Simplex® HV (Liquid)

Safety Data Sheet

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

Issue date: 9/4/2019 Revision date: 5/6/2021 Supersedes: 7/3/2020 Version: 1.2

SDS No: 11362-0018

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

1.1 Product identifier

Product name : Simplex® HV (Liquid)

Product form : Mixture

Product code : 6189-1-001 (1x40 g), 6189-1-010 (10x40 g)

1.2 Other means of identification

Other means of identification : Code SDS: 139-0015.04-04

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

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

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 : HSR002495

3.1B	Flammable liquids, Category 2
6.3A	Skin corrosion/irritation, Category 2
6.5B	Skin sensitisation, Category 1
6.1E (Respiratory tract irritant)	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
6.9B	Specific target organ toxicity — Repeated exposure, Category 2

2.2. Label elements

GHS NZ labelling

Hazard pictograms (GHS NZ) :

Signal word (GHS NZ) : Danger

Contains : Methyl methacrylate (≥ 95 %) ; N,N-dimethyl-p-toluidine (1 - 3 %)

Hazard statements (GHS NZ) : H225 - Highly flammable liquid and vapour
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H335 - May cause respiratory irritation.
H373 - May cause damage to organs through prolonged or repeated exposure.

Prevention	:	P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261 - Avoid breathing dust/fume/gas/mist/vapours/spray. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Response	:	P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312 - Call a POISON CENTER/doctor if you feel unwell.
Storage	:	P405 - Store locked up.
Disposal	:	P501 - Dispose of contents/container to an approved waste disposal plant.

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
Methyl methacrylate	CAS-No.: 80-62-6	≥ 95	3.1B: Flam. Liq. 2, H225 6.1E (Respiratory tract irritant) : STOT SE 3, H335 6.3A: Skin Irrit. 2, H315 6.5B: Skin Sens. 1, H317
N,N-dimethyl-p-toluidine	CAS-No.: 99-97-8	1 - 3	6.1C: Acute Tox. 3 (Oral), H301 6.1C: Acute Tox. 3 (Dermal), H311 6.1B: Acute Tox. 2 (Inhalation:dust,mist), H330 6.9B: STOT RE 2, H373 9.1C: Aquatic Chronic 3, H412

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	:	Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation	:	Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact	:	Rinse skin with water/shower. Take off immediately all 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. Contact lenses should be removed.
First-aid measures after ingestion	:	Do not induce vomiting. Rinse mouth. 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 inhalation	:	May cause respiratory irritation.
Symptoms/effects after skin contact	:	Irritation. May cause an allergic skin reaction.

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

Treatment	:	Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	:	Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour.
Hazardous decomposition products in case of fire : Toxic fumes may be released.

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 : 3YE.

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. No open flames, no sparks, and no smoking. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.

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

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Use only outdoors or in a well-ventilated area. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.
Hygiene measures : Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. 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

Technical measures : Ground/bond container and receiving equipment.
Storage conditions : Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up.
Information on mixed storage : Keep away from food, drink and animal feeding stuffs.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Methyl methacrylate (80-62-6)	
New Zealand - Occupational Exposure Limits	
Local name	Methyl methacrylate
WES-TWA (OEL TWA) [1]	208 mg/m³
WES-TWA (OEL TWA) [2]	50 ppm

Methyl methacrylate (80-62-6)	
WES-STEL (OEL STEL)	416 mg/m³
WES-STEL (OEL STEL) [ppm]	100 ppm
Remark (NZ)	skin (Skin absorption), sen (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 : Protective gloves. 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

Personal protective equipment symbol(s)

Environmental exposure controls : Avoid release to the environment.

SECTION 9: Physical and chemical properties

Physical state : Liquid
Appearance : No data available
Colour : No data available
Odour : Ester like
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 : Melting point: -48 °C methyl methacrylate
Boiling point : 100.3 °C methyl methacrylate
Flash point : 10 °C DIN 51755, methyl methacrylate
Auto-ignition temperature : No data available
Flammability (solid, gas) : Not applicable
Vapour pressure : Vapour pressure: 37 hPa 20°C, methyl methacrylate
Relative density : No additional information available
Density : Density: 0.94 g/cm³ 20°C, methyl methacrylate
Solubility : No additional information available
Log Pow : No data available
Viscosity, kinematic : 0.564 mm²/s
Viscosity, dynamic : 0.53 mPa·s 20°C, methyl methacrylate
Explosive properties : No data available
Explosive limits : 2.1 vol % methyl methacrylate
12.5 vol % methyl methacrylate
Minimum ignition energy : No data available
SAPT : > 75°C

SECTION 10: Stability and reactivity

Reactivity	:	Highly flammable liquid and vapour.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No dangerous reactions known under normal conditions of use.
Conditions to avoid	:	Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.
Incompatible materials	:	No additional information available
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	:	Causes skin irritation.
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	:	May cause respiratory irritation.

Methyl methacrylate (80-62-6)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : May cause damage to organs through prolonged or repeated exposure.

