

MESO POWER PEN

Cod. -MST2000

SAFETY DATA SHEET

Revision 1
Revision date 08/04/2021
Print date 08/04/2021

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

1.1. PRODUCT IDENTIFIER

Name: MESO POWER PEN

EC number: Not applicable

CAS number: Not applicable

REACH registration number: Not applicable

1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

1.2.1. Relevant uses identified

Microneedling

1.2.2. Uses advised against

No specific information

1.3. INFORMATION ON THE SUPPLIER OF THE SAFETY DATA SHEET

1.3.1. Supplier

Business name: MESOSKINLINE ApS

Address: Juelsmindevej 57, 7120 Vejle, Denmark

Telephone and fax numbers: (+45) 71741108- (+45) 40681108

E-mail of the competent person responsible for the [SDS : sales@mesotech.dk](mailto:sales@mesotech.dk)

1.3.2. Importer / representative

Business name: MESOSKINLINE ApS

1.4. EMERGENCY TELEPHONE NUMBER

For urgent information, please contact: : (+45) 71741108

SECTION 2: HAZARDS IDENTIFICATION

2.1. SUBSTANCE OR MIXTURE CLASSIFICATION

2.1.1. Classification in accordance with Regulation (EC) 1272/2008 (CLP)

No specific information

2.1.2. Classification in accordance with Directive 93/42 / EEC for Medical Devices

Class I

2.2. LABEL ELEMENTS

2.2.1. Labeling in accordance with ISO 15223-1:2017



WARNINGS: DANGER (DGR)

No specific information

SAFEGUARDS:

No specific information

2.3. OTHER DANGERS

2.3.1. Hazard Description

Not dangerous with normal use. Do not dismantle, open or shred the battery ingredients contained within or their ingredients products could be harmful.

2.3.2. Adverse health effects

MESO POWER PEN

Cod.

MST2000

SAFETY DATA SHEET

Revision 1

Revision date 08/04/2021

Print date 08/04/2021

Inhalation: Vapors or mists from a ruptured battery may cause respiratory irritation.

Ingestion: The battery ingredients contained within or their ingredients products can cause serious chemical burns of mouth, esophagus, and gastrointestinal tract.

Skin: Skin contact with contents of an open battery can cause severe irritation or burns to the skin.

Eye: Eye contact with contents of an open battery can cause severe irritation or burns to the eye.

2.3.3. Adverse effects on the environment

Information not available

When used correctly, as intended, the product is safe in accordance with the law. Any dangers to health and / or the environment are connected to its improper or accidental use.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS**3.1. COMPOSITION**

The MESO POWER PEN is made of the following parts:

1. Battery
2. Wired connector
3. Charger

3.2. MODEL

MS-5000

SECTION 4: FIRST AID MEASURES**4.1. DESCRIPTION OF FIRST AID MEASURES****4.1.1. General informations**

In the event that contact, use or handling of the product causes symptoms that require immediate help, follow the instructions below according to the type of exposure.

4.1.2. Following inhalation

Remove source of contamination or move victim to fresh air. Obtain medical advice.

4.1.3. Following contact with the skin

Remove contaminated clothes and rinse skin with plenty of water or shower for 15 minutes. Get medical aid.

4.1.4. Following eye contact

Irrigate with flowing water for 15 minutes. If irritation persists, consult a physician.

4.1.5. Following ingestion

Please rinse mouth thoroughly with water. Induce vomiting under the guidance of professional personage. Please seek medical treatment in time.

4.1.6. Self-protection of first aid providers

No specific information

4.2. MAIN SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED**4.2.1. Symptoms**

MESO POWER PEN

Cod.

MST2000

SAFETY DATA SHEET

Revision 1
Revision date 08/04/2021
Print date 08/04/2021

See section 11 (Toxicological information)

4.2.2. Effects

See section 11 (Toxicological information)

4.3. INDICATION OF ANY NEED TO SEE A DOCTOR IMMEDIATELY OR SPECIAL TREATMENTS**4.3.1. Information for the physician**

Information not available

4.3.2. Special treatments

Information not available

SECTION 5: FIRE-FIGHTING MEASURES**5.1. FIRE FIGHTING****5.1.1. Suitable extinguishing media**

The firemen should put on antigas masks and full fire-fighting suits.

5.1.2. Unsuitable extinguishing media

Nobody particular.

5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE**5.2.1. Hazardous Combustion Products**

Carbon monoxide, carbon dioxide, lithium oxide fumes and so on.

5.3. RECOMMENDATIONS FOR FIRE EXTINGUISHERS**5.3.1. Advice for firefighters**

Cool the containers with water to avoid any decomposition of the product with the development of substances potentially hazardous to health. Put on the complete equipment supplied for extinguishing fires. If possible, collect the extinguishing water and prevent it from reaching sewers and other waterways.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES****6.1.1. For general staff**

Wear appropriate protective equipment (see also Section 8 of the SDS).

