

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### primopoly Hardener

Revision date: 30.03.2023

Product code: 7070110

Page 1 of 10

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

### 1.1. Product identifier

primopoly Hardener

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

#### Use of the substance/mixture

dental use

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

Company name:	primotec - Joachim Mosch e.K	
Street:	Tannenwaldallee 4	
Place:	61348 Bad Homburg (GER)	
Telephone:	+49 (0)6172-997700-0	Telefax: +49 (0)6172-997700-99
e-mail:	primotec@primogroup.de	
Internet:	www.primogroup.de	
Responsible Department:	F&E	
	Telefax +49 (0)6172-997700-99	

### 1.4. Emergency telephone number:

Giftinformationszentrum Universitätsklinikum Mainz  
Telefon +49 (0)6131-19240

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Regulation (EC) No 1272/2008

Acute Tox. 4; H332  
Skin Irrit. 2; H315  
Eye Irrit. 2; H319  
Resp. Sens. 1; H334  
Skin Sens. 1; H317  
Carc. 2; H351  
STOT SE 3; H335  
STOT RE 2; H373

Full text of hazard statements: see SECTION 16.

### 2.2. Label elements

#### Regulation (EC) No 1272/2008

##### Hazard components for labelling

diphenylmethanediisocyanate, isomeres and homologues  
4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate  
o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate

**Signal word:** Danger

**Pictograms:**



##### Hazard statements

H332	Harmful if inhaled.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### primopoly Hardener

Revision date: 30.03.2023

Product code: 7070110

Page 2 of 10

H351 Suspected of causing cancer if inhaled.  
 H335 May cause respiratory irritation.  
 H373 May cause damage to organs (...) through prolonged or repeated exposure if inhaled.

#### Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.  
 P280 Wear protective gloves/protective clothing/eye protection/face protection.  
 P284 In case of inadequate ventilation wear respiratory protection.  
 P302+P352 IF ON SKIN: Wash with plenty of water.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P405 Store locked up.  
 P501 Dispose of contents/container in accordance with local regulation.

#### Special labelling of certain mixtures

EUH204 Contains isocyanates. May produce an allergic reaction.  
 Restricted to professional users.  
 As from 24 August 2023 adequate training is required before industrial or professional use.

#### 2.3. Other hazards

Sensitisation to the respiratory tract

### SECTION 3: Composition/information on ingredients

#### 3.2. Mixtures

##### Chemical characterization

Polyisocyanate on the basis of Diphenylmethane diisocyanate.

##### Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
9016-87-9	diphenylmethanediisocyanate, isomeres and homolgues			50 - 100 %
	Carc. 2, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Resp. Sens. 1, Skin Sens. 1, STOT SE 3, STOT RE 2; H351 H332 H315 H319 H334 H317 H335 H373			
101-68-8	4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate			10 < 25 %
	202-966-0	615-005-00-9		
	Carc. 2, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Resp. Sens. 1, Skin Sens. 1, STOT SE 3, STOT RE 2; H351 H332 H315 H319 H334 H317 H335 H373			
5873-54-1	o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate			2,5 < 10 %
	227-534-9	615-005-00-9		
	Carc. 2, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Resp. Sens. 1, Skin Sens. 1, STOT SE 3, STOT RE 2; H351 H332 H315 H319 H334 H317 H335 H373			

Full text of H and EUH statements: see section 16.

