

Safety data sheet

**complying with Regulation 1907/2006/EC (REACH Regulation), EU
2015/830 and Regulation No 1272/2008/EC (CLP)**

Printing date 04.08.2017 Revision: 04.08.2017 Version number 1
45.1.2

1.1 Product identifier

Trade name: YUM! BUBBLEGUM DENTAL STANDARD

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

No further relevant information available.

Application of the substance / the mixture:

ORAL ANESTHETIC

for professional use

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

ADELCO S.A. - Pharmaceuticals and Cosmetics

37, Pireos Str., 18346 Moschato

Athens, Greece

Tel: +30 210 4819311

Fax: +30 210 4816790

info@adelco.gr

1.4 Emergency telephone number:

European Emergency Tel.: 112

2.1 Classification of the substance or mixture

Classification according to Regulation EC No 1272/2008 CLP:

The product is not subject to classification according to the Regulation EC 1272/2008, (CLP), because it is a pharmaceutical product. This product does not meet the criteria for classification in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

2.2 Label elements

Labelling according to Regulation EC No 1272/2008 CLP:

The product is not subject to classification according to the Regulation EC 1272/2008, (CLP), because it is a pharmaceutical product.

Hazard pictograms: Void

Signal word: Void

Hazard statements: Void

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.

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vPvB: Not applicable.

3.2 Chemical characterisation: Mixtures

Description:

Mixture consisting of substances that either not classified or not required to be stated in the Safety Data Sheet according to Reg. (EU) 830/2015.

Ingredients according Regulation (EU) 830/2015: Void

Additional information: For the wording of the listed hazard phrases refer to section 16.

4.1 Description of first aid measures

General information:

No special measures required. Take affected persons out into the fresh air.

After inhalation: Seek medical treatment in case of complaints.

After skin contact:

Remove contaminated clothing. In case of skin irritation, consult a physician.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Avoid strong water jet-risk of cornea damage, consult a doctor.

After swallowing:

Drink plenty of water and provide fresh air. Call for a doctor immediately. Seek immediate medical advice.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5.1 Extinguishing media

Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray. Use fire extinguishing methods suitable to surrounding conditions.

5.2 Special hazards arising from the substance or mixture No further relevant information available.

5.3 Advice for firefighters

Protective equipment: No special measures required.

Additional information Collect contaminated fire fighting water separately. It must not enter the sewage system.

6.1 Personal precautions, protective equipment and emergency procedures:

6.1.1 For non-emergency personnel Ensure sufficient ventilation.

6.1.2 For emergency responders Wear protective equipment. Keep unprotected persons away.

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6.2 Environmental precautions: No special measures required.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust, silica gel).

6.4 Reference to other sections:

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7.1 Precautions for safe handling No special precautions are necessary if used correctly.

Information about fire - and explosion protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Store in cool, dry conditions in well sealed receptacles.

Requirements to be met by storerooms and receptacles: Store in a cool location.

Information about storage in one common storage facility: Not required.

Further information about storage conditions: None.

7.3 Specific end use(s) No further relevant information available.

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at

the workplace.

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Respiratory protection: Not required.

Protection of hands: Not required under normal conditions of use.

Eye protection: Not required under normal conditions of use.

Body protection: Not required under normal conditions of use.

9.1 Information on basic physical and chemical properties

General Information

Appearance:

Form: gel

Colour: Dark yellow to light brown

Odour: Bubble gum

Odour threshold: Not determined

pH value: Not determined

Melting point/freezing point: Not determined

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Initial boiling point and boiling range: Not determined

Flash point: Not Flammable

Flammability (solid, gas): Not applicable

Auto-ignition temperature: Not determined

Decomposition temperature: Not determined

Auto-ignition temperature: Product is not selfigniting.

Explosive properties: Product does not present an explosion hazard.

Explosion limits:

Lower: Not determined

Upper: Not determined

Oxidising properties Not considered as oxidising.

Vapour pressure: Not determined

Density: Not determined

Relative density Not determined

Vapour density Not determined

Evaporation rate Not determined

Solubility in / Miscibility with

water: Fully miscible

Partition coefficient: n-octanol/water: Not determined

Viscosity:

Dynamic: Not determined

Kinematic: Not determined

9.2 Other information No further relevant information available.

10.1 Reactivity Stable under normal conditions

10.2 Chemical stability Material is stable under normal conditions.

Thermal decomposition / conditions to be avoided

No decomposition if used and stored according to specifications.

Stable at environment temperature.

10.3 Possibility of hazardous reactions No dangerous reactions known.

10.4 Conditions to avoid No further relevant information available.

10.5 Incompatible materials No further relevant information available.

10.6 Hazardous decomposition products No dangerous decomposition products known.

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11.1 Information on toxicological effects

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

LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral LD50 >19,417 mg/kg (rat)

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/irritation Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

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

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

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

STOT-single exposure Based on available data, the classification criteria are not met.

STOT-repeated exposure Based on available data, the classification criteria are not met.

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

12.1 Toxicity

Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability No further relevant information available.

12.3 Bioaccumulative potential No further relevant information available.

12.4 Mobility in soil No further relevant information available.

Additional ecological information:

General notes:

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Not known to be hazardous to water.

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

13.1 Waste treatment methods

Recommendation

Dispose according to National Regulations.

Contact manufacturer for recycling information.

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Uncleaned packaging:**Recommendation:**

Disposal must be made according to official regulations.

Packaging may be reused or recycled after cleaning.

14.1 UN-Number

ADR, ADN, IMDG, IATA Void

14.2 UN proper shipping name

ADR, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)

ADR, ADN, IMDG, IATA

Class Void

14.4 Packing group

ADR, IMDG, IATA Void

14.5 Environmental hazards: Not applicable.

14.6 Special precautions for user Not applicable.

14.7 Transport in bulk according to Annex II of

Marpol and the IBC Code Not applicable.

UN "Model Regulation": Void

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

REACH Regulation 1907/2006/EC

Regulation (EU) 2015/830

CLP Regulation 1272/2008/EC

Directive 2012/18/EU

Named dangerous substances - ANNEX I Substance is not listed.

National regulations:**Other regulations, limitations and prohibitive regulations****Substances of very high concern (SVHC) according to REACH, Article 57**

It doesn't contain substances of very high concern (SVHC).

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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Training hints

Suitable training on safety in handling, storing and converting the product should be given to the employees based on all the existing information.

Department issuing SDS:

SUSTCHEM Engineering Ltd
REACH & Chemical Services Department
144, 3rd Septemvriou, GR 112 51, Athens, Greece
Tel.: +30 210 8252510 Fax: +30 210 8252575
E-mail: info@suschem.gr
Website: www.sustchem.gr

Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International

Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

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