

Atorvastatin impurity mixture

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
 Issue date: 03/04/2023 Revision date: 24/01/2025 Supersedes version of: 03/04/2023 Version: 2.0

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

1.1. Product identifier

Product form	: Mixture
Product name	: Atorvastatin impurity mixture
Product code	: 202200029

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

Relevant identified uses

Use of the substance/mixture	: Scientific research and development Technical testing and analysis For professional use only
Function or use category	: Laboratory chemicals

Uses advised against

Restrictions on use	: Not for food, drug or home use
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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
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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
Reproductive toxicity, Category 1B	H360
Hazardous to the aquatic environment – Chronic Hazard, Category 4	H413
Full text of H- and EUH-statements: see section 16	

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

Adverse physicochemical, human health and environmental effects

May cause long lasting harmful effects to aquatic life. Suspected of causing cancer. May damage fertility or the unborn child.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP)	: Danger
Contains	: (3S,5S)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid
Hazard statements (CLP)	: H351 - Suspected of causing cancer. H360 - May damage fertility or the unborn child. H413 - May cause long lasting harmful effects to aquatic life.

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Precautionary statements (CLP)

- : P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P273 - Avoid release to the environment.
- P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
- P308+P313 - IF exposed or concerned: Get medical advice/attention.
- 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)

:



GHS08

Hazardous ingredients

- : (3S,5S)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid

2.3. Other hazards

Contains no PBT and/or vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

Other information

- : Warning - The product has not been fully tested.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
(3S,5S)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid	CAS-No.: 501121-34-2	60 – 75	Carc. 2, H351 Repr. 1B, H360
Atorvastatin lactone	CAS-No.: 125995-03-1 EC-No.: 418-950-3	25 – 40	Aquatic Chronic 4, H413

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

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

- : In all cases of doubt, or when symptoms persist, seek medical attention.

First-aid measures after inhalation

- : Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.

First-aid measures after skin contact

- : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact

- : Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion

- : Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

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

No additional information available

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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 : Use extinguishing media appropriate for surrounding fire. Carbon dioxide. Water spray. Dry powder. Extinguishing blanket.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Incomplete combustion releases dangerous carbon monoxide, carbon dioxide and other toxic gases. Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Avoid contact with skin, eyes and clothing.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Absorb with an inert material and place in an appropriate waste disposal container.

Methods for cleaning up : Clean contaminated surfaces with an excess of water. Clean with the help of detergents.

6.4. Reference to other sections

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Do not expose pregnant or breastfeeding women.

Precautions for safe handling : Avoid all unnecessary exposure. Ensure good ventilation of the work station.

Hygiene measures : Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wash hands before work breaks and after finishing work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat and direct sunlight.

Packaging materials : Keep in original containers.

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7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Both local exhaust and general room ventilation are usually required. Material should be handled in a laboratory hood whenever possible.

Personal protection equipment

Eye and face protection

Eye protection:

Wear eye protection. Safety glasses with side shields. (EN 166)

Skin protection

Skin and body protection:

Wear suitable protective clothing. Laboratory use : Lab coat. (EN 13034)

Hand protection:

Wear suitable gloves. Chemically resistant protective gloves. (EN 374)

Respiratory protection

Respiratory protection:

In case of dust formation use respirator with filter: P3

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
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
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

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9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

No additional information available

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

No additional information available

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

Atorvastatin lactone (125995-03-1)

LD50 oral rat	> 2000 mg/kg
LD50 dermal rat	> 2000 mg/kg

(3S,5S)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid (501121-34-2)

LD50 oral rat	> 5000 mg/kg (estimated value)
LD50 dermal rat	> 2000 mg/kg (estimated value)

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Suspected of causing cancer.
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

11.2. Information on other hazards

No additional information available

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SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : May cause long lasting harmful effects to aquatic life.

