

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

1.1. Product identifier

Product form : Mixture
Trade name : Biodent EC40

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

1.2.1. Relevant identified uses

Intended for general public

Main use category : Professional use, Consumer use
Use of the substance/mixture : Agent for combating bacterial dental plaque.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Biodent B.V.
Graaf Lodewijkstraat 118
6821 EH Arnhem - Nederland
info@biodent.nl - www.biodent.nl

1.4. Emergency telephone number

Emergency number : +31 620143120

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 2 H225
Hazardous to the aquatic environment — H411
Chronic Hazard, Category 2

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Flammable liquid and vapour. Toxic to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS02

GHS09

Signal word (CLP) : Danger
Hazard statements (CLP) : H225 - Highly flammable liquid and vapour.
H411 - Toxic to aquatic life with long lasting effects.
Precautionary statements (CLP) : P102 - Keep out of reach of children.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed.
P273 - Avoid release to the environment.
P391 - Collect spillage.
P501 - Dispose of contents to an approved waste disposal plant.
Child-resistant fastening : Not applicable
Tactile warning : Applicable

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

Biodent EC40

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name | Product identifier | Conc. (% w/w) | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|--|---|---------------|---|
| ethanol, ethyl alcohol substance with national workplace exposure limit(s) (NL) | (CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5 (REACH-no) 01-2119457610-43 | 30 - 50 | Flam. Liq. 2, H225 |
| Chlorhexidine diacetate | (CAS-No.) 56-95-1 (EC-No.) 200-302-4 | 10 - 20 | Acute Tox. 4 (Oral), H302 Aquatic Chronic 1, H410 |

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Rinse skin with water/shower. Take off immediately all contaminated clothing.
First-aid measures after eye contact : Rinse eyes with water as a precaution.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Highly flammable liquid and vapour.
Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Collect spillage.
Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". Concerning disposal elimination after cleaning, see section 13.

Biodent EC40

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Ground/bond container and receiving equipment.
- Storage conditions : Store in a well-ventilated place. Keep cool. Keep container tightly closed.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

| ethanol, ethyl alcohol (64-17-5) | | |
|----------------------------------|--|--|
| Netherlands | Local name | Ethanol |
| Netherlands | Grenswaarde TGG 8H (mg/m ³) | 260 mg/m ³ |
| Netherlands | Grenswaarde TGG 15MIN (mg/m ³) | 1900 mg/m ³ |
| Netherlands | Remark (MAC) | H (Huidopname) Stoffen die relatief gemakkelijk door de huid kunnen worden opgenomen, hetgeen een substantiële bijdrage kan betekenen aan de totale inwendige blootstelling, hebben in de lijst een Haanduiding. Bij deze stoffen moeten naast maatregelen tegen inademing ook adequate maatregelen ter voorkoming van huidcontact worden genomen. |
| Netherlands | Regulatory reference | Arbeidsomstandighedenregeling 2017 |

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Materials for protective clothing:

Consider the use of flame resistant anti-static safety clothing.

Hand protection:

Protective gloves. Standard EN 374 - Protective gloves against chemicals.

| Type | Material | Permeation | Thickness (mm) | Penetration | Standard |
|------|-------------------------|-------------------|----------------|-------------|----------|
| | Polyvinylchloride (PVC) | 6 (> 480 minutes) | 0.12 | | EN 374 |

Eye protection:

EN 166. Wear security glasses which protect from splashes

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):



Biodent EC40

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|--|---------------------|
| Physical state | : Liquid |
| Colour | : brown. |
| Odour | : alcohol odour. |
| Odour threshold | : No data available |
| pH | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : Not applicable |
| Freezing point | : -90 °C |
| Boiling point | : 60 °C |
| Flash point | : <= 23 °C |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : Not applicable |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Solubility | : No data available |
| Log Pow | : No data available |
| Viscosity, kinematic | : No data available |
| Viscosity, dynamic | : No data available |
| Explosive properties | : No data available |
| Oxidising properties | : No data available |
| Explosive limits | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| | |
|-----------------------------|------------------|
| Acute toxicity (oral) | : Not classified |
| Acute toxicity (dermal) | : Not classified |
| Acute toxicity (inhalation) | : Not classified |

