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Tel.: +49 (0)800 4372522

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 10.01.2024 Version number 5 (replaces version 4) Revision: 10.01.2024

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

- · 1.1 Product identifier
 - Trade name: Signum Insulating pen II
- · 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
 - · Application of the substance / the mixture Auxiliary for manufacture of dental prothesis
- · 1.3 Details of the supplier of the safety data sheet
 - Manufacturer/Supplier:

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Informing department: E-Mail: msds@kulzer-dental.com

· 1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

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

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Repr. 2 H361f Suspected of damaging fertility.
STOT SE 3 H336 May cause drowsiness or dizziness.

STOT RE 2 H373 May cause damage to the nervous system through prolonged or repeated

exposure. Route of exposure: Inhalation.

Asp. Tox. 1 H304 May be fatal if swallowed and enters airways. Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

· 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 GHS07 GHS08 GHS09

- · Signal word Danger
- Hazard-determining components of labelling:
 Naphtha (petroleum), hydrotreated light [P: < 0,1 % w/w benzene (<u>EC: 200-753-7)</u>]
 n-hexane

Stoddard solvent

cyclohexane

· Hazard statements

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H361f Suspected of damaging fertility.

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H336 May cause drowsiness or dizziness.

H373 May cause damage to the nervous system through prolonged or repeated exposure. Route of exposure: Inhalation.

H304 May be fatal if swallowed and enters airways.

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

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

P261 Avoid breathing mist/vapours/spray.

P273 Avoid release to the environment.

P280 Wear protective gloves / eye protection.

P280 Wear protective clothing.

P284 In case of inadequate ventilation wear respiratory protection.

· 2.3 Other hazards -

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

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

Description: -

· Dangerous components:	:	
Index number: 649-328-00-1	Naphtha (petroleum), hydrotreated light [P: < 0,1 % w/w benzene (EC: 200-753-7)] Flam. Liq. 2, H225 Repr. 2, H361f; Asp. Tox. 1, H304 Aquatic Chronic 2, H411 Skin Irrit. 2, H315; STOT SE 3, H336	≥25-≤75%
CAS: 110-54-3 EINECS: 203-777-6 Index number: 601-037-00-0	n-hexane Flam. Liq. 2, H225 Repr. 2, H361f; STOT RE 2, H373; Asp. Tox. 1, H304 Aquatic Chronic 2, H411 Skin Irrit. 2, H315; STOT SE 3, H336 Specific concentration limit: STOT RE 2; H373: C ≥ 5 %	≥25-≤50%
CAS: 110-82-7 EINECS: 203-806-2 Index number: 601-017-00-1	cyclohexane Flam. Liq. 2, H225 Asp. Tox. 1, H304 Aquatic Acute 1, H400; Aquatic Chronic 1, H410 Skin Irrit. 2, H315; STOT SE 3, H336	≥5-<10%
CAS: 8052-41-3 EINECS: 232-489-3 Index number: 649-345-00-4	Stoddard solvent Flam. Liq. 3, H226 STOT RE 1, H372; Asp. Tox. 1, H304 Skin Irrit. 2, H315 Aquatic Chronic 3, H412	<i>≥</i> 0-<2.5%

Additional information For the wording of the listed hazard phrases refer to section 16.

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SECTION 4: First aid measures

- · 4.1 Description of first aid measures
 - · After inhalation Supply fresh air; consult doctor in case of symptoms.
 - After skin contact Instantly wash with water and soap and rinse thoroughly.
 - After eye contact Rinse opened eye for several minutes under running water.
 - After swallowing

Rinse out mouth and then drink plenty of water.

In case of persistent symptoms consult doctor.

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.

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.
- · 5.2 Special hazards arising from the substance or mixture

Can form explosive gas-air mixtures.

Formation of toxic gases is possible during heating or in case of fire.

- 5.3 Advice for firefighters
 - · Protective equipment: No special measures required.
 - · Additional information -

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 product reaches water or sewage system.

Prevent material from reaching sewage system, holes and cellars.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (diatomite, universal binders, for small amounts tissues).

Dispose of contaminated material as waste according to item 13.

Do not flush with water or aqueous cleansing agents

6.4 Reference to other sections

No dangerous materials are released.

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for information on disposal.

-

SECTION 7: Handling and storage

• 7.1 Precautions for safe handling Keep containers tightly sealed.

