

Safety Data Sheet

Sealapex Catalyst & Sealapex Catalyst Express

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

1.1. Product identifier

Product name : Sealapex Catalyst & Sealapex Catalyst Express

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

Relevant identified uses

Main use category : Professional use

Use of the substance/mixture : Preparation intended for dental medical use

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

KERRHAWE S.A.
Via Strecce n°4
6934 Bioggio (Switzerland)
T 00-800-41-050-505

Manufacturer

SybronEndo
1332 S. Lone Hill Avenue
Glendora, CA 91740 - USA
T +1.714.516.7979

Contact person : safety@kerrhawe.com - tel. 00-800-41-050-505 (08.00-17.00)

1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

Country	Organisation/Company	Address	Emergency number
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182/+44 191 2606180 24H

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

Not classified

2.2. Label elements

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

Extra phrases : The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).
A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Isobutyl salicylate	(CAS-No.) 87-19-4 (EC-No.) 201-729-9	1 - 30	Acute Tox. 4 (Oral), H302
Amorphous silica substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 67762-90-7 (EC-No.) 614-122-2 (REACH-no) N/A	< 10	Not classified
titanium dioxide substance with a Community workplace exposure limit substance with national workplace exposure limit(s) (GB, IE)	(CAS-No.) 13463-67-7 (EC-No.) 236-675-5 (REACH-no) 01-2119489379-17	< 10	Not classified

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general	: Move to fresh air. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.
First-aid measures after skin contact	: Gently wash with plenty of soap and water.
First-aid measures after eye contact	: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Drink plenty of water. Do NOT induce vomiting. Immediately call a POISON CENTER/doctor.

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

No additional information available

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

No specific measures identified.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO2) and powder.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Non flammable.
Hazardous decomposition products in case of fire	: Hazardous polymerization may occur if exposure to fire conditions.

5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment. Use water spray or fog for cooling exposed containers.
Protection during firefighting	: Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid contact with skin and eyes.
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For non-emergency personnel

Protective equipment	: See Heading 8.
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For emergency responders

No additional information available

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters. Discharging into rivers and drains is forbidden.

6.3. Methods and material for containment and cleaning up

- For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.
- Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Wash off with plenty of water.

6.4. Reference to other sections

For further information refer to section 13. For further information refer to section 8: "Exposure controls/personal protection".

SECTION 7: HANDLING AND STORAGE**7.1. Precautions for safe handling**

- Precautions for safe handling : Avoid contact with skin and eyes. Ensure good ventilation of the work station.
- Hygiene measures : Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a dry place. Keep cool. Store in original container. Keep container closed when not in use. Store in a well-ventilated place.
- Incompatible materials : Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control parameters**

Amorphous silica (67762-90-7)		
Ireland	Local name	Silica, amorphous respirable dust
Ireland	OEL (8 hours ref) (mg/m³)	2.4 mg/m³
United Kingdom	Local name	Silica, amorphous
United Kingdom	WEL TWA (mg/m³)	6 mg/m³ inhalable dust 2.4 mg/m³ respirable dust
titanium dioxide (13463-67-7)		
EU	Local name	Titanium dioxide
EU	Notes	SCOEL Recommendations (Ongoing)
Ireland	Local name	Titanium dioxide
Ireland	OEL (8 hours ref) (mg/m³)	10 mg/m³ total inhalable dust 4 mg/m³ respirable dust
United Kingdom	Local name	Titanium dioxide
United Kingdom	WEL TWA (mg/m³)	4 mg/m³ respirable 10 mg/m³ total inhalable

8.2. Exposure controls

- Appropriate engineering controls : Ensure good ventilation of the work station. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.
- Personal protective equipment : Gloves. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment. Avoid all unnecessary exposure.
- Hand protection : Wear protective gloves. PVC gloves. Layer thickness : 0,11 mm. Breakthrough time : >480 min. STANDARD EN 374.
- Eye protection : Not required
- Skin and body protection : Wear suitable protective clothing
- Respiratory protection : No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation

**Other information**

- : Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state	: Liquid
Appearance	: Paste.
Colour	: Off-white.
Odour	: characteristic.
Odour threshold	: Not determined
pH	: Not determined
Relative evaporation rate (butylacetate=1)	: Not determined
Melting point	: Not determined
Freezing point	: Not determined
Boiling point	: Not determined
Flash point	: Not determined
Auto-ignition temperature	: Not determined
Decomposition temperature	: Not determined
Flammability (solid, gas)	: No data available
Vapour pressure	: Not determined
Relative vapour density at 20 °C	: Not determined
Relative density	: > 1
Solubility	: insoluble in water.
Log Pow	: Not determined
Viscosity, kinematic	: Not determined
Viscosity, dynamic	: Not determined
Explosive properties	: Not explosive.
Oxidising properties	: Non flammable.
Explosive limits	: Not determined

9.2. Other information

Additional information : None to our knowledge.

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

No polymerization.

10.4. Conditions to avoid

None to our knowledge.

10.5. Incompatible materials

None to our knowledge.

10.6. Hazardous decomposition products

No decomposition if stored and used normally.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects**

Acute toxicity : Not classified

Titanium(IV) isopropoxide (546-68-9)	
LD50 oral rat	7236 mg/kg
LD50 dermal rat	> 15.5 g/kg
LC50 inhalation rat (mg/l)	7.78 mg/l/4h
Isobutyl salicylate (87-19-4)	
LD50 oral rat	1560 mg/kg
titanium dioxide (13463-67-7)	
LD50 oral rat	> 100000 mg/kg

Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: Not determined
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met pH: Not determined
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

titanium dioxide (13463-67-7)	
LC50 fish 1	> 1000 mg/l Fundulus heteroclitus
EC50 Daphnia 1	> 1000 mg/l (48 hours - Daphnia magna)

12.2. Persistence and degradability

Sealapex Catalyst & Sealapex Catalyst Express	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Sealapex Catalyst & Sealapex Catalyst Express	
Log Pow	Not determined
Bioaccumulative potential	Not established.

12.4. Mobility in soil

Sealapex Catalyst & Sealapex Catalyst Express	
Ecology - soil	insoluble in water.

12.5. Results of PBT and vPvB assessment

Sealapex Catalyst & Sealapex Catalyst Express	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Other adverse effects	: None to our knowledge.
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SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Regional legislation (waste)	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Waste treatment methods	: Do not discharge into drains.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.
Ecology - waste materials	: Avoid release to the environment.
European List of Waste (LoW) code	: 18 01 07 - chemicals other than those mentioned in 18 01 06

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number	Not regulated for transport
14.2. UN proper shipping name	
14.3. Transport hazard class(es)	
14.4. Packing group	
14.5. Environmental hazards	
No supplementary information available	

14.6. Special precautions for user**14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

IBC code : Not applicable.

SECTION 15: REGULATORY INFORMATION**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU-Regulations**

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10	Sealapex Catalyst & Sealapex Catalyst Express - Isobutyl salicylate
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Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

National regulations

The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d).
 EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Indication of changes:

Composition/information on ingredients. Hazards identification.

2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Added	
2.2	Precautionary statements (CLP)	Added	
2.2	Signal word (CLP)	Added	
2.2	Hazard pictograms (CLP)	Added	
2.2	Hazard statements (CLP)	Added	
2.2	EUH-statements	Removed	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures after ingestion	Modified	
4.1	First-aid measures after eye contact	Modified	
4.2	Symptoms/effects after eye contact	Added	
4.2	Symptoms/effects	Removed	
6.1	General measures	Added	
6.4	Reference to other sections (8, 13)	Modified	

300903		Sealapex Catalyst & Sealapex Catalyst Express	30/09/2017
7.1	Hygiene measures	Added	
7.1	Precautions for safe handling	Modified	
8.2	Appropriate engineering controls	Modified	
8.2	Personal protective equipment	Modified	
8.2	Hand protection	Modified	
8.2	Eye protection	Modified	
11.1	Potential adverse human health effects and symptoms	Added	

Date of issue : 15/04/2013
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 Date of total revision : 30/09/2017
 Version : 4.0
 Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.