



## SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:  
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 09-Nov-2023

Revision Number 1

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

#### 1.1. Product identifier

**Product Code(s)** CAT 627  
**Product Name** 3-Formylrifamycin SV  
**Form** Not applicable

*NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II*

**EC No (EU Index No)** 236-311-5  
**CAS No.** 13292-22-3  
**Pure substance/mixture** Substance  
**Formula** C38H47NO13  
**Molecular weight** 725.78

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

**Recommended use** Laboratory use  
**Uses advised against** No information available

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

##### **Supplier**

British Pharmacopoeia Commission  
MHRA  
10 South Colonnade  
Canary Wharf  
London E14 4PU  
United Kingdom

Tel : +44 (0)20 3080 6561  
eMail: bpcrs@mhra.gov.uk

For further information, please contact \_\_\_\_\_



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E-mail address bpcrs@mhra.gov.uk

### 1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008	
Europe	112
Austria	No information available
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

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

Serious eye damage/eye irritation	Category 1 - (H318)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 1 - (H410)

### 2.2. Label elements

Contains 3-Formylrifamycin SV





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3-Formylrifamycin SV 13292-22-3	90 - 100%	-	236-311-5	Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)			
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### Full text of H- and EUH-phrases: see section 16

#### Acute Toxicity Estimate

No information available

This product does not contain candidate substances of very high concern at a concentration  $\geq 0.1\%$  (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## **SECTION 4: First aid measures**

### 4.1. Description of first aid measures

<b>General advice</b>	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air. Get medical attention immediately if symptoms occur.
<b>Eye contact</b>	Get immediate medical attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a doctor.
<b>Self-protection of the first aider</b>	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

**Symptoms** Burning sensation.

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

**Note to doctors** Treat symptomatically.



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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

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

**Specific hazards arising from the chemical** No information available.

### 5.3. Advice for firefighters

**Special protective equipment and precautions for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## SECTION 6: Accidental release measures

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

**Personal precautions** Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

**Other information** Refer to protective measures listed in Sections 7 and 8.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

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

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.



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## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

<b>Advice on safe handling</b>	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.
<b>General hygiene considerations</b>	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.

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

<b>Storage Conditions</b>	Please refer to the manufacturer's certificate for specific storage and transport temperature conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.
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### 7.3. Specific end use(s)

<b>Risk Management Methods (RMM)</b>	The information required is contained in this Safety Data Sheet.
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## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

<b>Exposure Limits</b>	This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
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#### **Biological occupational exposure limits**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

<b>Derived No Effect Level (DNEL)</b>	No information available.
<b>Predicted No Effect Concentration (PNEC)</b>	No information available.



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### 8.2. Exposure controls

#### Personal protective equipment

<b>Eye/face protection</b>	Avoid contact with eyes. Wear safety glasses with side shields (or goggles). Tight sealing safety goggles.
<b>Hand protection</b>	The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear protective butyl rubber gloves. Wear suitable gloves.
<b>Skin and body protection</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
<b>General hygiene considerations</b>	Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection.
<b>Environmental exposure controls</b>	Do not allow into any sewer, on the ground or into any body of water.

## **SECTION 9: Physical and chemical properties**

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

<b>Physical state</b>	Solid
<b>Appearance</b>	Solid
<b>Colour</b>	dark red
<b>Odour</b>	No information available.
<b>Odour threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>Melting point / freezing point</b>	>122	None known
<b>Initial boiling point and boiling range</b>	No data available	None known
<b>Flammability</b>	No data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Flash point</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known



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<b>Decomposition temperature</b>		None known
<b>pH</b>	No data available	None known
<b>pH (as aqueous solution)</b>	No data available	No information available
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Water solubility</b>	No data available	None known
<b>Solubility(ies)</b>	DMSO, Methanol, Chloroform, slightly soluble	
<b>Partition coefficient</b>	No data available	None known
<b>Vapour pressure</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Bulk density</b>	No data available	
<b>Liquid Density</b>	No data available	
<b>Relative vapour density</b>	No data available	None known
<b>Particle characteristics</b>		
<b>Particle Size</b>	No information available	
<b>Particle Size Distribution</b>	No information available	

### 9.2. Other information

<b>Molecular weight</b>	725.78
<b>Molecular formula</b>	C <sub>38</sub> H <sub>47</sub> NO <sub>13</sub>

9.2.1. Information with regards to physical hazard classes  
Not applicable

9.2.2. Other safety characteristics  
No information available

## **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

**Reactivity** No information available.

### 10.2. Chemical stability

**Stability** Stable under normal conditions.

### Explosion data

**Sensitivity to mechanical impact** None.

**Sensitivity to static discharge** None.

### 10.3. Possibility of hazardous reactions

**Possibility of hazardous reactions** None under normal processing.





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### 10.4. Conditions to avoid

**Conditions to avoid** None known based on information supplied.

### 10.5. Incompatible materials

**Incompatible materials** Strong acids. Strong bases. Strong oxidising agents.

**Hazardous decomposition products** None known based on information supplied.

## **SECTION 11: Toxicological information**

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

#### Information on likely routes of exposure

##### Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available. Causes serious eye damage. May cause irreversible damage to eyes.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. May cause irritation.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea.

#### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Redness. Burning. May cause blindness.

#### Numerical measures of toxicity

No information available

#### **Acute toxicity**

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Skin corrosion/irritation** May cause skin irritation.



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<b>Serious eye damage/eye irritation</b>	Classification based on data available for ingredients. Causes burns. Causes serious eye damage.
<b>Respiratory or skin sensitisation</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

#### 11.2.2. Other information

**Other adverse effects** No information available.

## **SECTION 12: Ecological information**

### 12.1. Toxicity

**Ecotoxicity** Very toxic to aquatic life with long lasting effects.



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#### 12.2. Persistence and degradability

Persistence and degradability No information available.

#### 12.3. Bioaccumulative potential

Bioaccumulation No information available.

#### 12.4. Mobility in soil

Mobility in soil No information available.

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

PBT and vPvB assessment No information available.

#### 12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

#### 12.7. Other adverse effects

No information available.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

### SECTION 14: Transport information

#### IATA

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (3-Formylrifamycin SV)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (3-Formylrifamycin SV), 9, III



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<b>14.5 Environmental hazards</b>	Yes
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	A97, A158, A179, A197, A215
<b>ERG Code</b>	9L
<b>IMDG</b>	
<b>14.1 UN number or ID number</b>	UN3077
<b>14.2 UN proper shipping name</b>	Environmentally hazardous substances, solid, n.o.s. (3-Formylrifamycin SV)
<b>14.3 Transport hazard class(es)</b>	9
<b>14.4 Packing group</b>	III
<b>Description</b>	UN3077, Environmentally hazardous substances, solid, n.o.s. (3-Formylrifamycin SV), 9, III, Marine pollutant
<b>14.5 Marine pollutant</b>	P
<b>Environmental hazards</b>	Yes
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	274, 335, 966, 967, 969
<b>EmS-No.</b>	F-A, S-F No information available
<b>14.7 Maritime transport in bulk according to IMO instruments</b>	No information available
<b>RID</b>	
<b>14.1 UN number or ID number</b>	UN3077
<b>14.2 UN proper shipping name</b>	Environmentally hazardous substances, solid, n.o.s. (3-Formylrifamycin SV)
<b>14.3 Transport hazard class(es)</b>	9
<b>14.4 Packing group</b>	III
<b>Description</b>	UN3077, Environmentally hazardous substances, solid, n.o.s. (3-Formylrifamycin SV), 9, III
<b>14.5 Environmental hazards</b>	Yes
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	274, 335, 375, 601
<b>Classification code</b>	M7
<b>ADR</b>	
<b>14.1 UN number or ID number</b>	UN3077
<b>14.2 UN proper shipping name</b>	Environmentally hazardous substances, solid, n.o.s. (3-Formylrifamycin SV)
<b>14.3 Transport hazard class(es)</b>	9
<b>14.4 Packing group</b>	III
<b>Description</b>	UN3077, Environmentally hazardous substances, solid, n.o.s. (3-Formylrifamycin SV), 9, III, (-)
<b>14.5 Environmental hazards</b>	Yes
<b>14.6 Special precautions for user</b>	
<b>Special Provisions</b>	274, 335, 601, 375
<b>Classification code</b>	M7
<b>Tunnel restriction code</b>	(-)



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

### National regulations

#### Germany

**Water hazard class (WGK)** strongly hazardous to water (WGK 3)

#### Poland

**SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650). Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).**

#### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)



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### **DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors**

Not applicable

### **Persistent Organic Pollutants**

Not applicable

### **Dangerous substance category per Seveso Directive (2012/18/EU)**

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

### **Ozone-depleting substances (ODS) regulation (EC) 1005/2009**

Not applicable

### International Inventories

#### **TSCA**

Complies under research and development exemption or is regulated by a different government agency.

#### **DSL/NDSL**

Contact supplier for inventory compliance status

#### **EINECS/ELINCS**

Contact supplier for inventory compliance status

#### **ENCS**

Contact supplier for inventory compliance status

#### **IECSC**

Contact supplier for inventory compliance status

#### **KECL**

Contact supplier for inventory compliance status

#### **PICCS**

Contact supplier for inventory compliance status

#### **AIC**

Contact supplier for inventory compliance status

### Legend:

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

#### **Chemical Safety Report**

A Chemical Safety Assessment is not required for this substance



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## SECTION 16: Other information

### Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

H318 - Causes serious eye damage

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: Exposure controls/personal protection

TWA

TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling

Maximum limit value

\*

Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGl(s))



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U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
U.S. Environmental Protection Agency High Production Volume Chemicals  
Food Research Journal  
Hazardous Substance Database  
International Uniform Chemical Information Database (IUCLID)  
Japan GHS Classification  
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
NIOSH (National Institute for Occupational Safety and Health)  
National Library of Medicine's ChemID Plus (NLM CIP)  
National Library of Medicine's PubMed database (NLM PUBMED)  
National Toxicology Program (NTP)  
New Zealand's Chemical Classification and Information Database (CCID)  
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications  
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme  
Organisation for Economic Co-operation and Development Screening Information Data Set  
World Health Organization

Revision date 09-Nov-2023

**This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**

### Disclaimer

**The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.**

**End of Safety Data Sheet**