

# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## TECHNOVENT & FACTOR II INTRINSIC COLOURS

Revision date: 02.11.2020

Page 1 of 11

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

#### 1.1. Product identifier

**Product Name:**

Technovent & Factor II Intrinsic Colours

**Product Code(s):**

P101 - P199 – Technovent Master Colours  
P401 – P499 – Technovent Skin Shades  
FI201 – FI299 – FACTOR II Intrinsic Colours  
FI-SK01 – FI-SK99 – FACTOR II Intrinsic Skin Shades  
I100A – I100Z – FACTOR II Paste Colours

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

Intrinsic colouring of uncured silicones for maxillofacial prosthetics

#### 1.3. Details of the supplier of the safety data sheet

Company name: Technovent Ltd  
Street: Unit 5 York Park  
Bridgend CF31 3TB  
Place: UK  
Telephone: +44 1656 768566  
e-mail: info@technovent.com  
Internet: www.technovent.com

Emergency number: +44 1656768566

This number is only obtainable during office hours  
(Monday - Thursday 9.00 am - 5.00 pm, Friday 9.00 am - 4.00 pm)

#### 1.4. Emergency telephone number

+4401656 768566

This number is only obtainable during office hours  
(Monday - Thursday 8.00 am - 5.00 pm, Friday 8.00 am - 4.00 pm)

### SECTION 2: Hazards Identification

#### 2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

#### 2.2. Label elements

Additional advice on labelling  
According to Regulation (EC) 1272/2008



# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## TECHNOVENT & FACTOR II INTRINSIC COLOURS

Revision date: 02.11.2020

Page 3 of 11

After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

### **After ingestion**

Let water be drunken in little sips (dilution effect).

Do not induce vomiting. If you feel unwell, seek medical advice.

### **4.2. Most important symptoms and effects, both acute and delayed**

No information available.

### **4.3. Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

## SECTION 5: Firefighting Measures

### **5.1. Extinguishing media**

#### **Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

### **5.2. Special hazards arising from the substance or mixture**

Non-flammable. Vapours can form explosive mixtures with air.

### **5.3. Advice for firefighters**

In case of fire: Wear self-contained breathing apparatus.

#### **Additional information**

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

## SECTION 6: Accidental Release Measures

### **6.1. Personal precautions, protective equipment and emergency procedures**

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

### **6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

### **6.3. Methods and material for containment and cleaning up**

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

### **6.4. Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## TECHNOVENT & FACTOR II INTRINSIC COLOURS

Revision date: 02.11.2020

Page 4 of 11

Disposal: see section 13

### SECTION 7: Handling & Storage

#### 7.1. Precautions for safe handling

##### **Advice on safe handling**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

##### **Advice on protection against fire and explosion**

No special fire protection measures are necessary.

#### 7.2. Conditions for safe storage, including any incompatibilities

##### **Requirements for storage rooms and vessels**

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

##### **Advice on storage compatibility**

Do not store with acids, lyes, alcohols, metallic powders and metallic oxides (release of hydrogen is favoured).

##### **Further information on storage conditions**

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

#### 7.3. Specific end use(s)

Intrinsic colouration of uncured silicone for maxillofacial prosthetics  
For use by trained specialist staff.

### SECTION 8: Exposure Control/Personal Protection

#### 8.1. Control parameters

#### 8.2. Exposure controls

##### **Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

##### **Protective and hygiene measures**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary . When using do not eat or drink.

##### **Eye/face protection**

Wear eye/face protection.

# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## TECHNOVENT & FACTOR II INTRINSIC COLOURS

Revision date: 02.11.2020

Page 5 of 11

### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: NBR (Nitrile rubber)

### Skin protection

Wear suitable protective clothing.

### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

## SECTION 9: Physical/Chemical Properties

### 9.1. Information on basic physical and chemical properties

Physical state: Viscous liquid  
Colour: Varies (depending on product code)  
Odour: characteristic

pH-Value: not determined

#### Test method

### Changes in the physical state

Melting point: not determined  
Initial boiling point and boiling range: not determined

Flash point: >100 °C DIN 51755

### Flammability

Solid: not applicable  
Gas: not applicable

Lower explosion limits: not determined  
Upper explosion limits: not determined

Ignition temperature: >400 °C DIN 51794

### Auto-ignition temperature

Solid: not applicable  
Gas: not applicable

Decomposition temperature: >180 °C

### Oxidizing properties

Not oxidizing.

