

**BUPRENORPHINE, 2 (N\*)**

Version 1.13

Revision Date 2014-05-23

Print Date 2014-06-16

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

**1.1 Product identifier**

Trade name : BUPRENORPHINE, 2 (N\*)  
Substance name : BUPRENORPHINE  
buprenorphine  
Substance No. : 257-950-6  
Product code : 497074  
Reference number : JNJ-16972852-AAA  
R371605

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

Use of the : Active Pharmaceutical Ingredient  
Substance/Mixture

**1.3 Details of the supplier of the safety data sheet**

Company : Janssen Pharmaceutica NV  
Turnhoutseweg 30  
2340 Beerse  
Belgium  
Telephone : +3214602111  
Telefax : +3214602841  
E-mail address :  
Responsible/issuing person : SDSJanssen@its.jnj.com

**1.4 Emergency telephone number +32 14 60 24 44**

**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

**Classification (REGULATION (EC) No 1272/2008)**

Acute toxicity , Category 4	H302: Harmful if swallowed.
Respiratory sensitisation , Category 1	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation , Category 1	H317: May cause an allergic skin reaction.
Specific target organ toxicity - single exposure , Category 1	H370: Causes damage to organs.
Reproductive toxicity , Category 2	H361fd: Suspected of damaging fertility. Suspected of damaging the unborn child.
Reproductive toxicity , Category 2	H362: May cause harm to breast-fed children.
Target Organ Systemic Toxicant - Single exposure , Category 3	H336: May cause drowsiness or dizziness.

**Classification (67/548/EEC, 1999/45/EC)**

Harmful R22: Harmful if swallowed.

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Harmful	R42: May cause sensitisation by inhalation.
Irritant	R43: May cause sensitisation by skin contact.
Toxic	R39/23: Toxic: danger of very serious irreversible effects through inhalation.
Harmful	R62: Possible risk of impaired fertility.
	R63: Possible risk of harm to the unborn child.
	R64: May cause harm to breastfed babies.
	R67: Vapours may cause drowsiness and dizziness.

**2.2 Label elements**

**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Danger

Hazard statements	:	H302 H311 H334	Harmful if swallowed. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
		H336 H361fd	May cause drowsiness or dizziness. Suspected of damaging fertility. Suspected of damaging the unborn child.
		H362 H370	May cause harm to breast-fed children. Causes damage to organs if inhaled.

Precautionary statements	:	<b>Prevention:</b> P201 P260 P263	Obtain special instructions before use. Do not breathe dust or mist. Avoid contact during pregnancy/ while nursing.
		<b>Response:</b> P302 + P352 P304 + P340	IF ON SKIN: Wash with plenty of soap and water. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
		<b>Storage:</b> P405	Store locked up.

**2.3 Other hazards**

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May be absorbed via the skin. Substance or its vapour is narcotic.

**SECTION 3: Composition/information on ingredients**

**3.1 Substances**

Chemical nature : Solid

Chemical Name	CAS-No. EINECS-No. / ELINCS No.	Concentration [%]
BUPRENORPHINE	52485-79-7	<= 100

**SECTION 4: First aid measures**

**4.1 Description of first aid measures**

- If inhaled : If breathed in, move person into fresh air.  
Artificial respiration and/or oxygen may be necessary.  
Call a physician immediately.
- In case of skin contact : Take off contaminated clothing and shoes immediately.  
Wash off immediately with plenty of water.  
Call a physician immediately.  
Wash contaminated clothing before reuse.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,  
for at least 5 minutes.  
Remove contact lenses.  
If eye irritation persists, consult a specialist.
- If swallowed : If swallowed, rinse mouth with water (only if the person is  
conscious).  
Call a physician immediately.

**4.2 Most important symptoms and effects, both acute and delayed**

- Symptoms : Nausea  
Vomiting  
Sweating  
Dizziness  
headache  
Abdominal pain  
Vertigo  
calming  
constipation  
weakness  
Shivering fit  
Small pupils  
Severe allergic skin reactions, bronchospasm and  
anaphylactic shock

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Liver disorders  
Heart disease

**4.3 Indication of any immediate medical attention and special treatment needed**

Treatment : Treat symptomatically.

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**SECTION 5: Firefighting measures**

**5.1 Extinguishing media**

Suitable extinguishing media : Water mist, Dry powder, Foam, Carbon dioxide (CO<sub>2</sub>), Sand, Aqueous film forming foam (AFFF).

**5.2 Special hazards arising from the substance or mixture**

Specific hazards during firefighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Heating can release hazardous gases.

Hazardous combustion products : No hazardous combustion products are known

**5.3 Advice for firefighters**

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

Further information : Avoid dust formation. In the event of fire, cool tanks with water spray.

