



SAFETY DATA SHEET

Trio Elisse® TR204 Medical Skin Barrier Spray, 50ml Aerosol

This Safety Data Sheet contains information concerning the potential risks to those involved in handling, transporting and working with the material, as well as describing potential risks to the consumer and the environment. This information must be made available to those who may come into contact with the material or are responsible for the use of the material. This Safety Data Sheet is prepared in accordance with formatting described in the REACH Regulation (EC) No 1907/2006, and described in CLP Regulation (EC) No 1272/2008.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trio Elisse® TR204 Medical Skin Barrier Spray, 50ml Aerosol

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

Medical device for application to skin

1.3 Details of the supplier of the safety data sheet

Trio Healthcare Ltd
Unit 2A- 2B, Sandylands Business Centre,
Carleton New Road, Skipton
BD23 2AA
Tel: +44 (0)1756 700599
Email: mail@triohealthcare.co.uk

1.4 Emergency telephone number

Tel. +44 (0)1756 700599 Fax. +44 (0)1756 700708 (UK 9:00 am – 5:00 pm, Mon-Fri)

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

Classification in accordance with the CLP Regulation (EC) No 1272/2008

Fam Liq. 2, H225 Highly flammable liquid and vapour
Aquatic Acute 1, H400 Very toxic to aquatic organisms
Aquatic Chronic 2 H411 Toxic to aquatic organisms with long lasting effects

2.2 Label elements

Labelling in accordance with the CLP Regulation (EC) No 1272/2008

Bulk liquid



Danger

H225 Extremely flammable liquid and vapour
H410 Very toxic to aquatic organisms with long lasting effects
P102 Keep out of reach of children.

P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

Aerosol product



Danger

H222 Extremely flammable aerosol

H229 Pressurised container. May burst if heated

H410 Very toxic to aquatic organisms with long lasting effects

P102 Keep out of reach of children.

P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

P251 Do not pierce or burn, even after use.

P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

Note that for supply as a Medical Device for use directly onto the patient, CLP labelling does not apply, but there will be specific labelling requirements including those for aerosols, CE marking and Instructions for Use.

2.3 Other hazards

None identified. None of the components are considered to be PBT or vPvB.

SECTION 3: Composition

3.1 Substances

Not applicable - product is a mixture

3.2 Mixtures

EC	CAS	Name	TR101	Classification
203-492-7	107-46-0	Hexamethyldisiloxane	> 90%	Flam. Liq. 2, H225, Aquatic Acute 1 H400 (M=1) Aquatic Chronic 2 H411
310-094-8	102242-62-6	Zanthoxylum extract	≤ 1%	Acute Tox. 4 H302

Other non-hazardous ingredients to 100%

Propellant is air.

See section 16 for full description of H statements.

SECTION 4: First Aid Measures

4.1 Description of first aid measures

EYE CONTACT: Wash thoroughly with water for several minutes and obtain medical attention if signs of discomfort persist.

INHALATION: Remove from exposure. If breathing becomes difficult call a doctor.

SKIN CONTACT: No known adverse effects. If discomfort is experienced, seek medical advice. Take the package or SDS with you to show the doctor.

INGESTION: If swallowed, rinse mouth with water. If you feel unwell seek immediate medical advice. Take the package or SDS with you to show the doctor. **DO NOT INDUCE VOMITING**

4.2 Most important symptoms and effects, both acute and delayed

EYE CONTACT: If liquid gets into the eye it may cause irritation with redness, stinging, watering of the eye.

INHALATION: Inhalation may cause symptoms of dizziness, nausea, vomiting.

SKIN CONTACT: No known adverse effects

INGESTION: No known adverse effects. Low viscosity liquid and may enter lungs.

4.3 Indication of any immediate medical attention and special treatments needed

No specific treatments, but low viscosity liquid and may enter lungs if ingested

SECTION 5: Firefighting Measures

5.1 Extinguishing media

Water spray, alcohol resistant foam, dry powder and carbon dioxide extinguishers are suitable for small fires (< 5 litres). For large fires, foam recommended

5.2 Special hazards arising from the substance or mixture

Aerosol cans: Pressurised container. May explode if heated. Keep containers cool using water spray. Prevent entry of liquid into drains and watercourses.

5.3 Advice for fire fighters

Fire fighters should wear protective clothing and breathing apparatus as appropriate. Treat fire as for water insoluble oils.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Remove unnecessary personnel from the spillage area. Wear protective clothing including overall, gloves and eye protection to prevent skin and eye contact. Open doors and windows to ensure good ventilation.

