

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

1.1. Product identifier

Product form	: Substance
Substance name	: Bupivacaine impurity F
Chemical name	: 2,6-xylidine; 2,6-dimethylaniline
EC Index-No.	: 612-161-00-X
EC-No.	: 201-758-7
CAS-No.	: 87-62-7
Product code	: 201601046

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 - 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]

Carcinogenicity, Category 2	H351
Acute toxicity (inhal.), Category 4	H332
Acute toxicity (dermal), Category 4	H312
Acute toxicity (oral), Category 4	H302
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335
Skin corrosion/irritation, Category 2	H315
Hazardous to the aquatic environment – Chronic Hazard, Category 2	H411
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)



Bupivacaine impurity F

Safety Data Sheet

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

Signal word (CLP)	: Warning
Hazard statements (CLP)	: H351 - Suspected of causing cancer. H332 - Harmful if inhaled. H312 - Harmful in contact with skin. H302 - Harmful if swallowed. H335 - May cause respiratory irritation. H315 - Causes skin irritation. H411 - Toxic to aquatic life with long lasting effects.
Precautionary statements (CLP)	: P202 - Do not handle until all safety precautions have been read and understood. P308+P313 - IF exposed or concerned: Get medical advice/attention.

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

Hazard pictograms (CLP)



GHS08

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]
2,6-xylylidine; 2,6-dimethylaniline	CAS-No.: 87-62-7 EC-No.: 201-758-7 EC Index-No.: 612-161-00-X	≤ 100	Carc. 2, H351 Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Dermal), H312 (ATE=1100 mg/kg bodyweight) Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) STOT SE 3, H335 Skin Irrit. 2, H315 Aquatic Chronic 2, H411

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.

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

Bupivacaine impurity F

Safety Data Sheet

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

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

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

Bupivacaine impurity F

Safety Data Sheet

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

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	: Liquid
Colour	: Not available
Odour	: Not available
Odour threshold	: Not available
Melting point	: 123 – 127 °C
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

Bupivacaine impurity F

Safety Data Sheet

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

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)	: Harmful if swallowed.
Acute toxicity (dermal)	: Harmful in contact with skin.
Acute toxicity (inhalation)	: Harmful if inhaled.
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: Not classified
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

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

12.2. Persistence and degradability

No additional information available

Bupivacaine impurity F

Safety Data Sheet

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

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
14.1. UN number or ID number		
UN 1711	UN 1711	UN 1711
14.2. UN proper shipping name		
XYLIDINES, LIQUID	XYLIDINES, LIQUID	Xylidines, liquid
Transport document description		
UN 1711 XYLIDINES, LIQUID, 6.1, II, (D/E), ENVIRONMENTALLY HAZARDOUS	UN 1711 XYLIDINES, LIQUID, 6.1, II, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS	UN 1711 Xylidines, liquid, 6.1, II, ENVIRONMENTALLY HAZARDOUS
14.3. Transport hazard class(es)		
6.1	6.1	6.1
		
14.4. Packing group		
II	II	II
14.5. Environmental hazards		
Dangerous for the environment: Yes	Dangerous for the environment: Yes Marine pollutant: Yes	Dangerous for the environment: Yes
No supplementary information available		

Bupivacaine impurity F

Safety Data Sheet

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

14.6. Special precautions for user

Overland transport

Classification code (ADR)	: T1
Limited quantities (ADR)	: 100ml
Excepted quantities (ADR)	: E4
Packing instructions (ADR)	: P001, IBC02
Mixed packing provisions (ADR)	: MP15
Portable tank and bulk container instructions (ADR)	: T7
Portable tank and bulk container special provisions (ADR)	: TP2
Tank code (ADR)	: L4BH
Tank special provisions (ADR)	: TU15, TE19
Vehicle for tank carriage	: AT
Transport category (ADR)	: 2
Special provisions for carriage - Loading, unloading and handling (ADR)	: CV13, CV28
Special provisions for carriage - Operation (ADR)	: S9, S19
Hazard identification number (Kemler No.)	: 60
Orange plates	: 
Tunnel restriction code (ADR)	: D/E

Transport by sea

Limited quantities (IMDG)	: 100 ml
Excepted quantities (IMDG)	: E4
Packing instructions (IMDG)	: P001
IBC packing instructions (IMDG)	: IBC02
Tank instructions (IMDG)	: T7
Tank special provisions (IMDG)	: TP2
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-A
Stowage category (IMDG)	: A
Properties and observations (IMDG)	: Toxic if swallowed, by skin contact or by inhalation.
MFAG-No	: 154

Air transport

PCA Excepted quantities (IATA)	: E4
PCA Limited quantities (IATA)	: Y641
PCA limited quantity max net quantity (IATA)	: 1L
PCA packing instructions (IATA)	: 654
PCA max net quantity (IATA)	: 5L
CAO packing instructions (IATA)	: 662
CAO max net quantity (IATA)	: 60L
ERG code (IATA)	: 6L

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

Bupivacaine impurity F

Safety Data Sheet

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

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:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment – Chronic Hazard, Category 2
Carc. 2	Carcinogenicity, Category 2
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.
H411	Toxic to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

Bupivacaine impurity F

Safety Data Sheet

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

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.