6.1.2. For emergency responders

Wear appropriate protective equipment (see also Section 8 of the SDS) .

6.2. ENVIRONMENTAL PRECAUTIONS**6.2.1. Environmental precautions**

Prevent the product from penetrating into sewers, surface waters, groundwater.

6.3. METHODS AND MATERIALS FOR CONTAINMENT AND RECLAMATION**6.3.1. For containment**

Collect any leaked product with mechanical means (if the product is flammable, use means with non-sparking devices) and place it in suitable containers for recovery and disposal. Evaluate the compatibility of the container to be used with the product by checking Section 10.

6.3.2. For remediation

Absorb the remaining product with inert absorbent material. Provide sufficient ventilation of the place affected by the leak. Check for any incompatibilities for container material in Section 7. Disposal of contaminated material must be done in accordance with Section 13.

6.3.3. Other information

No specific information

6.4 REFERENCE TO OTHER SECTIONS

MESO POWER PEN

Cod.

MST2000

SAFETY DATA SHEET

Revision 1

Revision date 08/04/2021

Print date 08/04/2021

6.4.1. Reference to other sections

For safe handling see Section 7.

For waste treatment see Section 13.

For exposure controls see Section 8.

SECTION 7: HANDLING AND STORAGE**7.1. PRECAUTIONS FOR SAFE HANDLING****7.1.1. General protection measures****Do not apply it to the man as follow:**

1. Who has acute disease or bloody disease over 38 °C
2. Who has allergy and hemophilia
3. Who has melanosis of the face
4. Who has high internal heat
5. Who regularly visits hospital
6. Who takes medicines
7. Who is under 12 years old

7.1.2 - Measures for fire prevention**Do not use it on the power other than AC 220V.**

It may cause fires or malfunction

Do not use the stripped cord or propped cord.

It may cause fires (Be sure to replace it with another).

7.1.3 - Measures to prevent the electric shock**Do not touch the device or detach the power cords with wet hands.**

It may cause electric shock.

7.1.4. Environmental protection measures

Always and in any case avoid the dispersion of the product in the environment. Keep the containers tightly closed.

7.1.5. Professional hygiene recommendations

Do not eat, drink, smoke during use. Remove any contaminated clothing. Wash hands at each interruption of work and after work.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES**7.2.1. Technical measures and storage conditions**

If possible, keep in a cool place, away from direct light and sources of ignition if the product is flammable.

Do not storage the battery haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.**Keep out of reach of children.****7.2.2. Containers**

Keep the product in the original containers, requesting them well after use. If the product is transposed into other containers, affix the same labeling as the original containers.

7.2.3. Requirements for storage rooms and containers

Store in a ventilated and cool place. If the product is flammable, keep away from sources of ignition. If incompatible materials with the product are indicated (see Section 10 of this SDS) keep containers away from such materials.

7.3. PARTICULAR END USES**7.3.1. Recommendations**

No specific information

7.3.2. Solutions for specific industrial sectors

No specific information

SECTION 8: EXPOSURE CONTROL / PERSONAL PROTECTION

MESO POWER PEN

Cod.

MST2000

SAFETY DATA SHEET

Revision 1

Revision date 08/04/2021

Print date 08/04/2021

8.1. CONTROL PARAMETERS**8.1.1. Occupational Exposure Limits**

When you don't use it for a long time, unplug it from the outlet.

8.1.2. National biological limit values

Information not available

8.1.3. Exposure limits for intended use

Information not available

8.1.4. DNEL / PNEC values

Information not available

8.1.5. Risk management measures for strategies based on control bands

Information not available

8.2. EXPOSURE CONTROLS**8.2.1. Engineering Controls**

No engineering controls are required for handling batteries that have not been damaged. Personal protective equipments for damaged batteries should include chemical resistant gloves and safety glasses.

8.2.2. Personal Protective Equipment

Respiratory Protection: In case of battery venting, provide as much ventilation as possible. Avoid confined areas with venting cell cores. Respiratory Protection is not necessary under conditions of normal use. Not necessary under conditions of normal use.

Protective Gloves: Not necessary under conditions of normal use.

Other Protective Clothing or Equipment: Not necessary under conditions of normal use.

Personal Protection is recommended for venting battery: Respiratory Protection, Protective Gloves, Protective Clothing and safety glass with side shields.

8.2.3. Environmental exposure controls

However, implement all appropriate procedures to protect the environment from product contamination.

