

Safety Data Sheet

acc. to OSHA HCS

Printing date 11/20/2020

Reviewed on 11/16/2020

1 Identification

- **1.1 Product identifier**
- **Trade name: Buprenorphine HCl**
Buprenorphin HCl medium / fein / mikronisiert
Buprenorphine HCl dry (US) / milled (US) / micronized (US)
- **Article number:**
290482, 294595, 291690, 294227, 295823, 295809, 295810, 295811, 297013, 297046, 297101, 299355, 104082, 296565, 102517, 50420, 103463
- **CAS Number:**
53152-21-9
- **EC number:**
258-396-8
- **Application of the substance / the mixture** Pharma Active ingredients
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Siegfried USA, LLC
33 Industrial Park Road
Pennsville, NJ 08070
- **Information department:** Tel. +1 856 678 3601
- **1.4 Emergency telephone number:**
ChemTel. Inc. (Contract No. MIS0008071): +01-813-248-0585
For the United States, Canada, Puerto Rico, U.S Virgin Islands: 1-800-255-3924

Initial Supplier Identifier
Données relatives au fournisseur
Univar Solutions Canada Ltd.
64 Arrow Road
North York, ON M9M 2L9
Telephone: 1-866-686-4827

2 Hazard(s) identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Acute Tox. 4 H302 Harmful if swallowed.
Repr. 2 H361 Suspected of damaging fertility or the unborn child.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labeled according to the CLP regulation.
- **Hazard pictograms**


GHS07 GHS08
- **Signal word** Warning
- **Hazard statements**
H302 Harmful if swallowed.
H361 Suspected of damaging fertility or the unborn child.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P312 If swallowed: Call a poison center/doctor if you feel unwell.
P330 Rinse mouth.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 1
 Fire = 0
 Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 1
 Fire = 0
 Reactivity = 0

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **3.1 Substances**
- **CAS No. Description**
 53152-21-9 Buprenorphine HCl
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- **Identification number(s)** n/a
- **EC number:** 258-396-8

4 First-aid measures

- **4.1 Description of first aid measures**
- **General information:**
 Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** Immediately call a doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**
 Dizziness
 Profuse sweating
 Nausea
 palpitation
- **4.3 Indication of any immediate medical attention and special treatment needed**
 No further relevant information available.

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5 Fire-fighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture**
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** Mouth respiratory protective device.

6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Not required.
- **6.2 Environmental precautions:**
Damp down dust with water spray.
Do not allow to enter sewers/ surface or ground water.
Keep contaminated washing water and dispose of appropriately.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
- **6.4 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

- **7.1 Precautions for safe handling**
No special measures required.
No special precautions are necessary if used correctly.
- **Information about protection against explosions and fires:** No special measures required.
- **7.2 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:** storage temperature (15-25°C).
- **7.3 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.
- **8.1 Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.

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- **OELs (Siegfried)** 1 - 10 µg/m³
- **Additional information:** The lists that were valid during the creation were used as basis.
- **exposure category (Siegfried)** 3
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
 Keep away from foodstuffs, beverages and feed.
 Wash hands before breaks and at the end of work.
- **Breathing equipment:** Filter ABEK-2P3
- **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:**
 Goggles recommended during refilling.
 Not required.
- **Body protection:**
 Full head, face and neck protection
 Use protective suit such as TYVEK.

9 Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid material
Color:	White
Odor:	Odorless
Odor threshold:	Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/Melting range:	265 – 271 °C (509 – 519.8 °F)
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Product is not flammable.
- **Ignition temperature:** Not determined.
- **Decomposition temperature:** Not determined.
- **Auto igniting:** Not determined.

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- | | |
|---|---|
| · 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: | - g/l
Slightly soluble. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| Dynamic: | Not applicable. |
| Kinematic: | Not applicable. |
| · 9.2 Other information | No further relevant information available. |

10 Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity:**
Harmful if swallowed.
- **LD/LC50 values that are relevant for classification:**
- Oral LD50 > 1000 mg/kg (rat)
- **Primary irritant effect:**
- **on the skin:** Based on available data, the classification criteria are not met.
- **on the eye:** Based on available data, the classification criteria are not met.
- **Sensitization:** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)** Substance is not listed.
- **NTP (National Toxicology Program)** Substance is not listed.

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· OSHA-Ca (Occupational Safety & Health Administration) Substance is not listed.

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12 Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

13 Disposal considerations

- **13.1 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

- | | |
|---|-----------------|
| · 14.1 UN-Number | |
| · DOT, ADR/RID, IMDG, IATA | not regulated |
| · 14.2 UN proper shipping name | |
| · DOT, ADR/RID, IMDG, IATA | not regulated |
| · 14.3 Transport hazard class(es) | |
| · DOT, ADR/RID, ADN, IMDG, IATA | |
| · Class | not regulated |
| · 14.4 Packing group | |
| · DOT, ADR/RID, IMDG, IATA | not regulated |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not evaluated |

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· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	not regulated

15 Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Hazardous Air Pollutants** Substance is not listed.
- **National regulations:**
- **Water hazard class:** Water hazard class 3 (Self-assessment): extremely hazardous for water.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing SDS:** Safety and security
- **Contact:** K. Klinger
- **Date of preparation / last revision** 11/20/2020 / 2
- **Abbreviations and acronyms:**
 ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
 IMDG: International Maritime Code for Dangerous Goods
 DOT: US Department of Transportation
 IATA: International Air Transport Association
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 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
 OSHA: Occupational Safety & Health
 TLV: Threshold Limit Value
 PEL: Permissible Exposure Limit
 REL: Recommended Exposure Limit
 Acute Tox. 4: Acute toxicity – Category 4
 Repr. 2: Reproductive toxicity – Category 2
- *** Data compared to the previous version altered.**

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