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Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Inhalative worker industrial, acute, systemic

worker industrial, acute, local

worker industrial, long term, systemic

worker industrial, long term, local

general population, acute, systemic

- · 7.2 Conditions for safe storage, including any incompatibilities
 - · Storage
 - · Requirements to be met by storerooms and containers: Store in cool location.
 - Information about storage in one common storage facility: Not required.
 - · Further information about storage conditions: Store in cool, dry conditions in well sealed containers.
- 7.3 Specific end use(s) No further relevant information available.

	ol parameters		
· Comp	onents with cri	tical values that require	monitoring at the workplace:
110-54-3	n-hexane		
OEL (Irela	and)	Long-term value: 72 mg/m³, 20 ppm IOELV, Sk	
IOELV (E	uropean Union)	Long-term value: 72 mg/	/m³, 20 ppm
110-82-7	cyclohexane		
OEL (Ireland)		Long-term value: 700 mg/m³, 200 ppm IOELV	
IOELV (E	uropean Union)	Long-term value: 700 mg	g/m³, 200 ppm
8052-41-3	3 Stoddard solv	rent	
OEL (Ireland) Long-term value: 573 Carc 1B, Muta 1B		Long-term value: 573 mç Carc 1B, Muta 1B	g/m³, 100 ppm
· DN	ELs		
8052-41-3	3 Stoddard solv	rent	
Oral	general population, long term, systemic		10.56 mg/Kg (not defined)
Dermal	worker industrial, acute, systemic		30 mg/Kg/d (not defined)
	worker industrial, long term, systemic		80 mg/Kg/d (not defined)
	worker industrial, long term, local		7.56 mg/Kg/d (not defined)
	general population, acute, systemic general population, long term, systemic		60 mg/Kg/d (not defined)
			40 mg/Kg/d (not defined)
	general population, long term, local		3.78 mg/Kg/d (not defined)
	1	-	· · · · · · · · · · · · · · · · · · ·

55 mg/m3 (not defined) 55 mg/m3 (not defined)

44 mg/m3 (not defined)

44 mg/m3 (not defined)

55 mg/m3 (not defined)

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		55 mg/m3 (not defined)	(Contd. of page 4)	
general population, acute	general population, acute, local		, , , , ,	
general population, long t	term, systemic	22 mg/m3 (not defined)		
general population, long t	general population, long term, local			
· PNECs	· PNECs			
8052-41-3 Stoddard solvent	8052-41-3 Stoddard solvent			
freshwater	0.14 mg/l (not	defined)		
marine water 0.35 mg/l (not		defined)		
sediment, dry weight, freshwater 1.14 mg/Kg (n		ot defined)		
sediment, dry weight, marine water 0.14 mg/Kg (no		ot defined)		

· Additional information: The lists that were valid during the compilation were used as basis.

· 8.2 Exposure controls

- Appropriate engineering controls No further data; see section 7.
- Individual protection measures, such as personal protective equipment
 - General protective and hygienic measures

Keep away from foodstuffs, beverages and food.

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

Avoid contact with the eyes and skin.

Breathing equipment:

Not neccessary with efficient local exhaust. If exposition to vapours is possible, use breathing protective mask (filter A).

Hand protection

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

Use protective gloves, if skin contact cannot be avoided.

Solvent resistant gloves

Check protective gloves prior to each use for their proper condition.

recommended

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.

Penetration time of glove material

Value for the permeation: Level ≤ 2

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

For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:

Butyl rubber, BR

Nitrile rubber, NBR

• Eye/face protection Tightly sealed safety glasses.

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Fluid

69°C

240 °C

7

Colourless Benzen-like

Not determined

Not applicable.

1.2 Vol % 7.4 Vol %

Not determined.

Not determined.

0.7 g/cm³ Not determined.

160 hPa

< 20.5 mm2/s

Not determined.

Not miscible or difficult to mix

Not determined.

-22 °C (110-54-3 n-hexane)

Trade name: Signum Insulating pen II

· Body protection: Light weight protective clothing

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

· Physical state · Colour:

· Smell: Odour threshold:

• Melting point/freezing point:

· Boiling point or initial boiling point and

boiling range · Flammability

Lower and upper explosion limit

· Lower:

· Upper: · Flash point:

Auto-ignition temperature:

Decomposition temperature:

·SADT

pH at 20 °C

· Viscosity:

Kinematic viscosity at 40 °C

· Kinematic viscosity · dynamic:

Solubility

· Water:

· Partition coefficient n-octanol/water (log

value)

Steam pressure at 20 °C:

Vapour pressure:

Density and/or relative density

 Density at 20 °C Relative density

· Vapour density

No further relevant information available.

Not determined.

· 9.2 Other information Appearance:

> Form: · Important information on protection of health

and environment, and on safety.

Self-inflammability:

Explosive properties:

Solvent content: Solids content: Liquid on inert carrier material

Product is not selfigniting.

Product is not explosive. However, formation of

explosive air/vapour mixtures is possible.

9.7 %

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	(Contd. of page
· Change in condition	Not data wai in a d
· Evaporation rate	Not determined.
Information with regard to physical hazard	
classes	
· Explosives	Void
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	
Highly flammable liquid and vapour.	
Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit	
flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
 - Conditions to be avoided: No decomposition if used and stored 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: None
 - · Additional information: -

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
 - · Acute toxicity Based on available data, the classification critèria are not met.