SECTION 9: STABILITY AND REACTIVITY**9.1. REACTIVITY**

There are no particular risks of reaction with other substances in normal conditions of use and storage

9.2. CHEMICAL STABILITY

The product is stable under normal conditions of use and storage

9.3. POSSIBILITY OF DANGEROUS REACTIONS

No dangerous reactions are foreseeable in normal conditions of use and storage

9.4. CONDITIONS TO AVOID

MESO POWER PEN

Cod.

MST2000

SAFETY DATA SHEET

Revision 1

Revision date 08/04/2021

Print date 08/04/2021

Heat above 70°C or Incinerate, Deform, Mutilate, Crush, Disassemble, Overcharge, Short circuit, Expose over a long period to humid conditions.

9.5. INCOMPATIBLE MATERIALS

Information not available

9.6. HAZARDOUS DECOMPOSITION PRODUCTS

Toxic Fumes, and may form peroxides.

9.1. REACTIVITY

There are no particular risks of reaction with other substances in normal conditions of use and storage

9.2. CHEMICAL STABILITY

The product is stable under normal conditions of use and storage

9.3. POSSIBILITY OF DANGEROUS REACTIONS

If leaked, forbidden to contact with strong oxidizers, mineral acids, strong alkalis, halogenated hydrocarbons.

9.4. CONDITIONS TO AVOID

Heat above 70°C or Incinerate, Deform, Mutilate, Crush, Disassemble, Overcharge, Short circuit, Expose over a long period to humid conditions.

9.5. INCOMPATIBLE MATERIALS

Information not available

9.6. HAZARDOUS DECOMPOSITION PRODUCTS

Information not available

SECTION 10: TOXICOLOGICAL INFORMATION**10.1. INFORMATION ON TOXICOLOGICAL EFFECTS****10.1.1. Acute toxicity**

The product is not toxic. In any case, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present

10.1.2. Skin corrosion / irritation

In the event of exposure to internal contents, vapor fumes may be very irritating to the eyes and skin.

10.1.3. Serious eye damage / eye irritation

No specific information is available for the product; however, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present.

10.1.4. Respiratory or skin sensitization

No specific information is available for the product; however, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present.

10.1.5. Germ cell mutagenicity

No specific information is available for the product; however, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present.

10.1.6. Carcinogenicity

No specific information is available for the product; however, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present.

MESO POWER PEN

Cod.

MST2000

SAFETY DATA SHEET

Revision 1

Revision date 08/04/2021

Print date 08/04/2021

10.1.7. Reproductive toxicity

No specific information is available for the product; however, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present.

10.1.8. Evaluation summary for CMR substances

No specific information is available for the product; however, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present.

10.1.9. Specific target organ toxicity (STOT) - single exposure

No specific information is available for the product; however, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present.

10.1.10. Specific target organ toxicity (STOT) - repeated exposure

No specific information is available for the product; however, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present.

10.1.11. Aspiration hazard

No specific information is available for the product; however, see Section 2 of the SDS for the identification and description of the dangers associated with any dangerous substances present.

SECTION 11: ECOLOGICAL INFORMATION

Use according to good working practices, avoiding to disperse the product in the environment. Notify the competent authorities if the product reaches water courses or sewers or if it has contaminated the soil or vegetation.

11.1. TOXICITY**11.1.1. Acute (short-term) toxicity**

The product is not toxic. Residues of ethylene oxide used for the sterilization process can cause irritation and sensitization

11.1.2. Chronic (long-term) toxicity

Information not available

11.2. PERSISTENCE AND DEGRADABILITY**11.2.1. Abiotic degradation**

Information not available

11.2.2. Physical and photochemical elimination

Information not available

11.2.3. Biodegradation

Information not available

11.3. POTENTIAL OF BIOACCUMULATION**11.3.1. Partition coefficient n-octanol / water (log Kow)**

Information not available

11.3.2. Bioconcentration factor (BCF)

Information not available

11.4. MOBILITY IN THE SOIL**11.4.1. Distribution in environmental compartments, known or expected**

Information not available

11.4.2. Surface tension

Information not available

11.4.3. Adsorption / desorption

Information not available

11.5. RESULTS OF PBT AND VPVB EVALUATION

Information not available

MESO POWER PEN

Cod. MST2000

SAFETY DATA SHEETRevision 1
Revision date 08/04/2021
Print date 08/04/2021**11.6. OTHER ADVERSE EFFECTS**

Information not available

11.7. OTHER INFORMATION

Information not available

SECTION 12: DISPOSAL CONSIDERATIONS**12.1. METHODS OF WASTE TREATMENT****12.1.1. Disposal of the product and packaging**

Reuse if possible. Contaminated packaging must be sent for recovery or disposal in compliance with national waste management laws.

12.1.2. Information relating to waste treatment

Recycle or dispose of in accordance with government, state & local regulations.