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**SECTION 6: Accidental release measures**

**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Evacuate personnel to safe areas.  
Avoid dust formation.  
Avoid breathing dust.  
Keep away from open flames, hot surfaces and sources of ignition.  
Refer to protective measures listed in sections 7 and 8.  
Evacuate personnel to safe areas.

**6.2 Environmental precautions**

Environmental precautions : Should not be released into the environment.  
Do not flush into surface water or sanitary sewer system.

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### **6.3 Methods and materials for containment and cleaning up**

Methods for cleaning up : Pick up and arrange disposal without creating dust.  
Sweep up and shovel into suitable containers for disposal.  
Keep in properly labelled containers.  
Keep in suitable, closed containers for disposal.  
Treat recovered material as described in the section "Disposal considerations".

### **6.4 Reference to other sections**

For personal protection see section 8., For disposal information, see section 13

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## **SECTION 7: Handling and storage**

### **7.1 Precautions for safe handling**

Advice on safe handling : Ensure all equipment is electrically grounded before beginning transfer operations. To avoid thermal decomposition, do not overheat. For personal protection see section 8. Keep away from heat and sources of ignition. Avoid formation of dust and aerosols.

Advice on protection against fire and explosion : Avoid dust formation. Keep away from heat and sources of ignition.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

Dust explosion class : St1

### **7.2 Conditions for safe storage, including any incompatibilities**

Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep away from heat and sources of ignition. Keep locked up.

Storage temperature : 15 - 30 °C

### **7.3 Specific end use(s)**

Specific use(s) : Consult the technical guidelines for the use of this substance/mixture.

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## **SECTION 8: Exposure controls/personal protection**

### **8.1 Control parameters**

Components	CAS-No.	Value type	Control	Update	Basis
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		(Form of exposure)	parameters		
BUPRENORPHINE	52485-79-7	TWA	0,0015 mg/m <sup>3</sup>		J&J OEL/PBOEL HHC
BUPRENORPHINE	52485-79-7	STEL	0,012 mg/m <sup>3</sup>		J&J OEL/PBOEL HHC
BUPRENORPHINE	52485-79-7	STV	0,015 mg/100cm <sup>2</sup>		J&J PBOEL-HHC list
BUPRENORPHINE	52485-79-7	PBOEL-HHC	3 B		J&J OEL/PBOEL HHC
Further information		J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 3B.			
Further information		Notation DSEN: has the potential to cause delayed allergic skin reaction (sensitization), such as wheals and rashes			
Further information		Notation RSEN: has the potential to cause delayed allergic reactions(sensitization), such as shortness of breath, asthma and anaphylaxis.			
Further information		Notation SKIN: has the potential for absorption via the skin.			

## 8.2 Exposure controls

### Engineering measures

Engineering controls should be used as the primary means to control possible exposures. Use process enclosures, local exhaust ventilation or other engineering controls to keep exposure levels below recommended exposure limits.

### Personal protective equipment

Eye protection	: Tightly fitting safety goggles
Hand protection	
Material	: Nitrile rubber
Remarks	: Long sleeve gloves Take note of the information given by the producer concerning permeability and break through times, and of special workplace conditions (mechanical strain, duration of contact).
Skin and body protection	: closed work clothing Long sleeved clothing
Respiratory protection	: Engineering controls should always be the primary method of controlling exposures. If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.

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Respirator with a full face mask  
P3

Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Environmental exposure controls**

General advice : Should not be released into the environment.  
Do not flush into surface water or sanitary sewer system.

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

Appearance : crystalline, powder  
Colour : white  
Odour : odourless  
Odour Threshold : No data available  
pH : No data available  
Melting point/range : 210 °C  
Boiling point/boiling range : No data available  
Flash point : No data available  
Evaporation rate : No data available  
Flammability (solid, gas) : No information available.

Auto-ignition temperature : No data available  
Upper explosion limit : No data available  
Lower explosion limit : No data available  
Vapour pressure : No data available  
Relative vapour density : No data available  
Relative density : No data available  
Density : No data available

**Solubility(ies)**

Water solubility : < 0,2 g/l  
Partition coefficient: n-octanol/water : No data available

Ignition temperature : 460 °C Method: M.I.T. Dust Cloud Godbert-Greenwald

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METHOD

Thermal decomposition : 265 °C  
Minimum T  
560 kJ/kg

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

**9.2 Other information**

Burning number : 2, 20 °C, Air  
100 °C, Air

Molecular weight : 467,65 g/mol

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**SECTION 10: Stability and reactivity**

**10.1 Reactivity**

None reasonably foreseeable.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous reactions : Risk of dust explosion.

**10.4 Conditions to avoid**

Conditions to avoid : To avoid thermal decomposition, do not overheat.  
Heat, flames and sparks.

