

# Bupivacaine impurity D

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 31/01/2023 Version: 1.0

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

#### 1.1. Product identifier

Product form : Substance  
Substance name : Bupivacaine impurity D  
Chemical name : Hexanamide, 2,6-dichloro-N-(2,6-dimethylphenyl)-  
Product code : 202100102

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

##### 1.2.1. Relevant identified uses

Main use category : The product is intended for research, analysis and scientific education.  
Use of the substance/mixture : For professional use only  
Function or use category : Laboratory chemicals

##### 1.2.2. Uses advised against

Restrictions on use : Do not use : Ingestion, Inhalation, Dermal

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

European Directorate for the Quality of Medicines & Healthcare  
EDQM, Council of Europe 7, Allée Kastner, CS30026  
F- 67081 Strasbourg  
France  
T +33(0)388412035 - F +33(0)388412771  
[sds@edqm.eu](mailto:sds@edqm.eu) - [www.edqm.eu](http://www.edqm.eu)

#### 1.4. Emergency telephone number

Emergency number : +33(0)390215608

### SECTION 2: Hazards identification

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

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

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Skin sensitisation, Category 1	H317
Germ cell mutagenicity, Category 2	H341
Hazardous to the aquatic environment – Acute Hazard, Category 1	H400
Hazardous to the aquatic environment – Chronic Hazard, Category 1	H410

Full text of H- and EUH-statements: see section 16

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

Expert judgement and weight of evidence determination.

#### 2.2. Label elements

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

Hazard pictograms (CLP)



Signal word (CLP)

: Warning

Hazard statements (CLP)

: H315 - Causes skin irritation.  
H317 - May cause an allergic skin reaction.  
H319 - Causes serious eye irritation.

# Bupivacaine impurity D

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Precautionary statements (CLP)

H341 - Suspected of causing genetic defects.  
H410 - Very toxic to aquatic life with long lasting effects.  
: P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P272 - Contaminated work clothing should not be allowed out of the workplace.  
P273 - Avoid release to the environment.  
P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.  
P302+P352 - IF ON SKIN: Wash with plenty of water.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P308+P313 - IF exposed or concerned: Get medical advice/attention.  
P321 - Specific treatment (see supplemental first aid instruction on this label).  
P332+P313 - If skin irritation occurs: Get medical advice/attention.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P337+P313 - If eye irritation persists: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.  
P391 - Collect spillage.  
P405 - Store locked up.  
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Labelling according to: exemption for inner packaging where the contents do not exceed 10ml

### Hazard pictograms (CLP)



### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Hexanamide, 2,6-dichloro-N-(2,6-dimethylphenyl)-	-	≤ 100	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 Muta. 2, H341 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H- and EUH-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 skin contact : Wipe off as much as possible (using a clean, soft, absorbent material).  
First-aid measures after eye contact : Rinse eyes with water as a precaution.

# Bupivacaine impurity D

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 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

No additional information available

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Extinguishing blanket.

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

Fire hazard : See Heading 2.2.

### 5.3. Advice for firefighters

Firefighting instructions : Use extinguishing media appropriate for surrounding fire.

## SECTION 6: Accidental release measures

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

#### 6.1.1. For non-emergency personnel

Emergency procedures : Avoid all unnecessary exposure.

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

No additional information available

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

No additional information available

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

No additional information available

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

No additional information available

### 7.3. Specific end use(s)

See Heading 1.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

# Bupivacaine impurity D

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 8.1.2. Recommended monitoring procedures

No additional information available

### 8.1.3. Air contaminants formed

No additional information available

### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Keep in a well-ventilated room. Both local exhaust and general room ventilation are usually required.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

No additional information available

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Lab coat

##### Hand protection:

Protective gloves

#### 8.2.2.3. Respiratory protection

No additional information available

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

No additional information available

## SECTION 9: Physical and chemical properties

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

Physical state	: Solid
Colour	: Not available
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available

# Bupivacaine impurity D

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Stable under normal conditions.

### 10.2. Chemical stability

No additional information available

### 10.3. Possibility of hazardous reactions

None known.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

None under normal use. See Section 7.

### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Lack of data)
Acute toxicity (dermal)	: Not classified (Lack of data)
Acute toxicity (inhalation)	: Not classified (Lack of data)
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Suspected of causing genetic defects.
Carcinogenicity	: Not classified (Lack of data)
Reproductive toxicity	: Not classified (Lack of data)
STOT-single exposure	: Not classified (Lack of data)
STOT-repeated exposure	: Not classified (Lack of data)
Aspiration hazard	: Not classified (Technical impossibility to obtain the data)

### 11.2. Information on other hazards

No additional information available

# Bupivacaine impurity D

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : Presents no specific risk for the environment.  
Hazardous to the aquatic environment, short-term (acute) : Very toxic to aquatic life.  
Hazardous to the aquatic environment, long-term (chronic) : Very toxic to aquatic life with long lasting effects.  
Not rapidly degradable

#### 12.2. Persistence and degradability

No additional information available

#### 12.3. Bioaccumulative potential

No additional information available

#### 12.4. Mobility in soil

No additional information available

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

No additional information available

#### 12.6. Endocrine disrupting properties

No additional information available

#### 12.7. Other adverse effects

No additional information available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

No additional information available

### SECTION 14: Transport information




In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
<b>14.1. UN number or ID number</b>		
UN 3077	UN 3077	UN 3077
<b>14.2. UN proper shipping name</b>		
ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	Environmentally hazardous substance, solid, n.o.s.
<b>Transport document description</b>		
UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (-)	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT	UN 3077 Environmentally hazardous substance, solid, n.o.s., 9, III
<b>14.3. Transport hazard class(es)</b>		
9	9	9

# Bupivacaine impurity D


## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA
		
<b>14.4. Packing group</b>		
III	III	III
<b>14.5. Environmental hazards</b>		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes
No supplementary information available		

### 14.6. Special precautions for user

#### Overland transport

Classification code (ADR)	: M7
Special provisions (ADR)	: 274, 335, 375, 601
Limited quantities (ADR)	: 5kg
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P002, IBC08, LP02, R001
Special packing provisions (ADR)	: PP12, B3
Mixed packing provisions (ADR)	: MP10
Portable tank and bulk container instructions (ADR)	: T1, BK1, BK2, BK3
Portable tank and bulk container special provisions (ADR)	: TP33
Tank code (ADR)	: SGAV, LGBV
Vehicle for tank carriage	: AT
Transport category (ADR)	: 3
Special provisions for carriage - Packages (ADR)	: V13
Special provisions for carriage - Bulk (ADR)	: VC1, VC2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13
Hazard identification number (Kemler No.)	: 90
Orange plates	: 

Tunnel restriction code (ADR)

: -

#### Transport by sea

Special provisions (IMDG)	: 274, 335, 966, 967, 969
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: LP02, P002
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: BK1, BK2, BK3, T1
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-F
Stowage category (IMDG)	: A
Stowage and handling (IMDG)	: SW23

#### Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG

# Bupivacaine impurity D

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197, A215
ERG code (IATA)	: 9L

### 14.7. Maritime transport in bulk according to IMO instruments

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

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Not applicable.

##### POP Regulation (Persistent Organic Pollutants)

Not applicable.

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

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

Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H341	Suspected of causing genetic defects.



# Bupivacaine impurity D

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Muta. 2	Germ cell mutagenicity, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1

Safety Data Sheet (SDS), EU

**DISCLAIMER OF LIABILITY** The EDQM has created this SDS as a downstream user for regulatory compliance to rules applicable to chemicals only. This article is intended only for small-volume laboratory analysis and other routine testing prescribed in the pharmacopoeia or EDQM study protocol, under controlled conditions and by professionals only. Any other use of this article or the SDS information is the sole responsibility of the user. This substance is present in articles in quantities totalling under 10 kg per year. There is no human or environmental exposure under intended and foreseeable conditions of use. The user has the responsibility for handling, storage, use conditions and disposal of this article and for any use of the information in this SDS. The information has been obtained from suppliers and is without any warranty, express or implied, regarding its correctness. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the article.