SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Buprenorphine Solid Formulation

Version 2.4
Revision Date: 09/13/2019
SDS Number: 918680-00007
Date of last issue: 2019/04/24
Date of first issue: 2016/10/03

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Buprenorphine Solid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 199 Wenhui North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>solid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>

May damage the unborn child.

GHS Classification
Reproductive toxicity: Category 1A

GHS label elements
Hazard pictograms:

Signal word: Danger
Hazard statements: H360D May damage the unborn child.
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/
Physical and chemical hazards
Not classified based on available information.

Health hazards
May damage the unborn child.

Environmental hazards
Not classified based on available information.

Other hazards which do not result in classification
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Starch</td>
</tr>
<tr>
<td></td>
<td>Buprenorphine Hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Citric acid</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice
In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled
If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact
In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact
If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

If swallowed
If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms
May damage the unborn child.
5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spills cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding
certain local or national requirements.

7. HANDLING AND STORAGE

Handling
Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling: Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.
Avoidance of contact: Oxidizing agents

Storage
Conditions for safe storage: Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types:
Strong oxidizing agents
Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starch</td>
<td>9005-25-8</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Buprenorphine Hydrochloride</td>
<td>53152-21-9</td>
<td>TWA</td>
<td>0.2 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>2 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

**Personal protective equipment**

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

- **Filter type**: Particulates type
- **Eye/face protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hand protection**

- **Material**: Chemical-resistant gloves
- **Remarks**: Consider double gloving.

**Hygiene measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: solid

**Colour**: white

**Odour**: No data available

**Odour Threshold**: No data available
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10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : May form explosive dust-air mixture during processing, han-
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Conditions to avoid: Heat, flames and sparks. Avoid dust formation. Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Starch:
Acute oral toxicity: LD50 (Mouse): > 5,000 mg/kg

Buprenorphine Hydrochloride:
Acute oral toxicity: LD50 (Mouse): 261 mg/kg
LD50 (Rat): 600 mg/kg
Acute inhalation toxicity: Remarks: No data available
Acute dermal toxicity: Remarks: No data available
Acute toxicity (other routes of administration): LD50 (Rat): 31 mg/kg
Application Route: Intravenous
LD50 (Mouse): 24 mg/kg
Application Route: Intravenous

Citric acid:
Acute oral toxicity: LD50 (Mouse): 5,400 mg/kg
Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Skin corrosion/irritation
Not classified based on available information.

Components:
Buprenorphine Hydrochloride:
Remarks : No data available

Citric acid:
Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:
Buprenorphine Hydrochloride:
Remarks : No data available

Citric acid:
Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Buprenorphine Hydrochloride:
Remarks : No data available

Germ cell mutagenicity
Not classified based on available information.

Components:
Buprenorphine Hydrochloride:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: equivocal

Test Type: Chromosomal aberration
Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-
thesis in mammalian cells (in vitro)
Result: positive

Germ cell mutagenicity - 
Assessment : Weight of evidence does not support classification as a germ cell mutagen.

Citric acid:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

type: in vitro micronucleus test
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Buprenorphine Hydrochloride:
Species : Rat
Application Route : Oral
Exposure time : 27 Months
LOAEL : 56 mg/kg body weight
Result : positive
Target Organs : Testes
Remarks : The significance of these findings for humans is not certain.

Species : Mouse
Application Route : Oral
Exposure time : 86 weeks
NOAEL : 100 mg/kg body weight
Result : negative
Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

Reproductive toxicity
May damage the unborn child.

Components:

Buprenorphine Hydrochloride:
Effects on fertility : Test Type: Fertility
Species: Rat
Application Route: Oral  
Fertility: NOAEL: 80 mg/kg body weight  
Result: No effects on fertility

Test Type: Fertility  
Species: Rat  
Application Route: Subcutaneous  
Fertility: NOAEL: 5 mg/kg body weight  
Result: No effects on fertility

Test Type: Fertility  
Species: Rabbit  
Application Route: Oral  
Fertility: LOAEL: 1 mg/kg body weight  
Result: Preimplantation loss

Test Type: Fertility  
Species: Rabbit  
Application Route: Intravenous  
Fertility: LOAEL: 0.2 mg/kg body weight  
Result: Postimplantation loss.

