



# Lacosamide

## Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830  
Date of issue: 8/12/2010 Revision date: 5/9/2019 Supersedes: 11/6/2018 Version: 7.0

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

#### 1.1. Product identifier

Name : Lacosamide  
CAS No : 175481-36-4  
REACH registration No : This substance is exempted from Registration according to the provisions of Article 2(5)a.  
Product code : SPM927  
Formula : C<sub>13</sub>H<sub>18</sub>N<sub>2</sub>O<sub>3</sub>  
Synonyms : (R)-2-acetamido-N-benzyl-3-methoxypropanamide  
Product group : Vimpat

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

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : Active pharmaceutical ingredient

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

UCB Pharma SA/NV  
Allée de la Recherche, 60  
1070 Brussels - Belgium  
T +32 2 386 6582 - F +32 2 386 3113  
[corporatehse@ucb.com](mailto:corporatehse@ucb.com)

#### 1.4. Emergency telephone number

Emergency number : +32 1 458 4545 (24 hrs/7 days)  
info@big.be  
Competent third party provider. Multi-language response both for in-country and international calls.

For Switzerland:  
Centre Suisse d'Information Toxicologique  
CH-8032 ZÜRICH  
Tel.: +41 (0) 44 251 51 51  
National emergency number: 145

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (oral), Category 3 H301  
Serious eye damage/eye irritation, Category 2 H319  
Full text of H statements : see section 16

##### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS06

Signal word (CLP) :

Danger

Hazard statements (CLP) :

H301 - Toxic if swallowed.  
H319 - Causes serious eye irritation.

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Precautionary statements (CLP)	: P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P280 - Wear protective clothing, protective gloves, eye protection, face protection. P301+P310 - IF SWALLOWED: immediately call a POISON CENTER or doctor/physician. P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P330 - Rinse mouth. P337+P313 - If eye irritation persists: Get medical advice/attention. P405 - Store locked up. P501 - Dispose of contents/container to in accordance with local regulation.
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### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	Conc. (% w/w)	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Lacosamide	(CAS No) 175481-36-4 (REACH-no) This substance is exempted from Registration according to the provisions of Article 2(5)a.	98	Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319

Full text of H-statements: see section 16

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Remove victim to uncontaminated area. Allow the victim to rest.
First-aid measures after skin contact	: After contact with skin, wash immediately and thoroughly with plenty of water. Remove contaminated clothing.
First-aid measures after eye contact	: Immediately flush eyes thoroughly with water for at least 30 minutes.
First-aid measures after ingestion	: Immediately call a POISON CENTER or doctor/physician. If possible show him this sheet. Failing this, show him the packaging or label.

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

No additional information available

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

Get immediate medical advice/attention. If possible, show him this sheet. Failing this, show him the packaging or label.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Extinguishing media: water spray, extinguishing powder, carbon dioxide, foam. Use the extinguishing material recommended for the primary cause of fire.
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### 5.2. Special hazards arising from the substance or mixture

No additional information available

### 5.3. Advice for firefighters

Firefighting instructions	: Prevent material from entering waterways, sewers or surface draining systems.
Protection during firefighting	: Wear self-contained breathing apparatus and protective suit (see section 8).

## SECTION 6: Accidental release measures

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

General measures	: Wear appropriate personal protective equipment in case of accidental release.
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#### 6.1.1. For non-emergency personnel

No additional information available

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Sweep spilled substance into containers; if appropriate, moisten first to prevent dusting. Collect spillage. Keep in suitable, closed containers for disposal. Clean contaminated surfaces with an excess of water.
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### 6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. Disposal: see section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Take precautionary measures against static discharge. Avoid creating or spreading dust. Provide local exhaust or general room ventilation to minimize exposure to dust.

Hygiene measures : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not wear contaminated clothing.

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

Storage conditions : Use good housekeeping practices during storage, transfer, handling, to avoid excessive dust accumulation. Store at temperatures not exceeding 25°C. Store in a dry place.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Lacosamide (175481-36-4)

#### DNEL/DMEL (Workers)

Acute - local effects, inhalation

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In-house Occupational Exposure Limit (OEL) : 0.1 (mg/m<sup>3</sup> - 8h)

### 8.2. Exposure controls

#### Appropriate engineering controls:

All liquid/powder handling operations should be performed in a contained manner using a suitably designed and performance verified containment system. Both local exhaust and general room ventilation are usually required. Access forbidden to unauthorised personnel. Manipulations are to be done only by qualified and authorised persons. Ground equipment electrically. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Use in combination with respiratory protective equipment until containment performance monitoring has verified that the respiratory protective equipment is not required.