Vapour pressure: <10 hPa (at 20 °C)

# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## TECHNOVENT & FACTOR II INTRINSIC COLOURS

Revision date: 02.11.2020

Page 6 of 11

Density (at 20 °C):	1,1 g/cm <sup>3</sup>	DIN 51757
Water solubility:	practically insoluble	
Solubility in other solvents	not determined	
Partition coefficient:	not determined	
Viscosity / dynamic: (at 23 °C)	100-350 cSt	
Vapour density:	not determined	
Evaporation rate:	not determined	
<b>9.2. Other information</b>		
Solid content:	not determined	

## SECTION 10: Stability & Reactivity

### **10.1. Reactivity**

No hazardous reaction when handled and stored according to provisions.

### **10.2. Chemical stability**

The product is stable under storage at normal ambient temperatures.

### **10.3. Possibility of hazardous reactions**

Reacts with : Acids, alkalis, alcohols, powdered metals or metal oxides with release of hydrogen.

### **10.4. Conditions to avoid**

Temperatures > 150°C/ 302 °F.

### **10.5. Incompatible materials**

No information available.

### **10.6. Hazardous decomposition products**

In case of thermic decomposition hydrogen is released.

At a temperature of approx. 150°C/ 302°F a small amount of formaldehyde can be released by oxidative degradation.

## SECTION 11: Toxicological Information

### **11.1. Information on toxicological effects**

#### **Acute toxicity**

Based on available data, the classification criteria are not met.

For the product itself no toxicological data are available. In products with a comparable composition, a LD50

(orally, species rat) of > 5000 mg/kg has been found.



# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## TECHNOVENT & FACTOR II INTRINSIC COLOURS

Revision date: 02.11.2020

Page 8 of 11

relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

### Aspiration hazard

Based on available data, the classification criteria are not met.

## SECTION 12: Ecological Information

### 12.1. Toxicity

The product is not: Ecotoxic.

### 12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			

### 12.3. Bioaccumulative potential

The product has not been tested.

### 12.4. Mobility in soil

The product has not been tested.

### 12.5. Results of PBT and vPvB assessment

The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that the product does not lead to biomagnification in aquatic and terrestrial food chains.

### 12.6. Other adverse effects

No information available.

### Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

## SECTION 13: Disposal Considerations

### 13.1. Waste treatment methods

Advice on disposal



# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## TECHNOVENT & FACTOR II INTRINSIC COLOURS

Revision date: 02.11.2020

Page 9 of 11

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

### Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

## SECTION 14: Transport Information

### Land transport (ADR/RID)

- 14.1. UN number:** No dangerous good in sense of this transport regulation.
- 14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.
- 14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.
- 14.4. Packing group:** No dangerous good in sense of this transport regulation.

### Inland waterways transport (ADN)

- 14.1. UN number:** No dangerous good in sense of this transport regulation.
- 14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.
- 14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.
- 14.4. Packing group:** No dangerous good in sense of this transport regulation.

### Marine transport (IMDG)

- 14.1. UN number:** No dangerous good in sense of this transport regulation.
- 14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.
- 14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.
- 14.4. Packing group:** No dangerous good in sense of this transport regulation.

### Air transport (ICAO-TI/IATA-DGR)

- 14.1. UN number:** No dangerous good in sense of this transport regulation.
- 14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.
- 14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.
- 14.4. Packing group:** No dangerous good in sense of this transport regulation.
- 14.6. Special precautions for user**

# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## TECHNOVENT & FACTOR II INTRINSIC COLOURS

Revision date: 02.11.2020

Page 10 of 11

No dangerous good in sense of this transport regulation.

### **14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

No dangerous good in sense of this transport regulation.

## SECTION 15: Regulatory Information

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

#### **EU regulatory information**

##### **Additional information**

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

#### **National regulatory information**

Employment restrictions:

Observe restrictions to employment for juvenils according to the ' juvenile work protection guideline' (94/33/EC).

Water contaminating class (D):

2 - clearly water contaminating

### **15.2. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

## SECTION 16: Other Information

### **Abbreviations and acronyms**

ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road )

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

### **Relevant H and EUH statements (number and full text)**

H372 Causes damage to organs (lung) through prolonged or repeated exposure if inhaled.

### **Further Information**

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

# Safety Data Sheet

according to Regulation (EC) No 1907/2006

## TECHNOVENT & FACTOR II INTRINSIC COLOURS

Revision date: 02.11.2020

Page 11 of 11