Printing date 11.10.2016 Version number 7 Revision: 11.10.2016

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

- · 1.1 Product identifier
- · Trade name: Xeno Select
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture Adhesive
- · Uses advised against No further relevant information available.
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

DENTSPLY DeTrey GmbH

De-Trey-Str. 1

D-78467 Konstanz

**GERMANY** 

Tel.: +49-(0)7531-583-0 Fax: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsplysirona.com

- · Further information obtainable from:
- Departement Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

## SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 3 H226 Flammable liquid and vapour.

Acute Tox. 4 H302 Harmful if swallowed.

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

Eye Dam. 1 H318 Causes serious eye damage.

STOT SE 3 H335 May cause respiratory irritation.

- · 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







GHS02

GHS05 GHS07

· Signal word Danger

## · Hazard-determining components of labelling:

Bifunctional acrylates

Ethyl 2-[5-dihydrogen phosphoryl-5,2-dioxapentyl]acrylate

Acidic Acrylate

· Hazard statements

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.

· Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No P210 smoking.

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

(Contd. on page 2)

Printing date 11.10.2016 Version number 7 Revision: 11.10.2016

Trade name: Xeno Select

(Contd. of page 1)

P310 Immediately call a POISON CENTER/doctor.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

#### · Additional information:

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

Contains 4-(dimethylamino)benzonitrile. May produce an allergic reaction.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable. · **vPvB**: Not applicable.

## SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
	Bifunctional acrylates	25-50%
	•• Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 75-65-0	tert-butyl alcohol	10-<25%
EINECS: 200-889-7	♠ Flam. Liq. 2, H225; ♠ Acute Tox. 4, H332; Eye Irrit. 2, H319; STOT SE 3, H335	3
CAS: 752235-00-0	Ethyl 2-[5-dihydrogen phosphoryl-5,2-dioxapentyl]acrylate	2.5-<10%
	♦ Skin Corr. 1B, H314	
	Acidic Acrylate	2.5-<10%
CAS: 1197-19-9	4-(dimethylamino)benzonitrile	0.1-<1%
EINECS: 214-819-8	• Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	

<sup>·</sup> Additional information For the wording of the listed hazard phrases refer to section 16.

## SECTION 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 Drink plenty of water and provide fresh air. Call for a doctor immediately.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Information for doctor No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed No further relevant information available.

## **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents CO2, sand, extinguishing powder. Do not use water.
- · For safety reasons unsuitable extinguishing agents Water.

(Contd. on page 3)

Printing date 11.10.2016 Version number 7 Revision: 11.10.2016

Trade name: Xeno Select

(Contd. of page 2)

· 5.2 Special hazards arising from the substance or mixture

During heating or in case of fire poisonous gases are produced.

· 5.3 Advice for firefighters

· Protective equipment: Self-contained respiratory protective device.

## SECTION 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 to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

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

Use neutralising agent.

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· 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.

## SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Observe normal care for working with chemicals.

- · Handling Product is intended for dental use only.
- · Information about fire and explosion protection:



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
- Storage
- Requirements to be met by storerooms and receptacles: Store in a cool location.
- · Information about storage in one common storage facility: Store away from oxidising agents.
- · Further information about storage conditions: Store in cool, dry conditions in well sealed receptacles.
- $\cdot$  7.3 Specific end use(s) No further relevant information available.

## SECTION 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:

CAS: 75-65-0 tert-butyl alcohol

WEL Short-term value: 462 mg/m³, 150 ppm Long-term value: 308 mg/m³, 100 ppm

- · Regulatory information WEL: EH40/2011
- · Additional information: The lists valid during the making were used as basis.

(Contd. on page 4)

Printing date 11.10.2016 Version number 7 Revision: 11.10.2016

Trade name: Xeno Select

(Contd. of page 3)

- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures

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: Not necessary if room is well-ventilated.
- · Protection of hands:



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

#### · Material of 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.

Natural rubber, NR

Recommended thickness of the material:  $\geq 0.12$  mm

Permeation: Level  $\geq 1$ 

#### · Penetration time of glove material

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

· Eye protection:



Tightly sealed goggles.

· **Body protection:** Protective work clothing.

## SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

- · General Information · Appearance: Form: Fluid Colour: Light yellow · Odour: Product specific · Odour threshold:
- · pH-value at 20 °C:
- · Change in condition

*Melting point/Melting range:* undetermined Boiling point/Boiling range: 91 °C · Flash point: *33* °*C* · Flammability (solid, gaseous) Not applicable. 470°C · Ignition temperature:

Not determined.

· Decomposition temperature: Not determined.

(Contd. on page 5)

Printing date 11.10.2016 Version number 7 Revision: 11.10.2016

Trade name: Xeno Select

	(Contd. of page
Self-igniting:	Product is not selfigniting.
Danger of explosion:	Product is not explosive. However, formation of explosive air vapour mixtures are possible.
Explosion limits:	
Lower:	2.4 Vol % (tert-Butanol)
Upper:	8.0 Vol % (tert-Butanol)
Vapour pressure at 20 °C:	41 hPa (tert-Butanol)
Density at 20 °C:	$1.04 \text{ g/cm}^3$
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Partly miscible
Partition coefficient (n-octanol/w	vater): Not determined.
Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
Solvent content:	
Organic solvents:	0.0 %
Water:	36.0 %
Solids content:	50.0 %
9.2 Other information	No further relevant information available.

