

Safety Data Sheet  
according to 1907/2006/EC, Article 31,

**1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**1.1 PRODUCT IDENTIFIER**

Product name: F160-1 POLYOL (A) – Resin cartridge for Össur Direct Socket system  
Product code: Not available

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

**1.2.1 RELEVANT IDENTIFIED USES**

Application of the substance/mixture: Polyurethane resin to be used with Össur Direct Socket system

**1.2.2 USES ADVISED AGAINST**

No further relevant information available

**1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET**

Supplier: Össur  
Grjothals 5, 110 Reykjavik,  
Iceland  
sds@ossur.com

**1.4 EMERGENCY TELEPHONE NUMBER:**

Emergency number: +1 703-741-5970 (CHEMTREC, International) / 800-424-9300 (CHEMTREC, USA)

**2 HAZARDS IDENTIFICATION**

**2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE**

Classification according to Regulation (EC) No 1272/2008

Eye Irrit. 2 H319 Causes serious eye irritation.  
Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.

**2.2 LABEL ELEMENTS**

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

**Hazard pictograms**



GHS07



GHS08

**Signal word**

Danger

**Hazard-determining components of labelling:**

Hydrocarbons, C12-C16, isoalkanes, cyclics, < 2% aromatics

**Hazard statements**

H319 Causes serious eye irritation.  
H304 May be fatal if swallowed and enters airways.

**Precautionary statements**

P280 Wear eye protection / face protection.  
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P337+P313 If eye irritation persists: Get medical advice/attention.  
P331 Do NOT induce vomiting.

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P501

Dispose of contents/container in accordance with local/regional/national/international regulations.

### 3 COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 CHEMICAL CHARACTERISATION: MIXTURES

**Description:** Mixture of substances listed below with nonhazardous additions.

Dangerous components:		
CAS: 25214-63-5 NLP: 500-035-6 Reg.nr.:01-2119471485-32	Propoxylated ethylenediamine Eye Irrit. 2, H319	10-25%
CAS: 102-60-3 EINECS: 203-041-4 Reg.nr.: 01-2119552434-41	1,1',1'',1'''-ethylenedinitrilotetrapropan-2-ol Eye Irrit. 2, H319	10-25%
EC number: 927-676-8 Reg.nr.: 01-2119456377-30	Hydrocarbons, C12-C16, isoalkanes, cyclics, < 2% aromatics Asp. Tox. 1, H304	10-25%
EC number: 920-901-0 Reg.nr.: 01-2119456810-40	Hydrocarbons, C11-C13, isoalkanes, < 2% aromatics Asp. Tox. 1, H304	2.5-10%

**Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 FIRST AID MEASURES

#### 4.1 DESCRIPTION OF FIRST AID MEASURES

**General information:**

Immediately remove any clothing soiled by the product.

**After inhalation:**

Supply fresh air; consult doctor in case of complaints.

**After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

**After eye contact:**

Rinse opened eye for several minutes under running water. Then consult a doctor.

**After swallowing:**

Do not induce vomiting; call for medical help immediately.

#### 4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

No further relevant information available.

#### 4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No further relevant information available.

### 5 FIREFIGHTING MEASURES

#### 5.1 EXTINGUISHING MEDIA

**Suitable extinguishing agents:** CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray.

#### 5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

In case of fire, the following can be released:

Carbon monoxide (CO)

Nitrogen oxides (NO<sub>x</sub>)

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### 5.3 ADVICE FOR FIREFIGHTERS

- Protective equipment:** Wear self-contained respiratory protective device.  
**Additional information** Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

## 6 ACCIDENTAL RELEASE MEASURES

### 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Wear protective equipment. Keep unprotected persons away.

### 6.2 ENVIRONMENTAL PRECAUTIONS:

Do not allow product to reach sewage system or any water course.

### 6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.

### 6.4 REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

## 7 HANDLING AND STORAGE

### 7.1 PRECAUTIONS FOR SAFE HANDLING

Inform personnel of risks associated with the product, the precautions to be taken and procedures to follow where an accident occurs.

**Information about fire - and explosion protection:** Protect from heat.

### 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

**Storage:**

**Requirements to be met by storerooms and receptacles:**

Use only receptacles specifically permitted for this substance/product.

**Information about storage in one common storage facility:**

Store away from foodstuffs.

**Further information about storage conditions:**

Keep receptacle tightly sealed.  
Protect from humidity and water.  
This product is hygroscopic.

### 7.3 SPECIFIC END USE(S)

No further relevant information available.

## 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

**Additional information about design of technical facilities:**

No further data; see item 7.

### 8.1 CONTROL PARAMETERS

**Ingredients with limit values that require monitoring at the workplace:**

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

**Additional information:**

The lists valid during the making were used as basis.

