

Creation Date 03-May-2016

Revision Date 03-May-2016

Revision Number 1

## SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identification

Product Description: **Rifaximin**  
 Cat No. : **461680000; 461680010; 461680050**  
 CAS-No **80621-81-4**  
 Molecular Formula **C43 H51 N3 O11**

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

Recommended Use Laboratory chemicals.  
 Uses advised against No Information available

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

Company Acros Organics BVBA  
 Janssen Pharmaceuticaaan 3a  
 2440 Geel, Belgium  
 E-mail address [begeel.sdsdesk@thermofisher.com](mailto:begeel.sdsdesk@thermofisher.com)

### 1.4. Emergency telephone number

For information **US** call: 001-800-ACROS-01 / **Europe** call: +32 14 57 52 11  
 Emergency Number **US**:001-201-796-7100 / **Europe**: +32 14 57 52 99  
**CHEMTREC** Tel. No.**US**:001-800-424-9300 / **Europe**:001-703-527-3887

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture

#### CLP Classification - Regulation (EC) No 1272/2008

##### Physical hazards

Based on available data, the classification criteria are not met

##### Health hazards

Reproductive Toxicity

Category 2

##### Environmental hazards

Based on available data, the classification criteria are not met

### 2.2. Label elements



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## Signal Word

Warning

## Hazard Statements

H361 - Suspected of damaging fertility or the unborn child

## Precautionary Statements

P201 - Obtain special instructions before use

P280 - Wear protective gloves/ protective clothing/ eye protection/ face protection

P308 + P313 - IF exposed or concerned: Get medical advice/ attention

## 2.3. Other hazards

No information available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substances

Component	CAS-No	EC-No.	Weight %	CLP Classification - Regulation (EC) No 1272/2008
2,7-(Epoxy-pentadeca[1,11,13]trienimino)benzofuro[4,5-e]pyrido[1,2-a]benzimidazole-1,15(2H)-dione, 25-(acetyloxy)-5,6,21,23-tetrahydroxy-27-methoxy-2,4,11,16,20,22,24,26-octamethyl-, (2S,16Z,18E,20S,21	80621-81-4		>95	Repr. 2 (H361)

Full text of Hazard Statements: see section 16

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

#### General Advice

If symptoms persist, call a physician.

#### Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Obtain medical attention.

#### Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

#### Ingestion

Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

#### Inhalation

Move to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

#### Protection of First-aiders

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

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

None reasonably foreseeable.

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

#### Notes to Physician

Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

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## **5.1. Extinguishing media**

### **Suitable Extinguishing Media**

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

### **Extinguishing media which must not be used for safety reasons**

No information available.

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

Thermal decomposition can lead to release of irritating gases and vapors.

### **Hazardous Combustion Products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Nitrogen oxides (NO<sub>x</sub>).

## **5.3. Advice for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## **SECTION 6: ACCIDENTAL RELEASE MEASURES**

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

Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation.

### **6.2. Environmental precautions**

Should not be released into the environment.

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

Sweep up or vacuum up spillage and collect in suitable container for disposal. Keep in suitable, closed containers for disposal.

### **6.4. Reference to other sections**

Refer to protective measures listed in Sections 8 and 13.

## **SECTION 7: HANDLING AND STORAGE**

### **7.1. Precautions for safe handling**

Wear personal protective equipment. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation. Use only under a chemical fume hood.

### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use. Wash hands before breaks and at the end of workday.

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

Keep container tightly closed in a dry and well-ventilated place. Store in freezer.

### **7.3. Specific end use(s)**

Use in laboratories

## **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

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## 8.1. Control parameters

### Exposure limits

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

### Biological limit values

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

### Monitoring methods

BS EN 14042:2003 Title Identifier: Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents.

MDHS14/3 General methods for sampling and gravimetric analysis of respirable and inhalable dust

**Derived No Effect Level (DNEL)** No information available

Route of exposure	Acute effects (local)	Acute effects (systemic)	Chronic effects (local)	Chronic effects (systemic)
Oral Dermal Inhalation				

**Predicted No Effect Concentration (PNEC)** No information available.

## 8.2. Exposure controls

### Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

### Personal protective equipment

#### Eye Protection

Safety glasses with side-shields (European standard - EN 166)

#### Hand Protection

Protective gloves

Glove material	Breakthrough time	Glove thickness	EU standard	Glove comments
Nitrile rubber	See manufacturers	-	EN 374	(minimum requirement)
Neoprene	recommendations			
Natural rubber				
PVC				

#### Skin and body protection

Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

#### Respiratory Protection

When workers are facing concentrations above the exposure limit they must use

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	appropriate certified respirators. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly
Large scale/emergency use	Use a NIOSH/MSHA or European Standard EN 136 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced
Small scale/Laboratory use	<b>Recommended Filter type:</b> Particulates filter conforming to EN 143 Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. <b>Recommended half mask:-</b> Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted
Environmental exposure controls	No information available.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Appearance	Red Orange	
Physical State	Solid	
Odor	No information available	
Odor Threshold	No data available	
pH	No information available	
Melting Point/Range	218 - 220 °C / 424.4 - 428 °F	
Softening Point	No data available	
Boiling Point/Range	No information available	
Flash Point	No information available	<b>Method -</b> No information available
Evaporation Rate	Not applicable	Solid
Flammability (solid,gas)	No information available	
Explosion Limits	No data available	
Vapor Pressure	No data available	
Vapor Density	Not applicable	Solid
Specific Gravity / Density	No data available	
Bulk Density	No data available	
Water Solubility	No information available	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Autoignition Temperature	Not applicable	
Decomposition Temperature	No data available	
Viscosity	Not applicable	Solid
Explosive Properties	No information available	
Oxidizing Properties	No information available	

### 9.2. Other information

Molecular Formula	C43 H51 N3 O11
Molecular Weight	785.88

## SECTION 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

None known, based on information available

### 10.2. Chemical stability

Stable under recommended storage conditions.