#### Hand protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. The material, thickness and typical breakthrough times of the gloves must be defined after a workplace risk assessment.

#### Eye protection:

Use safety glasses and in case of splash risk face shield. Use equipment for eye protection tested and approved under appropriate standards such as EN 166 (EU). Eye protection must be defined after a workplace risk assessment.

#### Skin and body protection:

The type of protective equipment must be selected after a workplace risk assessment. At a minimum, a laboratory coat or equivalent protective clothing is required for work with this product.

#### Respiratory protection:

Where workplace risk assessment shows air-purifying respirators are required, conduct an exposure assessment to determine the type and amount of contaminant. The respirator must have an Assigned Protection Factor (APF) adequate to the workplace exposure. Use respirators and components tested and approved under appropriate standards such as CEN (EU).

#### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Crystalline powder.

Molecular mass : 250.3

Colour : White.

Odour : No data available

Odour threshold : No data available

pH : No data available

Relative evaporation rate (butylacetate=1) : Not applicable

Melting point : 140 - 146 °C (20°C)

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Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: 0.093 mPa (25°C)
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Solubility in phosphate buffered solutions; pH : 4,5; 25°C : 28.4 - 28.9 g/l. Solubility in phosphate buffered solutions; pH : 7,5; 25°C : 20.1 - 20.8 g/l. Water: 30.2 - 30.8 g/l in pure water
Log Pow	: No data available
Log Kow	: 0.25 (OECD 107)
Viscosity, kinematic	: No data available
Viscosity, dynamic	: Not applicable
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No additional information available.

### 10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

### 10.3. Possibility of hazardous reactions

No additional information available

### 10.4. Conditions to avoid

No additional information available.

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Hazardous decomposition products may be released during prolonged heating like smokes, carbon monoxide and dioxide, nitrogen oxides (NOx).

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Toxic if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Additional information	: No additional information available

### Lacosamide (175481-36-4)

LD50 oral rat	253 mg/kg
LD50, oral, mouse	383 mg/kg
LD50, i.v, rat	> 100 mg/kg
LD50, i.v, mouse	> 178 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

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### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general	: Not classified. Data which is conclusive for non-classification.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

#### Lacosamide (175481-36-4)

NOEC (acute)	>= 100 mg/l Algal growth inhibition test (OECD 201) - 72h
NOEC chronic fish	>= 10 mg/l Fish early life stage test (Fathead Minnows; OECD 210)
NOEC chronic crustacea	32 mg/l (21 days - Daphnia reprotoxicity study - OECD 211)
NOEC	≥ 1000 mg/l (Activated Sludge respiration Inhibition test (OECD 209))

#### 12.2. Persistence and degradability

##### Lacosamide (175481-36-4)

Persistence and degradability	Abiotic degradation: hydrolysis is not expected to contribute significantly to rapid dissipation of Lacosamide from aquatic and terrestrial environmental compartments No hydrolysis. Not readily biodegradable (OECD 301B).
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#### 12.3. Bioaccumulative potential

##### Lacosamide (175481-36-4)

Log Kow	0.25 (OECD 107)
Bioaccumulative potential	Not expected to bioaccumulate due to the low log Kow (log Kow < 4).

#### 12.4. Mobility in soil

No additional information available

#### 12.5. Results of PBT and vPvB assessment

##### Lacosamide (175481-36-4)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

#### 12.6. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of waste product or used containers according to local regulations. Ensure all national/local regulations are observed.

### SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

#### 14.1. UN number

UN-No. (ADR)	: UN 2811
UN-No. (IMDG)	: UN 2811
UN-No. (IATA)	: UN 2811
UN-No. (ADN)	: UN 2811
UN-No. (RID)	: UN 2811

#### 14.2. UN proper shipping name

Proper Shipping Name (ADR)	: TOXIC SOLID, ORGANIC, N.O.S.
Proper Shipping Name (IMDG)	: TOXIC SOLID, ORGANIC, N.O.S.
Proper Shipping Name (IATA)	: TOXIC SOLID, ORGANIC, N.O.S.
Proper Shipping Name (ADN)	: TOXIC SOLID, ORGANIC, N.O.S.
Proper Shipping Name (RID)	: TOXIC SOLID, ORGANIC, N.O.S.
Transport document description (ADR)	: UN 2811 TOXIC SOLID, ORGANIC, N.O.S. ((R)-2-acetamido-N-benzyl-3-methoxypropanamide), 6.1, III, (E)
Transport document description (IMDG)	: UN 2811 TOXIC SOLID, ORGANIC, N.O.S. ((R)-2-acetamido-N-benzyl-3-methoxypropanamide), 6.1, III
Transport document description (IATA)	: UN 2811 TOXIC SOLID, ORGANIC, N.O.S. ((R)-2-acetamido-N-benzyl-3-methoxypropanamide), 6.1, III
Transport document description (ADN)	: UN 2811 TOXIC SOLID, ORGANIC, N.O.S. ((R)-2-acetamido-N-benzyl-3-methoxypropanamide), III

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Transport document description (RID) : UN 2811 TOXIC SOLID, ORGANIC, N.O.S. ((R)-2-acetamido-N-benzyl-3-methoxypropanamide), 6.1

### 14.3. Transport hazard class(es)

#### ADR

Transport hazard class(es) (ADR) : 6.1  
Danger labels (ADR) : 6.1



#### IMDG

Transport hazard class(es) (IMDG) : 6.1  
Danger labels (IMDG) : 6.1



#### IATA

Transport hazard class(es) (IATA) : 6.1  
Hazard labels (IATA) : 6.1



#### ADN

Transport hazard class(es) (ADN) : 6.1  
Danger labels (ADN) : 6.1



#### RID

Transport hazard class(es) (RID) : 6.1  
Danger labels (RID) : 6.1



### 14.4. Packing group

Packing group (ADR) : III  
Packing group (IMDG) : III  
Packing group (IATA) : III  
Packing group (ADN) : III  
Packing group (RID) : Not applicable

### 14.5. Environmental hazards

Dangerous for the environment : No  
Marine pollutant : No  
Other information : No supplementary information available

### 14.6. Special precautions for user

#### Overland transport

Classification code (ADR) : T2

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Special provisions (ADR)	: 274, 614
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Hazard identification number (Kemler No.)	: 60
Orange plates	:



Tunnel restriction code (ADR) : E

### Transport by sea

Special provisions (IMDG)	: 223, 274
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: P002
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: T1
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-A
Stowage category (IMDG)	: A

### Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y645
PCA limited quantity max net quantity (IATA)	: 10kg
PCA packing instructions (IATA)	: 670
PCA max net quantity (IATA)	: 100kg
CAO packing instructions (IATA)	: 677
CAO max net quantity (IATA)	: 200kg
ERG code (IATA)	: 6L

### Inland waterway transport

Special provisions (ADN)	: 274, 614, 802
Limited quantities (ADN)	: 5 kg
Excepted quantities (ADN)	: E1
Carriage permitted (ADN)	: T
Equipment required (ADN)	: EP, PP
Number of blue cones/lights (ADN)	: 0

### Rail transport

No data available

## 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

## SECTION 15: Regulatory information

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

#### 15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Lacosamide is not on the REACH Candidate List

Lacosamide is not subject to REGULATION (EU) No 649/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 concerning the export and import of hazardous chemicals.

Lacosamide is not subject to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC

#### 15.1.2. National regulations

No additional information available

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### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

### SECTION 16: Other information

#### Indication of changes:

Section	Changed Items	Change.	
Section	Changed item	Change	Comments
8.1	OEL TWA	Modified	OEL revision based on latest non-clinical studies

#### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
EC50	Median effective concentration
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
vPvB	Very Persistent and Very Bioaccumulative

Other information : Avoid contact with eyes. Avoid contact with skin. Wear suitable protective clothing, gloves and eye/face protection.

#### Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed
H319	Causes serious eye irritation

SDS EU (REACH Annex II)

*This Safety Data Sheet is based on knowledge available at the time of compilation and is intended to describe the product in terms of the health, safety and environmental requirements. It does not signify any warranty with regard to specific properties and specifications.*