

**Material Safety Data Sheet**

Product : Skin marker HS : 9608 2000 00
Version : 2.3 Date print : 24/7/2017 Alteration: 24/10/2018

1 - Product and company identification

- 1.1 Identification of the substance or preparation:
Commercial product name : Skin Marker
Use of substance / preparation Medical device / draw on skin
- 1.2 Company/undertaking identification:
Company/undertaking identification: Dongguan Concord Medical Products Ltd
Manufacturer/distributor Fl., 4, Block C, Yue Neng Ind Park.
Xiabian Village, Houjie, Dongguan,
China
Emergency Telephone no. 86 - 769 - 8891 9066
Transportation emergency: 86 - 130 6848 0366
This SDS prepared by R&D department of Dongguan Concord Medical Products Ltd.

2 - Hazards Identification

- 2.1 Classification of the substance
Classification (GHS): Not a hazardous substance
- 2.2 Label elements
Labelling (GHS): No. Labelling according to GHS required
- 2.3 Other hazards No data available

3 - Composition/information on ingredients

- 3.1 Chemical characterization (preparation)
Chemical characteristics
Purified water medical grade solven and natural colorant compound
- 3.2 Information on ingredients:
this material does not contain any reportable hazardous ingredients.
Substances listed in the subsections "HAPS" and "California Proposition 65 listed toxins
or below 1% or none carcinogenic HAPS or they are inextricably bound in the product

4 - First-aid measures

- 4.1 General information
Get medical attention if irritation or other symptoms occur. Before seeking medical attention remove substance
- 4.2 After inhalation
Substance cannot be inhaled under normal conditions. No special measures required.
- 4.3 After contact with skin
Substance is suitable to contact with skin. No. special measures required.
- 4.4 After contact with eyes
If contact with eyes. Flush with plenty of water.
- 4.5 After swallowing
After swallowing No special treatment is required

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5 - Fire-fighting measures

5.1 Flammable properties:

Property:	Value:	Property:	Value:
Flash point	not applicable	Ignition temperature	not applicable
Boiling point/boiling range	not applicable	NFPA Hazard Class	9
Explosion limit	not applicable	(comb/flam.liquied)	

5.2 Fire and explosion hazards:

this material does not present any unusual fire or explosion hazards.

5.3 Recommended extinguishing media

water-mist, carton dioxide, sand, dry chemical or alcohol-resistant foam.

5.4 Unsuitable extinguishing media:

water-spry, sharp water jet

5.5 Fire fighting procedures:

Fire fighters should wear full protective clothing including a self-contained breath apparatus.
cool endangered containers with water.

6 - Accidental release measures

6.1 Precautions:

Not applicable

6.2 Containment:

Prevent substance from entering surface waters, drains or sewers and soil. Contain any fluid that runs out using suitable material (e.g. earth). Close leak if possible without risk.

Spills of substance which could reach surface waters must be reported to the National response.

6.3 Methods for cleaning up

Not applicable

7 - Handling and storage

7.1 Handling

Precautions for safe handling:

Spelled substance increases risk of slipping.

Precautions against fire and explosion

Observe the general rules for fire prevention.

7.2 Storage

Conditions for storage rooms and vessels:

a. Prevent direct contact with sun shine, expose to rain and avoid from high temperature.

b. Store under cool and ventilated indoor conditions.

Advice for storage of incompatible materials:

Not applicable

Further information for storage:

Keep packing un-pressed. Store in a dry and cool place.

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8 - Exposure controls and personal protection

8.1 Engineering controls

Ventilation:

Use with adequate ventilation

Local exhaust:

not necessary

8.2 Associate substances with specific control parameters such as limit values

8.3 Personal protection equipment (PPE)

Respiratory protection:

Not required

Hand Protection:

Not required

Eye protection:

Safety glasses

Other protective clothing or equipment

Not required

8.4 General hygiene and protection measures:

Not required

9 - Physical and chemical properties

9.1 Appearance

Physical state / form liquied

Colour purple

Odour opac

9.2 Safety parameters

Property: Value:

Melting point / melting range not determined

Boiling point / boiling range not applicated

flash point not applicable

Ignition temperature not applicable

Lower explosion limit (LEL) not applicable

Upper explosion limit (UEL) not applicable

Vapour pressure not applicable

Density 0.98 g/cm³ at 25 °C (77 °F), at 1013 hPa

Water solubility / miscibility not applicable

pH-Value not applicable

Viscosity not applicable

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9.3 Further information

Thermal decomposition not applicable

10 - Stability and reactivity

10.1 General information

If stored and handled in accordance with standard industrial practices no hazardous reaction are known

10.2 Conditions to avoid

none know

10.3 Materials to avoid

none know

10.4 Hazardous decomposition products

If stored and handled properly: none know

10.5 Further information

none

11 - Toxicological information

11.1.1 Information on toxicological effects

Acute toxicity

Assessment

Based on the available data acute toxic effects are not expected after single oral exposure

Based on the available data toxic effects are not expected after single dermal exposure

Product details:

Route of exposure	Result/Effect	Test system	Source
oral	LD 50: > 5000 mg/kg	rabbit	Conclusion by analogy
dermal	LD 50: > 2008 mg/kg	rabbit	Conclusion by analogy

11.1.2 Skin corrosion/irritation

Assessment :

based on the available data a clinically relevant skin irritation hazard is not expected.