## SECTION 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 No dangerous reactions known
- 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

## SECTION 11: Toxicological information

11.1 Information on toxicological effects

· 11.1 Injo		ioxicological effects
	if swallowed	d.
· LD/LC50	values rele	evant for classification:
ATE (Acı	ute Toxicity	Estimates)
Oral	LD50	1108 mg/kg
Inhalative	e LC50/4 h	75.4 mg/l
Bifunctio	nal acrylat	es
Oral	LD50	500 mg/kg (ATE)
CAS: 75-	65-0 tert-bi	utyl alcohol
Oral	LD50	2743 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (rabbit)
		(Contd. on page 6)

Printing date 11.10.2016 Version number 7 Revision: 11.10.2016

Trade name: Xeno Select

		(Contd. of page 5)
Inhala	tive LC50/4 h	11 mg/l (ATE)
Acidic	Acrylate	
Oral	LD50	1830 mg/kg (rat)
Inhala	tive LC50/4 h	11 mg/l (ATE)
CAS: 1	1197-19-9 4-(d	imethylamino)benzonitrile
Oral	LD50	500 mg/kg (ATE)

- · Primary irritant effect:
- · Skin corrosion/irritation

Causes severe skin burns and eye damage.

· Serious eye damage/irritation

Causes serious eye damage.

- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, 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

May cause respiratory irritation.

- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

## SECTION 12: Ecological information

· 12.1 Toxicity

· 12.1 Toxicuy		
· Aquatic toxicity:		
CAS: 75-65-0 tert-butyl alcohol		
LC50/96h	6,140 mg/l (Fish acute toxicity study)	
EC50/48h	933 mg/L (daphnia magna)	
Acidic Acr	ylate	
LC50/96h	170 mg/l (Fish acute toxicity study)	
EC50/48h	340 mg/L (daphnia magna)	

- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Do not allow product to reach ground water, water course or sewage system, even in small quantities. Must not reach sewage water or drainage ditch undiluted or unneutralised.

- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

## SECTION 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.

(Contd. on page 7)

Printing date 11.10.2016 Version number 7 Revision: 11.10.2016

Trade name: Xeno Select

	(Contd. of page 6)
· European	waste catalogue
18 01 06*	chemicals consisting of or containing hazardous substances
HP 3	Flammable
HP 4	Irritant - skin irritation and eye damage
HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP 6	Acute Toxicity

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

14 1 IIN Normal and	
14.1 UN-Number ADR, IMDG, IATA	UN2920
14.2 UN proper shipping name ADR	2920 CORROSIVE LIQUID, FLAMMABLE, N.O.S. (Eth
	2-[5-dihydrogen phosphoryl-5,2-dioxapentyl]acrylar BUTANOLS)
IMDG, IATA	CORROSIVE LIQUID, FLAMMABLE, N.O.S. (Ethyl 2-[dihydrogen phosphoryl-5,2-dioxapentyl]acrylat BUTANOLS)
14.3 Transport hazard class(es)	
ADR	
Class	8 (CF1) Corrosive substances.
Label 	8+3
IMDG	
Class	8 Corrosive substances.
Label	8/3
IATA	
Class Label	8 Corrosive substances. 8 (3)
14.4 Packing group	
ADR, IMDG, IATA	II
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Warning: Corrosive substances.
Danger code (Kemler): EMS Number:	83 F-E,S-C
Segregation groups	Alkalis

Printing date 11.10.2016 Version number 7 Revision: 11.10.2016

Trade name: Xeno Select

	(Contd. of page
· Stowage Category	E
· Stowage Code	SW1 Protected from sources of heat.
	SW2 Clear of living quarters.
· 14.7 Transport in bulk according to Anno	ex II of
Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· <i>ADR</i>	
· Limited quantities (LQ)	IL
· Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	IL
Excepted quantities (EQ)	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
UN ''Model Regulation'':	UN 2920 CORROSIVE LIQUID, FLAMMABLE, N.O
	(ETHYL 2-[5-DIHYDROGEN PHOSPHORYL-5,2
	DIOXAPENTYL]ACRYLATE, BUTANOLS), 8 (3), II

## **SECTION 15: Regulatory information**

- $\cdot$  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.
- · Seveso category P5c FLAMMABLE LIQUIDS
- Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t
- · REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

## SECTION 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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

#### · Relevant phrases

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H314 Causes severe skin burns and eye damage.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

(Contd. on page 9)

Printing date 11.10.2016 Version number 7 Revision: 11.10.2016

Trade name: Xeno Select

(Contd. of page 8)

· Department issuing SDS: Research & Development

· Contact: HotLine for urgent technical support: +49-7531-583-350

· 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

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity - Category 4

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation - Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

\* \* Data compared to the previous version altered.

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