

# Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)  
(This safety data sheet is for information only as it does not  
comply with the official language requirements of Article 31 (5)  
of REACH nor does it provide the national information in sections  
8 and 15 as specified in Annex II of REACH.)

## Nickel Concentrate

Version number: 2.0  
Replaces version of: 2024-01-18 (1)

Revision: 2024-01-18  
First version: 2021-04-14

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

#### 1.1 Product identifier

Identification of the substance	frits, chemicals
Trade name	<u>Nickel Concentrate</u>
Product number	FLX-142
Registration number (REACH)	This information is not available.
EC number	266-047-6
CAS number	65997-18-4

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

Relevant identified uses	Laboratory and analytical use
Uses advised against	Do not use for private purposes (household)

#### 1.3 Details of the supplier of the safety data sheet

FLUXANA® GmbH & Co. KG Borschelstraße 3 D-47551 Bedburg-Hau Germany	Telephone: +49 (0) 2821 - 48011-10 Telefax: +49 (0) 2821 - 48011-99 e-mail: info@fluxana.de Website: www.fluxana.de
e-mail (competent person)	sdb@csb-compliance.com
Please do not use this e-mail address to ask for the latest safety data sheet. For this purpose contact FLUXANA® GmbH & Co. KG.	

#### 1.4 Emergency telephone number

As above or nearest toxicological information centre.

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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## Classification according to Regulation (EC) No 1272/2008 (CLP)

Classification				
Section	Hazard class	Category	Hazard class and category	Hazard statement
3.4S	skin sensitisation	1	Skin Sens. 1	H317
3.6	carcinogenicity	2	Carc. 2	H351
3.9	specific target organ toxicity - repeated exposure	1	STOT RE 1	H372
4.1C	hazardous to the aquatic environment - chronic hazard	3	Aquatic Chronic 3	H412

For full text of abbreviations: see SECTION 16

## The most important adverse physicochemical, human health and environmental effects

Delayed or immediate effects can be expected after short or long-term exposure.

Spillage and fire water can cause pollution of watercourses.

## 2.2 Label elements

### Labelling according to Regulation (EC) No 1272/2008 (CLP)

**Signal word** danger

### Pictograms

GHS07, GHS08



### Hazard statements

**H317** May cause an allergic skin reaction.

**H351** Suspected of causing cancer.

**H372** Causes damage to organs (respiratory system) through prolonged or repeated exposure (if inhaled).

**H412** Harmful to aquatic life with long lasting effects.

### Precautionary statements

**P201** Obtain special instructions before use.

**P260** Do not breathe dust.

**P280** Wear protective gloves/protective clothing/eye protection/face protection.

**P302+P352** IF ON SKIN: Wash with plenty of soap and water.

**P308+P313** IF exposed or concerned: Get medical advice/attention.

**P405** Store locked up.

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## 2.3 Other hazards

### Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

### Endocrine disrupting properties

Not listed.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

**Name of substance** frits, chemicals

#### Identifiers

CAS No 65997-18-4

EC No 266-047-6

Impurities and additives		
Name of substance	Identifier	Wt%
nickel	CAS No 7440-02-0  EC No 231-111-4	21.01
iron	CAS No 7439-89-6  EC No 231-096-4	7.469
manganese	CAS No 7439-96-5  EC No 231-105-1	0.979
copper	CAS No 7440-50-8  EC No 231-159-6	0.933
Zinc	CAS No 7440-66-6  EC No 231-175-3	0.108

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

#### General notes

Self-protection of the first aider.

Remove affected person from the danger area and lay down.

Do not leave affected person unattended.

Take off immediately all contaminated clothing.

In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following inhalation

Provide fresh air.

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions.

#### Following skin contact

Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.

#### Following eye contact

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Remove contact lenses, if present and easy to do. Continue rinsing.

#### Following ingestion

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

### 4.2 Most important symptoms and effects, both acute and delayed

This information is not available.

### 4.3 Indication of any immediate medical attention and special treatment needed

None.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

#### Suitable extinguishing media

water, foam, alcohol resistant foam, fire extinguishing powder

#### Unsuitable extinguishing media

water jet

### 5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products: Section 10.

## 5.3 Advice for firefighters

Non-combustible.

Keep containers cool with water spray.

In case of fire and/or explosion do not breathe fumes.

Co-ordinate firefighting measures to the fire surroundings.

Do not allow firefighting water to enter drains or water courses.

