

Safety Data Sheet GUTTA PERCHA

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

1.1. Product identifier

Product name : GUTTA PERCHA

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

Relevant identified uses

Main use category : Professional use

Function or use category : Dental materials

Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Kerr Italia S.r.l.
Via Passanti, 332
84018 Scafati (SA) - Italy
T +39-081-850-8311
E-mail: safety@kerrhawe.com

Manufacturer

ORMCO B.V./SybronEndo
Basicweg, 20
NL 3821 BR AMERSFOORT - NETHERLAND
T 00-800-3032-3032

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

1.4. Emergency telephone number

Emergency number : CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

| Country | Organisation/Company | Address | Emergency number |
|----------------|-------------------------------------------------------|---------------------------------------------------|-------------------------------------|
| 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]

Aquatic Acute 1 H400

Aquatic Chronic 1 H410

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) :



GHS09

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H410 - Very toxic to aquatic life with long lasting effects

Precautionary statements (CLP) :

P273 - Avoid release to the environment
P391 - Collect spillage
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

EUH-statements :

EUH208 - Contains Tartrazine. May produce an allergic reaction

Extra phrases :

The product is seen as a medical device and therefore not subject to labelling (EU-

regulation 1907/2006, article 2, paragraph 6c)

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

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. Substance**

Not applicable

3.2. Mixture

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|----------|-----------------------------------------------------------------|
| zinc oxide | (CAS No) 1314-13-2 (EC no) 215-222-5 (EC index no) 030-013-00-7 (REACH-no) 01-2119463881-32 | =>60-<70 | Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |
| trans-Polyisoprene | (CAS No) 9003-31-0 (EC no) 618-362-9 (REACH-no) N/A | =>15-<25 | Not classified |
| barium sulphate | (CAS No) 7727-43-7 (EC no) 231-784-4 (REACH-no) 01-2119491274-35 | =>8-<18 | Not classified |
| calcium carbonate | (CAS No) 471-34-1 (EC no) 207-439-9 (REACH-no) 01-2119486795-18 | =>1-<10 | Not classified |
| Beeswax | (CAS No) 8012-89-3 (EC no) 232-383-7 (REACH-no) N/A | =>1-<10 | Not classified |
| 2,6-Di-tert-butyl-4-methylphenol | (CAS No) 128-37-0 (EC no) 204-881-4 (REACH-no) 01-2119480433-40 | < 1 | Aquatic Acute 1, H400 Aquatic Chronic 1, H410 |
| Tartrazine | (CAS No) 1934-21-0 (EC no) 217-699-5 (REACH-no) N/A | < 1 | Skin Sens. 1, H317 Resp. Sens. 1, H334 |
| Barium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate | (CAS No) 17852-98-1 (EC no) 241-806-4 (REACH-no) N/A | < 1 | Not classified |

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES**4.1. Description of first aid measures**

- First-aid measures general : No particular/specific measures required.
- First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical advice/attention if you feel unwell.
- First-aid measures after skin contact : Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.
- First-aid measures after eye contact : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.
- First-aid measures after ingestion : If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER or doctor/physician if you feel unwell.

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

Symptoms/injuries : Not expected to present a significant hazard under anticipated conditions of normal use.

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

No specific measures identified.

SECTION 5: FIREFIGHTING MEASURES**5.1. Extinguishing media**

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Foam, carbon dioxide (CO₂) and powder.
- 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 : zinc oxide.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.
- 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 : Avoid contact with skin and eyes.

For non-emergency personnel

Protective equipment : See Heading 8.

For emergency responders

No additional information available

6.2. Environmental precautions

Discharging into rivers and drains is forbidden.

6.3. Methods and material for containment and cleaning up

For containment : Collect all waste in suitable and labelled containers and dispose according to local legislation.

Methods for cleaning up : Recover mechanically the product. Wash off with plenty of water.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling : Do not eat, drink or smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry place. Store in a closed container. Store in original container.

Storage area : Store in a well-ventilated place.

7.3. Specific end use(s)

Consult the supplier for further information.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

| inert or nuisance dust, inhalable | | |
|-----------------------------------|-------------------------------|----------------------------------------------------------------------------|
| United Kingdom | WEL STEL (mg/m ³) | 10 mg/m ³ |
| barium sulphate (7727-43-7) | | |
| United Kingdom | Local name | Barium sulphate |
| United Kingdom | WEL TWA (mg/m ³) | 10 mg/m ³ inhalable dust 4 mg/m ³ respirable dust |

8.2. Exposure controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Personal protective equipment : Gloves.

Hand protection : Wear suitable gloves. Chemical resistant PVC gloves (to European standard EN 374 or equivalent). Layer thickness : 0,09mm. Breakthrough time : >480 min

Eye protection : In case of dust production: protective goggles. STANDARD EN 166

Skin and body protection : Wear suitable protective clothing

Respiratory protection : Respiratory protection not applicable. Dust production: dust mask with filter type P2. Standard EN 149