N,N-dimethyl-p-toluidine (99-97-8)	
STOT-repeated exposure	May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard : Not classified

Simplex® HV (Liquid)	
Viscosity, kinematic	0.564 mm²/s

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	:	The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	:	Not classified
Hazardous to the aquatic environment, long-term (chronic)	:	Not classified
Soil toxicity	:	Not classified
Terrestrial vertebrate toxicity	:	Not classified
Terrestrial invertebrate toxicity	:	Not classified

N,N-dimethyl-p-toluidine (99-97-8)	
LC50 fish 1	49.9 mg/l

12.2. Persistence and degradability

Simplex® HV (Liquid)	
Persistence and degradability	No additional information available

N,N-dimethyl-p-toluidine (99-97-8)
Not rapidly degradable

12.3. Bioaccumulative potential

Simplex® HV (Liquid)	
Bioaccumulative potential	No additional information available

12.4. Mobility in soil

Simplex® HV (Liquid)	
Mobility in soil	No additional information available

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.
Additional information : Flammable vapours may accumulate in the container.

SECTION 14: Transport information

14.1. UN number

UN-No.(UN RTDG) : 1247
UN-No. (IMDG) : 1247
UN-No. (IATA) : 1247

14.2. Proper Shipping Name

Proper Shipping Name (UN RTDG) : METHYL METHACRYLATE MONOMER, STABILIZED
Proper Shipping Name (IMDG) : METHYL METHACRYLATE MONOMER, STABILIZED
Proper Shipping Name (IATA) : Methyl methacrylate monomer, stabilized

14.3. Transport hazard class(es)

UN RTDG

Transport hazard class(es) (UN RTDG) : 3
Danger labels (UN RTDG) : 3
:

IMDG

Transport hazard class(es) (IMDG) : 3
Danger labels (IMDG) : 3
:

IATA

Transport hazard class(es) (IATA) : 3
Danger labels (IATA) : 3

:

14.4. Packing group

Packing group (UN RTDG)	:	II
Packing group (IMDG)	:	II
Packing group (IATA)	:	II

14.5. Environmental hazards

Dangerous for the environment	:	False
Marine pollutant	:	No
Other information	:	No supplementary information available

14.6. Special precautions for user

UN RTDG

Special provisions (UN RTDG)	:	386
Limited quantities (UN RTDG)	:	1L
Excepted quantities (UN RTDG)	:	E2
Packing instruction (UN RTDG)	:	P001, IBC02
Portable tank and bulk container special instructions (UN RTDG)	:	T4
Portable tank and bulk container special provisions (UN RTDG)	:	TP1

IMDG

Special provisions (IMDG)	:	386
Limited quantities (IMDG)	:	1 L
Excepted quantities (IMDG)	:	E2
Packing instructions (IMDG)	:	P001
IBC packing instructions (IMDG)	:	IBC02
Tank instructions (IMDG)	:	T4
Tank special provisions (IMDG)	:	TP1
EmS-No. (Fire)	:	F-E - FIRE SCHEDULE Echo - NON-WATER-REACTIVE FLAMMABLE LIQUIDS
EmS-No. (Spillage)	:	S-D - SPILLAGE SCHEDULE Delta - FLAMMABLE LIQUIDS
Stowage category (IMDG)	:	C
Flash point (IMDG)	:	8°C c.c.

IATA

PCA Excepted quantities (IATA)	:	E2
PCA Limited quantities (IATA)	:	Y341
PCA limited quantity max net quantity (IATA)	:	1L
PCA packing instructions (IATA)	:	353
PCA max net quantity (IATA)	:	5L
CAO packing instructions (IATA)	:	364
CAO max net quantity (IATA)	:	60L
Special provisions (IATA)	:	A209
ERG code (IATA)	:	3L

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	:	3YE.

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 : HSR002495

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 : 03/07/2020

Indication of changes

Section	Changed item	Change	Comments
1	Address Information	Modified	

Full text of H-statements

3.1B: Flam. Liq. 2	3.1B: Flammable liquids, Category 2
6.1B: Acute Tox. 2 (Inhalation:dust,mist)	6.1B: Acute toxicity (inhalation:dust,mist) Category 2
6.1C: Acute Tox. 3 (Dermal)	6.1C: Acute toxicity (dermal), Category 3
6.1C: Acute Tox. 3 (Oral)	6.1C: Acute toxicity (oral), Category 3
6.1E (Respiratory tract irritant) : STOT SE 3	6.1E (Respiratory tract irritant) : Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
6.3A: Skin Irrit. 2	6.3A: Skin corrosion/irritation, Category 2
6.5B: Skin Sens. 1	6.5B: Skin sensitisation, Category 1
6.9B: STOT RE 2	6.9B: Specific target organ toxicity — Repeated exposure, Category 2
9.1C: Aquatic Chronic 3	9.1C: Hazardous to the aquatic environment — Chronic Hazard, Category 3
H225	Highly flammable liquid and vapour
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H330	Fatal if inhaled.
H335	May cause respiratory irritation.
H373	May cause damage to organs through prolonged or repeated exposure.
H412	Harmful 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.