- Special precautions to be taken by the person administering the veterinary medicinal product to animals:
 - Wear gloves.
 - Wash hands after use.
 - Care should be taken to avoid accidental self-injection.
 - In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation may occur.

SUITABLE CONTAINER

- Packaging as recommended by manufacturer.
- Check that containers are clearly labelled.
- Tamper-proof containers.
- Polyethylene or polypropylene containers.

STORAGE INCOMPATIBILITY

None known.

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STORAGE REQUIREMENTS

NOTE: Special security requirements may be mandated under Federal/State Regulation(s).

- Store in original containers.
- Store in vault fitted with warning devices or detectors recommended by various Federal/State authorities.
- Store in vault used only for the purpose of storage of drugs of addiction.
- Vault must be locked at all times except when the materials stored therein are required.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records:

- fentanyl citrate: CAS:990- 73- 8
- propyl paraben: CAS:94- 13- 3
- methyl paraben: CAS:99- 76- 3

PERSONAL PROTECTION

RESPIRATOR

- Particulate. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

EYE

- 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 lens 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].

HANDS/FEET

- Wear chemical protective gloves, e.g. PVC.
- Wear safety footwear or safety gumboots, e.g. Rubber.

The selection of the 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.

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.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:

OTHER

- Overalls.
- P.V.C. apron.
- Barrier cream.
- Skin cleansing cream.

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ENGINEERING CONTROLS

■ Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

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.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Clear liquid; miscible with water, stored in uncoloured glass vials with a chlorobutyl rubber stopper and secured with an aluminium cap.

PHYSICAL PROPERTIES

Liquid.

Mixes with water.

State	liquid
Melting Range (°C)	0 approx
Boiling Range (°C)	100 approx
Viscosity	as for water cSt@40°C
Solubility in water (g/L)	miscible
Vapour Pressure (kPa)	as for water
Specific Gravity (water=1)	1 approx
Relative Vapour Density (air=1)	as for water
Evaporation Rate	as for water

Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.
- Hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Morphine and other analgesics cause nausea, vomiting, constipation, drowsiness and confusion. Urination can be difficult, and the bowel and bile ducts can spasm.

■ 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.

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EYE

■ Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).

SKIN

■ There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons.

■ Contact dermatitis has been reported with morphine and other narcoticanalgesics.

■ Open cuts, abraded or irritated skin should not be exposed to this material.

■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

■ Skin contact with the material may be harmful; systemic effects may result following absorption.

CHRONIC HEALTH EFFECTS

Substance accumulation, in the human body, is likely and may cause some concern following repeated or long-term occupational exposure.

Chronic morphine poisoning or addiction causes pin-point pupils, rapid mood changes and poor social adaptation. As dependence and tolerance occurs, there is an overwhelming need to continue taking the drug or similar drugs and to increase the dose. Prolonged therapy or abuse may cause abnormal lung function, increased body temperature, and kidney failure. Withdrawal symptoms can last for months. Abrupt withdrawal of the opiates may produce yawning, dilated pupils, tears, runny nose, sneezing, muscle tremor, headache, weakness, sweating, anxiety, irritability, disturbed sleep or insomnia, restlessness, orgasm, loss of appetite, nausea, vomiting, loss of weight, diarrhoea, dehydration, increase in the number of white blood cells, bone pain, abdominal and muscle cramps, increase in heart rate, breathing rate and blood pressure, rise in temperature and gooseflesh and blood vessel dilation or constriction.

TOXICITY AND IRRITATION

■ No significant acute toxicological data identified in literature search.

Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.

Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema.

Section 12 - ECOLOGICAL INFORMATION

No data.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
fentanyl citrate	No Data Available	No Data Available	No Data Available	No Data Available
propyl paraben	LOW	No Data Available	LOW	MED
methyl paraben	LOW	No Data Available	LOW	MED

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Section 13 - DISPOSAL CONSIDERATIONS

■ Valuable substance, hold all residues for recovery. Disposal of the material must be carried out in accordance with the requirements of the relevant Federal/State Act(s) or Code(s) regulating the disposal of Drugs of Addiction

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 manufacturer or local or regional waste management authority for disposal if no suitable 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 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.

Section 14 - TRANSPORTATION INFORMATION

HAZCHEM:

None

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: ADR, IATA, IMDG

Section 15 - REGULATORY INFORMATION

RISK

Risk Codes

R33

Risk Phrases

- Danger of cumulative effects.

