

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

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

1.1 Product identifier

Trade name / designation	SOFT NUDE	
Product code	FXR795 -*	*: any character string
Synonyms	none	
REACH Registration number	not necessary	
Version number	003	
Revision date	05.06.2023	

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

1.2.1 Identified uses

Mixture for use in tattoos or permanent make-up.

1.2.2 Uses advised against

Any use not pointed out in 1.2.1.

1.3 Details of the supplier of the safety data sheet

Company name	Elitederma S.r.l.
Address	Via Terni 90/a 00182 Roma Italy
E-Mail	commerciale.elitederma@gmail.com
Telephone	+39 06 49771723

1.4 Emergency telephone number

Contact supplier of the data sheet.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Hazard summary	Not to be classified according to Regulation (EC) No 1272/2008 (CLP). Mixture for use in tattoos or permanent make-up in accordance with Regulation (EC) No 1907/2006, Annex XVII.
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Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

Physical hazards	none to be expected
Health hazards	Contains nickel. Can cause allergic reactions. Contains chromium (VI). Can cause allergic reactions.
Environmental hazards	none to be expected
Specific hazards	none to be expected
Main symptoms	none to be expected



2.1.1 Additional hazards identification for humans / environment

None to be expected.

2.2 Label elements

The labelling is based on the labelling of the pure compound ethanol, no labelling is necessary for the final product.

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

Hazard pictograms	 
Signal word	Danger
Hazard statements	H225 + H319

Precautionary statements

Prevention	P210, P240, P305 + P351 + P338
Storage	P403 + P233
Disposal	none

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

3.2.1 General information

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

Suspension of coloured pigments in a water based liquid.

3.2.2 Composition

Chemical Identity	CAS-No.	INCI Name / C.I. No.	Quantity [FDA-code]
Water	7732-18-5	Aqua	B
Iron oxide red	1309-37-1	CI 77491	C
Propan-1,2-diol	57-55-6	Propylene glycol	C
Ethanol	64-17-5	Alcohol	C
Titanium dioxide	13463-67-7	CI 77891	C
Glycerol	56-81-5	Glycerin	E
Polyethylene glycol 400	25322-68-3	PEG-400	E
VP/VA Copolymer	25086-89-9	VP/VA Copolymer	E
Iron oxide black	1317-61-9	CI 77499	F

Codes FDA :

A1	=	75 – 100 %
A2	=	50 – 75 %
B	=	25 – 50 %
C	=	10 – 25 %
D	=	5 – 10 %
E	=	1 – 5 %
F	=	0,1 – 1 %
G	=	< 0,1 %

SECTION 4: First aid measures

General information

As no serious harm is to be expected regardless kind and duration of any exposition, a mild cleaning of the related area is suggested.

4.1 Description of first aid measures

Inhalation	In case of discomfort seek medical advice.
Skin contact	Product is intended to be applied into the skin, generally no harm possible due to the product itself. In case the skin has to be cleaned prior to use, use mild cleaning products / water.

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

Eye contact	Flush with plenty of water for 15 minutes or use eyewash lotion. In case of discomfort seek medical advice.
Ingestion	Do not induce vomiting. Flush mouth with water. In case of discomfort seek medical advice.

4.1.1 Self-protection measures of the first aider

Not needed.

4.2 Most important symptoms and effects, both acute and delayed

Nothing known or to be expected.

4.3 Indication of any immediate medical attention / special treatment needed

Nothing known or to be expected.

SECTION 5: Firefighting measures

5.1 Extinguishing media

5.1.1 Suitable extinguishing media

Use fire-extinguishing media appropriate for surrounding materials.

5.1.2 Unsuitable extinguishing media

No restrictions known.

5.2 Details on fire-fighting measures

5.2.1 Special hazards arising from the substance or mixture

None known or to be expected.

5.2.2 Special protective equipment for firefighters

Follow the general fire precautions indicated in the affected area.

5.3 Additional information

None.

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	No harm expected. Wear appropriate equipment / clothing during clean-up.
For emergency responders	No harm expected. No special precautions necessary.

6.2 Environmental precautions

None needed, material is not harmful to the environment.

6.3 Methods and material for containment and cleaning up

Use common cleaning products. Small amounts can be disposed of with the regular waste.

6.4 Reference to other sections

For waste disposal see additionally section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

7.1.1 General handling

Seal packaging tightly after usage.