Collect contaminated firefighting water separately.

Fight fire with normal precautions from a reasonable distance.

### Special protective equipment for firefighters

Wear self-contained breathing apparatus

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Remove persons to safety.

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

#### For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

Retain contaminated washing water and dispose of it.

### 6.3 Methods and material for containment and cleaning up

#### Advice on how to contain a spill

Take up mechanically.

#### Advice on how to clean up a spill

Take up mechanically.

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

Ventilate affected area.

### 6.4 Reference to other sections

Personal protective equipment: see section 8.

Incompatible materials: see section 10.

Disposal considerations: see section 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Avoid contact with skin and eyes.

Do not breathe dust.

#### Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation.

Removal of dust deposits.

#### Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room.

#### Measures to protect the environment

Avoid release to the environment.

#### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

### 7.2 Conditions for safe storage, including any incompatibilities

#### Flammability hazards

None.

#### Incompatible substances or mixtures

Incompatible materials: see section 10.

#### Consideration of other advice

Keep away from food, drink and animal feeding stuffs.

#### Ventilation requirements

Provision of sufficient ventilation.

#### Specific designs for storage rooms or vessels

Keep container tightly closed and in a well-ventilated place.

Store in a dry place.

#### Packaging compatibilities

Keep only in original container.

### 7.3 Specific end use(s)

No information available.

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)									
Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Notation	Source
EU	manganese	7439-96-5	IOELV	-	0.2	-	-	i	2017/164/EU
EU	manganese	7439-96-5	IOELV	-	0.05	-	-	r	2017/164/EU

#### Notation

i inhalable fraction

r respirable fraction

STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

### Human health values

Relevant DNELs of components						
Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
nickel	7440-02-0	DNEL	0.05 mg/m³	human, inhalatory	worker (industry)	chronic - local effects
nickel	7440-02-0	DNEL	0.05 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
iron	7439-89-6	DNEL	3 mg/m³	human, inhalatory	worker (industry)	chronic - local effects
manganese	7439-96-5	DNEL	0.2 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
manganese	7439-96-5	DNEL	0.004 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
copper	7440-50-8	DNEL	137 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

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## Environmental values

Relevant PNECs of components				
Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
nickel	7440-02-0	PNEC	0.0086 mg/cm <sup>3</sup>	marine water
nickel	7440-02-0	PNEC	29.9 mg/cm <sup>3</sup>	soil
nickel	7440-02-0	PNEC	0.0036 mg/cm <sup>3</sup>	freshwater
nickel	7440-02-0	PNEC	0.33 mg/cm <sup>3</sup>	sewage treatment plant (STP)
nickel	7440-02-0	PNEC	7.1 µg/l	freshwater
nickel	7440-02-0	PNEC	8.6 µg/l	marine water
nickel	7440-02-0	PNEC	0.33 mg/l	sewage treatment plant (STP)
nickel	7440-02-0	PNEC	109 mg/kg	freshwater sediment
nickel	7440-02-0	PNEC	109 mg/kg	marine sediment
nickel	7440-02-0	PNEC	29.9 mg/kg	soil
manganese	7439-96-5	PNEC	0.034 mg/l	freshwater
manganese	7439-96-5	PNEC	0.003 mg/l	marine water
manganese	7439-96-5	PNEC	100 mg/l	sewage treatment plant (STP)
manganese	7439-96-5	PNEC	3.3 mg/kg	freshwater sediment
manganese	7439-96-5	PNEC	0.34 mg/kg	marine sediment
manganese	7439-96-5	PNEC	3.4 mg/kg	soil
copper	7440-50-8	PNEC	6.3 µg/l	freshwater
copper	7440-50-8	PNEC	5.2 µg/l	marine water
copper	7440-50-8	PNEC	230 µg/l	sewage treatment plant (STP)
copper	7440-50-8	PNEC	87 mg/kg	freshwater sediment
copper	7440-50-8	PNEC	676 mg/kg	marine sediment
copper	7440-50-8	PNEC	65 mg/kg	soil
Zinc	7440-66-6	PNEC	14.4 µg/l	freshwater
Zinc	7440-66-6	PNEC	7.2 µg/l	marine water



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Relevant PNECs of components				
Name of substance	CAS No	Endpoint	Threshold level	Environmental compartment
Zinc	7440-66-6	PNEC	100 µg/l	sewage treatment plant (STP)
Zinc	7440-66-6	PNEC	146.9 mg/kg	freshwater sediment
Zinc	7440-66-6	PNEC	162.2 mg/kg	marine sediment
Zinc	7440-66-6	PNEC	83.1 mg/kg	soil

## 8.2 Exposure controls

### Appropriate engineering controls

Use local and general ventilation.