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## 8.2 EXPOSURE CONTROLS

### Personal protective equipment:

#### General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

#### Respiratory protection:

Not necessary if room is well-ventilated

#### Protection of hands:



Protective gloves

#### Material of gloves

PVC gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

#### Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

#### Eye protection:



Safety glasses

Tightly sealed goggles

**Body protection:** Protective work clothing

## 9 PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

#### General Information

#### Appearance:

Form:	Fluid
Colour:	Beige
Odour:	Characteristic
pH-value at 20 °C:	NA

#### Change in condition

Melting point/freezing point:	NA °C
Flash point:	> 80 °C

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

Density at 20 °C: 0.99 g/cm<sup>3</sup> (ISO 1675:1985)

Solubility in / Miscibility with water: Not miscible or difficult to mix.

Organic solvents: Soluble in many organic solvents.

### 9.2 OTHER INFORMATION:

No further relevant information available.

## 10 STABILITY AND REACTIVITY

### 10.1 REACTIVITY

No further relevant information available.

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**10.2 CHEMICAL STABILITY**

**Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

**10.3 POSSIBILITY OF HAZARDOUS REACTIONS**

Reacts with oxidising agents.

**10.4 CONDITIONS TO AVOID:**

No further relevant information available.

**10.5 INCOMPATIBLE MATERIALS:**

No further relevant information available.

**10.6 HAZARDOUS DECOMPOSITION PRODUCTS:**

No dangerous decomposition products known.

**11 TOXICOLOGICAL INFORMATION**

**11.1 INFORMATION ON TOXICOLOGICAL EFFECTS**

**Acute toxicity**

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

LD/LC50 values relevant for classification: 25214-63-5 Propoxylated ethylenediamine		
Oral	LD50	>2000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rat)
102-60-3 1,1',1'',1'''-ethylenedinitrilotetrapropan-2-ol		
Oral	LD50	>2000 mg/kg (rat)
Derma	LD50	>2000 mg/kg (rat)

**Primary irritant effect:**

**Skin corrosion/irritation**

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

**Serious eye damage/irritation**

Causes serious eye irritation.

**Respiratory or skin sensitisation**

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

**CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

**Germ cell mutagenicity**

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

**Carcinogenicity**

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

**Reproductive toxicity**

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

**STOT-single exposure**

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

**STOT-repeated exposure**

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

**Aspiration hazard**

May be fatal if swallowed and enters airways.

**12 ECOLOGICAL INFORMATION**

**12.1 TOXICITY**

Aquatic toxicity: 25214-63-5 Propoxylated ethylenediamine	
LC50 (96h)	>100 mg / l (fish)

**12.2 PERSISTENCE AND DEGRADABILITY**

No further relevant information available.

**Other information:** The product is not easily biodegradable.

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**12.3 BIOACCUMULATIVE POTENTIAL:**

No further relevant information available.

**12.4 MOBILITY IN SOIL:**

No further relevant information available.

**Additional ecological information:**

**General notes:**

At present there are no ecotoxicological assessments.

**12.5 RESULTS OF PBT AND vPvB ASSESSMENT**

**PBT:** Not applicable.

**vPvB:** Not applicable.

**12.6 OTHER ADVERSE EFFECTS:**

No further relevant information available

## 13 DISPOSAL CONSIDERATIONS

**13.1 WASTE TREATMENT METHODS**

**Recommendation**

Dispose of the product by burning in a suitable incinerator or bury in an approved landfill following all applicable local and/or national regulations

European waste catalogue	
20 01 27*	paint, inks, adhesives and resins containing dangerous substances

**Uncleaned packaging:**

**Recommendation:**

Empty containers may not be disposed of unless any remaining material adhering to the internal walls has been removed. Disposal must be made according to official regulations.

## 14 TRANSPORT INFORMATION

**14.1 UN-NUMBER**

**ADR, IMDG, IATA** Void

**14.2 UN PROPER SHIPPING NAME**

**ADR** Void

**IMDG, IATA** Void

**14.3 TRANSPORT HAZARD CLASS(ES)**

**ADR, IMDG, IATA** Void

**Class**

**14.4 PACKING GROUP**

**ADR, IMDG, IATA** Void

**14.5 ENVIRONMENTAL HAZARDS:**

Not applicable

**14.6 SPECIAL PRECAUTIONS FOR USER**

Not applicable

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

Not applicable.

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**Transport/Additional information:** Not dangerous according to the above specifications.  
**UN "Model Regulation":** Void

## 15 REGULATORY INFORMATION

### 15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

**Directive 2012/18/EU**

**Named dangerous substances - ANNEX I**

None of the ingredients is listed.

**REGULATION (EC) No 1907/2006 ANNEX XVII**

Conditions of restriction: 3

**National regulations:**

**Waterhazard class:**

Water hazard class 1 (Self-assessment): slightly hazardous for water.

### 15.2 CHEMICAL SAFETY ASSESSMENT:

A Chemical Safety Assessment has not been carried out.

## 16 OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

### Relevant phrases

H304 May be fatal if swallowed and enters airways.  
H319 Causes serious eye irritation.

### 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 Harmonised 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 (division of the American Chemical Society)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
PBT: Persistent, Bioaccumulative and Toxic  
vPvB: very Persistent and very Bioaccumulative  
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2  
Asp. Tox. 1: Aspiration hazard – Category 1