Product details :	Species/Test system	Source
Result/effect not irritating	rabbit	Conclusion by analogy

11.1.4 Respiratory or skin sensitization

Assessment :

Based on the available data a sensitization reaction is not expected from this product

Product details :

Product details :	Result/Effect	Species/Test system	Source
dermal	not sensitizing	rabbit	Conclusion by analogy

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11.1.5 Germ cell mutagenicity

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.6 Carcinogenicity

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.7 Reproductive toxicity

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.8 Specific target organ toxicity (single exposure)

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.9 Specific target organ toxicity (repeated exposure)

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.10 Aspiration hazard

Assessment:

For this endpoint no toxicological test data is available for the whole product.

11.1.11 Further toxicological information

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP. No component of this product present at levels greater or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

12 - Ecological information

12.1 Toxicity

Assessment:

Evaluation in analogy to similar product. No expected damaging effects to aquatic organisms
According to current knowledge adverse effects on water purification plants are not expected

12.2 Persistence and degradability

Assessment:

Silicone content : biologically not degradable. Elimination by adsorption to activated sludge.

12.3 Bio accumulative potential

Assessment:

Bio accumulative is not expected to occur.



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12.4 Mobility in soil

Assessment:

Polymer component : insoluble in water. Adsorbs on soil

12.5 Other adverse effects

none known

13 - Disposal considerations

13.1 Product disposal

Recommendation:

Material that cannot be used, reprocessed or recycled should be disposed of in accordance with state and local regulations at an approved facility. Depending on the regulations, waste treatment methods may include, e.g. land field or incineration.

13.2 Packaging disposal

Recommendation:

Completely discharge packing material may be recycled or re-use observe local/State regulations.

14 - Transport information

14.1 US DOT & CANADA TDG SURFACE

Valuation not required

14.2 Transportation by sea IMDG-Code

Valuation not required

14.3 Air transport ICAO-TI/IATA-DGR

Valuation not required

15 - Regulatory information

15.1 U.S. Federal regulations

TSCA inventory status and TSCA information:

This product or its components are listed on or are in compliance with the requirements of the TSCA Chemical Substance inventory

TSCA 12 (b) Export Notification

this product does not contain any TSCA 12 (b) regulated chemicals.

CERCLA Regulated Chemicals:

This product does not contain any CERCLA regulated chemicals.

SARA 302 EHS Chemicals:

This product does not contain any SARA extremely hazardous substances

SARA 311/312 Hazard Class:

this product does not present any SARA 311/312 hazards.

SARA 313 Chemicals:

This product does not contain any SARA 313 chemicals above de minimus levels

HAPS (Hazardous Air Pollutants) :

CAS No.	Chemical	Upper limit wt%
108-88-3	Toluene	0.0118

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15.2 U.S. State regulations**California Proposition 65 Carcinogens:**

This product does not contain any chemicals known to the State of California to cause cancer.

California Proposition 65 Reproductive Toxins:

108-88-3 Toluene

Massachusetts Substance List:

This product contains no listed components

Pennsylvania Right-to Know Hazardous Substance List:

This product contains no listed components

15.3 Canadian regulations

This product has been classified in accordance with the Hazard criteria of the CPR and the SDS contains all the information required by the CPR.

WHMIS Hazzard Classes:

None.

DSL Status:

This product or its components are listed on the Canadian Domestic Substances list.

Non-DSL Chemicals

This product does not contain any non-DSL chemicals.

15.4 Details of international registration status

Relevant information about individual substance inventories, where available, is given:

South Korea (Republic of Korea)	ECL (Existing Chemicals List): This product is listed in, or complies with, the substance inventory.
Japan	ENCS (Handbook of Existing and New Chemical Substance) This product is listed in, or complies with, the substance inventory. AICS (Australian Inventory of Chemical Substances) This product is listed in, or complies with, the substance inventory.
Peoples Republic of China	IECSC (Inventory of Existing Chemicals Substance in China) This product is listed in, or complies with, the substance inventory.
Canada	DSL (Domestic Substance List) This product is listed in, or complies with, the substance inventory.
Philippines	PICCS (Philippine Inventory of Chemicals and Chemical substances) This product is listed in, or complies with, the substance inventory.
USA	TSCA (Toxic Substance Control Act Chemical Substance Inventory) This product is listed in, or complies with, the substance inventory.
European Economic Area (EEA)	Reach (Regulation (EC) No. 1907/2006) General Note: the registration obligations for substances imported into the EEA or Manufactured within the EEA by the supplier mentioned in section 1 are fulfilled by the said supplier. The registration obligations for substances imported in EEA by customers or other downstream users must be fulfilled by the latter



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康鈞醫療有限公司

www.concord-medical.com Client : Users



86-0769-8891 9066



86-0769-8891 9050

QR No. 編號 : QR720-18

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16 - Other information

16.1 Additional information:

This Safety Data Sheet (SDS) meets the requirements of the Federal OSHA Hazard Communication Standard (29 CFR 1910.1200). This product has been classified according to the hazard criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR. This information relates to the specific product designated and may not be valid for such product used in combination with any other products or in any process. Such information is to be best of our knowledge and belief accurate and reliable as of the date compiled. However, no representation, warranty of guarantee expressed or implied, is made as to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to suitability and completeness of such information for his own particular use. We do not accept liability for any loss or damages as to that may occur from the use of this information. Nothing herein shall be construed as a recommendation for users which infringe valid patents or as extending a license under valid patents. This SDS provides selected regulatory information on this product include its components. This is not intended to include all regulations. It is the responsibility of the user to know and comply with all applicable rules, regulations and laws relating to the product being used.

Dong Guan Concord Medical Products Ltd



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