

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

1.1 Product identifier

CopraSintec K, CopraSintec EVO K, CopraEasyMill NP

1.2 Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant uses

Alloy for dentures
Medical product

1.2.2 Uses advised against

None known.

1.3 Details of the supplier of the safety data sheet

Company Whitepeaks Dental Solutions GmbH
Weikenrott 17
46499 Hamminkeln
GERMANY
Phone +49 281 206458-0
Homepage www.white-peaks-dental.de
E-mail info@white-peaks-dental.de

Address enquiries to

Technical information info@white-peaks-dental.de
Safety Data Sheet sdb@chemiebuero.de

1.4 Emergency telephone number

Advisory body Call NHS 111 or a doctor
Company +49 281 206458-0

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture [REGULATION (GB) CLP]

Carc. 1B: H350 May cause cancer.
Repr. 1B: H360F May damage fertility.
Skin Sens. 1: H317 May cause an allergic skin reaction.
Resp. Sens. 1: H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Muta. 2: H341 Suspected of causing genetic defects.
Aquatic Chronic 4: H413 May cause long lasting harmful effects to aquatic life.

2.2 Label elements

This preparation is excluded as medical product from the regulation GB CLP.

2.3 Other hazards

Human health dangers The contained dangerous materials are not freely available with foreseeable use. Sintered substance in its non intact form present a health hazard. Operations such as grinding, cutting, heating or welding will produce dusts, fumes or vapors, which may present a health hazard if the occupational exposure limits are exceeded as detailed in section 8 of this dokument.limits are exceeded as detailed in section 8 of this dokument.

Environmental hazards Does not contain any PBT or vPvB substances.

Other hazards Further hazards were not determined with the current level of knowledge.

SECTION 3: Composition / Information on ingredients

3.1 Substances

not applicable

3.2 Mixtures

The product is a mixture.

Range [%]	Substance
55 - < 70	Cobalt
	CAS: 7440-48-4, EINECS/ELINCS: 231-158-0, EU-INDEX: 027-001-00-9
	GHS/CLP: Carc. 1B: H350 - Muta. 2: H341 - Repr. 1B: H360F - Resp. Sens. 1: H334 - Skin Sens. 1: H317 - Aquatic Chronic 4: H413
< 0.1	Nickel
	CAS: 7440-02-0, EINECS/ELINCS: 231-111-4, EU-INDEX: 028-002-00-7
	GHS/CLP: Carc. 2: H351 - STOT RE 1: H372 - Skin Sens. 1: H317

Comment on component parts

The contained dangerous materials are not freely available with foreseeable use.
Substances of Very High Concern - SVHC: substances are not contained or are below 0.1%.
For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures**4.1 Description of first aid measures****General information**

Measures apply only to the damaged product.
Change powdered clothing.

Inhalation

not applicable

Skin contact

When in contact with the skin, clean with soap and water.
Consult a doctor if skin irritation persists.

Eye contact

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Ingestion

Rinse out mouth and give plenty of water to drink.
Do not induce vomiting.
Get medical advice.

4.2 Most important symptoms and effects, both acute and delayed

No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Forward this sheet to your doctor.

SECTION 5: Fire-fighting measures**5.1 Extinguishing media****Suitable extinguishing media**

Product itself is non-combustible. Fire extinguishing method of surrounding areas must be considered.

Extinguishing media that must not be used

Full water jet.

5.2 Special hazards arising from the substance or mixture

Risk of formation of toxic pyrolysis products.

5.3 Advice for firefighters

Use self-contained breathing apparatus.

Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

No special measures necessary.

6.2 Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

6.3 Methods and material for containment and cleaning up

Take up mechanically. Avoid production of dust.
Dispose of absorbed material in accordance within the regulations.

6.4 Reference to other sections

See SECTION 8+13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

When sanding, minimize dust generation and accumulation. Wear the appropriate respiratory protection against dust.

Do not eat, drink or smoke when using this product.
Wash hands before breaks and after work.

7.2 Conditions for safe storage, including any incompatibilities

Keep only in original container.
Do not store together with food and animal food/diet.
Do not store together with acids and alkalies.
Keep container tightly closed.

