

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 Isocyanate (B) – 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

Acute Tox. 4	H332 Harmful if inhaled.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2	H319 Causes serious eye irritation.
Resp. Sens. 1	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin Sens. 1	H317 May cause an allergic skin reaction.
Carc. 2	H351 Suspected of causing cancer.
STOT SE 3	H335 May cause respiratory irritation.
STOT RE 2	H373 May cause damage to organs through prolonged or repeated exposure.

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:

diphenylmethanediisocyanate, isomeres and homologues

Hazard statements

H332 Harmful if inhaled.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

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- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H317 May cause an allergic skin reaction.
- H351 Suspected of causing cancer.
- H335 May cause respiratory irritation.
- H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements	P260 P284 P280 P305+P351+P338 P342+P311 P501	Do not breathe dust/fume/gas/mist/vapours/spray [In case of inadequate ventilation] wear respiratory protection. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If experiencing respiratory symptoms: Call a POISON CENTER/doctor. Dispose of contents/container in accordance with local/regional/national/international regulations.
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Additional information: EUH204 Contains isocyanates. May produce an allergic reaction.

3 COMPOSITION/INFORMATION ON INGREDIENTS

3.1 CHEMICAL CHARACTERISATION: MIXTURES

Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:		
9016-87-9	diphenylmethanediisocyanate, isomeres and homologues Resp. Sens. 1, H334; Carc. 2, H351; STOT RE 2, H373; Acute Tox. 4, H332; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	50–100%

4 FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General information:

Immediately remove any clothing soiled by the product.
Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
Where massive quantities of product have been inhaled in aerosol or concentrated vapour forms : remove patient from affected area.
Transfer to hospital (to an intensive care unit if necessary) by medically equipped ambulance. While awaiting the arrival of medical help, assist the patient's breathing if this is indicated. Clinical and radiographic monitoring will be required over a prolonged period, since delayed pulmonary oedema may occur.

After skin contact:

Immediately wash with water and soap and rinse thoroughly.
If skin irritation continues, consult a doctor.

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.

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5 FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing agents:

CO₂, 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:

Nitrogen oxides (NO_x)

Carbon monoxide (CO)

Hydrogen cyanide (HCN)

(Traces)

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 MEASURE

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Wear protective equipment. Keep unprotected persons away.

6.2 ENVIRONMENTAL PRECAUTIONS

Prevent seepage into sewage system, workpits and cellars.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

After approximately one hour, transfer to suitable drum containers. Do not close these (likelihood of CO₂ production). Cover tops only.

Leave open to air in a supervised area for 7 to 14 days before transferring to an authorized dumping site.

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

Ensure good ventilation/exhaustion at the workplace.

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

Avoid exposure to the material of persons having suffered from chronic respiratory affections (especially asthmatic and bronchitic persons) and those having an isocyanate allergy.

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:

Prevent any seepage into the ground.

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.

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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: 9016-87-9 diphenylmethanediisocyanate, isomeres and homologues	
WEL	Short-term value: 0.07 mg/m ³ Long-term value: 0.02 mg/m ³ Sen; as -NCO

Additional information: The lists valid during the making were used as basis.

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.

Avoid contact with the eyes and skin.

Respiratory protection:

Use suitable respiratory protective device in case of insufficient ventilation.

Fresh air mask

Short term filter device:



Filter A/P2

Protection of hands:



Protective gloves

Material of gloves

Neoprene 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.

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

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

Change in condition

Melting point/freezing point:	NA
Initial boiling point and boiling range:	NA
Flash point:	> 200 °C (P. Martens)
Ignition temperature:	> 500 °C (DIN 51 794)
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Vapour pressure at 20 °C:	< 0.0009 Pa
Density at 20 °C:	1.1 g/cm ³ (ISO 1675:1985)
Solubility in / Miscibility with water:	Insoluble.
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.

10.2 CHEMICAL STABILITY**Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Violent reactions with -NH_x, -OH and -SH- groups.

In the presence of water or humidity gas is produced (CO₂) and/or uncontrolled polymerization, possibly leading to internal pressure rises and consequent risk of container breach.

10.4 CONDITIONS TO AVOID

No further relevant information available.

10.5 INCOMPATIBLE MATERIALS:

No further relevant information available.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS:

Carbon monoxide and carbon dioxide

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11 TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity

Harmful if inhaled.

LD/LC50 values relevant for classification:		
9016-87-9 diphenylmethanediisocyanate, isomeres and homologues		
Oral	LD50	>10000 mg/kg (rat)
Dermal	LD50	>9400 mg/kg (rabbit)

Primary irritant effect:

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Tumors of the lung were observed on animals of laboratory exposed to the MDI in the form of respirable aerosol

Germ cell mutagenicity

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

Carcinogenicity

Suspected of causing cancer.

Reproductive toxicity

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

STOT-single exposure

May cause respiratory irritation.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard

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

12 ECOLOGICAL INFORMATION

12.1 TOXICITY

Aquatic toxicity:	
9016-87-9 diphenylmethanediisocyanate, isomeres and homologues	
LC50 (96h)	>1000 mg / l (fish) (OCDE - 203)
EC50 (24h)	>1000 mg / l (daphnia) (OCDE - 202)
EC50 (3h)	>100 mg / l (bacteria)

12.2 PERSISTENCE AND DEGRADABILITY

No further relevant information available.

Other information:

This product is not miscible in water. It acts on water, producing CO₂ and polyurea (a solid, non-fusible and insoluble compound) which is, to the best of our knowledge, inert and non-biodegradable. This reaction is promoted by the presence of surfactants such as liquide soap, or water-soluble solvents. Do not dispose of this product or the neutralization products in sewers, rivers or streams. The product is not easily biodegradable.

12.3 BIOACCUMULATIVE POTENTIAL

No further relevant information available.

12.4 MOBILITY IN SOIL

No further relevant information available.

Additional ecological information:

General notes:

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

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

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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

Must not be disposed together with household garbage. Do not allow product to reach sewage system. 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	
08 05 01*	waste isocyanates

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
Class Void

14.4 PACKING GROUP

ADR, IMDG, IATA Void

14.5 ENVIRONMENTAL HAZARDS:

Not applicable.

14.6 SPECIAL PRECAUTIONS FOR USER

Not applicable.

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE:

Not applicable.

Transport/Additional information:

Not dangerous according to the above specifications.

UN "Model Regulation":

Void

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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

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.
H373	May cause damage to organs through prolonged or repeated exposure.

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
Acute Tox. 4:	Acute toxicity – Category 4
Skin Irrit. 2:	Skin corrosion/irritation – Category 2
Eye Irrit. 2:	Serious eye damage/eye irritation – Category 2
Resp. Sens. 1:	Respiratory sensitisation – Category 1
Skin Sens. 1:	Skin sensitisation – Category 1
Carc. 2:	Carcinogenicity – Category 2
STOT SE 3:	Specific target organ toxicity (single exposure) – Category 3
STOT RE 2:	Specific target organ toxicity (repeated exposure) – Category 2