Effects on foetal development:  
Test Type: Development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 5 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects, Skeletal malformations

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 160 mg/kg body weight  
Result: No effects on foetal development

Test Type: Development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 0.1 mg/kg body weight  
Result: Effects on newborn

Test Type: Development  
Species: Rabbit  
Application Route: Intramuscular  
Developmental Toxicity: LOAEL: 5 mg/kg body weight  
Result: Embryo-foetal toxicity, Skeletal malformations

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: Embryo-foetal toxicity, Skeletal malformations

Reproductive toxicity - As:  
May damage the unborn child. Suspected of damaging fertili-
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Assessment

Citric acid:
Effects on foetal development:
Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

Components:

Buprenorphine Hydrochloride:
Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

Citric acid:
Species: Rat
NOAEL: 4,000 mg/kg
LOAEL: 8,000 mg/kg
Application Route: Ingestion
Exposure time: 10 Days

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Buprenorphine Hydrochloride:
Inhalation: Target Organs: Central nervous system
Symptoms: Drowsiness, sedation, Headache, Nausea, Vomiting, Dizziness, Vertigo, Sweating, constipation, insomnia, Pain, respiratory depression, constriction of pupils, decrease in heart rate, Lowered blood pressure
Remarks: May cause neonatal withdrawal

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Buprenorphine Hydrochloride:
Toxicity to algae/aquatic: EC50 (Pseudokirchneriella subcapitata (green algae)): 6.25
plants

Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.319 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):

NOEC (Pimephales promelas (fathead minnow)): 0.137 mg/l
Exposure time: 28 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC (Daphnia magna (Water flea)): 0.883 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

LOEC (Daphnia magna (Water flea)): 1.95 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms:

EC50: 588 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 135 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Citric acid:

Toxicity to fish:

LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:

EC50 (Daphnia magna (Water flea)): 1,535 mg/l
Exposure time: 24 h

Persistence and degradability

Components:

Buprenorphine Hydrochloride:
Biodegradability: Result: Not readily biodegradable.

Citric acid:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 97%
Exposure time: 28 d
Method: OECD Test Guideline 301B
Bioaccumulative potential

**Components:**

**Buprenorphine Hydrochloride:**
- **Bioaccumulation:** Species: Oncorhynchus mykiss (rainbow trout)
  Bioconcentration factor (BCF): 0.4
  Method: OECD Test Guideline 305
- **Partition coefficient: n-octanol/water:** log Pow: 3.11

**Citric acid:**
- **Partition coefficient: n-octanol/water:** log Pow: -1.72

**Mobility in soil**

**Components:**

**Buprenorphine Hydrochloride:**
- **Distribution among environmental compartments:** log Koc: 4.11

**Other adverse effects**
No data available

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
- **Waste from residues:** Dispose of in accordance with local regulations.
- **Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal.
  If not otherwise specified: Dispose of as unused product.

### 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**National Regulations**

**GB 6944/12268**
Not regulated as a dangerous good
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</tr>
</tbody>
</table>

**Special precautions for user**
Not applicable

### 15. REGULATORY INFORMATION

**National regulatory information**
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:
- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