· LD/LC50 values that are relevant for classification:

64742-49-0 Naphtha (petroleum), hydrotreated light [P: < 0,1 % w/w benzene (EC: 200-753-7)]

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal		>2,000 mg/kg (rabbit) (OECD 402)
Inhalative	LC0/4h	>5,610 mg/L (rat) (OECD 403)

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110-54-3 เ	n-hexane	
Oral	LD50	16,000 mg/kg (rat) (OECD 401)
Dermal	LD0	3,350 mg/kg (rabbit) (OECD 402)
Inhalative	LC50/4 h	259.354 mg/l (rat) (OECD 403)
110-82-7	cyclohexa	ne
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD0	>2,000 mg/kg (rabbit) (OECD 402)
Inhalative	LC0/4h	>328.8 mg/L (rat) (OECD 403)
8052-41-3	Stoddaro	solvent
Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
Dermal	LD50	>3,000 mg/kg (rabbit) (OECD 402)
Inhalative	LC0/4h	>5.5 mg/L (rat) (OECD 403)

· Skin corrosion/irritation

Causes skin irritation.

- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- 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

Suspected of damaging fertility.

· STOT-single exposure

May cause drowsiness or dizziness.

STOT-repeated exposure

May cause damage to the nervous system through prolonged or repeated exposure. Route of exposure: Inhalation.

· Aspiration hazard

May be fatal if swallowed and enters airways.

- Additional toxicological information:
 - · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
 Repr. 2
- 11.2 Information on other hazards
 - · Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:	
---------------------	--

8052-41-3 Stoddard solvent

LC50/96h 3.5 mg/l (daphnia) (EPA OPPTS 850.1020) NOEC / 21d 0.1 mg/l (daphnia) (OECD 211)

EC50/96h 1.2 mg/L (algae) (OECD 201) NOELR 0.76 mg/L (algae) (OECD 201)

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EL50/21d 0.33 mg/L (daphnia) (OECD 211)

12.2 Persistence and degradability

8052-41-3 Stoddard solvent

Biodegradation >63 % /28d (not defined) (OECD 301B; ISO/ 9439/ EEC 92/69/V, C.4-C)

- 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- 12.5 Results of PBT and vPvB assessment
 - · PBT: Not applicable.
 - · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties

For information on endocrine disrupting properties see section 11.

- · 12.7 Other adverse effects
 - · Remark: Toxic for fish
 - · Additional ecological information:
 - · General notes:

Also poisonous for fish and plankton in water bodies.

Toxic for aquatic organisms

Do not allow product to reach ground water, water bodies or sewage system.

Danger to drinking water if even small quantities leak into soil.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
 - Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

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

SECTION 14: Transport information	
· 14.1 UN number or ID number · ADR, IMDG, IATA	UN1866
· 14.2 UN proper shipping name · ADR · IMDG, IATA	1866 RESIN SOLUTION, special provision 640D RESIN SOLUTION

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· 14.3 Transport hazard class(es)		
· ADR		
· Class · Label	3 (F1) Flammable liquids.	
· IMDG		
· Class · Label	3 Flammable liquids. 3	
· IATA		
· Class · Label	3 Flammable liquids. 3	
· 14.4 Packing group · ADR, IMDG, IATA	II	
· 14.5 Environmental hazards:		
· Marine pollutant:	No Symbol (fish and tree)	
· Special marking (ADR):	Symbol (fish and tree)	
· 14.6 Special precautions for user · Kemler Number:	Warning: Flammable liquids.	
	33	
· EMS Number: · Stowage Category	<i>F-Е,<u>S-Е</u> В</i>	
· 14.7 Maritime transport in bulk according to instruments		
· Transport/Additional information:	-	
ADR	_,	
· Limited quantities (LQ)	5L	(Contd. on page



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· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml
· Transport category · Tunnel restriction code	Maximum net quantity per outer packaging: 500 ml 2 D/E
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	5L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1866 RESIN SOLUTION, SPECIAL PROVISION 640D, 3, II

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
 - Directive 2012/18/EU
 - Qualifying quantity (tonnes) for the application of lower-tier requirements 200 t
 - Qualifying quantity (tonnes) for the application of upper-tier requirements 500 t REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 57

 - · DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment - Annex II

None of the ingredients is listed.

- · REGULATION (EU) 2019/1148
 - · Annex I RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

no information available

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

no information available

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.



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SECTION 16: Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Relevant phrases

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H336 May cause drowsiness or dizziness.

H361f Suspected of damaging fertility.

H372 Causes damage to organs through prolonged or repeated exposure. H373 May cause damage to organs through prolonged or repeated exposure.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H411 Toxic to aquatic life with long lasting effects.

H412 Harmful to aquatic life with long lasting effects.

Date of previous version: 18.11.2020

Version number of previous version: 4

· Abbreviations and acronyms:

SADT: Self Accelerating Decomposition Temperature

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)

DNEL: Derived No-Effect Level (REACH)

PNEC: Predicted No-Effect Concentration (REACH)

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

Repr. 2: Reproductive toxicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 1
STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
Asp. Tox. 1: Aspiration hazard – Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic 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
Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard — Category 3

Data compared to the previous version altered.