SAFETY

Safety Codes

S23

S24

Safety Phrases

- Do not breathe gas/ fumes/ vapour/ spray.
- Avoid contact with skin.

REGULATIONS

Regulations for ingredients

fentanyl citrate (CAS: 990-73-8) is found on the following regulatory lists;

"European Chemical Agency (ECHA) Classification & Labelling Inventory - Chemwatch Harmonised classification", "European Chemical Agency (ECHA) Classification & Labelling Inventory - Notified classification and labelling according to CLP criteria", "European Customs Inventory of Chemical Substances (English)", "European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)", "European Union (EU) Directive 2008/1/EC concerning integrated pollution prevention and control, Annex III", "Sigma-AldrichTransport Information", "UK The Environmental Protection (Prescribed Processes and

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Substances) Regulations 1991 - Release into Air Prescribed Substances", "United Nations List of Narcotic Drugs Under International Control - Section 1"

propyl paraben (CAS: 94-13-3) is found on the following regulatory lists;

"EU Cosmetic Directive 76/768/EEC Annex VI Part 1 List of Preservatives Allowed (English)", "EU Cosmetic Directive 76/768/EEC Annex VI Part 1 List of Preservatives Allowed (German)", "Europe Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food - Annex I: Substances", "Europe ECHA Substances identified by industry to be registered by 31 May 2013", "Europe SCCNFP First Update of the Inventory of Ingredients Employed in Cosmetic Products - Section II: Perfume and Aromatic Raw Materials", "Europe Substances Listed in EU Directives on Plastics in Contact with Food", "European Chemical Agency (ECHA) Classification & Labelling Inventory - Chemwatch Harmonised classification", "European Chemical Agency (ECHA) Classification & Labelling Inventory - Notified classification and labelling according to CLP criteria", "European Customs Inventory of Chemical Substances (English)", "European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)", "European Union (EU) Inventory of Fragrance Ingredients (Perfume and Aromatic Raw Materials)", "European Union (EU) Inventory of Ingredients used in Cosmetic Products", "FisherTransport Information", "International Chemical Secretariat (ChemSec) SIN List (*Substitute It Now!)", "International Fragrance Association (IFRA) Survey: Transparency List", "International Numbering System for Food Additives", "Sigma-AldrichTransport Information", "UK The Environmental Protection (Prescribed Processes and Substances) Regulations 1991 - Release into Air Prescribed Substances"

methyl paraben (CAS: 99-76-3) is found on the following regulatory lists;

"EU Cosmetic Directive 76/768/EEC Annex VI Part 1 List of Preservatives Allowed (English)", "EU Cosmetic Directive 76/768/EEC Annex VI Part 1 List of Preservatives Allowed (German)", "EU European Chemicals Agency (ECHA) Community Rolling Action Plan (CoRAP) List of Substances", "Europe Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food - Annex I: Substances", "Europe ECHA Registered Substances - Classification and Labelling - DSD-DPD", "Europe ECHA Registered Substances - Classification and Labelling - GHS", "Europe European Chemicals Agency (ECHA) List of Registered Phase-in Substances", "Europe European Chemicals Agency (ECHA) List of Registered Substances", "Europe European Chemicals Agency (ECHA) List of substances identified for registration in 2010", "Europe Substances Listed in EU Directives on Plastics in Contact with Food", "European Chemical Agency (ECHA) Classification & Labelling Inventory – Chemwatch Harmonised classification", "European Chemical Agency (ECHA) Classification & Labelling Inventory - Notified classification and labelling according to CLP criteria", "European Customs Inventory of Chemical Substances (English)", "European Trade Union Confederation (ETUC) Priority List for REACH Authorisation", "European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)", "European Union (EU) Inventory of Ingredients used in Cosmetic Products", "FEMA Generally Recognized as Safe (GRAS) Flavoring Substances 23 - Examples of FEMA GRAS Substances with Non-Flavor Functions", "FisherTransport Information", "International Council of Chemical Associations (ICCA) - High Production Volume List", "International Fragrance Association (IFRA) Survey: Transparency List", "International Numbering System for Food Additives", "Sigma-AldrichTransport Information", "UK The Environmental Protection (Prescribed Processes and Substances) Regulations 1991 - Release into Air Prescribed Substances"

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/EEC, 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.

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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.

■ 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

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices.

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Issue Date: 4-Mar-2012

Print Date: 11-Feb-2013