

**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING****1.1 Product identifier**

PRODUCT NAME	<b>LIDOCAINE</b>
CAS No	137-58-6
EC No	205-302-8
INDEX No	Not available.
REACH Reg No	Exempted, according to Article 2(5a) of REACH.

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

IDENTIFIED USES	Manufacture of pharmaceutical formulations: local anaesthetic
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**1.3 Details of the supplier of the safety data sheet**

COMPANY	<b>Cambrex Karlskoga AB</b>
ADDRESS	SE-691 85 Karlskoga, SWEDEN
PHONE NO	+ 46 586 78 30 00
FAX	+ 46 586 78 30 09
E-MAIL	<a href="mailto:karlskoga@cambrex.com">karlskoga@cambrex.com</a>
INTERNET	<a href="http://www.cambrex.com">www.cambrex.com</a>

**1.4 Emergency telephone number**

EMERGENCY PHONE NO	+46 586 78 3122	(Office hours: CET, 08.00 to 17.00)
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**2 HAZARDS IDENTIFICATION****2.1 Classification of the substance or mixture**

*According to Regulation (EC) No 1272/2008:*  
ACUTE TOXICITY ORAL (CATEGORY 4)

**2.2 Label elements**

*According to Regulation (EC) No 1272/2008:*

Pictogram(s)



Signal word

Warning

Hazard statement(s):

H302

Harmful if swallowed.

Precautionary statement(s):

P280

Wear protective gloves/protective clothing/eye protection/face protection.

P301 + P312 + P330

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.

P501

Dispose of contents/container to an approved incineration plant.

**2.3 Other hazards**

See section 11.

### 3 COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

Chemical name	2-(Diethylamino)-N-(2,6-dimethylphenyl)acetamide
Synonyms	N-(Diethylaminoacetyl)-2,6-xylidine
Formula	C <sub>14</sub> H <sub>22</sub> N <sub>2</sub> O
Molar weight	234.34 g/mole

Substance	Conc.	CAS No	EC No	Index No	REACH Reg No
Lidocaine	>99%	137-58-6	205-302-8	See 1.1	See 1.1

#### 3.2 Mixtures

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### 4 FIRST AID MEASURES

#### 4.1 Description of first aid measures

INHALATION	If inhaled, remove to fresh air. Rinse nose and mouth with water. Get medical attention if symptoms persist.
SKIN CONTACT	Remove contaminated clothing. Wash skin with soap and water. If symptoms occur (irritation or blistering) get medical attention.
EYE CONTACT	Rinse eyes with plenty of water for at least 10 minutes, occasionally lifting the upper and lower eyelids. Get medical attention.
INGESTION	If swallowed, wash out mouth with water and give a few glasses of water to drink. Do NOT induce vomiting. Get medical attention.

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

Refer to sections 2 and 11.

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

Symptomatic treatment.

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### 5 FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

*Suitable extinguishing media:*

Water spray, foam, dry powder or carbon dioxide.

*Unsuitable extinguishing media:*

No limitations given for this substance.

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

Combustible, but not flammable. Airborne dust may cause combustible/explosive dust clouds. In case of fire toxic fumes of nitrogen oxides (NO<sub>x</sub>) and carbon monoxide (CO) may be formed.

#### 5.3 Advice for firefighters

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Prevent fire extinguishing water from contaminating the surface water or ground water.

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### 6 ACCIDENTAL RELEASE MEASURES

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

Use recommended personal protective equipment during removal of spillages. Avoid raising dust.

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**6.2 Environmental precautions**

Prevent spill from contaminating surface water or ground water.

**6.3 Methods and material for containment and cleaning up**

Small spill may be handled with water moisten disposable cloth and placed in container for chemical waste. Larger spill is collected and placed in container for disposal. Ventilate area and wash spill site with water after material pickup is complete.

**6.4 Reference to other sections**

See section 8 for personal protective equipment for handling the spills.

See section 13 for disposal considerations.

**7 HANDLING AND STORAGE****7.1 Precautions for safe handling**

Avoid dust generation and in halation of dust. Avoid contact with eyes, skin and clothing. Ensure good ventilation. The material may form flammable dust clouds in air. Dust clouds may be extremely sensitive to ignition by electrostatic discharge and other ignition sources. Consider bonding and earthing of equipment and personnel dealing with dust generating operations.

