

## Safety Data Sheet

### According to Regulation (EU) 2015/830

#### **IMPORTANT**

Read this MSDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.

#### **1. IDENTIFICATION**

##### **1.1 Product Identifier**

Product Name	Connect-E
--------------	-----------

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

Product Use	Dental use only.
Description	Dental Product

##### **1.3 Supplier of the Safety Data Sheet**

Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of Competent Person	Regulatory@perfectionplus.com

##### **1.4 Emergency telephone number**


Emergency telephone number	0044 (0) 230 866 677 (8am – 5pm Monday to Friday)
----------------------------	--

#### **2. HAZARDS IDENTIFICATION**

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

2.1.2. Classification - EC 1272/2008	Flam. Liq 2 Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Eye Irrit. 2 STOT SE 3
--------------------------------------	---

##### **2.2 Label Elements**

Hazard Pictograms	
Signal Word	Danger
Hazard Statement	H225: Highly flammable liquid and vapour. H302: Harmful if swallowed. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H335: May cause respiratory irritation.
Precautionary Statement: Prevention	P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P223 - Keep container tightly closed. P261 - Avoid breathing fumes. P264 – Wash hands thoroughly after handling. P270 – Do not eat, drink or smoke when using this product. P272 – Contaminated work clothing should not be allowed out of the workplace.

	P280: Wear protective gloves/protective clothing/eye protection/ face protection.
Precautionary Statement: Response	P301+P312 – IF SWALLOWED: Call a POISON CENTRE/doctor is you feel unwell. P302+P352 – IF ON SKIN: Wash with plenty of water. P304+P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. P330 – Rinse mouth. P333+P313 – If skin irritation or rash occurs: Get medical advice/attention. P337+P313 – If eye irritation persists: Get medical advice attention. P362+P364 – Take off contaminated clothing and wash before reuse.
Precaution Statement: Disposal	P501: Dispose of contents/container as required by national regulatory requirements.

### 2.3 Other hazards

Other hazards	PBT. vPvB. Not applicable.
---------------	----------------------------

### Further information

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	CONC. (%w/w)	Classification
2-Hydroxyethyl methacrylate	607-124-00-X	868-77-9	212-782-2		30-50%	Skin Irrit. 2: H315 Skin Sens 1: H317 Eye Irrit. 2: H319
Acetone	606-001-00-8	67-64-1	200-662-2		10-30%	Flamm Liq. 2: H225 Eye Irrit. 2: H319 STOT SE 3: H336
Triethylamine	612-004-00-5	121-44-8	204-469-4		<1	Flam. Liq. 2: H225 Acute Tox. 4: H302 Acute Tox. 4: H312 Skin Corr. 1A: H314 Acute Tox. 4: H332 STOT SE 3: H335

## 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

Inhalation	Remove the casualty from the hazardous area and take him to fresh air. If the casualty is not breathing give artificial respiration, notify emergency physician immediately.
Eye Contact	Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Refer for medical attention.
Skin contact	Take off contaminated clothing. Wash off with plenty of soap and water. Consult a physician. Wash contaminated clothing before reuse.
Ingestion	Never give anything by mouth to an unconscious person. Take casualty to the hospital. If the person is conscious rinse the mouth and spit the fluids out. DO NOT Induce vomiting. During spontaneous vomiting - hold the head of the casualty low with the body in a prone position in order to avoid the penetration of vomit into the airways. Refer for immediate medical attention.

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

Inhalation	No data available
Eye Contact	No data available
Skin contact	No data available
Ingestion	No data available

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

Inhalation	No data available
Eye Contact	No data available
Skin contact	No data available
Ingestion	No data available

**General information**

	If you feel unwell, seek medical advice (show the label where possible).
--	--

**5. FIRE FIGHTING MEASURES**
**5.1 Extinguishing media**

	Water spray, alcohol resistant foam, dry chemical, carbon dioxide.
--	--

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

	May form flammable vapours.
--	-----------------------------

**5.3 Advice for firefighters**

	Wear self-contained breathing apparatus for firefighting.
--	---

**6. ACCIDENTAL RELEASE MEASURES**
**6.1 Personal precautions, protective equipment and emergency procedures**

	Use personal protective equipment. Avoid vapour formation. Avoid breathing vapours. Ensure adequate ventilation. Keep away from sources of ignition. Wash hands thoroughly with soap and water after handling.
--	--