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### primopoly Hardener

Revision date: 30.03.2023

Product code: 7070110

Page 3 of 10

#### Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
		Specific Conc. Limits, M-factors and ATE	
9016-87-9		diphenylmethanediisocyanate, isomeres and homolgues	50 - 100 %
		inhalation: ATE = 11 mg/l (vapours); inhalation: LC50 = 0,31 mg/l (dusts or mists); dermal: LD50 = >9400 mg/kg; oral: LD50 = > 10000 mg/kg	
101-68-8	202-966-0	4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate	10 < 25 %
		inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); oral: LD50 = 9200 mg/kg Skin Irrit. 2; H315: >= 5 - 100 Eye Irrit. 2; H319: >= 5 - 100 Resp. Sens. 1; H334: >= 0,1 - 100 STOT SE 3; H335: >= 5 - 100	
5873-54-1	227-534-9	o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate	2,5 < 10 %
		inhalation: ATE = 11 mg/l (vapours); inhalation: LC50 = 0,387 mg/l (dusts or mists); dermal: LD50 = > 9400 mg/kg; oral: LD50 = > 2001 mg/kg Skin Irrit. 2; H315: >= 5 - 100 Eye Irrit. 2; H319: >= 5 - 100 Resp. Sens. 1; H334: >= 0,1 - 100 STOT SE 3; H335: >= 5 - 100	

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### General information

Symptoms may develop several hours following exposure; medical observation therefore necessary for at least 48 hours. Take off immediately all contaminated clothing and wash it before reuse.

##### After inhalation

Provide fresh air. Medical treatment necessary.

##### After contact with skin

After contact with skin, wash immediately with plenty of water and soap. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

##### After contact with eyes

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

##### After ingestion

Do NOT induce vomiting. Medical treatment necessary.

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

May cause respiratory irritation. Respiratory or skin sensitisation

#### 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

Extinguishing powder, Carbon dioxide, Water spray jet

##### Unsuitable extinguishing media

No information available.

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

In case of fire may be liberated: Carbon monoxide Carbon dioxide, Isocyanates

Possible in traces: Hydrogen cyanide (hydrocyanic acid)

#### 5.3. Advice for firefighters

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

##### Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately.

Do not allow entering drains or surface water.

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**primopoly Hardener**

Revision date: 30.03.2023

Product code: 7070110

Page 4 of 10

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

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****Other information**

Absorb with liquid-binding material (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

Disposal: see section 13

**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Advice on safe handling**

Provide good room ventilation. If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe vapour. Avoid contact with eyes and skin.

**Advice on protection against fire and explosion**

Keep away from sources of ignition - No smoking.

**Advice on general occupational hygiene**

Do not breathe gas/fumes/vapour/spray.

Keep away from food, drink and animal feedingstuffs.

Avoid contact with skin, eyes and clothes. 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.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Protect from the action of light. Keep only in the original container at a temperature between 4 -25 °C. Keep container tightly closed and dry.

**Hints on joint storage**

No special measures are necessary.

**SECTION 8: Exposure controls/personal protection****8.1. Control parameters**

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### primopoly Hardener

Revision date: 30.03.2023

Product code: 7070110

Page 5 of 10

#### DNEL/DMEL values

CAS No	Name of agent		
DNEL type	Exposure route	Effect	Value
101-68-8	4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate		
Consumer DNEL, acute	oral	systemic	20 mg/kg bw/day
Consumer DNEL, acute	dermal	systemic	25 mg/kg bw/day
Consumer DNEL, acute	dermal	local	17,2 mg/cm²
Consumer DNEL, acute	inhalation	systemic	0,05 mg/m³
Consumer DNEL, acute	inhalation	local	0,05 mg/m³
Consumer DNEL, long-term	inhalation	systemic	0,025 mg/m³
Consumer DNEL, long-term	inhalation	local	0,025 mg/m³

#### PNEC values

CAS No	Name of agent		
Environmental compartment			Value
9016-87-9	diphenylmethanediisocyanate, isomeres and homolgues		
Soil			1001 mg/kg
101-68-8	4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate		
Freshwater			1 mg/l
Marine water			0,1 mg/l
Soil			1 mg/kg

#### 8.2. Exposure controls

##### Individual protection measures, such as personal protective equipment

##### Eye/face protection

tightly fitting goggles

##### Hand protection

Gloves should be replaced regularly, especially after extended contact with the product. For each work-place a suitable glove type has to be selected.

Suitable gloves type nitrile rubber gloves (&gt; 0,4 mm), Break through time ca. 480 min (EN 374).

##### Skin protection

Wear suitable protective clothing.

