



according to Regulation (EC) No 1907/2006

# primopoly Hardener

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## 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: D-61348 Bad Homburg

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 Giftinformationszentrum Universitätsklinikum Mainz

<u>number:</u> Telefon +49 (0)6131-19240

#### **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

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

Hazard categories:

Acute toxicity: Acute Tox. 4
Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2 Respiratory or skin sensitisation: Resp. Sens. 1 Respiratory or skin sensitisation: Skin Sens. 1

Carcinogenicity: Carc. 2

Specific target organ toxicity - single exposure: STOT SE 3
Specific target organ toxicity - repeated exposure: STOT RE 2

Hazard Statements: Harmful if inhaled. Causes skin irritation. Causes serious eye irritation.

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

May cause an allergic skin reaction. Suspected of causing cancer. May cause respiratory irritation.

May cause damage to organs through prolonged or repeated exposure.

### 2.2. Label elements

## Regulation (EC) No. 1272/2008

#### Hazard components for labelling

diphenylmethanediisocyante, isomeres and homolgues

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

Signal word: Danger



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## 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.
 H351 Suspected of causing cancer by inhalation.
 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.

## 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 diisocyante.

# **Hazardous components**

CAS No	Chemical name						
	EC No	Index No	REACH No				
	Classification according to Regulation (EC) No. 1272/2008 [CLP]						
9016-87-9	diphenylmethanediisocyante, isomeres and homolgues						
	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						
	202-966-0	615-005-00-9					
	Carc. 2, Acute Tox. 4, STOT RE 2, Eye Irrit. 2, STOT SE 3, Skin Irrit. 2, Resp. Sens. 1, Skin Sens. 1; H351 H332 H373 ** H319 H335 H315 H334 H317						
5873-54-1	o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate						
	227-534-9	615-005-00-9					
	Carc. 2, Acute Tox. 4, STOT RE 2, Eye Irrit. 2, STOT SE 3, Skin Irrit. 2, Resp. Sens. 1, Skin Sens. 1; H351 H332 H373 ** H319 H335 H315 H334 H317						

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





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#### **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.

### **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



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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.

# 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.

# Advice on storage compatibility

No special measures are necessary.

## **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters

## **Exposure limits (EH40)**

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
-	Isocyanates, all (as -NCO) Except methyl isocyanate	-	0.02		TWA (8 h)	WEL
	·	-	0.07		STEL (15 min)	WEL

# **DNEL/DMEL values**

CAS No	Substance						
DNEL type Exposure route Effect Value							
101-68-8	01-68-8 4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate						
Consumer DNE	EL, acute	oral	systemic	20 mg/kg bw/day			
Consumer DNEL, acute dermal systemic 25 mg/kg bw/day							
Consumer DNE	EL, acute	dermal	local	17,2 mg/cm²			
Consumer DNE	EL, acute	inhalation	systemic	0,05 mg/m³			
Consumer DNE	EL, acute	inhalation	local	0,05 mg/m³			
Consumer DNE	EL, long-term	inhalation	systemic	0,025 mg/m³			
Consumer DNE	EL, long-term	inhalation	local	0,025 mg/m³			

### **PNEC values**

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



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### 8.2. Exposure controls

#### Protective and hygiene measures

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.

### 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 (> 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

pH-Value (at 20 °C): < 7 ISO 8975

Changes in the physical state

Melting point: not determined

Initial boiling point and boiling range: > 350 °C DIN 53171
Flash point: 229 °C DIN EN 22719

**Flammability** 

Solid: not applicable
Gas: not applicable
Lower explosion limits: not determined
Upper explosion limits: not determined

Ignition temperature: > 500 °C DIN 51794

**Auto-ignition temperature** 

Solid: not applicable Gas: not applicable not applicable Decomposition temperature: not determined Vapour pressure: 0,0002 hPa

(at 25 °C)

Density (at 20 °C): 1,22 g/cm³ DIN 51757

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: not determined





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Viscosity / dynamic: 145 mPa·s DIN 53019

(at 20 °C)

Vapour density: not determined Evaporation rate: not determined

9.2. Other information

Solid content: not determined

No data available

## **SECTION 10: Stability and reactivity**

### 10.1. Reactivity

No information available.