### 16. OTHER INFORMATION

**Further information**

Date format: yyyy/mm/dd

**Full text of other abbreviations**
- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **ACGIH / TWA**: 8-hour, time-weighted average
- **AICS**: Australian Inventory of Chemical Substances; **ANTT**: National Agency for Transport by Land of Brazil; **ASTM**: American Society for the Testing of Materials; **bw**: Body weight; **CMR**: Carcinogen, Mutagen or Reproductive Toxicant; **DIN**: Standard of the German Institute for Standardisation; **DSL**: Domestic Substances List (Canada); **Ecx**: Concentration associated with x% response; **ELx**: Loading rate associated with x% response; **EmS**: Emergency Schedule; **ENCS**: Existing and New Chemical Substances (Japan); **ErCx**: Concentration associated with x% growth rate response; **ERG**: Emergency Response Guide; **GHS**: Globally Harmonized System; **GLP**: Good Laboratory Practice; **IARC**: International Agency for Research on Cancer; **IATA**: International Air Transport Association; **IBC**: International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; **IC50**: Half maximal inhibitory concentration; **ICAO**: International Civil Aviation Organization; **IECSC**: Inventory of Existing Chemical Substances in China; **IMDG**: International Maritime Dangerous Goods; **IMO**: International Maritime Organization; **ISHL**: Industrial Safety and Health Law (Japan); **ISO**: International Organisation for Standardization; **KECI**: Korea Existing Chemicals Inventory; **LC50**: Lethal Concentration to 50% of a test population; **LD50**: Lethal Dose to 50% of a test population (Median Lethal Dose); **MARPOL**: International Convention for the Prevention of Pollution from Ships; **n.o.s.**: Not Otherwise Specified; **Nch**: Chilean Norm; **NO(A)EC**: No Observed (Adverse) Effect Concentration; **NO(A)EL**: No Observed (Adverse) Effect Level; **NOELR**: No Observable Effect Loading Rate; **NOM**: Official Mexican Norm; **NTP**: National Toxicology Program; **NZIoC**: New Zealand Inventory of Chemicals; **OECD**: Organization for Economic Co-operation and Development; **OPPTS**: Office of Chemical Safety and Pollution Prevention; **PBT**: Persistent, Bioaccumul-
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1. Product Identification

a. Product Identification:

Buprenorphine is an opioid analgesic drug used to treat pain and to reduce withdrawal symptoms in opioid-dependent persons.

2. Composition Information

a. Constituents:

Buprenorphine (C21H23NO3) is the active ingredient in the formulation.

b. Other Information:

3. Hazards Identification

a. Classification of the Substance or Mixture:

Very Persistent and Very Bioaccumulative (vPvB)

b. Hazard Statements:

1-Acute Toxicity
2-Acute Eye Damage
3-Acute Oral Toxicity
4-Irritating to Skin
5-Irritating to Eyes
6-Irritating to respiratory system

4. First-aid Measures

a. Must be reported to the Poison Control Center.

b. Inhalation:

1. Remove to fresh air.
2. Provide artificial respiration if necessary.
3. Do not give any stimulant.

5. Fire-fighting Measures

a. Fire-fighting:

1. Use dry chemical, carbon dioxide, or dry sand.

b. Special Fire-fighting Procedures:

1. Do not use water, foam, or water-based material.

6. Accidental Release and Emergency Measures

a. Personal Precaution:

1. Wear personal protective equipment such as gloves, protective clothing and goggles.

b. Environmental Protection:

1. Do not contaminate water, food, or feed by leaking or discharging the material.

7. Handling and Storage

a. Storage:

1. Store in a cool and dry place.

b. Precautions for Use:

1. Avoid contact with skin, eyes, or mucous membranes.

8. Exposure Controls/Personal Protection

a. Exposure Limits:

1. Not applicable.

b. Personal Protective Equipment:

1. Use respirator and protective clothing as necessary.

9. Physical and Chemical Properties

a. Physical Properties:

1. Color:
2. Odor:
3. Boiling point:
4. Melting point:
5. Density:
6. Viscosity:

b. Chemical Properties:

1. Reactivity:

10. Stability and Reactivity

a. Stability:

1. Stable under normal storage conditions.

b. Reactivity:

1. Avoid prolonged exposure to heat and moisture.

11. Toxicological Information

a. Route of Exposure:

1. Inhalation
2. Skin Contact
3. Ingestion

b. Toxicological Effects:

1. Acute Effects:
2. Chronic Effects:

12. Ecological Information

a. Toxicity:

1. Aquatic toxicity:
2. Land toxicity:

b. Ecotoxicity:

1.危害性:

13. Disposal Considerations

a. Disposal Method:

1. Hazardous waste.

b. Ordinary waste:

1. Not applicable.

14. Transportation Information

a. UN Number:

1. Not applicable.

b. Transport Risk Group:

1. Not applicable.

15. Regulatory Information

a. Regulatory Limits:

1. Not applicable.

b. Regulatory Requirements:

1. Not applicable.

16. Other Information

a. Additional Information:

1. Not applicable.

b. Contacts for Emergency Information:

1. MSDS number:
2. MSDS source:

17. Additional Information

a. Additional Information:

1. Not applicable.

b. References:

1. Not applicable.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

CN / EN