6.2 Environmental precautions

Prevent entry into sewers and watercourses.

6.3 Methods and materials for containment and clearing up

Small quantities of spilled liquid (<1 litre) can be absorbed onto paper towels and sealed in plastic bags for disposal as hazardous waste. Wash the spillage area with soap and water.

For larger spills, seek specialist advice. Prevent entry to water courses and collect onto absorbent materials. If indoors, ensure good through ventilation. Residues will evaporate.

6.4 References to other sections

See section 8 and 13 for further advice.

SECTION 7: Handling and Storage

7.1 Precautions for safe handling

Keep away from sources of ignition. Ensure adequate ventilation. Do not inhale directly.

7.2 Conditions for safe storage, including any incompatibilities

Store in its original labelled container. Keep locked up and out of reach of children. Aerosol containers should be protected from sources of heat, direct sunlight, etc.

7.3 Specific end uses(s)

For use as medical device

SECTION 8. Exposure Controls/Personal Protection

8.1 Control parameters

No control limits identified for components

DNELS

Hexamethyldisiloxane

Workers, systemic, inhalation	53.4 mg/m ³	General population, systemic, inhalation	13.3 mg/m ³
Workers, systemic, dermal	333 mg/kg bw/day	General population, systemic, dermal	167 mg/kg bw/day
Workers, systemic, oral	N/A	General population, systemic, oral	0.27 mg/kg bw/day

PNECS

PNEC	Hexamethyldisiloxane
PNEC aqua (freshwater):	0.002 mg/L
PNEC aqua (marine water):	0 mg/L
PNEC STP:	10 mg/L
PNEC sediment (freshwater):	8.9 mg/kg
PNEC sediment (marine water):	0.89 mg/kg

8.2 Exposure controls**Engineering controls**

Normal room ventilation is expected to be adequate.

Respiratory protection

Not normally required. Avoid exposure to vapours or spray. Avoid direct inhalation of product. If handling bulk product in enclosed spaces, there is a risk of asphyxiation

Hand Protection

Avoid unnecessary exposure. When working with the product, wear protective gloves suitable for alcohols, such as nitrile or polyvinyl alcohol. Gloves should be changed frequently and in accordance with manufacturers recommendations. If gloves are damaged during use, remove immediately and wash hands before replacing with new gloves

Eye protection

When handling the bulk product, wear safety glasses or goggles giving protection against liquid droplets/splashes.

Skin protection

When handling the bulk product, coveralls recommended. These should be changed after use or if contaminated. Wash before re-use.

Environmental exposure controls

When handling small quantities packaged for consumer use (less than 100 ml), no special precautions required. If handling bulk material, precautions should be taken to avoid accidental release to water courses.

SECTION 9: Physical and Chemical Properties**9.1 Information on basic physical and chemical properties**

a) Colour	Clear
b) Odour	Spicy/zesty
c) Melting/freezing point	< - 50°C
d) Boiling point	ca 100°C
e) Flammability (solids)	Not applicable
f) Upper/lower flammability limits	Not applicable

g) Flashpoint	- 6 °C
h) Autoignition temperature	340°C (Hexamethyldisiloxane)
i) Decomposition temperature	No data
j) pH	No data
k) Viscosity	Liquid Dynamic 0.5 mPa.s at 25 °C / Kinematic approx. 0.65 mm ² /s at 25 °C
l) Solubility	< 1 mg/l (water) Soluble in polar solvents
m) Partition coefficient (log Kow)	5.06 at 20°C (Hexamethyldisiloxane)
n) Vapour pressure	44 hPa at 20 °C
o) Relative density	1.12 g/cm ³
p) Relative vapour density	No data
q) Particle characteristics	Not applicable

9.2 Other information

None.

SECTION 10: Stability and Reactivity**10.1 Reactivity**

Not considered to be reactive.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

None expected.

10.4 Conditions to avoid

Avoid exposure to high and freezing temperatures.

10.5 Incompatible materials

Avoid contact with strong oxidisers.

10.6 Hazardous decomposition products

None known.

SECTION 11: Toxicological Information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

This product has not been tested. Judgements on the expected toxicity of this product have been made based upon consideration of its major components.

