1 Identification

- Product identifier
- Trade name: Fentanyl (hydrochloride)
- Article number: 14719
- CAS Number: 1443-54-5
- EC number: 685-598-7

2 Hazard(s) identification

- Classification of the substance or mixture
  - GHS06 Skull and crossbones
    - Acute Tox. 1 H300 Fatal if swallowed.
    - Acute Tox. 1 H330 Fatal if inhaled.
  - GHS09 Environment
    - Aquatic Acute 1 H400 Very toxic to aquatic life.
Hazard pictograms

GHS06  GHS09

Signal word: Danger

Hazard statements:
H300+H330 Fatal if swallowed or if inhaled.
H400 Very toxic to aquatic life.

Precautionary statements:
P260 Do not breathe dust/fume/gas/mist/vapors/spray.
P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P273 Avoid release to the environment.
P284 [In case of inadequate ventilation] wear respiratory protection.
P301+P310 If swallowed: Immediately call a poison center/doctor.
P330 Rinse mouth.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P320 Specific treatment is urgent (see on this label).
P391 Collect spillage.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system:

NFPA ratings (scale 0 - 4)

- Health = 4
- Fire = 0
- Reactivity = 0

HMIS-ratings (scale 0 - 4)

- Health = 4
- Fire = 0
- Reactivity = 0

Other hazards:

Results of PBT and vPvB assessment:

- PBT: Not applicable.
- vPvB: Not applicable.

3 Composition/information on ingredients

Chemical characterization: Substances

CAS No. Description
1443-54-5 Fentanyl (hydrochloride)

Identification number(s)

EC number: 685-598-7
4 First-aid measures

- Description of first aid measures
  - General information:
    Immediately remove any clothing soiled by the product.
    Remove breathing apparatus only after contaminated clothing have been completely removed.
    In case of irregular breathing or respiratory arrest provide artificial respiration.
  - After inhalation:
    Supply fresh air or oxygen; call for doctor.
    In case of unconsciousness place patient stably in side position for transportation.
  - After skin contact:
    Immediately wash with water and soap and rinse thoroughly.
  - After eye contact:
    Rinse opened eye for several minutes under running water. Then consult a doctor.
  - After swallowing:
    If symptoms persist consult doctor.
- Information for doctor:
  - Most important symptoms and effects, both acute and delayed
    May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude
    (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects.
    No further relevant information available.
  - Indication of any immediate medical attention and special treatment needed
    No further relevant information available.

5 Fire-fighting measures

- Extinguishing media
  - Suitable extinguishing agents:
    Use fire fighting measures that suit the environment.
    A solid water stream may be inefficient.
- Special hazards arising from the substance or mixture
  No further relevant information available.
- Advice for firefighters
  - Protective equipment:
    Mouth respiratory protective device.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  Not required.
- Environmental precautions:
  Do not allow to enter sewers/ surface or ground water.
- Methods and material for containment and cleaning up:
  Dispose contaminated material as waste according to item 13.
  Ensure adequate ventilation.
- Reference to other sections
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.
- Protective Action Criteria for Chemicals
  - PAC-1: Substance is not listed.
  - PAC-2: Substance is not listed.
  - PAC-3: Substance is not listed.
7 Handling and storage

· Handling:
· Precautions for safe handling
  Thorough dedusting.
  Ensure good ventilation/exhaustion at the workplace.
  Open and handle receptacle with care.
· Information about protection against explosions and fires:
  Keep respiratory protective device available.
· Conditions for safe storage, including any incompatibilities
· Storage:
  · Requirements to be met by storerooms and receptacles: No special requirements.
  · Information about storage in one common storage facility: Not required.
  · Further information about storage conditions: Keep receptacle tightly sealed.
· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see item 7.
· Control parameters
· Components with limit values that require monitoring at the workplace: Not required.
· Additional information: The lists that were valid during the creation were used as basis.
· Exposure controls
· Personal protective equipment:
  · General protective and hygienic measures:
    Keep away from foodstuffs, beverages and feed.
    Immediately remove all soiled and contaminated clothing.
    Wash hands before breaks and at the end of work.
    Store protective clothing separately.
  · Breathing equipment:
    In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
  · Protection of hands:
    The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
    Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
· Material of gloves
  The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
· Penetration time of glove material
  The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· Eye protection: Not required.
9 Physical and chemical properties