Chlorhexidine diacetate (56-95-1)

| | |
|-------------------------------|------------------|
| LD50 oral | 2000 mg/kg mouse |
| Skin corrosion/irritation | : Not classified |
| Serious eye damage/irritation | : Not classified |

Biodent EC40

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

| | |
|-----------------------------------|------------------|
| Respiratory or skin sensitisation | : Not classified |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : Not classified |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |

SECTION 12: Ecological information

12.1. Toxicity

| | |
|--------------------------|--|
| Ecology - general | : Toxic to aquatic life with long lasting effects. |
| Acute aquatic toxicity | : Not classified |
| Chronic aquatic toxicity | : Toxic to aquatic life with long lasting effects. |

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

| |
|--|
| BioC chx tooth varnish |
| 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

No additional information available






SECTION 13: Disposal considerations

13.1. Waste treatment methods

| | |
|-----------------------------------|---|
| Waste treatment methods | : Dispose of contents/container in accordance with licensed collector's sorting instructions. |
| Additional information | : Flammable vapours may accumulate in the container. |
| 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 | ADN | RID |
|---|---|--|--|--|
| 14.1. UN number | | | | |
| 1993 | 1993 | 1993 | 1993 | 1993 |
| 14.2. UN proper shipping name | | | | |
| FLAMMABLE LIQUID, N.O.S. (CONTAINS ; ethanol, ethyl alcohol) | FLAMMABLE LIQUID, N.O.S. (CONTAINS ; ethanol, ethyl alcohol) | Flammable liquid, n.o.s. (CONTAINS ; ethanol, ethyl alcohol) | FLAMMABLE LIQUID, N.O.S. (CONTAINS ; ethanol, ethyl alcohol) | FLAMMABLE LIQUID, N.O.S. (CONTAINS ; ethanol, ethyl alcohol) |
| Transport document description | | | | |
| UN 1993 FLAMMABLE LIQUID, N.O.S. (CONTAINS ; ethanol, ethyl alcohol), 3, II, (D/E), ENVIRONMENTALLY HAZARDOUS | UN 1993 FLAMMABLE LIQUID, N.O.S. (CONTAINS ; ethanol, ethyl alcohol), 3, II, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS | UN 1993 Flammable liquid, n.o.s. (CONTAINS ; ethanol, ethyl alcohol), 3, II, ENVIRONMENTALLY HAZARDOUS | UN 1993 FLAMMABLE LIQUID, N.O.S. (CONTAINS ; ethanol, ethyl alcohol), 3, II, ENVIRONMENTALLY HAZARDOUS | UN 1993 FLAMMABLE LIQUID, N.O.S. (CONTAINS ; ethanol, ethyl alcohol), 3, II, ENVIRONMENTALLY HAZARDOUS |
| 14.3. Transport hazard class(es) | | | | |
| 3 | 3 | 3 | 3 | 3 |
|  |  |  |  |  |

Biodent EC40

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

| ADR | IMDG | IATA | ADN | RID |
|--|---|-------------------------------------|-------------------------------------|-------------------------------------|
| 14.4. Packing group | | | | |
| II | II | II | II | II |
| 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 | Dangerous for the environment : Yes |
| No supplementary information available | | | | |

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : F1
Special provisions (ADR) : 274, 601, 640D
Limited quantities (ADR) : 1I
Excepted quantities (ADR) : E2
Packing instructions (ADR) : P001, IBC02, R001
Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions (ADR) : T7
Portable tank and bulk container special provisions (ADR) : TP1, TP8, TP28
Tank code (ADR) : LGBF
Vehicle for tank carriage : FL
Transport category (ADR) : 2
Special provisions for carriage - Operation (ADR) : S2, S20
Hazard identification number (Kemler No.) : 33
Orange plates :



