



SAFETY DATA SHEET

Trio Elisse® TR203 Skin Barrier, Wipes

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® TR203 Skin Barrier, Wipes

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
Email: mail@triohealthcare.co.uk
Tel. +44 (0)1756 700599

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 life
Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects

2.2 Label elements

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



Danger

H225 Highly flammable liquid and vapour
H410 Very toxic to aquatic life with long lasting effects
P102 Keep out of reach of children.
P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.

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 CE marking and Instructions for Use.

2.3 Other hazards

None of the components have been identified as PBT/vPvB. None of the components have been identified as causing endocrine disruption.

SECTION 3: Composition

3.1 Substances

Not applicable - product is a mixture

3.2 Mixtures

EC	CAS	Name	Conc	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

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

Prevent entry 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 cleaning up

Wipes should be picked up and disposed of as low-hazard waste.

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**

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.

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 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 siloxane components are not considered biodegradable in the environment.
- 12.3 Bioaccumulative potential**
Hexamethyldisiloxane does not meet the criteria for bioaccumulation according to REACH, BCF ≤ 2,000 L/kg.
- 12.4 Mobility in soil**
Hexamethyldisiloxane 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 have been identified as 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 containers from consumer use should be re-closed and bagged and disposed of in domestic waste.

SECTION 14: Transport Information

This product may be exempted from transport of dangerous goods regulations in accordance with ADR/IMDG Special Provision 216/ICAO Special Provision A46 provided there is no free liquid in the packet/container.

	ADR	IMDG	ICAO
14.1 UN number or ID number	3175	3175	3175
14.2 UN Proper shipping name	SOLIDS CONTAINING FLAMMABLE LIQUID, n.o.s. (Hexamethyldisiloxane)	SOLIDS CONTAINING FLAMMABLE LIQUID, n.o.s. (Hexamethyldisiloxane)	SOLIDS CONTAINING FLAMMABLE LIQUID, n.o.s. (Hexamethyldisiloxane)
14.3 Transport hazard class(es)	4.1	4.1	4.1
14.4 Packing group	II	II	II
14.5 Environmental hazards	Yes	Yes	Yes
14.6 Special precautions for user	None	None	None
14.7 Maritime transport in bulk according to IMO instruments	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.

Section 14 updated

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 life
H411 Toxic to aquatic life with long lasting effects

Training requirements for workers

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