- Information on basic physical and chemical properties
  - General Information
  - Appearance:
    - Form: Solid
    - Color: Not determined.
  - Odor: Characteristic
  - Structural Formula: C22H28N2O • HCl
  - Molecular Weight: 372.9 g/mol
  - Odor threshold: Not determined.

- pH-value: Not applicable.

- Change in condition
  - Melting point/Melting range: Undetermined.
  - Boiling point/Boiling range: Undetermined.

- Flash point: Not applicable.

- Flammability (solid, gaseous): Product is not flammable.

- Decomposition temperature: Not determined.

- Auto igniting: Not determined.

- Danger of explosion: Product does not present an explosion hazard.

- Explosion limits:
  - Lower: Not determined.
  - Upper: Not determined.

- Vapor pressure: Not applicable.

- Density: Not determined.
- Relative density: Not determined.
- Vapor density: Not applicable.
- Evaporation rate: Not applicable.

- Solubility in / Miscibility with
  - Water: Not determined.

- Partition coefficient (n-octanol/water): Not determined.

- Viscosity:
  - Dynamic: Not applicable.
  - Kinematic: Not applicable.

- SOLUBILITY
  - DMF: 10 mg/ml; DMSO: 10 mg/ml; Ethanol: 20 mg/ml;
    Methanol: 30 mg/ml; PBS (pH 7.2): 10 mg/ml

- Other information
  - No further relevant information available.

10 Stability and reactivity

- Reactivity
  - No further relevant information available.

- Chemical stability

- Thermal decomposition / conditions to be avoided:
  - No decomposition if used according to specifications.

- Possibility of hazardous reactions
  - No dangerous reactions known.
Trade name: Fentanyl (hydrochloride)

- **Conditions to avoid**: No further relevant information available.
- **Incompatible materials**: strong oxidizing agents
- **Hazardous decomposition products**: carbon dioxide, carbon monoxide, carbon monoxide

### 11 Toxicological information

- **RTECS Number**: UE5551000
- **Information on toxicological effects**
  - **Acute toxicity**:
    - LD/LC50 values that are relevant for classification:
      - Subcutaneous TDLO: 0.019 mg/kg (rat)
      - Intraperitoneal LD50: 45 mg/kg (mouse)
      - Intraperitoneal TDLO: 0.63 mg/kg (mouse)
      - Intraperitoneal TDLO: 2.5 mg/kg (mouse)
  - **Primary irritant effect**:
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
    - **Sensitization**: No sensitizing effects known.
  - **Additional toxicological information**:
    - **Carcinogenic categories**
      - IARC (International Agency for Research on Cancer) Substance is not listed.
      - NTP (National Toxicology Program) Substance is not listed.
      - OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

### 12 Ecological information

- **Toxicity**
  - **Aquatic toxicity**: No further relevant information available.
  - **Persistence and degradability**: No further relevant information available.
  - **Behavior in environmental systems**:
    - **Bioaccumulative potential**: No further relevant information available.
    - **Mobility in soil**: No further relevant information available.
  - **Ecotoxicological effects**:
    - **Remark**: Very toxic for fish
  - **Additional ecological information**:
    - **General notes**:
      - Water hazard class 3 (Self-assessment): extremely hazardous for water
      - Do not allow product to reach ground water, water course or sewage system, even in small quantities.
      - Danger to drinking water if even extremely small quantities leak into the ground.
      - Very toxic for aquatic organisms
  - **Results of PBT and vPvB assessment**
    - **PBT**: Not applicable.
    - **vPvB**: Not applicable.
    - **Other adverse effects**: No further relevant information available.