Tunnel restriction code (ADR) : D/E

- Transport by sea

Special provisions (IMDG) : 274
Packing instructions (IMDG) : P001
IBC packing instructions (IMDG) : IBC02
Tank instructions (IMDG) : T7
Tank special provisions (IMDG) : TP1, TP8, TP28
EmS-No. (Fire) : F-E
EmS-No. (Spillage) : S-E
Stowage category (IMDG) : B

- Air transport

PCA Excepted quantities (IATA) : E2
PCA Limited quantities (IATA) : Y341
PCA limited quantity max net quantity (IATA) : 1L
PCA packing instructions (IATA) : 353
PCA max net quantity (IATA) : 5L
CAO packing instructions (IATA) : 364
CAO max net quantity (IATA) : 60L
Special provisions (IATA) : A3
ERG code (IATA) : 3H

- Inland waterway transport

Classification code (ADN) : F1
Special provisions (ADN) : 274, 601, 640D
Limited quantities (ADN) : 1 L
Excepted quantities (ADN) : E2
Carriage permitted (ADN) : T

Biodent EC40

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

| | |
|---|---------------------|
| Equipment required (ADN) | : PP, EX, A |
| Ventilation (ADN) | : VE01 |
| Number of blue cones/lights (ADN) | : 1 |
| - Rail transport | |
| Classification code (RID) | : F1 |
| Special provisions (RID) | : 274, 601, 640D |
| Limited quantities (RID) | : 1L |
| Excepted quantities (RID) | : E2 |
| Packing instructions (RID) | : P001, IBC02, R001 |
| Mixed packing provisions (RID) | : MP19 |
| Portable tank and bulk container instructions (RID) | : T7 |
| Portable tank and bulk container special provisions (RID) | : TP1, TP8, TP28 |
| Tank codes for RID tanks (RID) | : LGBF |
| Transport category (RID) | : 2 |
| Colis express (express parcels) (RID) | : CE7 |
| Hazard identification number (RID) | : 33 |

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Netherlands

| | |
|---|-------------------------------------|
| SZW-lijst van kankerverwekkende stoffen | : ethanol, ethyl alcohol is listed |
| SZW-lijst van mutagene stoffen | : None of the components are listed |
| NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding | : ethanol, ethyl alcohol is listed |
| NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid | : ethanol, ethyl alcohol is listed |
| NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling | : ethanol, ethyl alcohol is listed |

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:

| | |
|------|---|
| | REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| OECD | Organisation for Economic Co-operation and Development |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| SDS | Safety Data Sheet |
| vPvB | Very Persistent and Very Bioaccumulative |

Biodent EC40

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Other information : DISCLAIMER OF LIABILITY The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. REACH Disclaimer: This information is based on current knowledge. Consistency of data in the SDS with CSR is considered, as far as the information is available at the time of compilation (cfr Revision date and Version number).

| Full text of H- and EUH-statements: | |
|-------------------------------------|---|
| Acute Tox. 4 (Oral) | Acute toxicity (oral), Category 4 |
| Aquatic Chronic 1 | Hazardous to the aquatic environment — Chronic Hazard, Category 1 |
| Aquatic Chronic 2 | Hazardous to the aquatic environment — Chronic Hazard, Category 2 |
| Flam. Liq. 2 | Flammable liquids, Category 2 |
| H225 | Highly flammable liquid and vapour. |
| H302 | Harmful if swallowed. |
| H410 | Very toxic to aquatic life with long lasting effects. |
| H411 | Toxic to aquatic life with long lasting effects. |

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

| | | |
|-------------------|------|-----------------------|
| Flam. Liq. 2 | H225 | On basis of test data |
| Aquatic Chronic 2 | H411 | Calculation method |

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product