12.1.3. Information on disposal

In general, waste treatment must be entrusted to a specifically authorized person, in compliance with current national and possibly local legislation.

12.1.4. Other disposal recommendations

Deserted batteries couldn't be treated as ordinary trash. Couldn't be thrown into fire or placed in high temperature. Couldn't be dissected, pierced, crushed or treated similarly. Best way is recycling.

SECTION 13: TRANSPORT INFORMATION

No specific information

13.1. ROAD OR RAIL TRANSPORT

UN number: Not applicable

ADR Class: Not applicable

Packing group: III - Slightly dangerous product

Label: Not applicable

Nr. Kemler: Not applicable

Limited quantity: -

Tunnel restriction code: -

Technical name: Not applicable

13.2. MARITIME TRANSPORT

UN number: Not applicable

IMO class: Not applicable

Packing group: III - Slightly dangerous product

Label: Not applicable

EMS: Not applicable

Marine contaminant: No

Technical name: Not applicable

13.3. TRASPORTO AEREO

UN number: Not applicable

IATA class: Not applicable

MESO POWER PEN

Cod. MST2000

SAFETY DATA SHEETRevision 1
Revision date 08/04/2021
Print date 08/04/2021

Packing group: III - Slightly dangerous product

Label: Not applicable

Cargo:

Packaging instructions:

Pass:

Special instructions:

Technical name: Not applicable

SECTION 14: REGULATORY INFORMATION**14.1. HEALTH, SAFETY AND ENVIRONMENTAL RULES AND LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE****14.1.1. EU regulations**

Directive 93/42/ EEC for Medical Devices

14.1.2. National regulations

No specific information

14.1.3. Occupational limits

No specific information

14.2. CHEMICAL SAFETY ASSESSMENT

No specific information

SECTION 15: OTHER INFORMATION**15.1. VERSION INFORMATION**

Changes from the previous version:

15.2. ABBREVIATIONS AND ACRONYMS**LEGEND:**

- ADR: European agreement for the transport of dangerous goods by road
- CAS Number: Number of the Chemical Abstract Service
- CE Number: Identification number in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived no effect level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System for Classification and Labeling of Chemicals
- IATA DGR: Regulations for the transport of dangerous goods of the International Air Transport Association
- IC50: Concentration of immobilization of 50% of the population subject to testing
- ICAO: Technical standards for the transport of dangerous goods by air
- IMDG: International maritime code for the transport of dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identification number in Annex VI of the CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- OEL: Occupational exposure level
- REACH: EC Regulation 1907/2006
- RID: Regulation for the international transport of dangerous goods by train
- VOC: Volatile organic compound
- vPvB: Very persistent and very bioaccumulating according to REACH

15.3. BIBLIOGRAPHICAL REFERENCES AND INFORMATION ON THE SOURCES**SOURCES:**

- Regulation (EU) 1907/2006 of the European Parliament (REACH)
- Regulation (EU) 1272/2008 of the European Parliament (CLP)
- Regulation (EU) 790/2009 of the European Parliament (I Atp. CLP)
- Regulation (EU) 286/2011 of the European Parliament (II Atp. CLP)
- Regulation (EU) 618/2012 of the European Parliament (III Atp. CLP)
- Regulation (EU) 487/2013 of the European Parliament (IV Atp. CLP)
- Regulation (EU) 944/2013 of the European Parliament (V Atp. CLP)

MESO POWER PEN

Cod.

MST2000

SAFETY DATA SHEET

Revision 1

Revision date 08/04/2021

Print date 08/04/2021

- Regulation (EU) 605/2014 of the European Parliament (VI Atp. CLP)
- Regulation (EU) 1221/2015 of the European Parliament (VII Atp. CLP)
- Regulation (EU) 2015/830 of the European Parliament
- Regulation (EU) 918/2016 of the European Parliament (VIII Atp. CLP)
- Regulation (EU) 1179/2016 of the European Parliament (IX Atp. CLP)
- ECHA Agency website
- Medical Device Symbols ISO 15223-1: 2017 standard

15.4. CLASSIFICATION OF MIXTURES AND ASSESSMENT METHODS USED IN ACCORDANCE WITH REGULATION (EC) 1272/2008 [CLP]

No specific information

15.5. TRAINING TIPS

No specific information

15.6. OTHER INFORMATION

Note for the user:

The information contained in this sheet is based on our knowledge available at the date of the latest version. The user must ensure the suitability and completeness of the information in relation to the specific use of the product. This document should not be construed as a guarantee of any specific property of the product. Since the use of the product does not fall under our direct control, it is the user's obligation to observe the laws and regulations in force regarding hygiene and safety under his own responsibility. No responsibility is assumed for improper use.