

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

#### 1.1. Product identifier

Product form : Mixture  
Product name : Rosuvastatin impurity mixture  
Product code : 202300216

#### 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

#### 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]

Acute toxicity (oral), Category 4	H302
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319
Reproductive toxicity, Category 2	H361
Reproductive toxicity, Additional category, Effects on or via lactation	H362
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335

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

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

Harmful if swallowed. Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children. Causes serious eye irritation. Causes skin irritation. May cause respiratory irritation.

#### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) : Warning

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

Contains	: N-[4-(4-fluorophenyl)-5-[(E)-2-[(2S,4R)-4-hydroxy-6-oxooxan-2-yl]ethenyl]-6-propan-2-ylpyrimidin-2-yl]-N-methylmethanesulfonamide; (2E,5R,6E)-7-[4-(4-fluorophenyl)-2-[methyl(methylsulfonyl)amino]-6-propan-2-ylpyrimidin-5-yl]-5-hydroxyhepta-2,6-dienoic acid
Hazard statements (CLP)	: H302 - Harmful if swallowed. H315 - Causes skin irritation. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation. H361 - Suspected of damaging fertility or the unborn child. H362 - May cause harm to breast-fed children.
Precautionary statements (CLP)	: P201 - Obtain special instructions before use. P202 - Do not handle until all safety precautions have been read and understood. P260 - Do not breathe dust/fume/gas/mist/vapours/spray. P263 - Avoid contact during pregnancy and while nursing. P264 - Wash hands, forearms and face thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P271 - Use only outdoors or in a well-ventilated area. P280 - Wear protective gloves/protective clothing/eye protection/face protection/hearing protection. P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell. P302+P352 - IF ON SKIN: Wash with plenty of water. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. 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. P312 - Call a POISON CENTRE or doctor if you feel unwell. P321 - Specific treatment (see supplemental first aid instruction on this label). P330 - Rinse mouth. P332+P313 - If skin irritation 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. P403+P233 - Store in a well-ventilated place. Keep container tightly closed. 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	: N-[4-(4-fluorophenyl)-5-[(E)-2-[(2S,4R)-4-hydroxy-6-oxooxan-2-yl]ethenyl]-6-propan-2-ylpyrimidin-2-yl]-N-methylmethanesulfonamide; (2E,5R,6E)-7-[4-(4-fluorophenyl)-2-[methyl(methylsulfonyl)amino]-6-propan-2-ylpyrimidin-5-yl]-5-hydroxyhepta-2,6-dienoic acid

### 2.3. Other hazards

Contains no PBT and/or vPvB substances  $\geq 0.1\%$  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.

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### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
N-[4-(4-fluorophenyl)-5-[(E)-2-[(2S,4R)-4-hydroxy-6-oxooxan-2-yl]ethenyl]-6-propan-2-ylpyrimidin-2-yl]-N-methylmethanesulfonamide	CAS-No.: 503610-43-3	≥ 65 - ≤ 70	Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
(2E,5R,6E)-7-[4-(4-fluorophenyl)-2-[methyl(methylsulfonyl)amino]-6-propan-2-ylpyrimidin-5-yl]-5-hydroxyhepta-2,6-dienoic acid	CAS-No.: 1422954-12-8	≥ 30 - ≤ 35	Repr. 2, H361 Lact., H362

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. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse immediately and thoroughly, pulling the eyelids well away from the eye (15 minutes minimum). Remove contact lenses, if present and easy to do. Continue rinsing. 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. Immediately call a POISON CENTER/doctor.

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

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation. Redness, pain.

#### 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.
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#### 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.

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### 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.

#### 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)

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### 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

### 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

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### 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) : Harmful if swallowed.  
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)

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ATE CLP (oral)	749,625 mg/kg bodyweight
Skin corrosion/irritation	: Causes skin irritation.
Serious eye damage/irritation	: Causes serious eye irritation.
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	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.
STOT-single exposure	: May cause respiratory irritation.

#### N-[4-(4-fluorophenyl)-5-[(E)-2-[(2S,4R)-4-hydroxy-6-oxooxan-2-yl]ethenyl]-6-propan-2-yl]pyrimidin-2-yl]-N-methylmethanesulfonamide (503610-43-3)

STOT-single exposure	May cause respiratory irritation.
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

## 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) : Not classified (Based on available data, the classification criteria are not met)

### 12.2. Persistence and degradability

#### Rosuvastatin impurity mixture

Persistence and degradability	Not rapidly degradable
<b>N-[4-(4-fluorophenyl)-5-[(E)-2-[(2S,4R)-4-hydroxy-6-oxooxan-2-yl]ethenyl]-6-propan-2-yl]pyrimidin-2-yl]-N-methylmethanesulfonamide (503610-43-3)</b>	
Persistence and degradability	Not rapidly degradable
<b>(2E,5R,6E)-7-[4-(4-fluorophenyl)-2-[methyl(methylsulfonyl)amino]-6-propan-2-yl]pyrimidin-5-yl]-5-hydroxyhepta-2,6-dienoic acid (1422954-12-8)</b>	
Persistence and degradability	Not rapidly degradable

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### 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>		
Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>		
Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>		
Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>		
Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>		
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

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### 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 (EU 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 (EC 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

### SECTION 16: Other information

Indication of changes		
Section	Changed item	Comments
	Supersedes version of	<b>Added</b>
	Revision date	<b>Added</b>
	Issue date	<b>Modified</b>
1.2	Restrictions on use	<b>Modified</b>
1.2	Use of the substance/mixture	<b>Modified</b>
1.2	Main use category	<b>Removed</b>
2.1	Adverse physicochemical, human health and environmental effects	<b>Modified</b>
2.3	Other information	<b>Added</b>
4.1	First-aid measures after ingestion	<b>Added</b>
4.1	First-aid measures after inhalation	<b>Added</b>
4.1	First-aid measures general	<b>Added</b>
4.1	First-aid measures after skin contact	<b>Modified</b>
4.1	First-aid measures after eye contact	<b>Modified</b>
4.2	Symptoms/effects after inhalation	<b>Added</b>
4.2	Symptoms/effects after skin contact	<b>Added</b>
4.2	Symptoms/effects after eye contact	<b>Added</b>

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Indication of changes		
Section	Changed item	Comments
5.1	Unsuitable extinguishing media	<b>Added</b>
5.1	Suitable extinguishing media	<b>Modified</b>
5.2	Hazardous decomposition products in case of fire	<b>Added</b>
5.2	Fire hazard	<b>Removed</b>
5.3	Protection during firefighting	<b>Added</b>
5.3	Firefighting instructions	<b>Modified</b>
6.1	Protective equipment	<b>Added</b>
6.1	General measures	<b>Added</b>
6.1	Emergency procedures	<b>Modified</b>
6.2	Environmental precautions	<b>Added</b>
6.3	For containment	<b>Added</b>
6.3	Methods for cleaning up	<b>Added</b>
6.4	Reference to other sections (8, 13)	<b>Added</b>
7.1	Additional hazards when processed	<b>Added</b>
7.1	Precautions for safe handling	<b>Added</b>
7.1	Hygiene measures	<b>Added</b>
7.2	Packaging materials	<b>Added</b>
7.2	Storage conditions	<b>Added</b>
7.3	Specific end uses	<b>Removed</b>
8.2	Eye protection	<b>Added</b>
8.2	Respiratory protection	<b>Added</b>
8.2	Hand protection	<b>Modified</b>
8.2	Appropriate engineering controls	<b>Modified</b>
8.2	Skin and body protection	<b>Modified</b>
10.1	Reactivity	<b>Removed</b>
10.3	Possibility of hazardous reactions	<b>Removed</b>
10.5	Incompatible materials	<b>Removed</b>
10.6	Hazardous decomposition products	<b>Removed</b>
12.1	Ecology - general	<b>Removed</b>

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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

Full text of H- and EUH-statements:	
H361	Suspected of damaging fertility or the unborn child.
H362	May cause harm to breast-fed children.
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 2	Reproductive toxicity, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Acute Tox. 4 (Oral)	H302	Calculation method
Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method
Repr. 2	H361	Calculation method
Lact.	H362	Calculation method
STOT SE 3	H335	Calculation method

Safety Data Sheet (SDS), EU

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