Handle with care and in accordance with good industrial hygiene and safety practice.

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

Keep container/package tightly closed. At humid conditions the substance absorbs humidity which over time will cause caking, with loss of free flowing properties. For recommended storage conditions, see product label.

**7.3 Specific and use(s)**

No further information than noted in section 1.2 is available.

**8 EXPOSURE CONTROLS/PERSONAL PROTECTION****8.1 Control parameters**

To our knowledge no national occupational exposure limit values have been established.

*Recommended Occupational Exposure Limit Value*

<b>Substance</b>	<b>Value</b>	<b>Control Parameters</b>
Lidocaine	1 mg/m <sup>3</sup>	TWA, 8h <sup>1)</sup>
Lidocaine	5 mg/m <sup>3</sup>	TWA, 15 min <sup>2)</sup>

<sup>1)</sup> Time-weighted average 8 hours.

<sup>2)</sup> Time-weighted average 15 minutes.

**8.2 Exposure controls***Appropriate engineering controls*

Use appropriate controls (e.g. containment, local exhaust ventilation) as specified in a workplace risk assessment to ensure that the defined exposure limits are met. Technical measures and appropriate operations should be given priority over the use of personal protective equipment. Handle in accordance with good industrial hygiene and safety practice.

*Personal protective equipment.*

**Eye face protection:** Use safety goggles. A device for eyewash should be available.

**Skin protection:** Handle with gloves. The selected gloves must comply with the specifications in EC Directive 89/686/EEC and the related standard EN374.

**Protective clothing:** Impervious clothing. The type should be selected according to

concentrations and quantities of the hazardous substance handled at the specific workplace.

**Respiratory protection:** Required when dusts are generated. Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. Use air-purifying respirator with combination filters for routine powder handling in process scale and positive-pressure air-supplied respirator, if there is a potential of uncontrolled release. Fume hoods or laminar flow booths in laboratory scale.

**Environmental exposure controls:** Do not empty into drains.

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## 9 PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

a) Appearance	White crystalline powder
b) Odour	No data available
c) Odour threshold	No data available
d) pH	No data available
e) Melting/freezing point	66-69°C
f) Initial boiling and boiling range	146°C at 1 mm Hg
g) Flash point	No data available
h) Evaporation rate	No data available
i) Flammability (solid/gas)	No data available
j) Upper/lower explosion limits	No data available
k) Vapour pressure	No data available
l) Vapour density	No data available
m) Relative density	No data available
n) Water Solubility	Practically insoluble
Other	Readily soluble in methanol, ethanol, acetone.
o) Partition coefficient, Log P <sub>ow</sub>	1.41
p) Auto-ignition temperature	No data available
q) Decomposition temperature	No data available
r) Viscosity	No data available
s) Explosive properties	No data available
t) Oxidising properties	No data available

### 9.2 Other information

None

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## 10 STABILITY AND REACTIVITY

### 10.1 Reactivity

No known reactivity hazards under normal conditions.

### 10.2 Chemical stability

The substance is chemically stable under standard ambient conditions.  
For recommended storage conditions, see product label.

### 10.3 Possibility of hazardous reactions

None known.

### 10.4 Conditions to avoid

Avoid exposure to heat and sunlight.

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**10.5 Incompatible materials**

Strong oxidants.

**10.6 Hazardous decomposition products**

Nitrogen oxides (NO<sub>x</sub>), carbon monoxide (CO).

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**11 TOXICOLOGICAL INFORMATION****11.1 Information on toxicological effects****a) Acute toxicity**

*Oral:*

LD<sub>50</sub> (rat): 317 mg/kg

**b) Skin corrosion/irritation**

May cause numbness.

**c) Serious eye damage/irritation**

May cause excessive watering of the eye (lachrymation).

**d) Respiratory or skin sensitisation**

Repeated and /or prolonged contact may cause skin sensitization in a small percentage of sensitizing susceptible individuals.

**e) Germ cell mutagenicity**

The substance is not expected to be genotoxic.

**f) Carcinogenicity**

No data available

**g) Reproductive toxicity**

There is no evidence of teratogenicity or embryo toxicity.