**6.2 Environmental precautions**

	Do not allow product to enter drains.
--	---------------------------------------

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

	Use personal protective equipment when cleaning. Soak up spills with inert absorbent material. Collect spills and put it into appropriate container if it is safe to do so. Dispose in a safe manner in accordance with national regulatory requirements.
--	---

**6.4 Reference to other sections**

	See section 13 for disposal information.
--	--

**7. HANDLING AND STORAGE**
**7.1 Precautions for safe handling**

	Use personal protective equipment when handling. Avoid contact with eyes and skin. Avoid breathing vapours. Take off all contaminated clothing immediately. Wash hands before breaks and immediately after handling the product. Do not eat, drink or smoke when using this product.
--	--

**7.2 Conditions for safe storage, including any incompatibilities**

	Keep container tightly closed in a dry, cool and well-ventilated place. Keep away from heat and direct sunlight. Storage temperature: 4-28°C.
--	---

**7.3 Specific end use(S)**

	For professional use in dentistry only.
--	---

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION**
**8.1 Control parameters**
**8.1.1 Exposure Limit Values**

Acetone	WEL 8-hr limit ppm:	500	WEL 8-hr limit mg/m <sup>3</sup> :	1210
	WEL 15 min limit ppm:	1500	WEL 15 min limit mg/m <sup>3</sup> :	3620
	WEL 8-hr limit mg/m <sup>3</sup> total inhalable dust:	-	WEL 15 min limit mg/m <sup>3</sup> total inhalable dust:	-
	WEL 8-hr limit mg/m <sup>3</sup> total respirable dust:	-	WEL 15 min limit mg/m <sup>3</sup> total respirable dust:	-

## 8.2 Exposure controls

Provide adequate ventilation. Storage properly (p.7). Preventive medical check-ups should be arranged.



### 8.2.1 Appropriate engineering controls

	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday
--	---

### 8.2.2 Individual protection measures

	Wear chemical protective clothing.
Eye/face protection	Wear eye / face protection equipment. Safety glasses with side-shields, conforming to EN 166.
Skin protection – Hand protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. For permanent contact in work areas without heightened risk of injury (e.g. laboratory) gloves made of the following material are suitable: PVC, neoprene, rubber. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Respiratory protection	Wear self-contained breathing apparatus. If you need to protect the airways use respirators, that have been tested and approved by the relevant governmental standards, such as CEN (EU) or NIOSH (USA).

### 8.2.3 Environmental exposure controls

	Do not let enter the environment.
--	-----------------------------------

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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

Appearance	Clear, yellowish liquid	Flash point °C	2.5
Odour	Specific of acetone	Initial boiling point °C	53±1

## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

	No data available.
--	--------------------

### 10.2 Chemical stability

	Stable under recommended storage conditions.
--	--

### 10.3 Possibility of hazardous reactions

	No data available.
--	--------------------

### 10.4 Conditions to avoid

	Protect from heat and direct sunlight.
--	--

### 10.5 Incompatible materials

	No data available.
--	--------------------

### 10.6 Hazardous decomposition products

	No data available.
--	--------------------

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity	Acute systemic toxicity (ISO 10993-11) of final device extract in mice by systemic injection. No obvious body weight loss, no clinical signs of toxicity, no animals died during 72 hours observation period.
Skin corrosion/irritation	Intracutaneous reactivity (ISO 10993-10) of final device extract in rabbits by intracutaneous injection. Erythema scores: 0 and oedema scores 0 during 72 hours observation period. Uncured medical device may cause skin irritation.

Serious eye damage/irritation	Uncured medical device may cause serious eye irritation.
Respiratory or skin sensitisation	Uncured medical device may cause an allergic skin reaction.
Germ cell mutagenicity	No data available.
Carcinogenicity	IARC: No components of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity	No data available.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	No data available.
Repeated or prolonged exposure	No data available.