7.3 Specific end use(s)

See product use, SECTION 1.2

SECTION 8: Exposure controls / personal protection

8.1 Control parameters

Ingredients with occupational exposure limits to be monitored (GB)

Substance
Cobalt
CAS: 7440-48-4, EINECS/ELINCS: 231-158-0, EU-INDEX: 027-001-00-9
Long-term exposure: 0,1 mg/m ³ , as Co, Sen, Carc
Nickel
CAS: 7440-02-0, EINECS/ELINCS: 231-111-4, EU-INDEX: 028-002-00-7
Long-term exposure: 0,5 mg/m ³ , Sk, Carc

8.2 Exposure controls

Additional advice on system design	Ensure adequate ventilation on workstation.
Eye protection	For mechanical processing: safety glasses
Hand protection	In full contact: 0.4 mm; Nitrile rubber, >480 min (EN 374-1/-2/-3). The details concerned are recommendations. Please contact the glove supplier for further information.
Skin protection	light protective clothing
Other	Avoid contact with eyes and skin.
Respiratory protection	Not required under normal conditions.
Thermal hazards	No information available.
Delimitation and monitoring of the environmental exposition	Protect the environment by applying appropriate control measures to prevent or limit emissions.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid
Color	silver-grey
Odor	odourless
Odour threshold	not determined
pH-value	not determined
pH-value [1%]	not determined
Boiling point [°C]	2260
Flash point [°C]	not determined
Flammability (solid, gas) [°C]	not determined
Lower explosion limit	not determined
Upper explosion limit	not determined
Oxidising properties	no
Vapour pressure/gas pressure [kPa]	not determined
Density [g/cm³]	7.3 (15 °C / 59,0 °F)
Relative density	not determined
Bulk density [kg/m³]	not applicable
Solubility in water	insoluble
Solubility other solvents	No information available.
Partition coefficient [n-octanol/water]	not applicable
Kinematic viscosity	not determined
Relative vapour density	not determined
Evaporation speed	not determined
Melting point [°C]	232
Auto-ignition temperature	not determined
Decomposition temperature [°C]	not determined
Particle characteristics	not applicable

9.2 Other information

none

SECTION 10: Stability and reactivity

10.1 Reactivity

See SECTION 10.3.

10.2 Chemical stability

Stable under normal ambient conditions (ambient temperature).

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

No information available.

10.5 Incompatible materials

Acids
Alkalies

10.6 Hazardous decomposition products

No hazardous decomposition products known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity

Product
oral, Based on the available information, the classification criteria are not fulfilled.
Substance
Nickel, CAS: 7440-02-0
LD50, oral, Rat, > 9000 mg/kg (IUCLID)

Acute dermal toxicity

Product
dermal, Based on the available information, the classification criteria are not fulfilled.

Acute inhalational toxicity

Product
inhalative, Based on the available information, the classification criteria are not fulfilled.

Serious eye damage/irritation Based on the available information, the classification criteria are not fulfilled.

Skin corrosion/irritation Based on the available information, the classification criteria are not fulfilled.

Respiratory or skin sensitisation May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Calculation method

Specific target organ toxicity — single exposure Based on the available information, the classification criteria are not fulfilled.

Specific target organ toxicity — repeated exposure Based on the available information, the classification criteria are not fulfilled.

Mutagenicity May cause genetic defects.
Calculation method

Reproduction toxicity May damage fertility.
Calculation method

Carcinogenicity May cause cancer.
Calculation method

Aspiration hazard Based on the available information, the classification criteria are not fulfilled.

General remarks

The contained dangerous materials are not freely available with foreseeable use.

11.2 Information on other hazards

Endocrine disrupting properties Contains no ingredients with endocrine-disrupting properties.

Other information none

SECTION 12: Ecological information

12.1 Toxicity

Substance
Nickel, CAS: 7440-02-0
LC50, (96h), Brachidanio rerio, > 100 mg/l (OECD 203)
EC50, (48h), Pseudomonas fluorescens, 250 mg/l (Lit.)
EC50, (48h), Daphnia magna, > 100 mg/l (OECD 202)
IC50, (72h), Selenastrum capricornutum, 100 mg/l (OECD 201)

12.2 Persistence and degradability

Behaviour in environment compartments	No information available.
Behaviour in sewage plant	No information available.
Biological degradability	No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

Based on all available information not to be classified as PBT or vPvB respectively.

12.6 Endocrine disrupting properties

Contains no ingredients with endocrine-disrupting properties.

12.7 Other adverse effects

Do not discharge product unmonitored into the environment.
Ecological data of complete product are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. It is not possible to determine a waste code for this product in accordance with the European Waste Catalogue (EWC) since it is only possible to classify it according to how it is used by the customer. The waste code is to be determined within the EU in liaison with the waste-disposal operator.

Product

Coordinate disposal with the authorities if necessary.

Waste no. (recommended)

060499

Contaminated packaging

Packaging that cannot be cleaned should be disposed of as for product.