Other information : Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

| | |
|--------------------------------------------|--------------------------------|
| Physical state | : Solid |
| Appearance | : Little spheres. |
| Colour | : pink. |
| Odour | : slight. aromatic. |
| Odour threshold | : No data available |
| pH | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : ≈ 68 °C |
| Freezing point | : No data available |
| Boiling point | : The substance decomposes |
| Flash point | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : > 220 °C |
| Flammability (solid, gas) | : No data available |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Solubility | : Material insoluble in water. |
| Log Pow | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : Product is not explosive. |
| Oxidising properties | : Non flammable. |
| Explosive limits | : No data available |

9.2. Other information

Additional information : None to our knowledge

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No polymerization.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

No decomposition if stored normally.

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

Acute toxicity : Not classified

| | |
|-------------------------------------|---------------|
| zinc oxide (1314-13-2) | |
| LD50 oral rat | > 5000 mg/kg |
| LD50 dermal rat | > 2000 mg/kg |
| LC50 inhalation rat (mg/l) | 0.4 mg/l/4h |
| barium sulphate (7727-43-7) | |
| LD50 oral rat | > 20000 mg/kg |
| calcium carbonate (471-34-1) | |
| LD50 oral rat | 6450 mg/kg |
| LD50 dermal rabbit | 500 mg/kg |

| Beeswax (8012-89-3) | |
|-----------------------------------------------------|------------------------------------------------------------------------------------|
| LD50 oral rat | > 5000 mg/kg bodyweight |
| 2,6-Di-tert-butyl-4-methylphenol (128-37-0) | |
| LD50 oral rat | 890 mg/kg bodyweight |
| LD50 dermal rat | 2400 mg/kg bodyweight |
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| Specific target organ toxicity (single exposure) | : Not classified |
| Specific target organ toxicity (repeated exposure) | : Not classified |
| Aspiration hazard | : Not classified |
| Potential adverse human health effects and symptoms | : Under normal conditions of use, no adverse effects to health have been observed. |

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - water : Very toxic to aquatic life with long lasting effects.

| zinc oxide (1314-13-2) | |
|----------------------------------------------------|------------------------------------------------------|
| LC50 fish 1 | 1.1 mg/l (96 hours - Rainbow trout) |
| EC50 Daphnia 1 | 24.6 mg/l (48 hours - Daphnia magna) |
| barium sulphate (7727-43-7) | |
| LC50 fish 1 | > 7600 mg/l (96 hours) |
| EC50 Daphnia 1 | > 32 mg/l (48 hours - Daphnia magna) |
| calcium carbonate (471-34-1) | |
| LC50 fish 1 | > 5600 (96 hours - Gambusia affinis - Mosquito fish) |
| 2,6-Di-tert-butyl-4-methylphenol (128-37-0) | |
| EC50 Daphnia 1 | 0.2 mg/l Daphnia magna, 48 hours |
| IC50 algae | 6 mg/l (IC50, 72 hours - Selenastrum capricornutum) |

12.2. Persistence and degradability

| GUTTA PERCHA | |
|----------------------------------------------------|---------------------------------------------------------|
| Persistence and degradability | No data available. |
| calcium carbonate (471-34-1) | |
| Persistence and degradability | There are no data on the degradability of this product. |
| 2,6-Di-tert-butyl-4-methylphenol (128-37-0) | |
| Biodegradation | 10 % (OECD 301D method) |

12.3. Bioaccumulative potential

| GUTTA PERCHA | |
|----------------------------------------------------|------------------------------------|
| Bioaccumulative potential | No data. |
| zinc oxide (1314-13-2) | |
| Log Pow | < 0 |
| trans-Polyisoprene (9003-31-0) | |
| Bioconcentration factor (BCF REACH) | 25.12 |
| Log Pow | 2.72 |
| calcium carbonate (471-34-1) | |
| Bioaccumulative potential | No bioaccumulation data available. |
| 2,6-Di-tert-butyl-4-methylphenol (128-37-0) | |
| Bioconcentration factor (BCF REACH) | 25 |
| Log Pow | 5.1 |

12.4. Mobility in soil

| GUTTA PERCHA | |
|-------------------------------------|---------------------------------------------------------------|
| Ecology - soil | Material insoluble in water. |
| calcium carbonate (471-34-1) | |
| Ecology - soil | The product is water soluble and may spread in water systems. |

12.5. Results of PBT and vPvB assessment**GUTTA PERCHA**

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

Component

calcium carbonate (471-34-1)

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 : No other effects known

SECTION 13: DISPOSAL CONSIDERATIONS**13.1. Waste treatment methods**

Regional legislation (waste) : Dispose as hazardous waste.

Waste treatment methods : Recover the product with absorbent material. Dispose of contents/container in accordance with licensed collector's sorting instructions.