### Individual protection measures (personal protective equipment)

#### Eye/face protection

Wear eye/face protection. (EN 166).

#### Hand protection

Protective gloves		
Material	Material thickness	Breakthrough times of the glove material
this information is not available	this information is not available	this information is not available

Wear suitable gloves.

Chemical protection gloves are suitable, which are tested according to EN 374.

Check leak-tightness/impermeability prior to use.

For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

#### Body protection

Protective clothing for use against solid particulates.

(EN 13832, EN 340, EN 14605).

#### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Particle filter device (DIN EN 143).

#### Environmental exposure controls

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

<b>Physical state</b>	solid (powder)
<b>Colour</b>	grey - brown
<b>Odour</b>	odourless
<b>Melting point/freezing point</b>	not determined
<b>Boiling point or initial boiling point and boiling range</b>	not determined
<b>Flammability</b>	non-combustible
<b>Lower and upper explosion limit</b>	not applicable (solid)
<b>Flash point</b>	not applicable
<b>Auto-ignition temperature</b>	not applicable (solid)
<b>Decomposition temperature</b>	not relevant
<b>pH (value)</b>	not applicable
<b>Viscosity</b>	not relevant (solid)
<b>Solubility(ies)</b>	
Water solubility	not miscible in any proportion
<b>Partition coefficient n-octanol/water (log value)</b>	not relevant (inorganic)
<b>Vapour pressure</b>	not determined
<b>Density and/or relative density</b>	
Density	not determined
Relative vapour density	not applicable
<b>Particle characteristics</b>	
Particle size	0 – 1.5 cm

### 9.2 Other information

<b>Information with regard to physical hazard classes</b>	hazard classes acc. to GHS (physical hazards): not relevant
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## Other safety characteristics

there is no additional information

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

See below "Conditions to avoid".

### 10.3 Possibility of hazardous reactions

No known hazardous reactions.

### 10.4 Conditions to avoid

Control of dust.

### 10.5 Incompatible materials

There is no additional information.

### 10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known.

## SECTION 11: Toxicological information

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

If not otherwise specified the classification is based on:

Animal studies; Evidence from any other toxicity tests; Expert judgement (weight of evidence determination).

#### Classification according to GHS (1272/2008/EC, CLP)

##### Acute toxicity

Acute toxicity of components							
Name of substance	CAS No	Exposure route	End-point	Value	Species	Method	Source
nickel	7440-02-0	oral	LD50	>9,000 mg/kg	rat	OECD Guideline 401	ECHA
iron	7439-89-6	oral	LD50	98,600 mg/kg	rat	OECD Guideline 401	ECHA

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Acute toxicity of components							
Name of substance	CAS No	Exposure route	End-point	Value	Species	Method	Source
manganese	7439-96-5	oral	LD0	>2,000 mg/kg	rat, female	OECD Guideline 420	ECHA
manganese	7439-96-5	inhalation: dust/mist	LC0	>5.14 mg/l/4h	rat	OECD Guideline 403	ECHA
copper	7440-50-8	inhalation: dust/mist	LC50	5.11 mg/l/4h	rat	OECD Guideline 436	ECHA
Zinc	7440-66-6	oral	LD50	>2,000 mg/kg	rat	OECD Guideline 401	ECHA
Zinc	7440-66-6	inhalation: dust/mist	LC50	>5.41 mg/l/4h	rat	OECD Guideline 403	ECHA

## Skin corrosion/irritation

Classification could not be established because:  
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Serious eye damage/eye irritation

Classification could not be established because:  
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Respiratory or skin sensitisation

### Skin sensitisation

May cause an allergic skin reaction.

## Respiratory sensitisation

Classification could not be established because:  
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Germ cell mutagenicity

Classification could not be established because:  
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Carcinogenicity

Suspected of causing cancer.

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## Reproductive toxicity

Classification could not be established because:  
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Specific target organ toxicity - single exposure

Classification could not be established because:  
Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Specific target organ toxicity - repeated exposure

Causes damage to organs (respiratory system) through prolonged or repeated exposure (if inhaled).

Hazard category	Target organ	Exposure route
1	respiratory system	if inhaled

## Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Not listed.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Aquatic toxicity (acute)

Based on available data, the classification criteria are not met.