Waste no. (recommended)

150102

SECTION 14: Transport information

14.1 UN number or ID number

Transport by land according to ADR/RID not applicable

Inland navigation (ADN) not applicable

Marine transport in accordance with IMDG not applicable

Air transport in accordance with IATA not applicable

14.2 UN proper shipping name

Transport by land according to ADR/RID NO DANGEROUS GOODS

Inland navigation (ADN) NO DANGEROUS GOODS

Marine transport in accordance with IMDG NOT CLASSIFIED AS "DANGEROUS GOODS"

Air transport in accordance with IATA NOT CLASSIFIED AS "DANGEROUS GOODS"

14.3 Transport hazard class(es)

Transport by land according to ADR/RID not applicable

Inland navigation (ADN) not applicable

Marine transport in accordance with IMDG not applicable

Air transport in accordance with IATA not applicable

14.4 Packing group

Transport by land according to ADR/RID not applicable

Inland navigation (ADN) not applicable

Marine transport in accordance with IMDG not applicable

Air transport in accordance with IATA not applicable

14.5 Environmental hazards

Transport by land according to ADR/RID no

Inland navigation (ADN) no

Marine transport in accordance with IMDG no

Air transport in accordance with IATA no

14.6 Special precautions for user

Relevant information under SECTION 6 to 8.

14.7 Maritime transport in bulk according to IMO instruments

not applicable

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SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EEC-REGULATIONS	2008/98/EC 2000/532/EC); 2010/75/EU; 2004/42/EC; (EC) 648/2004; (EC) 1907/2006 (REACH); (EU) 1272/2008; 75/324/EEC ((EC) 2016/2037); (EU) 2020/878; (EU) 2016/131; (EU) 517/2014
TRANSPORT-REGULATIONS	ADR (2021); IMDG-Code (2021, 40. Amdt.); IATA-DGR (2022)
NATIONAL REGULATIONS (GB):	EH40/2005 Workplace exposure limits (Second edition, published December 2011); UK REACH; GB CLP.
- Observe employment restrictions for people	no
- VOC (2010/75/CE)	not applicable

15.2 Chemical safety assessment

SECTION 16: Other information

16.1 Hazard statements (SECTION 3)

H372 Causes damage to organs through prolonged or repeated exposure.
H351 Suspected of causing cancer.
H413 May cause long lasting harmful effects to aquatic life.
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360F May damage fertility.
H341 Suspected of causing genetic defects.
H350 May cause cancer.

16.2 Abbreviations and acronyms:

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route
RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses
ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure
ATE = acute toxicity estimate
CAS = Chemical Abstracts Service
CLP = Classification, Labelling and Packaging
DMEL = Derived Minimum Effect Level
DNEL = Derived No Effect Level
EC50 = Median effective concentration
ECB = European Chemicals Bureau
EEC = European Economic Community
EINECS = European Inventory of Existing Commercial Chemical Substances
EL50 = Median effective loading
ELINCS = European List of Notified Chemical Substances
EmS = Emergency Schedules
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
IC50 = Inhibition concentration, 50%
IMDG = International Maritime Code for Dangerous Goods
IUCLID = International Uniform Chemical Information Database
IVIS = In vitro irritation score
LC50 = Lethal concentration, 50%
LD50 = Median lethal dose
LC0 = lethal concentration, 0%
LOAEL = lowest-observed-adverse-effect level
LL50 = Median lethal loading
LQ = Limited Quantities
MARPOL = International Convention for the Prevention of Marine Pollution from Ships
NOAEL = No Observed Adverse Effect Level
NOEC = No Observed Effect Concentration
PBT = Persistent, Bioaccumulative and Toxic substance
PNEC = Predicted No-Effect Concentration
REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals
STP = Sewage Treatment Plant
TLV@TWA = Threshold limit value – time-weighted average
TLV@STEL = Threshold limit value – short-time exposure limit
VOC = Volatile Organic Compounds
vPvB = very Persistent and very Bioaccumulative

16.3 Other information

Classification procedure

Carc. 1B: H350 May cause cancer. (Calculation method)
Repr. 1B: H360F May damage fertility. (Calculation method)
Skin Sens. 1: H317 May cause an allergic skin reaction. (Calculation method)
Resp. Sens. 1: H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. (Calculation method)
Muta. 2: H341 Suspected of causing genetic defects. (Calculation method)
Aquatic Chronic 4: H413 May cause long lasting harmful effects to aquatic life. (Calculation method)

Modified position

none



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