#### 10.2. Chemical stability

Polymerisation > 200°C,

Release of: Carbon dioxide (CO2).

## 10.3. Possibility of hazardous reactions

Exothermic reaction with: Amines, Alcohols

After contact with water: Release of: Carbon dioxide (CO2). 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 (CO2). Caution! Container under pressure.

# 10.6. Hazardous decomposition products

Carbon monoxide Nitrogen oxides (NOx)

Possible in traces: Hydrogen cyanide (hydrocyanic acid)

# **SECTION 11: Toxicological information**

### 11.1. Information on toxicological effects

### **Acute toxicity**

Harmful if inhaled.

## **ATEmix** calculated

ATE (inhalative vapour) 17,60 mg/l; ATE (inhalative aerosol) 0,573 mg/l



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CAS No	Chemical name						
	Exposure route	Dose		Species	Source	Method	
9016-87-9	diphenylmethanediisocya	ante, isome	res and homo	lgues			
	oral	LD50 mg/kg	> 10000	Rat	OECD 401		
	dermal	LD50 mg/kg	>9400	Rabbit	OECD 402		
	inhalative vapour	ATE	11 mg/l				
	inhalative (4 h) aerosol	LC50	0,31 mg/l	Rat	OECD 403		
101-68-8	4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate						
	oral	LD50 mg/kg	2200	Rat			
	dermal	LD50 mg/kg	> 9400	Rabbit			
	inhalative vapour	ATE	11 mg/l				
	inhalative aerosol	ATE	1,5 mg/l				
5873-54-1	o-(p-isocyanatobenzyl)ph	nenyl isocya	anate; diphen	ylmethane-2,4'-diisocyan	ate		
	oral	LD50 mg/kg	> 2001	Rat			
	dermal	LD50 mg/kg	> 9400	Rabbit			
	inhalative vapour	ATE	11 mg/l				
	inhalative (4 h) aerosol	LC50 mg/l	0,387	Rat			

### Irritation and corrosivity

Causes skin irritation.

Causes serious eye irritation.

#### Sensitising effects

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

May cause an allergic skin reaction.

## Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of causing cancer by inhalation.

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. ( (diphenylmethanediisocyante, isomeres and homolgues);

(4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate))

### STOT-repeated exposure

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

## **Aspiration hazard**

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

#### **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



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CAS No	Chemical name							
	Aquatic toxicity	Dose		[h]   [d]	Species	Source	Method	
9016-87-9	diphenylmethanediisocyante, isomeres and homo			gues				
	Acute fish toxicity	LC50 mg/l	>1001		Brachydanio rerio (zebra-fish)	OECD 203		
	Acute algae toxicity ErC50 >1640 mg/l		72 h	Scenedesmus subspicatus				
	Crustacea toxicity	NOEC	10 mg/l		Daphnia magna (Big water flea)	OECD 202		
5873-54-1	o-(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate							
	Acute fish toxicity	LC50 mg/l	> 1000	96 h		OECD 203		
	Acute algae toxicity	ErC50 > 1640 7		72 h	Scenedesmus subspicatus	OECD 201		
	Crustacea toxicity	NOEC mg/l	> 10	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 product has not been tested.

### 12.6. 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

# **SECTION 13: Disposal considerations**

## 13.1. Waste treatment methods

### Advice on disposal

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

### 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)



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

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 56: 4,4'-methylenediphenyl diisocyanate; diphenylmethane-4,4'-diisocyanate; o-

(p-isocyanatobenzyl)phenyl isocyanate; diphenylmethane-2,4'-diisocyanate

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

## **National regulatory information**

Water contaminating class (D): 1 - slightly water contaminating

## **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

Indication of changes:

SECTION 2: Hazards identification; Additional information Exposure route H351; H373

SECTION 3: Composition / information on ingredients

## 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%



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## 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 by inhalation.

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	SU main	SU	PC	PROC	ERC	AC	Specification
1		22	-	-	4, 8a, 8b, 10, 13	8c, 8f	-	

 SU main: Main user groups
 SU: Sectors of use

 PC: Product categories
 PROC: Process categories

 ERC: Environmental release 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.)