

Safety Data Sheet Impression Compound (Green/Grey/Red)

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : Impression Compound (Green/Grey/Red)

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

Relevant identified uses

Use of the substance/mixture : Preparation intended for dental medical use

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

SpofaDental a.s.
Markova 238
CZ-506 01 Jicin Czech Republic
T +420 493 583 204

Manufacturer

SpofaDental a.s.
Markova 238
CZ-506 01 Jicin Czech Republic
T +420 493 583 204

Contact person : safety@kerrhawe.com - tel. 00-800-41-050-505 (08.00-17.00)

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number
Gibraltar	GHA Call Centre Zone 2, Level3, St Bernard's Hospital	Harbour Views Road	+350 200 79700 +350 200 72266
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals- 24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504
United Kingdom	National Poisons Information Service (Newcastle Unit)	Claremont Place Newcastle-upon-Tyne, Newcastle	+44 191 2606182/+44 191 2606180 24H

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Eye Irrit. 2 H319

Skin Sens. 1 H317

Full text of hazard classes and H-statements : see section 16

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazardous ingredients :

rosin; colophony

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation

Precautionary statements (CLP)	: P261 - Avoid breathing dust, vapours P280 - Wear protective gloves, eye protection P333+P313 - If skin irritation or rash occurs: Get medical advice/attention P337+P313 - If eye irritation persists: Get medical advice/attention P362+P364 - Take off contaminated clothing and wash it before reuse
Extra phrases	: The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d). A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
talcc	(CAS-No.) 14807-96-6;14807-96-6 (EC-No.) 238-877-9;204-471-5 (REACH-no) N/A	20 - 60	Not classified
Copals	(CAS-No.) 9000-14-0 (EC-No.) 232-527-9	5 - 20	Eye Irrit. 2, H319 STOT SE 3, H335
rosin; colophony	(CAS-No.) 8050-09-7 (EC-No.) 232-475-7 (EC Index-No.) 650-015-00-7 (REACH-no) 01-2119480418-32	1 - 10	Skin Sens. 1, H317

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Assure fresh air breathing. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after 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.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Causes serious eye irritation.

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

Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: Non flammable.
Hazardous decomposition products in case of fire	: Carbon oxides (CO, CO ₂). metallic oxide.

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
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Protection during firefighting : Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Do not breathe vapour.

For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.

For emergency responders

Protective equipment : Equip cleanup crew with proper protection.

Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep or shovel into suitable containers. Store away from other materials. Minimize generation of dust.

6.4. Reference to other sections

For further information refer to section 13. See Heading 8. Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing vapours.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Store in a dry place. Store in a well-ventilated place.

Incompatible materials : Keep away from heat and direct sunlight. Sources of ignition. Direct sunlight.

Storage temperature : 18 - 25 °C

7.3. Specific end use(s)

No additional data.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

talc (14807-96-6;14807-96-6)		
Ireland	Local name	Talc
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³ total inhalable dust 0.8 mg/m ³ respirable dust
United Kingdom	Local name	Talc
United Kingdom	WEL TWA (mg/m ³)	1 mg/m ³ respirable dust
rosin; colophony (8050-09-7)		
United Kingdom	Local name	Rosin-based solder flux fume
United Kingdom	WEL TWA (mg/m ³)	0.05 mg/m ³
United Kingdom	WEL STEL (mg/m ³)	0.15 mg/m ³
United Kingdom	Remark (WEL)	Sen (Capable of causing occupational asthma. See paragraphs 53–56)

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal protective equipment : Avoid all unnecessary exposure. Gloves. Safety glasses.

Hand protection	: Wear protective gloves. Butylrubber protective gloves. Layer thickness : 0,1 mm. Breakthrough time : 8 (> 480 minutes). EN 374
Eye protection	: Chemical goggles or safety glasses. EN 166
Respiratory protection	: Not required



Other information	: Do not eat, drink or smoke during use. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment.
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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Wax.
Colour	: Various.
Odour	: Paraffine.
Odour threshold	: Not determined
pH	: Not determined
Relative evaporation rate (butylacetate=1)	: Not determined
Melting point	: 42 °C
Freezing point	: Not determined
Boiling point	: Not determined
Flash point	: Not determined
Auto-ignition temperature	: Not determined
Decomposition temperature	: Not determined
Flammability (solid, gas)	: Non flammable
Vapour pressure	: Not determined
Relative vapour density at 20 °C	: Not determined
Relative density	: > 1
Solubility	: insoluble in water.
Log Pow	: Not determined
Viscosity, kinematic	: Not determined
Viscosity, dynamic	: Not determined
Explosive properties	: Not explosive.
Oxidising properties	: Non flammable.
Explosive limits	: Not determined

9.2. Other information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

None to our knowledge.

10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None to our knowledge.

10.5. Incompatible materials

No information.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on toxicological effects**

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met pH: Not determined
Serious eye damage/irritation	: Causes serious eye irritation. pH: Not determined
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified Based on available data, the classification criteria are not met
STOT-single exposure	: Not classified Based on available data, the classification criteria are not met
STOT-repeated exposure	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION**12.1. Toxicity**

talc (14807-96-6;14807-96-6)	
LC50 fish 1	> 100 mg/l (24 hours - Brachydanio rerio, zebra-fish)
rosin; colophony (8050-09-7)	
LC50 fish 1	10000 mg/l (96 hours - Brachydanio rerio, zebra-fish)
EC50 Daphnia 1	4.5 mg/l (48 hours - Daphnia magna)

12.2. Persistence and degradability

Impression Compound (Green/Grey/Red)	
Persistence and degradability	Not established.
rosin; colophony (8050-09-7)	
Persistence and degradability	Not readily biodegradable.
Biodegradation	70 - 80 % (OECD 301C method)

12.3. Bioaccumulative potential

Impression Compound (Green/Grey/Red)	
Log Pow	Not determined
Bioaccumulative potential	Not established.

12.4. Mobility in soil

Impression Compound (Green/Grey/Red)	
Ecology - soil	insoluble in water.

12.5. Results of PBT and vPvB assessment

Impression Compound (Green/Grey/Red)	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	

12.6. Other adverse effects

Other adverse effects	: None to our knowledge.
Additional information	: Avoid release to the environment

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

- Regional legislation (waste) : Dispose of contents/container in accordance with licensed collector's sorting instructions.
- Waste treatment methods : Do not discharge into drains.
- Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to a hazardous or special waste collection point.
- Ecology - waste materials : Avoid release to the environment.
- European List of Waste (LoW) code : 18 01 06* - chemicals consisting of or containing dangerous substances

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number	Not regulated for transport
14.2. UN proper shipping name	
14.3. Transport hazard class(es)	
14.4. Packing group	
14.5. Environmental hazards	
No supplementary information available	

14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

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

EU-Regulations

- Contains no REACH substances with Annex XVII restrictions
- Contains no substance on the REACH candidate list
- Contains no REACH Annex XIV substances

National regulations

EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

- Data sources : EC-regulation 2015/830 /EC, 1907/2006/EC (REACH), 1272/2008/EC (CLP), 790/2009/EC. Transport of dangerous goods (ADR/RID, IMDG, IATA/ICAO). Workplace exposure limits.
- Other information : None.
- Date of issue : 30/08/2016
- Revision date : 30/04/2017
- Supersedes : 30/08/2016
- Date of total revision : 30/04/2017
- Version : 2.0
- Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation

H335

May cause respiratory irritation

The information in this safety data sheet is based on information from the manufacturer/supplier, present european and national legislation, and presupposes that the product is used within the specified area of application.