12.2. Persistence and degradability

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Persistence and degradability	Not rapidly degradable
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Atorvastatin lactone (125995-03-1)

Persistence and degradability	Not rapidly degradable
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(3S,5S)-7-[2-(4-fluorophenyl)-3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoic acid (501121-34-2)

Persistence and degradability	Not rapidly degradable
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12.3. Bioaccumulative potential

Atorvastatin lactone (125995-03-1)

Partition coefficient n-octanol/water (Log Pow)	4.55
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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		
Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name		
Not applicable	Not applicable	Not applicable

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ADR	IMDG	IATA
14.3. Transport hazard class(es)		
Not applicable	Not applicable	Not applicable
14.4. Packing group		
Not applicable	Not applicable	Not applicable
14.5. Environmental hazards		
Not applicable	Not applicable	Not applicable
No supplementary information available		

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

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

EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Council Regulation (EC) for the control of dual-use items

Contains no substance subject to the COUNCIL REGULATION (EC) for the control of dual-use items

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)

15.2. Chemical safety assessment

No additional information available

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SECTION 16: Other information

Indication of changes

Section	Changed item	Comments
	Supersedes version of	Added
	Revision date	Added
1.2	Main use category	Removed
1.2	Restrictions on use	Modified
1.2	Use of the substance/mixture	Modified
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified
2.1	Adverse physicochemical, human health and environmental effects	Modified
2.2	Hazard statements (CLP)	Modified
2.2	Precautionary statements (CLP)	Modified
2.3	Other information	Added
3	Composition/information on ingredients	Modified
4.1	First-aid measures after ingestion	Modified
4.1	First-aid measures after eye contact	Modified
4.1	First-aid measures after skin contact	Modified
4.1	First-aid measures after inhalation	Modified
4.1	First-aid measures general	Added
4.2	Symptoms/effects after skin contact	Removed
4.2	Symptoms/effects after inhalation	Removed
4.2	Symptoms/effects after eye contact	Removed
4.2	Symptoms/effects	Removed
4.3	Other medical advice or treatment	Removed
5.1	Suitable extinguishing media	Modified
5.1	Unsuitable extinguishing media	Added
5.2	Fire hazard	Removed
5.2	Hazardous decomposition products in case of fire	Added
5.3	Protection during firefighting	Added
5.3	Firefighting instructions	Modified
6.1	General measures	Modified
6.1	Protective equipment	Added
6.1	Emergency procedures	Modified
6.2	Environmental precautions	Added
6.3	For containment	Added
6.3	Methods for cleaning up	Modified
6.4	Reference to other sections (8, 13)	Added

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Indication of changes		
Section	Changed item	Comments
7.1	Hygiene measures	Modified
7.1	Additional hazards when processed	Modified
7.1	Precautions for safe handling	Modified
7.2	Packaging materials	Added
7.2	Technical measures	Removed
7.2	Storage conditions	Modified
7.3	Specific end uses	Removed
8.2	Eye protection	Modified
8.2	Appropriate engineering controls	Modified
8.2	Skin and body protection	Modified
8.2	Respiratory protection	Modified
8.2	Hand protection	Modified
9	Odour	Removed
10.1	Reactivity	Removed
10.5	Incompatible materials	Removed
10.6	Hazardous decomposition products	Removed
12.1	Ecology - general	Removed
13.1	Regional waste regulation	Removed

Full text of H- and EUH-statements:	
Aquatic Chronic 4	Hazardous to the aquatic environment – Chronic Hazard, Category 4
Carc. 2	Carcinogenicity, Category 2
H351	Suspected of causing cancer.
H360	May damage fertility or the unborn child.
H413	May cause long lasting harmful effects to aquatic life.
Repr. 1B	Reproductive toxicity, Category 1B

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Carc. 2	H351	Calculation method
Repr. 1B	H360	Calculation method
Aquatic Chronic 4	H413	Calculation method

Safety Data Sheet (SDS), EU

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