7.1.2 General hygiene measures

Do not eat, drink and/or smoke during handling. Clean already opened packages outward disinfectant and seal it again after usage. Follow the mandatory shelf life of the products before and after opening. Wash hands prior to use and follow local hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

7.2.1 Storage conditions

Store indoors in a dry place and not exposed to direct sunlight. Keep temperature above freezing point and below 35°C.

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

7.2.2 Packaging materials

Use original packaging.

7.2.3 Requirements for storage areas and containers

The storage area has to stay dry and should not have direct sunlight. Frequent temperature fluctuations should be avoided and should only exceed the in 7.2.1 mentioned long term conditions for short amounts of time, but must not be above 45°C.

7.2.4 Incompatibilities during storage

None known if kept in the original packaging.

7.3 Specific end use(s)

Intradermal application using needle techniques commonly used for permanent make-up and tattoo excluding direct injections.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.1.1. Occupational exposure limits

component	limit value	form
Ethanol	200 ml/m ³ / 380 mg/m ³	vapour / gas

8.1.2 Additional exposure limits under working conditions

None known.

8.2 Exposure controls

8.2.1 Occupational exposure controls

Provide adequate ventilation of the working place.

8.2.2 Individual protection measures, such as personal protective equipment

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

General information	Product contact is supposed to cause no harm. The following protection measures are supposed to minimize the risk for example of irritations from vapours or unwanted staining of objects.
Eye/face protection	Wear safety goggles where there is risk of eye contact.
Skin protection	Wear suitable gloves. Suitable gloves can be recommended by the glove supplier.
Respiratory protection	Provide adequate ventilation.
Thermal hazards	None known.
Hygiene measures	Do not eat, drink, and/or smoke during application. Always observe good personal hygiene measures, such as washing hands after handling the material.
Environmental exposure controls	Contain spills and prevent releases and observe national regulations on emissions.

SECTION 9: Physical and chemical properties

9.1 General information

Appearance	Coloured opaque liquid
Physical state	Liquid
Form	viscous Liquid
Colour	red
Odour	Neutral to slightly alcoholic
Odour threshold	Not available

9.1.1 Important health, safety and environmental information

pH value / range	6,5 - 8
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Flammability limit – lower (%)	Not available.
Flammability limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density (d_{20}^{20})	1,03 – 1,55
Solubility(ies)	Liquid is soluble in water. Pigments are insoluble.
Partition coefficient (n-octanol/water)	Not available.
Autoignition temperature	Not available.
Decomposition temperature	Not available.

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

Viscosity	Not determined.
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

9.2 Other information

None.

SECTION 10: Stability and reactivity

The product is stable and non reactive under normal conditions of use, storage and transport.

10.1 Reactivity

No reactions expected under in this data sheet mentioned storage and usage conditions. Do not mix with products not to be intended for that use.

10.2 Chemical stability

No reactions expected under in this data sheet mentioned storage and usage conditions. Do not mix with products not to be intended for that use.

10.3 Possibility of dangerous reactions

No dangerous reactions known or expected.

10.4 Conditions to avoid

Avoid exceeded temperatures like pointed out in section 7 for the product may become more viscous or dry and will be no longer applicable.

10.5 Materials to avoid

None known.

10.6 Hazardous decomposition products

No hazardous decomposition products are known if used, stored and transported under normal conditions pointed out in this MSDS.

SECTION 11: Toxicological information

General information

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

The product does not have any known toxic or comparable adverse effects on human health.

Information on likely routes of exposure

Ingestion	Inhalation may irritate respiratory system.
Inhalation	Inhalation may irritate respiratory system.
Skin contact	No adverse effects known or expected.
Eye contact	Direct contact may irritate the eyes.

Symptoms related to physical, chemical and toxicological properties

Irritations may occur after above mentioned exposures, other symptoms not known and unlikely.

11.1 Information on toxicological effects

Acute toxicity	No acute toxicity known by any ingredient concerning the used concentration.
Skin corrosion/irritation	None known or expected.
Serious eye damage/irritation	Direct contact may irritate the eyes.
Sensitisation	None known.
Toxicity - repeated exposure	None known for single ingredients, not available for mixture.
Carcinogenicity	None known for single ingredients, not available for mixture.
Mutagenicity	None known for single ingredients, not available for mixture.
Reproductive toxicity	None known for single ingredients, not available for mixture.

Other information

No other specific acute or chronic health impact noted.

SECTION 12: Ecological information

12.1 Ecotoxicity

The product is not expected to be hazardous to the environment.