**h) STOT-single exposure**

Inhalation: May cause tingling/numbness in exposed areas (paraesthesia). High concentrations in air may lead to anaesthetic effects. May lead to reduced heart frequency and a lowering of the blood pressure, with a resulting feeling of dizziness.

Oral: May produce numbness of the tongue and anaesthetic effects in the stomach.

**i) STOT-repeated exposure**

High exposure levels in animal experiments produces adverse effects on the liver and central nervous system.

**j) Aspiration hazard**

No information available.

**11.2 Other information**

To the best of our knowledge the chemical, physical and toxicological properties have not been fully investigated.

Other hazardous properties cannot be excluded. Handle in accordance with good industrial hygiene and safety practice.

## 12 ECOLOGICAL INFORMATION

### 12.1 Toxicity

#### *Toxicity to bacteria*

EC <sub>50</sub> Microtox, 15 min	6860 mg/l
Species:	Photobacterium phosphoreum
Method:	ISO 11348-3 2007
Results:	Not toxic to aquatic organisms.

#### *Toxicity to Daphnia and other aquatic invertebrates*

EC <sub>50</sub> 48h	112 mg/l
Species:	Daphnia magna (water flea)
Results:	Low toxicity to aquatic organisms.

#### *Toxicity to green algae*

EC <sub>50</sub> 72h	780 mg/l
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#### *Toxicity to zebra fish*

LC <sub>50</sub> 96h	106 mg/l
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### 12.2 Persistence and degradability

#### *Biodegradability*

BOD <sub>7</sub>	0.07 g O <sub>2</sub> /g
Method:	SS-EN 1899-1:1998
COD	1.75 g O <sub>2</sub> /g
Method:	SS 02 81 42
Results:	Not readily biodegradable (BOD <sub>7</sub> /COD = 0.04).

### 12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water

Log P <sub>ow</sub>	1.41
Method:	OECD Test Guideline 117
Results:	Not expected to accumulate in organisms (log P <sub>ow</sub> <4).

### 12.4 Mobility in soil

The substance is practically insoluble in water. The mobility in soil is expected to be low.

### 12.5 Results of PBT and vPvB assessment

No data available.

### 12.6 Other adverse effects

No further information available.

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## 13 DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Dispose waste at authorized plant, in accordance with Directive 2008/98/EC and applicable national and local laws.

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## 14 TRANSPORT INFORMATION

Classified as not dangerous goods according to transport regulations.

### 14.1 UN number

IATA (Air)	-
ADR/RID (Road/Train)	-
IMDG (Sea)	-

**14.2 UN proper shipping name**

IATA (Air) -  
ADR/RID (Road/Train) -  
IMDG (Sea) -

**14.3 Transport hazard class(es)**

IATA (Air) -  
ADR/RID (Road/Train) -  
IMDG (Sea) -

**14.4 Packing group**

IATA (Air) -  
ADR/RID (Road/Train) -  
IMDG (Sea) -

**14.5 Environmental hazards**

IATA (Air) -  
ADR/RID (Road/Train) -  
IMDG (Sea) -

**14.6 Special precautions for user:**

See section 4, 5, 6, 7 and 8 for details on First aid, Firefighting, Accidental release, Handling & Storage and Personal protection measures.

*Additional information:*

IATA (Air) -  
ADR/RID (Road/Train) -  
IMDG (Sea) -

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

Not applicable.

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**15 REGULATORY INFORMATION**

This safety data sheet complies with the requirements of Regulation (EC) No 1907/2006.

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

The list below is just an overview of major regulations, not an exhaustive summary. Local and national legislation should be consulted for additional requirements.

EC Directive on waste.	2008/98/EC
EC Regulation on classification, labeling and packaging of substances and mixtures.	1272/2008
EC Regulation on registration, evaluation, authorization and restriction of chemicals.	453/2010

**15.2 Chemical safety assessment**

No chemical safety assessment has been carried out for this substance.

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**16 OTHER INFORMATION**

The following sections contain revisions or new statements: Sections 2, 5, 7-10, 12 and 14. Supersedes edition 9 from October 14, 2016.

*The information contained herein is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.*

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