#### 11.1.4 Toxicological Information

2-Hydroxyethyl methacrylate	<b>ORAL Rat LD50:</b> >5000 mg/kg	<b>DERMAL Rabbit LD50:</b> >5000 mg/kg
Acetone	<b>ORAL Rat LD50:</b> 5800 mg/kg <b>INHALATION Rat LC50:</b> 76 mg/l 4h	<b>DERMAL Rabbit LD50:</b> >7400 mg/kg
Triethylamine	<b>ORAL Rat LD50:</b> 730 mg/kg <b>INHALATION Rat LC50:</b> 7.1 mg/l 4h	<b>DERMAL Rabbit LD50:</b> 580 mg/kg

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

	No data available
--	-------------------

### 12.2 Persistence and degradability

	No data is available on this product.
--	---------------------------------------

### 12.3 Bio accumulative potential

	No data is available on this product.
--	---------------------------------------

### 12.4 Mobility in soil

	No data is available on this product.
--	---------------------------------------

### 12.5 Results of PBT and vPvB assessment

	No data is available on this product.
--	---------------------------------------

### 12.6 Other adverse effects

	No data is available on this product.
--	---------------------------------------

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

	Dispose of in compliance with all local, state or national legislation. Offer surplus and non-recyclable solutions to a licensed disposal company. Contaminated packaging Dispose of as unused product. Do not remove the information from the package.
--	---

#### General information

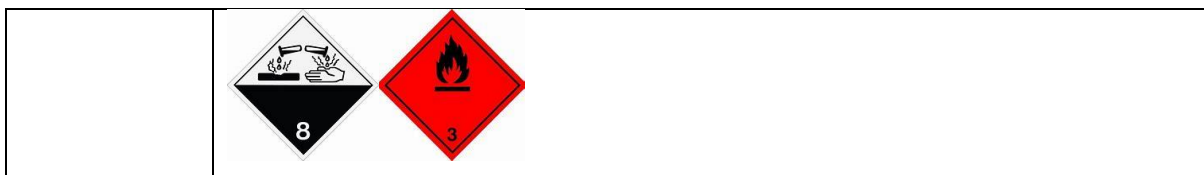
	18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans. 18 01 06 chemicals consisting of or containing dangerous substances.
--	---

#### Disposal Methods

	Do not empty in to drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.
--	---

## 14. TRANSPORT INFORMATION

Hazard pictograms


**14.1 UN number**

	UN2924
--	--------

**14.2 UN proper shipping name**

	ADR/RID: FLAMMABLE LIQUID, CORROSIVE N.O.S. (Acetone, Triethylamine) 3 (8). II (D/E) IMDG: FLAMMABLE LIQUID, CORROSIVE, N.O.S. (Acetone, Triethylamine) IATA: Flammable liquid, corrosive, n.o.s. (Acetone, Triethylamine)
--	--

**14.3 Transport hazard class(es)**

ADR/RID	3 (8)
Subsidiary risk	-
IMDG	3 (8)
Subsidiary risk	-
IATA	3 (8)
Subsidiary risk	-

**14.4 Packing group**

Packing Group	II
---------------	----

**14.5 Environmental hazards**

Environmental hazards	No
Marine pollutant	No

**14.6 Special precautions for user**

	Read safety instructions, SDS and emergency procedures before handling. Ensure that persons transporting the product know what to do in the event of an accidental spillage.
--	--

**14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

	No data available.
--	--------------------

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

Regulations	This safety datasheet complies with the requirements of Regulation (EC) No 1907/2006 as amended by Regulation (EU) No 453/2010. Other Regulations: EINECS: Components of mixture are on the European Inventory of Existing Commercial Chemical Substances. This safety data sheet information is not a professional risk assessment.
-------------	--

**15.2 Chemical Safety Assessment**

	No data available.
--	--------------------

**16. OTHER INFORMATION**
**Other information**

Text of Hazard and Precautionary Statements	H225: Highly flammable liquid and vapour. H302: Harmful if swallowed. H312: Harmful in contact with skin. H314: Causes severe skin burns and eye damage. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H332: Harmful if inhaled. H335: May cause respiratory irritation. H336: May cause drowsiness or dizziness. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed.
---	--

	<p>P261: Avoid breathing fume/vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. P302+P352: IF ON SKIN: Wash with plenty of water. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P330: Rinse mouth. P333+P313: If skin irritation or rash occurs: Get medical advice/ attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash before reuse. P501: Dispose of contents/container to as required by national regulatory requirements.</p>
--	---

#### Further information

The information used in this SDS is believed to be correct however, the information is provided without any warranty, neither expressed nor implied, regarding its correctness.

This SDS is relevant for large quantities of product, the instructions for safe use of quantities typically used during a normal procedure is as referenced in the Instructions for Use.

The conditions or methods for handling, storage, lone use and/or in combination with other products and disposal are beyond our control.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable.