

1 Identification of the substance or mixture and of the supplier

· **Other means of identification**

· **Trade name:** SprintRay Surgical Guide 3

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Industrial and Professional Use

· **Uses advised against** Any non-intended use

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Clinical & Regulatory Services Limited

POBox 766

Hastings

New Zealand

+64 275086002

carsl@xtra.co.nz

· **Further information obtainable from:**

Product safety department

1-800-424-9300 (U.S.A. and Canada)

· **Emergency telephone number:**

Chemtrec 1-800-424-9300 (U.S.A. & Canada) 1-703-527-3887 (All Other Countries) Emergency Action: In the event of a medical enquiry involving this product, please contact your doctor or local hospital accident and emergency department or the NHS enquiry service.

2 Hazards identification

· **Classification of the substance or mixture**

Skin sensitisation Category 1

H317 May cause an allergic skin reaction.

Carcinogenicity – Category 2

H351 Suspected of causing cancer.

Reproductive toxicity Category 2

H361 Suspected of damaging fertility or the unborn child.

Hazardous to the aquatic environment chronic Category 2H411 Toxic to aquatic life with long lasting effects.

· **Label elements**

· **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS07

GHS08

GHS09

· **Signal word** Warning

· **Hazard-determining components of labelling:**

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate

2-ethyl-2-[[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl]diacrylate

diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **Hazard statements**

May cause an allergic skin reaction.

Suspected of causing cancer.

Suspected of damaging fertility or the unborn child.

Toxic to aquatic life with long lasting effects.

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- **Precautionary statements**
If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Read carefully and follow all instructions.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
IF exposed or concerned: Get medical advice/attention.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable

3 Composition/Information on ingredients

- **Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 41637-38-1	Poly(oxy-1,2-ethanediyl), α, α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	>20- <50%
	Hazardous to the aquatic environment chronic Category 4, H413	
CAS: 72869-86-4 EINECS: 276-957-5	7,7,9 (or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate	10-25%
	⚠ Skin sensitisation Sub-category 1B, H317	
CAS: 15625-89-5 EINECS: 239-701-3	2-ethyl-2-[[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl]diacrylate	1-10%
	⚠ Carcinogenicity – Category 2, H351; ⚠ Hazardous to the aquatic environment acute Category 1, H400; Hazardous to the aquatic environment chronic Category 1, H410; ⚠ Skin irritation Category 2, H315; Eye irritation Category 2, H319; Skin sensitisation Category 1, H317	
CAS: 75980-60-8 EINECS: 278-355-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	=< 5%
	⚠ Hazardous to the aquatic environment chronic Category 2, H411; ⚠ Skin sensitisation Sub-category 1B, H317	

· **SVHC**

75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- **General information:** Immediately remove any clothing soiled by the product.
- **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** No further relevant information available.

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire fighting measures

- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to section 13.
Ensure adequate ventilation.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required
- **Further information about storage conditions:** Keep container tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Appropriate engineering controls** No further data; see section 7.
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.

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Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.

- **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:** Goggles recommended during refilling

9 Physical and chemical properties

- **General Information**

- **Appearance:**

- **Form:**

Fluid

- **Colour:**

According to product specification

- **Odour:**

Characteristic

- **Odour threshold:**

Not determined

- **pH-value:**

Not determined

- **Change in condition**

- **Melting point/freezing point:**

Undetermined

- **Initial boiling point and boiling range:**

Undetermined

- **Flash point:**

>94 °C

- **Flammability**

Not applicable

- **Decomposition temperature:**

Not determined

- **Ignition temperature:**

Product is not selfigniting.

- **Explosive properties:**

Product does not present an explosion hazard.

- **Explosion limits:**

- **Lower:**

Not determined

- **Upper:**

Not determined

- **Vapour pressure:**

Not determined

- **Density:**

Not determined

- **Relative density**

Not determined

- **Vapour density**

Not determined

- **Evaporation rate**

Not determined

- **Solubility in / Miscibility with**

- **water:**

Fully miscible.

- **Partition coefficient: n-octanol/water:**

Not determined

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- **Viscosity:**
- **Dynamic:** Not determined
- **Kinematic:** Not determined
- **Solvent content:**
- **Organic solvents:** 6.0 %
- **VOC (EC)** 6.00 %
- **Solids content:** 15.5–<26 %

- **Other information**
- **Particle characteristics** Not applicable
- **Physical state** Liquid

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

41637-38-1 Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-

Oral	LD50	>2,000 mg/kg (rat)
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Dermal	LD50	>2,000 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation** May cause an allergic skin reaction.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Suspected of causing cancer.
- **Reproductive toxicity** Suspected of damaging fertility or the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.

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- **Ecotoxicological effects:**
- **Remark:** Toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Toxic for aquatic organisms
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable
- **vPvB:** Not applicable
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

<ul style="list-style-type: none"> · UN-Number · NZS, IMDG, IATA 	not regulated
<ul style="list-style-type: none"> · UN proper shipping name · NZS, IMDG, IATA 	not regulated
<ul style="list-style-type: none"> · Transport hazard class(es) · NZS, ADN, IMDG, IATA · Class 	not regulated
<ul style="list-style-type: none"> · Packing group · NZS, IMDG, IATA 	not regulated
<ul style="list-style-type: none"> · Environmental hazards: 	Not applicable
<ul style="list-style-type: none"> · Special precautions for user 	Not applicable
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code 	Not applicable
<ul style="list-style-type: none"> · UN "Model Regulation": 	not regulated

* 15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- | |
|--|
| <ul style="list-style-type: none"> · New Zealand Inventory of Chemicals |
| <ul style="list-style-type: none"> · All ingredients are listed. |

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· **HSNO Approval numbers**

None of the ingredients is listed.

· **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS07 GHS08 GHS09

· **Signal word** Warning

· **Hazard-determining components of labelling:**

7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diylbismethacrylate
2-ethyl-2-[[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl]diacrylate
diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **Hazard statements**

May cause an allergic skin reaction.
Suspected of causing cancer.
Suspected of damaging fertility or the unborn child.
Toxic to aquatic life with long lasting effects.

· **Precautionary statements**

If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Read carefully and follow all instructions.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid release to the environment.
Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
IF exposed or concerned: Get medical advice/attention.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Directive 2012/18/EU**

· **Named dangerous substances - ANNEX I** None of the ingredients is listed.

· **Seveso category E2** Hazardous to the Aquatic Environment

· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t

· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

· **Substances of very high concern (SVHC) according to REACH, Article 57**

75980-60-8 | diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Relevant phrases**

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H351 Suspected of causing cancer.

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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.

H413 May cause long lasting harmful effects to aquatic life.

· **Department issuing SDS:** Environment protection department.

· **Contact:** -

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Skin irritation Category 2: Skin corrosion/irritation – Category 2

Eye irritation Category 2: Serious eye damage/eye irritation – Category 2

Skin sensitisation Category 1: Skin sensitisation – Category 1

Skin sensitisation Sub-category 1B: Skin sensitisation – Category 1B

Carcinogenicity – Category 2: Carcinogenicity – Category 2

Reproductive toxicity Category 2: Reproductive toxicity – Category 2

Hazardous to the aquatic environment acute Category 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Hazardous to the aquatic environment chronic Category 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Hazardous to the aquatic environment chronic Category 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Hazardous to the aquatic environment chronic Category 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

· *** Data compared to the previous version altered.**