(Contd. from page 5)
13 Disposal considerations

· Waste treatment methods
  · Recommendation:
    Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· Uncleaned packagings:
  · Recommendation: Disposal must be made according to official regulations.

14 Transport information

· UN-Number
  · DOT, IMDG, IATA UN2811

· UN proper shipping name
  · DOT 
  · IMDG
  · IATA

· Transport hazard class(es)
  · DOT
    · Class
      6.1 Toxic substances
    · Label
      6.1

  · IMDG, IATA
    · Class
      6.1 Toxic substances
    · Label
      6.1

· Packing group
  · DOT, IMDG, IATA II

· Environmental hazards:
  Environmentally hazardous substance, solid

· Special precautions for user
  · Warning: Toxic substances
  · Hazard identification number (Kemler code): 60
  · EMS Number: F-A,S-A
  · Stowage Category B

· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
  Not applicable.
Trade name: Fentanyl (hydrochloride)

- **Transport/Additional information:**
  - **DOT**
  - **Quantity limitations**
    - On passenger aircraft/rail: 25 kg
    - On cargo aircraft only: 100 kg
  - **IMDG**
    - **Limited quantities (LQ)**
      - 500 g
    - **Excepted quantities (EQ)**
      - Code: E4
      - Maximum net quantity per inner packaging: 1 g
      - Maximum net quantity per outer packaging: 500 g
  - **IATA**
    - **Remarks:**
      - When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.
  - **UN "Model Regulation":**
    - UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (FENTANYL (HYDROCHLORIDE)), 6.1, II, ENVIRONMENTALLY HAZARDOUS

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - No further relevant information available.
- **Sara**
- **Section 355 (extremely hazardous substances):** Substance is not listed.
- **Section 313 (Specific toxic chemical listings):** Substance is not listed.
- **TSCA (Toxic Substances Control Act):** Substance is not listed.
- **Hazardous Air Pollutants** Substance is not listed.
- **Proposition 65**
  - **Chemicals known to cause cancer:** Substance is not listed.
  - **Chemicals known to cause reproductive toxicity for females:** Substance is not listed.
  - **Chemicals known to cause reproductive toxicity for males:** Substance is not listed.
  - **Chemicals known to cause developmental toxicity:** Substance is not listed.
- **Carcinogenic categories**
- **EPA (Environmental Protection Agency)** Substance is not listed.
- **TLV (Threshold Limit Value)** Substance is not listed.
- **NIOSH-Ca (National Institute for Occupational Safety and Health)** Substance is not listed.
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 16 Other information

All chemicals may pose unknown hazards and should be used with caution. This SDS applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. Cayman Chemical Company assumes no responsibility for incidental or consequential damages, including lost profits, arising from the use of these data. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Cayman Chemical Company assumes no responsibility for the completeness or accuracy of the information contained herein.
Trade name: Fentanyl (hydrochloride)

- Department issuing SDS: Environment protection department.
- Contact: -
- Date of preparation / last revision 08/27/2021 / -
- Abbreviations and acronyms:
  - IMDG: International Maritime Code for Dangerous Goods
  - DOT: US Department of Transportation
  - IATA: International Air Transport Association
  - EINECS: European Inventory of Existing Commercial Chemical Substances
  - CAS: Chemical Abstracts Service (division of the American Chemical Society)
  - NFPA: National Fire Protection Association (USA)
  - HMIS: Hazardous Materials Identification System (USA)
  - LC50: Lethal concentration, 50 percent
  - LD50: Lethal dose, 50 percent
  - PBT: Persistent, Bioaccumulative and Toxic
  - vPvB: very Persistent and very Bioaccumulative
  - NIOSH: National Institute for Occupational Safety
  - OSHA: Occupational Safety & Health
  - TLV: Threshold Limit Value
  - PEL: Permissible Exposure Limit
  - REL: Recommended Exposure Limit
  - Acute Tox. 1: Acute toxicity – Category 1
  - Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
- * Data compared to the previous version altered.