

## SAFETY DATA SHEET

Creation Date 24-Aug-2015 Revision Date 25-Aug-2015 Revision Number 1

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

#### 1.1. Product identification

Product Description: <u>Gatifloxacin</u>

Cat No. : 460230000; 460230010; 460230050; 460230250

**CAS-No** 112811-59-3 **Molecular Formula** C19 H22 F N3 O4

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 Pharmaceuticalaan 3a

2440 Geel, Belgium

E-mail address begel.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**

Acute oral toxicity

Acute dermal toxicity

Acute Inhalation Toxicity - Dusts and Mists

Category 4

Category 4

#### **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**

H302 - Harmful if swallowed

H312 - Harmful in contact with skin

H332 - Harmful if inhaled

#### **Precautionary Statements**

P280 - Wear protective gloves/ protective clothing

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

P312 - Call a POISON CENTER or doctor/ physician if you feel unwell

P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing

#### 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
Gatifloxacin	112811-59-3		>95	Acute Tox. 4 (H302) Acute Tox. 4 (H312) Acute Tox. 4 (H332)

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. Obtain medical attention.

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

symptoms occur.

**Inhalation** Move to fresh air. If breathing is difficult, give oxygen. Obtain medical attention.

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 (CO2), Nitrogen oxides (NOx).

#### 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. See Section 12 for additional ecological information.

## 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.

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

Keep container tightly closed in a dry and well-ventilated place. To maintain product quality: Store in freezer.

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

Use in laboratories

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

#### 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

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**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 availabl	e		
Route of exposure	Acute effects (local)	Acute effects (systemic)	Chronic effects (local)	Chronic effects (systemic)
Oral		, ,	• •	, , ,
Dermal				
Inhalation				

Predicted No Effect Concentration No information available. (PNEC)

#### 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  Nitrile rubber  Neoprene  Natural rubber  PVC	Breakthrough time See manufacturers recommendations	Glove thickness	EU standard EN 374	Glove comments (minimum requirement)
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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 compatability, 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 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	Recommended Filter type: Particulates filter conforming to EN 143 Use a NIOSH/MSHA or European Standard EN 149:2001 approved respirator if exposure

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limits are exceeded or if irritation or other symptoms are experienced.

Recommended half mask:- Particle filtering: EN149:2001 When RPE is used a face piece Fit Test should be conducted

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice.

**Environmental exposure controls** No information available.

## **SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

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

White to yellow **Appearance** 

Solid **Physical State** 

No information available Odor **Odor Threshold** No data available

рΗ No information available

185 - 187 °C / 365 - 368.6 °F Melting Point/Range

**Softening Point** No data available **Boiling Point/Range** No information available

No information available **Flash Point** Method - No information available

Not applicable **Evaporation Rate** Solid

Flammability (solid,gas) No information available

No data available **Explosion Limits** 

No data available **Vapor Pressure** 

**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** 

**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** C19 H22 F N3 O4

**Molecular Weight** 375.39

## **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.

10.4. Conditions to avoid

Incompatible products. Excess heat. Avoid dust formation.

10.5. Incompatible materials

Oxidizing agents.

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#### 10.6. Hazardous decomposition products

Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>). Nitrogen oxides (NOx).

## **SECTION 11: TOXICOLOGICAL INFORMATION**

#### 11.1. Information on toxicological effects

**Product Information** 

(a) acute toxicity;

OralCategory 4DermalCategory 4InhalationCategory 4

(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; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

Target Organs No information available.

(j) aspiration hazard; Not applicable

Solid

Other Adverse Effects The toxicological properties have not been fully investigated.

Symptoms / effects,both acute and No information available

delayed

## **SECTION 12: ECOLOGICAL INFORMATION**

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** No data available for assessment.

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assessment

12.6. Other adverse effects

Endocrine Disruptor Information Persistent Organic Pollutant Ozone Depletion Potential This product does not contain any known or suspected endocrine disruptors

This product does not contain any known or suspected substance 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

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

X = listed The product is classified and labeled according to EC directives or corresponding national laws The product is classified and labeled in accordance with Directive 1999/45/EC

International Inventories

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#### **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 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

H302 - Harmful if swallowed

H312 - Harmful in contact with skin

H332 - Harmful if inhaled

#### Legend

**CAS** - Chemical Abstracts Service

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

EINECS/ELINCS - European Inventory of Existing Commercial Chemical DSL/NDSL - Canadian Domestic Substances List/Non-Domestic

Substances/EU List of Notified Chemical Substances

Substances List

PICCS - Philippines Inventory of Chemicals and Chemical Substances **IECSC** - Chinese Inventory of Existing Chemical Substances

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

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

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

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

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

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

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

#### Key literature references and sources for data

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

#### **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.

**Creation Date** 24-Aug-2015 **Revision Date** 25-Aug-2015 **Revision Summary** Not applicable.

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

#### **Disclaimer**

The information provided on 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

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# **End of Safety Data Sheet**