##### Respiratory protection

Breathing apparatus in case of high concentrations, short term: filter appliance, filter A

### SECTION 9: Physical and chemical properties

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

Physical state: Liquid  
 Colour: brown  
 Odour: earthy

##### Test method

Melting point/freezing point: not determined  
 Boiling point or initial boiling point and boiling range: > 350 °C DIN 53171  
 Flammability: not applicable  
 Lower explosion limits: not applicable  
 not determined

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**primopoly Hardener**

Revision date: 30.03.2023

Product code: 7070110

Page 6 of 10

Upper explosion limits:	not determined
Flash point:	229 °C DIN EN 22719
Auto-ignition temperature:	> 500 °C DIN 51794
Decomposition temperature:	not determined
pH-Value (at 20 °C):	< 7 ISO 8975
Water solubility:	The study does not need to be conducted because the substance is known to be insoluble in water.

**Solubility in other solvents**

The substance is not soluble in water.

Partition coefficient n-octanol/water:

not determined

Vapour pressure:

0,0002 hPa

(at 25 °C)

Density (at 20 °C):

1,22 g/cm<sup>3</sup> DIN 51757

Relative vapour density:

not determined

**9.2. Other information****Information with regard to physical hazard classes**

Self-ignition temperature

Solid:

not applicable

Gas:

not applicable

**Other safety characteristics**

Evaporation rate:

not determined

Solid content:

not determined

Viscosity / dynamic:

145 mPa·s DIN 53019

(at 20 °C)

**Further Information**

No data available

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No information available.

**10.2. Chemical stability**

Polymerisation &gt; 200°C,

Release of: Carbon dioxide (CO<sub>2</sub>).**10.3. Possibility of hazardous reactions**

Exothermic reaction with: Amines, Alcohols

After contact with water: Release of: Carbon dioxide (CO<sub>2</sub>). Caution! Container under pressure.**10.4. Conditions to avoid**

Keep away from heat.

**10.5. Incompatible materials**

Exothermic reaction with: Amines Alcohols

After contact with water: Release of: Carbon dioxide (CO<sub>2</sub>). Caution! Container under pressure.**10.6. Hazardous decomposition products**Carbon monoxide Nitrogen oxides (NO<sub>x</sub>)

Possible in traces: Hydrogen cyanide (hydrocyanic acid)

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### primopoly Hardener

Revision date: 30.03.2023

Product code: 7070110

Page 7 of 10

#### Acute toxicity

Harmful if inhaled.

#### ATEmix calculated

ATE (inhalation vapour) 17,60 mg/l; ATE (inhalation dust/mist) 0,573 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
9016-87-9	diphenylmethanediisocyanate, isomeres and homolgues				
	oral	LD50 > 10000 mg/kg	Rat	OECD 401	
	dermal	LD50 > 9400 mg/kg	Rabbit	OECD 402	
	inhalation vapour	ATE 11 mg/l			
	inhalation (4 h) dust/mist	LC50 0,31 mg/l	Rat	OECD 403	
101-68-8	4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate				
	oral	LD50 9200 mg/kg	Rat	GESTIS	
	inhalation vapour	ATE 11 mg/l			
	inhalation dust/mist	ATE 1,5 mg/l			
5873-54-1	o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate				
	oral	LD50 > 2001 mg/kg	Rat		
	dermal	LD50 > 9400 mg/kg	Rabbit		
	inhalation vapour	ATE 11 mg/l			
	inhalation (4 h) dust/mist	LC50 0,387 mg/l	Rat		

#### Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

#### Sensitising effects

Contains isocyanates. May produce an allergic reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. (diphenylmethanediisocyanate, isomeres and homolgues; 4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate; o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate)

May cause an allergic skin reaction. (diphenylmethanediisocyanate, isomeres and homolgues; 4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate; o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate)

#### Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of causing cancer. (diphenylmethanediisocyanate, isomeres and homolgues; 4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate; o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate)

Germ cell mutagenicity: 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

May cause respiratory irritation. (diphenylmethanediisocyanate, isomeres and homolgues; 4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate)

#### STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure. (diphenylmethanediisocyanate, isomeres and homolgues; 4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate)

## Safety Data Sheet

according to Regulation (EC) No 1907/2006

### primopoly Hardener

Revision date: 30.03.2023

Product code: 7070110

Page 8 of 10

#### Aspiration hazard

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

#### 11.2. Information on other hazards

##### Further information

Product has not been tested. The statement is derived from the properties of the components.