### 10.3. Possibility of hazardous reactions

Hazardous Polymerization	No information available.
Hazardous Reactions	None under normal processing.

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## 10.4. Conditions to avoid

Incompatible products.

## 10.5. Incompatible materials

Strong oxidizing agents.

## 10.6. Hazardous decomposition products

Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>). Nitrogen oxides (NO<sub>x</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

#### Product Information

#### (a) acute toxicity;

Oral

Based on available data, the classification criteria are not met

Dermal

No data available

Inhalation

No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
2,7-(Epoxy-pentadeca[1,11,13]trienimino)benzofuro[4,5-e]pyrido[1,2-a]benzimidazole-1,15(2H)-dione, 25-(acetyloxy)-5,6,21,23-tetrahydroxy-27-methoxy-2,4,11,16,20,22,24,26-octamethyl-, (2S,16Z,18E,20S,21	LD50 > 2 g/kg ( Rat )		

#### (b) skin corrosion/irritation;

No data available

#### (c) serious eye damage/irritation;

No data available

#### (d) respiratory or skin sensitization;

Respiratory

No data available

Skin

No data available

#### (e) germ cell mutagenicity;

No data available

#### (f) carcinogenicity;

No data available

There are no known carcinogenic chemicals in this product

#### (g) reproductive toxicity; Reproductive Effects

Category 2

Possible risk of impaired fertility. Possible risk of harm to the unborn child.

#### (h) STOT-single exposure;

No data available

#### (i) STOT-repeated exposure;

No data available

Target Organs

None known.

#### (j) aspiration hazard;

Not applicable

Solid

#### Other Adverse Effects

The toxicological properties have not been fully investigated.

Symptoms / effects, both acute and delayed

No information available

## SECTION 12: ECOLOGICAL INFORMATION

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## 12.1. Toxicity

### **Ecotoxicity effects**

Contains no substances known to be hazardous to the environment or that are not degradable in waste water treatment plants.

**12.2. Persistence and degradability** No information available

**12.3. Bioaccumulative potential** No information available

**12.4. Mobility in soil** No information available

**12.5. Results of PBT and vPvB assessment** No data available for assessment.

## **12.6. Other adverse effects**

### **Endocrine Disruptor Information**

This product does not contain any known or suspected endocrine disruptors

### **Persistent Organic Pollutant**

This product does not contain any known or suspected substance

### **Ozone Depletion Potential**

This product does not contain any known or suspected substance

## **SECTION 13: DISPOSAL CONSIDERATIONS**

### **13.1. Waste treatment methods**

#### **Waste from Residues / Unused Products**

Waste is classified as hazardous. Dispose of in accordance with the European Directives on waste and hazardous waste. Dispose of in accordance with local regulations.

#### **Contaminated Packaging**

Dispose of this container to hazardous or special waste collection point.

#### **European Waste Catalogue (EWC)**

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.

#### **Other Information**

Waste codes should be assigned by the user based on the application for which the product was used. Do not empty into drains.

## **SECTION 14: TRANSPORT INFORMATION**

### **IMDG/IMO**

Not regulated

#### **14.1. UN number**

#### **14.2. UN proper shipping name**

#### **14.3. Transport hazard class(es)**

#### **14.4. Packing group**

### **ADR**

Not regulated

#### **14.1. UN number**

#### **14.2. UN proper shipping name**

#### **14.3. Transport hazard class(es)**

#### **14.4. Packing group**

### **IATA**

Not regulated

#### **14.1. UN number**

#### **14.2. UN proper shipping name**

#### **14.3. Transport hazard class(es)**

#### **14.4. Packing group**

#### **14.5. Environmental hazards**

No hazards identified

#### **14.6. Special precautions for user**

No special precautions required

**14.7. Transport in bulk according to** Not applicable, packaged goods

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Annex II of MARPOL73/78 and the IBC Code

## SECTION 15: REGULATORY INFORMATION

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

**International Inventories** X = listed

### **National Regulations**

Take note of Control of Substances Hazardous to Health Regulations (COSHH) 2002 and 2005 Amendment.  
Take note of Dir 94/33/EC on the protection of young people at work  
Take note of Dir 92/85/EC on the protection of pregnant and breastfeeding women at work  
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

### 15.2. Chemical safety assessment

A Chemical Safety Assessment/Report (CSA/CSR) has not been conducted

## SECTION 16: OTHER INFORMATION

### Full Text of H-/EUH-Statements Referred to Under Section 3

H361 - Suspected of damaging fertility or the unborn child

#### Legend

**CAS** - Chemical Abstracts Service

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

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

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

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

**WEL** - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**DNEL** - Derived No Effect Level

**RPE** - Respiratory Protective Equipment

**LC50** - Lethal Concentration 50%

**NOEC** - No Observed Effect Concentration

**PBT** - Persistent, Bioaccumulative, Toxic

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

#### **Key literature references and sources for data**

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

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

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

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

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**TWA** - Time Weighted Average

**IARC** - International Agency for Research on Cancer

**PNEC** - Predicted No Effect Concentration

**LD50** - Lethal Dose 50%

**EC50** - Effective Concentration 50%

**POW** - Partition coefficient Octanol:Water

**vPvB** - very Persistent, very Bioaccumulative

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

**MARPOL** - International Convention for the Prevention of Pollution from Ships

**ATE** - Acute Toxicity Estimate

**VOC** - Volatile Organic Compounds

### **Training Advice**

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

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ACR46168



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Revision Summary

Not applicable.

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

## Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Safety Data Sheet**