

# Simplex® HV with Gentamicin (Powder)

## Safety Data Sheet

according to the Hazardous Substances and New Organisms Act (1996)

Issue date: 9/4/2019

Revision date: 5/6/2021

Supersedes: 6/26/2020 Version: 1.2

SDS No: 11362-0021



### SECTION 1: Identification of the hazardous chemical and of the supplier

#### 1.1 Product identifier

Product name : Simplex® HV with Gentamicin (Powder)  
Product form : Mixture  
Product code : 6193-1-001 (1x40 g), 6193-1-010 (10x40 g)

#### 1.2 Other means of identification

Other means of identification : Code SDS: 139-0024.04-04

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

Recommended use : Bone cements

#### 1.4 Supplier's details

##### Manufacturer

OSARTIS GmbH  
Auf der Beune 101  
64839 Münster  
T +49 (0) 6071 929-0 - F +49 (0) 6071 929-100  
[Info@osartis.de](mailto:Info@osartis.de)

##### Sponsor

Stryker Australia  
8 Herbert Street  
St Leonards, NSW - Australia 2065  
T +61 02 9467 1000 - F +61 02 9467 1010

##### Sponsor

Stryker New Zealand  
511 Mt Wellington Highway  
Auckland - New Zealand, 1060  
T +64 09 573 1890 - F +64 09 573 1891

E-mail address of competent person responsible for the SDS: [sds@gbk-ingelheim.de](mailto:sds@gbk-ingelheim.de)

#### 1.5. Emergency phone number

Emergency number : Poisons and hazardous chemicals emergency: 0800 764 766

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

HSNO Approval Number : None allocated  
6.5B : Skin sensitisation, Category 1  
9.1B : Hazardous to the aquatic environment — Chronic Hazard, Category 2

#### 2.2. Label elements

##### GHS NZ labelling

Hazard pictograms (GHS NZ) :



Signal word (GHS NZ) : Warning  
Contains : Gentamicin, sulfate (1 - 3 %) ; dibenzoyl peroxide (0.5 – 1 %)  
Hazard statements (GHS NZ) : H317 - May cause an allergic skin reaction.  
H411 - Toxic to aquatic life with long lasting effects.  
Prevention : P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.  
P273 - Avoid release to the environment  
P280 - Wear protective gloves/protective clothing/eye protection/face protection.  
Response : P302+P352 - IF ON SKIN: Wash with plenty of water/...  
P391 - Collect spillage  
Disposal : P501 - Dispose of contents/container to an approved waste disposal plant.

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### 2.3. Other hazards not contributing to the classification

No additional information available

## SECTION 3: Composition and information of the ingredients of the hazardous chemical

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to GHS NZ
Gentamicin, sulfate	CAS-No.: 1405-41-0	1 - 3	6.5B: Skin Sens. 1, H317
dibenzoyl peroxide	CAS-No.: 94-36-0	0.5 – 1	5.2B: Org. Perox. B, H241 6.4A: Eye Irrit. 2, H319 6.5B: Skin Sens. 1, H317 9.1A: Aquatic Acute 1, H400 9.1A: Aquatic Chronic 1, H410

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Treatment	: Treat symptomatically.
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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam.
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### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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### 5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
EAC code	: 2Z.

## SECTION 6: Accidental release measures

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

No additional information available

#### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.
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### 6.1.2. 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. Notify authorities if product enters sewers or public waters.

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

For containment : Collect spillage.  
Methods for cleaning up : Mechanically recover the product.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment.  
Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

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

Storage conditions : Store in a well-ventilated place. Keep cool.  
Information on mixed storage : Keep away from food, drink and animal feeding stuffs.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

dibenzoyl peroxide (94-36-0)	
New Zealand - Occupational Exposure Limits	
Local name	Benzoyl peroxide
WES-TWA (OEL TWA) [1]	5 mg/m <sup>3</sup>
Remark (NZ)	dsen (Dermal sensitiser)
Regulatory reference	Workplace Exposure Standards and Biological Exposure Indices, 12th Edition

### Exposure limit values for the other components

No additional information available

### 8.2. Monitoring

No additional information available

### 8.3. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

### 8.4. Individual protection measures, such as personal protective equipment (PPE)

Hand protection : Select the appropriate glove material adhering to the breakthrough time, permeation rate and the degradation  
Eye protection : Safety glasses  
Skin and body protection : Wear suitable protective clothing  
Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment

Device	Filter type	Condition	Standard
Breathing equipment	Type P1		

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### Personal protective equipment symbol(s)



Environmental exposure controls : Avoid release to the environment.