#### Aquatic toxicity (acute) of components

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
nickel	7440-02-0	LC50	96 h	15.3 mg/l	rainbow trout (Oncorhynchus mykiss)	-	ECHA
nickel	7440-02-0	LC50	96 h	40 µg/l	Ceriodaphnia dubia (water flea)	-	-
nickel	7440-02-0	EC50	48 h	>0.081 – <0.148 mg/l	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA
nickel	7440-02-0	EC50	48 h	0.013 mg/l	daphnia	-	-
nickel	7440-02-0	ErC50	48 h	-	(top) predators	-	-

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Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
nickel	7440-02-0	ErC50	72 h	<148 µg/l	algae (pseudokirchneriella subcapitata)	OECD Guideline 201	ECHA
manganese	7439-96-5	LC50	96 h	>3.6 mg/l	rainbow trout (Oncorhynchus mykiss)	OECD Guideline 203	ECHA
manganese	7439-96-5	EC50	48 h	>1.6 mg/l	daphnia magna	OECD Guideline 202	ECHA
manganese	7439-96-5	EC50	72 h	2.8 mg/l	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
manganese	7439-96-5	ErC50	72 h	4.5 mg/l	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
copper	7440-50-8	LC50	96 h	193 µg/l	fathead minnow (pimephales promelas)	-	ECHA
Zinc	7440-66-6	LC50	96 h	439 µg/l	fish	-	ECHA
Zinc	7440-66-6	EC50	48 h	1,833 µg/l	daphnia magna	OECD Guideline 202	ECHA
Zinc	7440-66-6	ErC50	72 h	350 µg/l	algae	OECD Guideline 201	ECHA

## Aquatic toxicity (chronic)

Harmful to aquatic life with long lasting effects.

## Aquatic toxicity (chronic) of components

Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
nickel	7440-02-0	NOEC	7 d	15.3 µg/l	Ceriodaphnia dubia (water flea)	-	ECHA
nickel	7440-02-0	NOEC	28 d	40 µg/l	striped brill (Brachydanio rerio)	-	-

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Name of substance	CAS No	Endpoint	Exposure time	Value	Species	Method	Source
nickel	7440-02-0	NOEC	28 d	1.4 µg/l	daphnia	-	-
nickel	7440-02-0	NOEC	28 d	12.4 µg/l	algae	-	-
nickel	7440-02-0	LOEC	36 d	0.141 mg/l	saltwater invertebrates (Mysidopsis bahia)	-	ECHA
nickel	7440-02-0	growth rate (ErCx) 10%	40 d	3,599 µg/l	fish	-	ECHA
manganese	7439-96-5	EC50	21 d	19.5 mg/l	daphnia magna	-	ECHA
manganese	7439-96-5	NOEC	8 d	1.7 mg/l	Ceriodaphnia dubia (water flea)	OECD Guideline 211	ECHA
manganese	7439-96-5	NOEC	72 h	2.5 mg/l	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
manganese	7439-96-5	LOEC	72 h	5.3 mg/l	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
manganese	7439-96-5	growth (Eb-Cx) 20%	21 d	<1.1 mg/l	daphnia magna	-	ECHA
manganese	7439-96-5	growth (Eb-Cx) 10%	72 h	2.6 mg/l	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
manganese	7439-96-5	growth (Eb-Cx) 20%	72 h	2.6 mg/l	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
manganese	7439-96-5	growth rate (ErCx) 10%	72 h	3.4 mg/l	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
manganese	7439-96-5	growth rate (ErCx) 20%	72 h	3.7 mg/l	algae (Desmodesmus subspicatus)	OECD Guideline 201	ECHA
copper	7440-50-8	NOEC	45 d	11.4 µg/l	rainbow trout (Oncorhynchus mykiss)	-	ECHA
Zinc	7440-66-6	LC50	95 h	330 µg/l	fathead minnow (Pimephales promelas)	-	ECHA

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Name of sub-stance	CAS No	Endpoint	Expos-ure time	Value	Species	Method	Source
Zinc	7440-66-6	EC50	21 d	117 µg/l	daphnia magna	OECD Guideline 211	ECHA
Zinc	7440-66-6	NOEC	116 d	250 µg/l	fish	OECD Guideline 210	ECHA
Zinc	7440-66-6	NOEC	7 d	100 µg/l	Ceriodaphnia dubia (water flea)	-	ECHA

## 12.2 Persistence and degradability

### Biodegradation

The study does not need to be conducted because the substance is inorganic.

