

**Material Safety Data Sheet**

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

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

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

**1.1 Product identifier**

|                           |                |                         |
|---------------------------|----------------|-------------------------|
| Trade name / designation  | Royal Blue     |                         |
| Product code              | F- TB035 -*    | *: any character string |
| Synonyms                  | none           |                         |
| REACH Registration number | Not necessary. |                         |
| Version number            | 02             |                         |
| Revision date             | 13.05.2015     |                         |
| Supersedes date           | 01.04.2015     |                         |

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

1.2.1 Identified uses

Intradermal application for body tattoos.

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 | MT.DERM GmbH                                   |
| Address      | Gustav-Krone-Str. 3<br>14167 Berlin<br>Germany |
| e-mail       | info@mtderm.de                                 |
| Telephone    | +49(30) – 845 885 - 4                          |

**1.4 Emergency telephone number**

Contact supplier of the data sheet.

**Material Safety Data Sheet**

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

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**

|                              |  |
|------------------------------|--|
| <b>Hazard summary</b>        | Not to be classified regarding regulation 1999/45/EC.            |
| <b>Physical hazards</b>      | none to be expected  |
| <b>Health hazards</b>        | none to be expected acutely; sensitization possible but unlikely |
| <b>Environmental hazards</b> | none to be expected  |
| <b>Specific hazards</b>      | none to be expected  |
| <b>Main symptoms</b>         | 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 2-propanol, no labelling is necessary for the final product.

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

|                          |   |
|--------------------------|---|
| <b>Hazard pictograms</b> |  |
| <b>Signal word</b>       | Danger  |
| <b>Hazard statements</b> | H225 + H319 + H336  |

Label according to Regulation 67/548/EWG or 1999/45/EC

|                          |   |
|--------------------------|---|
| <b>Hazard pictograms</b> |  |
| <b>R-phrases</b>         | R: 11-36-67   |

Precautionary statements

|                   |                    |
|-------------------|--------------------|
| <b>Prevention</b> | P210 + P233 + P280 |
| <b>Storage</b>    | P403 + P404 + P235 |
| <b>Disposal</b>   | none               |

**2.3 Other hazards**

None known.

**Material Safety Data Sheet**

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

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

**SECTION 3: Composition/information on ingredients**

**3.1 Substance**

Not applicable.

**3.2 Mixtures**

**3.2.1 General information**

Suspension of coloured pigments in a water based liquid.

**3.2.2 Composition**

| Chemical Identity                    | CAS-No.    | INCI Name / C.I. Nr.                 | Quantity [FDA-code] |
|--------------------------------------|------------|--------------------------------------|---------------------|
| Water                                | 7732-18-5  | Aqua                                 | B                   |
| Pigment Blue 15.3                    | 147-14-8   | CI 74160                             | C                   |
| Propan-2-ol                          | 67-63-0    | Isopropyl alcohol                    | C                   |
| Titanium dioxide                     | 13463-67-7 | CI 77891                             | C                   |
| Propan-1,2-diol                      | 57-55-6    | Propylene glycol                     | C                   |
| Polyglycol Esters                    | N/A        | Polyglycol Esters                    | E                   |
| Glycerol                             | 56-81-5    | Glycerin                             | E                   |
| Polyethylene glycol 400              | 25322-68-3 | PEG-400                              | E                   |
| Hamamelis Virginiana Extract         | 84696-19-5 | Hamamelis Virginiana Extract         | E                   |
| Calendula Officinales Flower Extract | 84776-23-8 | Calendula Officinales Flower Extract | E                   |
| Modified Organo Siloxanes            | N/A        | Modified Organo Siloxanes            | F                   |

FDA-codes:

- 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 %

**3.3 Additional information**

None.

**Material Safety Data Sheet**

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

**Trade name:** Royal Blue

**Version no.:** 02

**Revision date:** 13.05.2015

**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**

|                     |   |
|---------------------|---|
| <b>Inhalation</b>   | In case of discomfort seek medical advice.  |
| <b>Skin contact</b> | 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. |
| <b>Eye contact</b>  | Flush with plenty of water for 15 minutes or use eyewash lotion. In case of discomfort seek medical advice.   |
| <b>Ingestion</b>    | 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.

**Material Safety Data Sheet**

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

Page 5 / 13

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

**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**

Nothing.

**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

|                                    |  |
|------------------------------------|--|
| <b>For non-emergency personnel</b> | No harm expected. Wear appropriate equipment / clothing during clean-up. |
| <b>For emergency responders</b>    | 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.  
For waste disposal see additionally section 13.

**6.4 additional information**

None.

**SECTION 7: Handling and storage****7.1 Precautions for safe handling****7.1.1 General handling.**

Seal packaging tightly after usage.

**Material Safety Data Sheet**

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

**Trade name:** Royal Blue

**Version no.:** 02

**Revision date:** 13.05.2015

**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.

**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  | value   | form   |
|------------|---|--------|
| 2-propanol | 200 ml/m <sup>3</sup> / 500 mg/m <sup>3</sup> | vapour |

**8.1.2 Additional exposure limits under working conditions**

None known.