## SECTION 9: Physical and chemical properties

Physical state	: Solid
Appearance	: No data available
Colour	: No data available
Odour	: No data available
Odour threshold	: No additional information available
pH	: No additional information available
Evaporation rate	: No additional information available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point / Freezing point	: Freezing point: Not applicable
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapour pressure	: No additional information available
Relative density	: No additional information available
Density	: No additional information available
Solubility	: insoluble in water.
Log Pow	: No data available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Explosive limits	: Not applicable
Minimum ignition energy	: No data available

## SECTION 10: Stability and reactivity

Reactivity	: Dust may form explosive mixture in air. Exothermic reaction with: Acids.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: None under normal use.
Conditions to avoid	: None under recommended storage and handling conditions (see section 7).
Incompatible materials	: reducing materials. Strong oxidizing agent.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

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Viscosity, kinematic	Not applicable
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## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: Toxic to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Toxic to aquatic life with long lasting effects.
Soil toxicity	: Not classified
Terrestrial vertebrate toxicity	: Not classified
Terrestrial invertebrate toxicity	: Not classified

### 12.2. Persistence and degradability

#### Simplex® HV with Gentamicin (Powder)

Persistence and degradability	No additional information available
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### 12.3. Bioaccumulative potential

#### Simplex® HV with Gentamicin (Powder)

Bioaccumulative potential	No additional information available
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### 12.4. Mobility in soil

#### Simplex® HV with Gentamicin (Powder)

Mobility in soil	No additional information available
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### 12.5. Other adverse effects

Ozone	: Not classified
Other adverse effects	: No additional information available

## SECTION 13: Disposal considerations

Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations	: Entrust the uncontaminated packaging to a licensed waste contractor. Recycling is preferred to disposal or incineration.

## SECTION 14: Transport information

### 14.1. UN number

UN-No. (UN RTDG)	: 3077
UN-No. (IMDG)	: 3077
UN-No. (IATA)	: 3077

### 14.2. Proper Shipping Name

Proper Shipping Name (UN RTDG)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)
Proper Shipping Name (IMDG)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (dibenzoyl peroxide)
Proper Shipping Name (IATA)	: Environmentally hazardous substance, solid, n.o.s. (dibenzoyl peroxide)

### 14.3. Transport hazard class(es)

#### UN RTDG

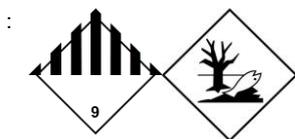
Transport hazard class(es) (UN RTDG)	: 9
Danger labels (UN RTDG)	: 9

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### IMDG

Transport hazard class(es) (IMDG)

: 9

Danger labels (IMDG)

: 9



### IATA

Transport hazard class(es) (IATA)

: 9

Danger labels (IATA)

: 9



## 14.4. Packing group

Packing group (UN RTDG)

: III

Packing group (IMDG)

: III

Packing group (IATA)

: III

## 14.5. Environmental hazards

Dangerous for the environment

: True

Marine pollutant

: Yes

Other information

: No supplementary information available

## 14.6. Special precautions for user

### UN RTDG

Special provisions (UN RTDG)

: 274, 331, 335, 375

Limited quantities (UN RTDG)

: 5 kg

Excepted quantities (UN RTDG)

: E1

Packing instruction (UN RTDG)

: P002, IBC08, LP02

Special packing provisions (UN RTDG)

: PP12, B3

Portable tank and bulk container special

: T1, BK2, BK3

instructions (UN RTDG)

Portable tank and bulk container special provisions

: TP33

(UN RTDG)

### IMDG

Special provisions (IMDG)

: 274, 335, 966, 967, 969

Limited quantities (IMDG)

: 5 kg

Excepted quantities (IMDG)

: E1

Packing instructions (IMDG)

: LP02, P002

Special packing provisions (IMDG)

: PP12

IBC packing instructions (IMDG)

: IBC08

IBC special provisions (IMDG)

: B3

Tank instructions (IMDG)

: BK1, BK2, BK3, T1

Tank special provisions (IMDG)

: TP33

EmS-No. (Fire)

: F-A - FIRE SCHEDULE Alfa - GENERAL FIRE SCHEDULE

EmS-No. (Spillage)

: S-F - SPILLAGE SCHEDULE Foxtrot - WATER-SOLUBLE MARINE POLLUTANTS

Stowage category (IMDG)

: A

### IATA

PCA Excepted quantities (IATA)

: E1

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PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197
ERG code (IATA)	: 9L

### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

### 14.8. Hazchem or Emergency Action Code

EAC code : 2Z.

## SECTION 15: Regulatory information

### 15.1. Safety, health, and environmental national regulations specific for the product

#### Hazardous Substances and New Organisms Act

HSNO Approval Number : None allocated

### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

SDS Major/Minor	: None
Issue date	: 9/4/2019
Revision date	: 06/05/2021
Supersedes	: 26/06/2020

### Indication of changes

Section	Changed item	Change	Comments
1	Address Information	Modified	

### Full text of H-statements

5.2B: Org. Perox. B	5.2B: Organic Peroxides, Type B
6.4A: Eye Irrit. 2	6.4A: Serious eye damage/eye irritation, Category 2
6.5B: Skin Sens. 1	6.5B: Skin sensitisation, Category 1
9.1A: Aquatic Acute 1	9.1A: Hazardous to the aquatic environment — Acute Hazard, Category 1
9.1A: Aquatic Chronic 1	9.1A: Hazardous to the aquatic environment — Chronic Hazard, Category 1
9.1B: Aquatic Chronic 2	9.1B: Hazardous to the aquatic environment — Chronic Hazard, Category 2
H241	Heating may cause a fire or explosion.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.