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

· 1.1 Product identifier

· Trade name: Exakto-Form Komponente B

· Article number: 520 0017 3

- · 1.2 Relevant identified uses of the substance or mixture and uses advised against: -
- · Application of the substance / the mixture: Model resin.
- · 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier: bredent GmbH & Co.KG Weißenhorner Straße 2

89250 Senden

Tel: +49 (0) 7309/872-0 *Fax:* +49 (0) 7309/872-24

· Further information obtainable from:

R & D

e-mail: R.D@bredent.com

· 1.4 Emergency telephone number: (001) 352 323 3500

SECTION 2: Hazards identification

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



health hazard

Resp. Sens. 1 H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Carc. 2 H351 Suspected of causing cancer.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.



environment

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.



Acute Tox. 4 H332 Harmful if inhaled. Skin Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
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 GHS07, GHS08, GHS09
- · 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.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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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.

H411 Toxic to aquatic life with long lasting effects.

· 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.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

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

regulations.

Additional information:

Contains isocyanates. 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:				
CAS: 9016-87-9	diphenylmethanediisocyanate,isomeres and homologues	10-25%		
	 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 			
CAS: 38640-62-9	Bis(isopropyl)naphthalin	10-25%		
EINECS: 254-052-6	Asp. Tox. 1, H304 Aquatic Chronic 1, H410			

[·] 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.

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.

Take affected persons into fresh air and keep quiet.

Seek medical treatment.

Use a respiratory bag or breathing device.

· 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.

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· 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:

Carbon dioxide

Fire-extinguishing powder

Foam

Use fire extinguishing methods suitable to surrounding conditions.

- · For safety reasons unsuitable extinguishing agents: Water
- · 5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Hydrogen cyanide (HCN)

Carbon monoxide (CO)

Nitrogen oxides (NOx)

- · 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.

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:

Inform respective authorities in case of seepage into water course or sewage system.

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).

Ensure adequate ventilation.

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.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

The product may be used only by dentists, dental technicians or under their authority.

Open and handle receptacle with care.

- · 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:

Store only in the original receptacle.

Use only receptacles specifically permitted for this substance/product.

Prevent any seepage into the ground.

- · Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions:

Keep container tightly sealed.

Protect from humidity and water.

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· Storage class: 10

· 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Additional information about design of technical facilities: No further data; see item 7.
- · Ingredients with limit values that require monitoring at the workplace:

9016-87-9 diphenylmethanediisocyanate, isomeres and homologues (10-25%)

WEL Short-term value: 0.07 mg/m³ Long-term value: 0.02 mg/m³

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

Preventive skin protection by use of skin-protecting agents is recommended.

· 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. 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 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

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		(Contd. of page
Colour:	Beige	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not determined.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range:	Undetermined.	
Flash point:	>200 °C	
Flammability (solid, gas):	Not applicable.	
Ignition temperature:	>500 °C	
Decomposition temperature:	Not determined.	
· Auto-ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapour pressure:	Not determined.	
Density at 20 °C:	1.68 g/cm³	
Relative density	Not determined.	
· Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Not miscible or difficult to mix.	
Partition coefficient: n-octanol/water:	Not determined.	
· Viscosity:		
Dynamic:	Not determined.	
Kinematic at 40 °C:	$>20.5 \text{ mm}^2/\text{s}$	
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

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

Reacts violently with water.

Exothermic polymerisation.

- · 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

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity

Harmful if inhaled.

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		(Contd. of page 5)
· LD/LC50	values releva	nt for classification:
9016-87-9) diphenylmet	hanediisocyanate,isomeres and homologues
Oral	LD50	>10,000 mg/kg (rat)
Dermal	LD50	>9,400 mg/kg (rabbit)
	LC50 / 96 h	>1,000 mg/l (fish) (OECD 203)
38640-62-	9 Bis(isoprop	yl)naphthalin
Oral	LD50	>3,900 mg/kg (rat)
Dermal	LD50	>4,500 mg/kg (rat)
Inhalative	LC50/4h	>5.64 mg/l (rat)

- 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.

- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · 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.

SECTION 12: Ecological information

- · 12.1 Toxicity
- Aquatic toxicity:

 9016-87-9 diphenylmethanediisocyanate,isomeres and homologues

 LC50
 >1,000 mg/l (fish) (OECD 203)

 EC50
 >100 mg/l (bacteria)

 >1,000 mg/l (daphnia) (OECD 202)

 38640-62-9 Bis(isopropyl)naphthalin

 LC50
 mg/l (rat)

 EC0 / 48 h
 0.16 mg/l (daphnia)

 LC0 / 96 h
 0.5 mg/l (fish) (OECD 203)
 - · 12.2 Persistence and degradability No further relevant information available.
 - Other information: 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.
 - · Ecotoxical effects:
 - · Remark: Harmful to fish
 - · Additional ecological information:
 - · General notes:

Harmful to aquatic organisms

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

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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.

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. After prior treatment product has to be landfilled or incinerated adhering to the regulations pertaining to the disposal of especially hazardous waste.

- · Uncleaned packaging:
- · Recommendation:

Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning. Packagings that may not be cleansed are to be disposed of in the same manner as the product. Disposal must be made according to official regulations.

14.1 UN-Number ADR, IMDG, IATA	UN3082
14.2 UN proper shipping name	
ADR	3082 ENVIRONMENTALLY HAZARDOUS SUBSTANC
IMDG	LIQUID, N.O.S. (Bis(isopropyl)naphthalin) ENVIRONMENTALLY HAZARDOUS SUBSTANC LIQUID, N.O.S. (Bis(isopropyl)naphthalin), MARII POLLUTANT
IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANC LIQUID, N.O.S. (Bis(isopropyl)naphthalin)
14.3 Transport hazard class(es)	
ADR, IMDG, IATA	
Class Label	9 Miscellaneous dangerous substances and articles. 9
14.4 Packing group	
ADR, IMDĞ, IATA	III
14.5 Environmental hazards:	
Marine pollutant:	Yes
Special marking (ADR):	Symbol (fish and tree) Symbol (fish and tree)
Special marking (ADK). Special marking (IATA):	Symbol (fish and tree)
14.6 Special precautions for user	Warning: Miscellaneous dangerous substances a articles.
Hazard identification number (Kemler code):	90
EMS Number:	F-A,S-F

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· 14.7 Transport in bulk according to A Marpol and the IBC Code	nnex II of Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5L
Excepted quantities (EQ)	Code: E1
• • • •	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
· Transport category	3
· Tunnel restriction code	-
· IMDG	
· Limited quantities (LQ)	5L
· Excepted quantities (EQ)	Code: E1
• • • •	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 1000 ml
· UN "Model Regulation":	UN 3082 ENVIRONMENTALLY HAZARDOU
3	SUBSTANCE, LIQUID, N.O.S. (BIS(ISOPROPYL
	NAPHTHALIN), 9, ĨĬĬ

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Labelling according to Regulation (EC) No 1272/2008

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

- · Hazard pictograms GHS07, GHS08, GHS09
- · 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.

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.

H411 Toxic to aquatic life with long lasting effects.

· 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.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

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

regulations.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category E2 Hazardous to the Aquatic Environment
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t

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· 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.

· Relevant phrases

H304 May be fatal if swallowed and enters airways.

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.

H410 Very toxic to aquatic life with long lasting effects.

· Department issuing SDS: R & D

· Contact: R & D

· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international 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

Asp. Tox. 1: Aspiration hazard - Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard - Category 2

* * Data compared to the previous version altered.

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