**Material Safety Data Sheet**

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

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

**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**

|  |  |
|--|--|
| <b>General information</b>             | 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. |
| <b>Eye/face protection</b>             | Wear safety goggles where there is risk of eye contact.  |
| <b>Skin protection</b>                 | Wear suitable gloves. Suitable gloves can be recommended by the glove supplier.  |
| <b>Respiratory protection</b>          | Provide adequate ventilation.  |
| <b>Thermal hazards</b>                 | None known.  |
| <b>Hygiene measures</b>                | Do not eat, drink, and/or smoke during application. Always observe good personal hygiene measures, such as washing hands after handling the material.                                      |
| <b>Environmental exposure controls</b> | Contain spills and prevent releases and observe national regulations on emissions.   |

**SECTION 9: Physical and chemical properties**

**9.1 General information**

|                        |                               |
|------------------------|-------------------------------|
| <b>Appearance</b>      | Coloured opaque liquid        |
| <b>Physical state</b>  | Liquid                        |
| <b>Form</b>            | Liquid                        |
| <b>Colour</b>          | blue                          |
| <b>Odour</b>           | Neutral to slightly alcoholic |
| <b>Odour threshold</b> | Not available                 |

**9.1.1 Important health, safety and environmental information**

|  |                |
|--|----------------|
| <b>pH value / range</b>                        | 6.5 - 8        |
| <b>Melting point/freezing point</b>            | Not available. |
| <b>Initial boiling point and boiling range</b> | Not available. |
| <b>Flash point</b>                             | Not available. |
| <b>Evaporation rate</b>                        | Not available. |
| <b>Flammability (solid, gas)</b>               | Not available. |
| <b>Flammability limit – lower (%)</b>          | Not available. |
| <b>Flammability limit – upper (%)</b>          | Not available. |

**Material Safety Data Sheet**

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

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

|   |   |
|---|---|
| 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.                                      |
| Decomposition temperature               | Not available.                                      |
| 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**

None known or to be 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.



**Material Safety Data Sheet**

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

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

**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**

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

**Information on likely routes of exposure**

|                     |   |
|---------------------|---|
| <b>Ingestion</b>    | Ingestion may cause irritation and malaise. |
| <b>Inhalation</b>   | Inhalation may irritate respiratory system. |
| <b>Skin contact</b> | No adverse effects known or expected.       |
| <b>Eye contact</b>  | 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**

|   |   |
|---|---|
| <b>Acute toxicity</b>                                     | May cause discomfort if swallowed. No acute toxicity known by any ingredient concerning the used concentration. |
| <b>Skin corrosion/irritation</b>                          | None known or expected.   |
| <b>Serious eye damage/irritation</b>                      | Direct contact may irritate the eyes.   |
| <b>Respiratory sensitisation</b>                          | None known.   |
| <b>Skin sensitisation</b>                                 | None known or expected.   |
| <b>Germ cell mutagenicity</b>                             | None known.   |
| <b>Carcinogenicity</b>                                    | None known for single ingredients, not available for mixture.   |
| <b>Reproductive toxicity</b>                              | None known for single ingredients, not available for mixture.   |
| <b>Specific target organ toxicity - single exposure</b>   | None known.   |
| <b>Specific target organ toxicity - repeated exposure</b> | None known.   |
| <b>Aspiration hazard</b>                                  | Not classified.   |

**Material Safety Data Sheet**

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

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

|   |                |
|---|----------------|
| <b>Mixture versus substance information</b> | Not available. |
|---|----------------|

**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**

|                                       |   |
|---------------------------------------|---|
| <b>Abiotic degradability</b>          | The degradability of the product has not been stated. |
| <b>Photochemical degradability</b>    | No significant photochemical decomposition expected.  |
| <b>Biodegradability</b>               | The degradability of the product has not been stated. |
| <b>Bio concentration factor (BCF)</b> | Not available.  |
| <b>Longterm eco-toxicity</b>          | 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.

**Material Safety Data Sheet**

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

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

**SECTION 13: Disposal considerations**

**13.1 Waste treatment methods**

Dispose of residual waste in accordance with local regulations.

**13.2 waste codes**

|                 |                                 |
|-----------------|---------------------------------|
| <b>EAK/AVV</b>  | 08 01 20                        |
| <b>EU</b>       | 08 01 20                        |
| <b>EPA (US)</b> | Not defined as hazardous waste. |

**13.3 Contaminated packaging**

Dispose of in accordance with local regulations.

**13.4 Additional information / Special precautions**

None.

**SECTION 14: Transport information**

**14.1 Land transportation**

|              |   |
|--------------|---|
| <b>ADR</b>   | The product is not covered by international regulation on the transport of dangerous goods. |
| <b>RID</b>   | The product is not covered by international regulation on the transport of dangerous goods. |
| <b>ADN</b>   | The product is not covered by international regulation on the transport of dangerous goods. |
| <b>GGVSE</b> | The product is not covered by international regulation on the transport of dangerous goods. |

**14.2 Sea transportation**

|               |   |
|---------------|---|
| <b>IMDG</b>   | The product is not covered by international regulation on the transport of dangerous goods. |
| <b>GGVSee</b> | The product is not covered by international regulation on the transport of dangerous goods. |

**Material Safety Data Sheet**

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

Page 12 / 13

**Trade name:** Royal Blue

**Version no.:** 02

**Revision date:** 13.05.2015

**14.3 Air freight**

|             |   |
|-------------|---|
| <b>IATA</b> | The product is not covered by international regulation on the transport of dangerous goods. |
| <b>DGR</b>  | 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**

Resolution ResAP(2008)1 on requirements and criteria for the safety of tattoos and permanent make-up

**15.1.2 National regulations**

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

|             |   |
|-------------|---|
| Germany     | Verordnung über Mittel zum Tätowieren einschließlich bestimmter vergleichbarer Stoffe und Zubereitungen aus Stoffen (Tätowiermittel-Verordnung)   |
| 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) |

**Material Safety Data Sheet**

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

Page 13 / 13

Trade name: Royal Blue

Version no.: 02

Revision date: 13.05.2015

|             |   |
|-------------|---|
| 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: Highly flammable liquid and vapour.

**16.2 Training information**

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