12.2 Persistence and degradability

Abiotic degradability	The degradability of the product has not been stated.
Photochemical degradability	No significant photochemical decomposition expected.
Biodegradability	The degradability of the product has not been stated.

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

Bio concentration factor (BCF)	Not available.
Longterm eco-toxicity	Not available.

12.3 Bioaccumulative potential

Bioaccumulation is unlikely to be significant due to the general insolubility of the solid compounds. Accumulation of the water soluble compounds is unlikely as well.

12.4 Mobility

The liquid phase of the product is water soluble, the solid phase of the product is insoluble and will sediment in static liquid systems.

12.5 Results of PBT and vPvB assessment

Not a PBT or vPvB mixture.

12.6 Other adverse effects

Not available.

12.7 Other ecological information

None.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Dispose of residual waste in accordance with local regulations. Disposal into waste water is not recommended

13.2 Waste codes

EAK/AVV	08 01 20
EU	08 01 20
EPA (US)	Not defined as hazardous waste.

13.3 Contaminated packaging

Dispose of in accordance with local regulations.

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

13.4 Additional information / Special precautions

None.

SECTION 14: Transport information

14.1 Land transportation

ADR	The product is not covered by international regulation on the transport of dangerous goods.
RID	The product is not covered by international regulation on the transport of dangerous goods.
ADN	The product is not covered by international regulation on the transport of dangerous goods.
GGVSE	The product is not covered by international regulation on the transport of dangerous goods.

14.2 Sea transportation

IMDG	The product is not covered by international regulation on the transport of dangerous goods.
GGVSee	The product is not covered by international regulation on the transport of dangerous goods.

14.3 Air freight

IATA	The product is not covered by international regulation on the transport of dangerous goods.
DGR	The product is not covered by international regulation on the transport of dangerous goods.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1 EU regulations

Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards substances in tattoo inks or permanent make-up

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

15.1.2 National regulations

Follow national and local regulations related to this kind of product, the following list might be incomplete:

Germany	Deutsche Tätowiermittel-Verordnung über Mittel zum Tätowieren einschließlich bestimmter vergleichbarer Stoffe und Zubereitungen aus Stoffen
Austria	BGBI. 139. Verordnung: Zugangsvoraussetzungen für das reglementierte Gewerbe der Kosmetik (Schönheitspflege)
	BGBI. 141. Verordnung: Ausübungsregeln für das Piercen und Tätowieren durch Kosmetik(Schönheitspflege)-Gewerbetreibende
	BGBI. 261. Verordnung: Änderung der Verordnung über Ausübungsregeln für das Piercen und Tätowieren durch Kosmetik(Schönheitspflege)-Gewerbetreibende
	BGBI. 262. Verordnung: Ausübungsregeln für Fußpflege, Kosmetik und Massage durch Gewerbetreibende, Anlage 1
Netherlands	Besluit van 14 augustus 2003 tot het stellen van regels betreffende de veiligheid van tatoeagekleurstoffen (Warenwetbesluit tatoeagekleurstoffen)
France	Décret n° 2008-210 du 3 mars 2008 fixant les règles de fabrication, de conditionnement et d'importation des produits de tatouage, instituant un système national de vigilance et modifiant le code de la santé publique (dispositions réglementaires)
Switzerland	Verordnung des EDI über Gegenstände für den Schleimhaut-, Haut- und Haarkontakt sowie über Kerzen, Streichhölzer, Feuerzeuge und Scherzartikel (Verordnung über Gegenstände für den Humankontakt)

Other regulations

None known.

15.2 Chemical Safety Assessment

A safety assessment for this product has been carried out.

SECTION 16: Other information

16.1 Full text of any statements or R-phrases and H-statements under Sections 2 to 15

H225 (=R11): Highly flammable liquid and vapour.

H319: Causes serious eye irritation.

16.2 Training information

Material Safety Data Sheet

according to Regulation (EC) 1907/2006 (REACH)

Trade name: FXR795 , SOFT NUDE

Revision date: 05.06.2023

May only be used by medical personnel or trained micropigmentation personnel.

16.3 Disclaimer

The information in the sheet was written based on the best knowledge and experience currently available.

16.4 Other information

Abbreviations:

PBT	Persistent, bioaccumulative and toxic
vPvB	Very persistent, very bioaccumulative

16.5 References

HSDB® - Hazardous Substances Data Bank

GESTIS-database on hazardous substances