



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)

Tel.: +49 (0)800 4372522

· **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 GB 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 (EC: 200-753-7)]

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:

CAS: 64742-49-0 EINECS: 265-151-9 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	≥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.
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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.

· **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.

SECTION 8: Exposure controls/personal protection

· **8.1 Control parameters**

· **Components with critical values that require monitoring at the workplace:**

110-54-3 n-hexane

WEL (Great Britain) Long-term value: 72 mg/m³, 20 ppm

IOELV (European Union) Long-term value: 72 mg/m³, 20 ppm

110-82-7 cyclohexane

WEL (Great Britain) Short-term value: 1050 mg/m³, 300 ppm

Long-term value: 350 mg/m³, 100 ppm

IOELV (European Union) Long-term value: 700 mg/m³, 200 ppm

· **DNELs**

8052-41-3 Stoddard solvent

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	60 mg/Kg/d (not defined)
	general population, long term, systemic	40 mg/Kg/d (not defined)
Inhalative	general population, long term, local	3.78 mg/Kg/d (not defined)
	worker industrial, acute, systemic	55 mg/m ³ (not defined)
	worker industrial, acute, local	55 mg/m ³ (not defined)
	worker industrial, long term, systemic	44 mg/m ³ (not defined)
	worker industrial, long term, local	44 mg/m ³ (not defined)
	general population, acute, systemic	55 mg/m ³ (not defined)
	general population, acute, local	55 mg/m ³ (not defined)
	general population, long term, systemic	22 mg/m ³ (not defined)
	general population, long term, local	22 mg/m ³ (not defined)

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· **PNECs**

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 (not defined)
sediment, dry weight, marine water	0.14 mg/Kg (not 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 necessary 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.

· **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	Fluid
· Colour:	Colourless
· Smell:	Benzen-like
· Odour threshold:	Not determined.
· Melting point/freezing point:	Not determined
· Boiling point or initial boiling point and boiling range	69 °C
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	1.2 Vol %
· Upper:	7.4 Vol %
· Flash point:	-22 °C (110-54-3 n-hexane)
· Auto-ignition temperature:	240 °C
· Decomposition temperature:	Not determined.
· SADT	
· pH at 20 °C	7
· Viscosity:	
· Kinematic viscosity at 40 °C	< 20.5 mm ² /s
· Kinematic viscosity	
· dynamic:	Not determined.
· Solubility	
· Water:	Not miscible or difficult to mix
· Partition coefficient n-octanol/water (log value)	Not determined.
· Steam pressure at 20 °C:	160 hPa
· Vapour pressure:	
· Density and/or relative density	
· Density at 20 °C	0.7 g/cm ³
· Relative density	Not determined.
· Vapour density	Not determined.

9.2 Other information

No further relevant information available.

· Appearance:

· Form: Liquid on inert carrier material

· Important information on protection of health and environment, and on safety.

· Self-inflammability: Product is not selfigniting.
 · Explosive properties: Product is not explosive. However, formation of explosive air/vapour mixtures is possible.

· Solvent content:

· Solids content: 9.7 %

· Change in condition

· Evaporation rate: Not determined.

· Information with regard to physical hazard classes

· Explosives: Void

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· 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 criteria 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	LD0	>2,000 mg/kg (rabbit) (OECD 402)
Inhalative	LC0/4h	>5,610 mg/L (rat) (OECD 403)

110-54-3 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 cyclohexane

Oral	LD50	>5,000 mg/kg (rat) (OECD 401)
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Dermal	LD0	>2,000 mg/kg (rabbit) (OECD 402)
Inhalative	LC0/4h	>328.8 mg/L (rat) (OECD 403)
8052-41-3 Stoddard 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)
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)
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- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

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· **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.

· **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

· **14.3 Transport hazard class(es)**

- **ADR**



- **Class**
- **Label**

3 (F1) Flammable liquids.
3

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· **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)
Symbol (fish and tree)

· **Special marking (ADR):**

· **14.6 Special precautions for user**

Warning: Flammable liquids.

· **Kemler Number:**

33

· **EMS Number:**

F-E,S-E

· **Stowage Category**

B

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

Not applicable.

· **Transport/Additional information:**

-

· **ADR**

· **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

· **Transport category**
· **Tunnel restriction code**

2
D/E

· **IMDG**

· **Limited quantities (LQ)**

5L

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

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.

· **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 (UK REACH)

PNEC: Predicted No-Effect Concentration (UK REACH)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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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 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.**

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