### Persistence

The study does not need to be conducted because the substance is inorganic.

## 12.3 Bioaccumulative potential

### n-octanol/water (log KOW)

not relevant  
(inorganic)

### Bioaccumulative potential of components

Name of substance	CAS No	BCF	Log KOW
nickel	7440-02-0	270	-
manganese	7439-96-5	19	-
Zinc	7440-66-6	69.48	-

## 12.4 Mobility in soil

No data available.

## 12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

## 12.6 Endocrine disrupting properties

Not listed.

## 12.7 Other adverse effects

Data are not available.

### Remarks

Wassergefährdungsklasse, WGK (water hazard class): Nwg.



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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

Completely emptied packages can be recycled.

Handle contaminated packages in the same way as the substance itself.

#### Remarks

Please consider the relevant national or regional provisions.

## SECTION 14: Transport information

14.1	UN number or ID number	not assigned
14.2	UN proper shipping name	-
14.3	Transport hazard class(es)	-
14.4	Packing group	-
14.5	Environmental hazards	-
14.6	Special precautions for user	-
14.7	Maritime transport in bulk according to IMO instruments	-

## SECTION 15: Regulatory information

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

#### Relevant provisions of the European Union (EU)

#### Restrictions according to REACH, Annex XVII

Name	Name acc. to inventory	CAS No	Restriction
nickel	nickel	7440-02-0	R27
nickel	substances in tattoo inks and permanent make-up	-	R75

#### Legend

- R27 1. Shall not be used:
- (a) in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0,2 µg/cm<sup>2</sup>/week (migration limit);
  - (b) in articles intended to come into direct and prolonged contact with the skin such as:
    - earrings,

## Legend

- necklaces, bracelets and chains, anklets, finger rings,
  - wrist-watch cases, watch straps and tighteners,
  - rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments,
- if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 µg/cm<sup>2</sup>/week.
- (c) in articles referred to in point (b) where these have a non-nickel coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0,5 µg/cm<sup>2</sup>/week for a period of at least two years of normal use of the article.
2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements set out in that paragraph.
  3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2.

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## Legend

- R75
1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
    - (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
    - (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
    - (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
    - (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
      - (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
      - (ii) 0,01 % by weight, in all other cases;
    - (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
    - (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
      - (i) "Rinse-off products";
      - (ii) "Not to be used in products applied on mucous membranes";
      - (iii) "Not to be used in eye products";
    - (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
    - (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
  2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
  3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
  4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
    - (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
    - (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
  5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
  6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
  7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

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## Legend

- (a) the statement "Mixture for use in tattoos or permanent make-up";
- (b) a reference number to uniquely identify the batch;
- (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
- (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
- (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
- (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
- (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

## List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

Not listed.

## Seveso Directive

Not assigned.

## Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

Not listed.

## Regulation on the marketing and use of explosives precursors

Not listed.

## Regulation on drug precursors

Not listed.

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## Regulation on substances that deplete the ozone layer (ODS)

Not listed.

## Regulation concerning the export and import of hazardous chemicals (PIC)

Not listed.

## Regulation on persistent organic pollutants (POP)

Not listed.

## 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance by the supplier.

## SECTION 16: Other information

### Indication of changes (revised safety data sheet)

Indication of changes: Section 2, 3, 8, 14, 15

### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2017/164/EU	Commission Directive establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 91/322/EEC, 2000/39/EC and 2009/161/EU
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control

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Abbr.	Descriptions of used abbreviations
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
IMDG	International Maritime Dangerous Goods Code
IOELV	Indicative occupational exposure limit value
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LOEC	Lowest Observed Effect Concentration
log KOW	n-Octanol/water
NLP	No-Longer Polymer
NOEC	No Observed Effect Concentration
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
vPvB	Very Persistent and very Bioaccumulative

## Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.  
Regulation (EC) No. 1907/2006 (REACH).

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN).

International Maritime Dangerous Goods Code (IMDG).

Dangerous Goods Regulations (DGR) for the air transport (IATA).

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## List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
H372	Causes damage to organs (respiratory system) through prolonged or repeated exposure (if inhaled).
H412	Harmful to aquatic life with long lasting effects.

## Responsible for the safety data sheet

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## Disclaimer

This information is based upon the present state of our knowledge.  
This SDS has been compiled and is solely intended for this product.