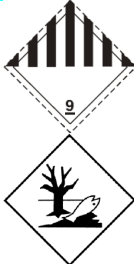

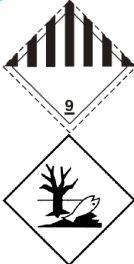
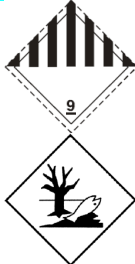
Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

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

| ADR | IMDG | IATA | RID |
|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|
| 14.1. UN number | | | |
| 3077 | 3077 | 3077 | 3077 |
| 14.2. UN proper shipping name | | | |
| ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. | Environmentally hazardous substance, solid, n.o.s. | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. |
| Transport document description | | | |
| UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide(1314-13-2)), 9, III, (E) | UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS | | |
| 14.3. Transport hazard class(es) | | | |
| 9 | 9 | 9 | 9 |
|  |  |  |  |
| 14.4. Packing group | | | |
| III | III | III | III |
| 14.5. Environmental hazards | | | |
| Dangerous for the environment : Yes | Dangerous for the environment : Yes Marine pollutant : Yes | Dangerous for the environment : Yes | Dangerous for the environment : Yes |
| No supplementary information available | | | |


14.6. Special precautions for user**- Overland transport**

Classification code (ADR) : M7

Special provisions (ADR) : 274, 335, 601, 375

Limited quantities (ADR) : 5kg

Excepted quantities (ADR) : E1

| | | |
|-------------------------------------------------------------------------|---|-----------------------------------------------------------------------------------|
| Packing instructions (ADR) | : | P002, IBC08, LP02, R001 |
| Special packing provisions (ADR) | : | PP12, B3 |
| Mixed packing provisions (ADR) | : | MP10 |
| Portable tank and bulk container instructions (ADR) | : | T1, BK1, BK2 |
| Portable tank and bulk container special provisions (ADR) | : | TP33 |
| Tank code (ADR) | : | SGAV, LGBV |
| Vehicle for tank carriage | : | AT |
| Transport category (ADR) | : | 3 |
| Special provisions for carriage - Packages (ADR) | : | V13 |
| Special provisions for carriage - Bulk (ADR) | : | VC1, VC2 |
| Special provisions for carriage - Loading, unloading and handling (ADR) | : | CV13 |
| Hazard identification number (Kemler No.) | : | 90 |
| Orange plates | : |  |
| Tunnel restriction code (ADR) | : | E |
| EAC code | : | 2Z |

- Transport by sea

| | | |
|-----------------------------------|---|-------------------------|
| Special provisions (IMDG) | : | 274, 335, 966, 967, 969 |
| Limited quantities (IMDG) | : | 5 kg |
| Excepted quantities (IMDG) | : | E1 |
| Packing instructions (IMDG) | : | P002, LP02 |
| Special packing provisions (IMDG) | : | PP12 |
| IBC packing instructions (IMDG) | : | IBC08 |
| IBC special provisions (IMDG) | : | B3 |
| Tank instructions (IMDG) | : | T1, BK1, BK2, BK3 |
| Tank special provisions (IMDG) | : | TP33 |
| EmS-No. (Fire) | : | F-A |
| EmS-No. (Spillage) | : | S-F |
| Stowage category (IMDG) | : | A |

- Air transport

| | | |
|----------------------------------------------|---|-----------------------|
| PCA Excepted quantities (IATA) | : | E1 |
| PCA Limited quantities (IATA) | : | Y956 |
| PCA limited quantity max net quantity (IATA) | : | 30kgG |
| PCA packing instructions (IATA) | : | 956 |
| PCA max net quantity (IATA) | : | 400kg |
| CAO packing instructions (IATA) | : | 956 |
| CAO max net quantity (IATA) | : | 400kg |
| Special provisions (IATA) | : | A97, A158, A179, A197 |
| ERG code (IATA) | : | 9L |

Rail transport

No data available

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 453/2010/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 for the substance or the mixture by the supplier

SECTION 16: OTHER INFORMATION

Date of issue : 03/12/2015
 Revision date : 03/12/2015
 :
 Version : 1.0
 Signature : A. Åsebø Murel

Full text of H- and EUH-statements:

| | |
|-------------------|---------------------------------------------------------------------------|
| Aquatic Acute 1 | Hazardous to the aquatic environment — Acute Hazard, Category 1 |
| Aquatic Chronic 1 | Hazardous to the aquatic environment — Chronic Hazard, Category 1 |
| Resp. Sens. 1 | Sensitisation — Respiratory, Category 1 |
| Skin Sens. 1 | Sensitisation — Skin, Category 1 |
| H317 | May cause an allergic skin reaction |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled |
| H400 | Very toxic to aquatic life |
| H410 | Very toxic to aquatic life with long lasting effects |
| EUH208 | Contains . May produce an allergic reaction |

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.