**10.5 Incompatible materials**

Materials to avoid : Strong oxidizing agents

**10.6 Hazardous decomposition products**

Hazardous decomposition products : Carbon monoxide  
Nitrogen oxides (NOx)



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**SECTION 11: Toxicological information**

**11.1 Information on toxicological effects**

**Acute toxicity**

**Product**

Acute oral toxicity : LD50 rat:  $\geq 600$  mg/kg

LD50 mouse: 261 mg/kg

Narcotic

Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

Acute toxicity (other routes of administration) : LD50 rat: 31 mg/kg  
Application Route: intravenous injection

LD50 mouse: 24 mg/kg  
Application Route: intravenous injection

**Skin corrosion/irritation**

**Product**

No data available

**Serious eye damage/eye irritation**

**Product**

No data available

**Respiratory or skin sensitisation**

**Product**

May cause sensitisation by inhalation and skin contact.

**Germ cell mutagenicity**

**Product**

Germ cell mutagenicity-Assessment : In vitro tests showed mutagenic effects which were not observed with in vivo test.

**Carcinogenicity**

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**Product**

Species: rat  
Application Route: Oral  
Exposure time: 27 months  
Dose: 57 mk/kg/day

Species: mouse  
Application Route: Oral  
Exposure time: 86 weeks  
Dose: 100 mg/kg/day

Carcinogenicity - Assessment : Animal testing did not show any carcinogenic effects.

**Reproductive toxicity**

**Toxicity to reproduction/fertility**

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

No data available

**Reprod.Tox./Development/Teratogenicity**

**Product**

Teratogenicity - Assessment : Suspected of damaging fertility.

Effects on or via lactation

**STOT - single exposure**

**Product**

Assessment: May cause drowsiness or dizziness.

Assessment: Causes damage to organs.

**STOT - repeated exposure**

No data available

**Aspiration toxicity**

No data available

**Product**

Danger of resorption through skin

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**SECTION 12: Ecological information**

**12.1 Toxicity**

**Product:**

Toxicity to fish : No data available

Toxicity to daphnia and other aquatic invertebrates : No data available

Toxicity to algae : No data available

Toxicity to bacteria : No data available

**12.2 Persistence and degradability**

**Product:**

Biodegradability : No data available

**12.3 Bioaccumulative potential**

**Product:**

Bioaccumulation : No data available

Partition coefficient: n-octanol/water : No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

No data available

**12.6 Other adverse effects**

**Product:**

Environmental fate and pathways : No data available

Additional ecological information : No data available, No data available

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**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

Product : Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.  
In accordance with National, Federal, State and Local

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regulations.

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**SECTION 14: Transport information**

**14.1 UN number**

ADN : 1544  
ADR : 1544  
RID : 1544  
IMDG : 1544  
IATA : 1544

**14.2 Proper shipping name**

ADN : ALKALOIDS, SOLID, N.O.S.  
(buprenorphine)  
ADR : ALKALOIDS, SOLID, N.O.S.  
(buprenorphine)  
RID : ALKALOIDS, SOLID, N.O.S.  
(buprenorphine)  
IMDG : ALKALOIDS, SOLID, N.O.S.  
(buprenorphine)  
IATA : ALKALOIDS, SOLID, N.O.S.  
(buprenorphine)

**14.3 Transport hazard class**

ADN : 6.1  
ADR : 6.1  
RID : 6.1  
IMDG : 6.1  
IATA : 6.1

**14.4 Packing group**

**ADN**  
Packaging group : III  
Classification Code : T2  
Hazard Identification Number : 60  
Labels : 6.1  
**ADR**  
Packaging group : III  
Classification Code : T2  
Hazard Identification Number : 60  
Labels : 6.1  
Tunnel restriction code : (E)  
**RID**  
Packaging group : III  
Classification Code : T2  
Hazard Identification Number : 60  
Labels : 6.1  
**IMDG**  
Packaging group : III  
Labels : 6.1  
EmS Number : F-A, S-A

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**IATA**

Packing instruction (CAO) : 677  
Packing instruction (PAX and CAO) : 670  
Packing instruction (LQ) : Y645  
Packaging group : III  
Labels : 6.1

**14.5 Environmental hazards**

**ADN**

Environmentally hazardous : no

**ADR**

Environmentally hazardous : no

**RID**

Environmentally hazardous : no

**IMDG**

Marine pollutant : no

**IATA**

Environmentally hazardous : no

**14.6 Special precautions for user**

For personal protection see section 8.

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

No data available

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**SECTION 15: Regulatory information**

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

Major Accident Hazard Legislation

96/82/EC : Update: 2003  
Toxic

Quantity1  
50 t

Quantity2  
200 t

**15.2 Chemical Safety Assessment**

A Chemical Safety Assessment is not required for this substance.  
A Chemical Safety Assessment is not required for this substance.

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**SECTION 16: Other information**

**Date and Number Formats**

This document uses the following notation for printing dates and numbers:

**Date:** Dec 31th, 2012 as 2012-12-31

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**Numbers:** 123456,78 as 123 456,78

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