Possible sensitization in case of persons suffering from hypersensitivity.

### SECTION 12: Ecological information

#### 12.1. Toxicity

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
9016-87-9	diphenylmethanediisocyanate, isomeres and homologues					
	Acute fish toxicity	LC50 >1001 mg/l	96 h	Danio rerio (zebrafish)	OECD 203	
	Acute algae toxicity	ErC50 >1640 mg/l	72 h	Scenedesmus subspicatus		
	Crustacea toxicity	NOEC 10 mg/l	21 d	Daphnia magna (Big water flea)	OECD 202	
5873-54-1	o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate					
	Acute fish toxicity	LC50 > 1000 mg/l	96 h		OECD 203	
	Acute algae toxicity	ErC50 > 1640 mg/l	72 h	Scenedesmus subspicatus	OECD 201	
	Crustacea toxicity	NOEC > 10 mg/l	21 d	Daphnia magna (Big water flea)	OECD 202	

#### 12.2. Persistence and degradability

The product has not been tested.

#### 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 substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

The product has not been tested.

#### 12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

#### 12.7. Other adverse effects

No information available.

##### Further information

Do not allow uncontrolled discharge of product into the environment. Do not allow to enter into surface water or drains.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

##### Disposal recommendations

Send to a hazardous waste incinerator facility under observation of official regulations. Do not allow to enter into surface water or drains.



**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**primopoly Hardener**

Revision date: 30.03.2023

Product code: 7070110

Page 9 of 10

**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.

The Waste-Key-Numbers have to be given from the waste-producer depending on the respective trade.

Therefore no information can be stated from the manufacturer.

European waste catalogue:

HP 4: Irritant - skin irritation and eye damage

HP 5: Specific Target Organ Toxicity (STOT)/ Aspiration Toxicity

HP 7: Carcinogenic

HP 13: Sensitising

**SECTION 14: Transport information****Land transport (ADR/RID)****Other applicable information (land transport)**

No dangerous good in sense of these transport regulations.

**Inland waterways transport (ADN)****Other applicable information (inland waterways transport)**

No dangerous good in sense of these transport regulations.

**Marine transport (IMDG)****Other applicable information (marine transport)**

No dangerous good in sense of these transport regulations.

**Air transport (ICAO-TI/IATA-DGR)****Other applicable information (air transport)**

No dangerous good in sense of these transport regulations.

**14.6. Special precautions for user**

No information available.

**14.7. Maritime transport in bulk according to IMO instruments**

not applicable

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 56, Entry 75

2010/75/EU (VOC): 0,00 %

**National regulatory information**

Water hazard class (D): 1 - slightly hazardous to water

**Additional information**

This mixture contains the following substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH: none

**15.2. Chemical safety assessment**

For this mixture a chemical safety assessment has been carried out.

**SECTION 16: Other information****Changes**

This data sheet contains changes from the previous version in section(s): 16.  
according to Regulation (EC) No. 1149/2020 (REACH)

**Abbreviations and acronyms**

**Safety Data Sheet**

according to Regulation (EC) No 1907/2006

**primopoly Hardener**

Revision date: 30.03.2023

Product code: 7070110

Page 10 of 10

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)**

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 if inhaled.  
H351 Suspected of causing cancer.  
H373 May cause damage to organs (...) through prolonged or repeated exposure if inhaled.  
H373 May cause damage to organs through prolonged or repeated exposure.  
EUH204 Contains isocyanates. May produce an allergic reaction.

**Further Information**

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

**Identified uses**

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
1	May displace oxygen and cause rapid suffocation.	-	22	-	4, 8a, 8b, 10, 13	8c, 8f	-	-	

LCS: Life cycle stages

PC: Product categories

ERC: Environmental release categories

TF: Technical functions

SU: Sectors of use

PROC: Process categories

AC: Article categories

*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*