(a) acute toxicity	This product is not expected to be harmful if swallowed or in contact with skin or inhaled. The classifications are based on estimations of published toxicity figures for the components.
(b) skin corrosion/irritation	Considered non-irritating to skin.
(c) serious eye damage/irritation	Considered non-irritating to the eye, but may cause slight discomfort if in contact with the eye
(d) respiratory/skin sensitisation	Not classified as a sensitiser.
(e) germ cell mutagenicity	Contains no known mutagens above thresholds of concern.
(f) carcinogenicity	Contains no known carcinogens above thresholds of concern.
(g) reproductive toxicity	Contains no known reproductive toxins above thresholds of concern.
(h) STOT-single exposure	Not expected to have any target organ effects
(i) STOT-repeated exposure	Not expected to have any target organ effects.
(j) aspiration hazard	Not expected to present an aspiration hazard.

11.2 Information on other hazards

None of the components are known to have endocrine disrupting properties

SECTION 12: Ecological Information**12.1 Toxicity**

Main component toxic to aquatic organisms in the range of 0.1 – 1 mg/l.

12.2 Persistence and degradability

The components are not considered biodegradable in the environment.

12.3 Bioaccumulative potential

None of the components are considered to present a bioaccumulation hazard.

12.4 Mobility in soil

The siloxane component is expected to partition mainly to the atmosphere, with a small amount partitioning to sewage sludge if washed down the drain.

12.5 Results of PBT and vPvB assessment

None of the components are considered to be PBT or vPvB.

12.6 Endocrine disrupting properties

None of the components have been identified as having endocrine disrupting properties.

12.7 Other adverse effects

None identified.

SECTION 13: Disposal Considerations**13.1 Waste treatment methods**

Bulk waste should be treated as hazardous chemical waste in a manner that complies with local regulations. Incineration may be suitable. Advice should be sought from local agencies.

Used aerosol containers from consumer use should be recycled wherever local facilities exist. If no such facilities exist, dispose of in domestic waste or according to local regulations. Never pierce, cut or burn empty aerosol containers.

SECTION 14: Transport Information

This product is considered to be dangerous goods for transport. Note that limited quantity exemptions will apply to consumer packaging.

Different Transport criteria will apply whether transported as liquid in simple container or as ready-to-use aerosols.

Bulk liquid

	ADR	IMDG	ICAO
14.1 UN Number	1993	1993	1992
14.2 UN Proper shipping name	FLAMMABLE LIQUID, N.O.S (Hexamethyldisiloxane)	FLAMMABLE LIQUID, N.O.S (Hexamethyldisiloxane)	FLAMMABLE LIQUID, N.O.S (Hexamethyldisiloxane)
14.3 Transport hazard class(es)	3	3	3
14.4 Packing group	II	II	II
14.5 Environmental hazards	Yes	Yes	Yes
14.6 Special precautions for user	Tunnel code D/E	EmS F-E, S-E	None

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable	Not transported in bulk	Not applicable
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Transport as consumer aerosol product :

	ADR	IMDG	ICAO
14.1 UN Number	1950	1950	1950
14.2 UN Proper shipping name	Aerosols Flammable	Aerosols Flammable	Aerosols Flammable
14.3 Transport hazard class(es)	2.1	2.1	2.1
14.4 Packing group	Not Applicable	Not Applicable	
14.5 Environmental hazards	Yes	Yes	Yes
14.6 Special precautions for user	Tunnel Code: D	EmS-No F-D, S-U	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable	Not transported in bulk	Not applicable

SECTION 15: Regulatory Information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

All components are listed as existing substances in Europe
The product is considered to be a Medical Device

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out for this product. Chemical Safety Assessments have been carried out by the REACH Registrants for the major components.

SECTION 16: Other Information**Revision information:**

Revision to format in accordance with Regulation (EU) 2020/878.

List of Abbreviations used in this SDS:

CAS	Chemical Abstracts Service
CLP	Classification, Labelling and Packaging Regulation (EC) no 1272/2008
EC	European Community/Commission
MARPOL	International Convention for the Prevention of Pollution from Ships
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) no 1907/2006
STOT	Specific Target Organ Toxicity
vPvB	very Persistent, very Bioaccumulative

References:

ECHA CHEM Databases of Registered Substances and Classification and Labelling Inventory
Suppliers SDS
EH40, 2020
Data from ECHA web-site "Source: European Chemicals Agency, <http://echa.europa.eu/>".
Further references available on request

Method used for classification of mixtures:

Ingredient based approaches and expert judgment.

H Statements used in Section 3

H225 Highly flammable liquid and vapour
H400 Very toxic to aquatic organisms
H411 Toxic to aquatic organisms with long lasting effects

Training requirements for workers

No special training requirements. Instructions for use must be provided to consumers.