YETI Dentalprodukte GmbH According to 1907/2006/EG, Artikel 31

AQUA-Sep Isolation

1. Identification of the Substance/ Preparation and Company Identification

Article description: AQUA Sep Isolating liquid

Item-no. 589-1001

Use: Isolating liquid for dental technique

Producer: Yeti Dentalprodukte GmbH

Industriestr. 3 78234 Engen Germany

Information: Tel.: +49 7733 9410-0 Fax: +49 7733 9410-22

(Mo.-Thu. 8:00 – 16:30, Fr. 8:00 – 14:00)

Emergency: Tel.: +49 7733 9410-0 Fax: +49 7733 9410-22

(Mo.-Thu. 8:00 – 16:30, Fr. 8:00 – 14:00)

2. Hazard Identification

<u>Classification</u>

This preparation is not classified as dangerous according to the new dangerous preparations directive 1999/45/EC.

Further hazard indications for humans and the environment

No special dangers to be mentioned. But please respect the indications of this safety data sheet.

3. Composition / Information on Ingredients

Chemical characterization:

Active compound mixture

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4. First-Aid Measures

General indications:

Immediately take off contaminated and soaked clothes. Wash contaminated clothes before reuse. Consult a doctor if necessary. Show this safety data sheet to the attending doctor.

After inhalation:

Provide fresh air and seek for medical assistance if necessary.

After skin contact:

Immediately wash off with water and soap. Use preventive skin protection.

After eye contact:

Rinse the eye with plenty of water for 15 minutes. If irritation continues consult an ophthalmologist. <u>After ingestion:</u>

Immediately rinse off the mouth. Do not induce vomiting, seek medical advice immediately.

Advice for the doctor:

Symptomatical treatment. After ingestion the stomach has to be emptied by gavage under medical surveillance.

5. Fire-Fighting Measures

Suitable extinguishing media:

Adapt fire fighting measures to the environment.

Spray water, carbon dioxide (CO²), foam, dry extinguishing agent, sand.

Extinguishing media to avoid because of security reasons:

Don't use full water jet to prevent diffusion and expansion of the fire.

Special danger caused by the products, its combustion products or emerging gases:

In case of fire dense black smoke containing dangerous decomposition products is formed.

Dangerous gases which emerge in case of non-complete burning contain possibly: carbon monoxide, carbon dioxide (CO2), hydrocarbons, smoke. Fire gases of organic materials are generally characterized as respiratory poison.

Special protection equipment during fire extinguishment:

In case of fire wear respiratory protection independent from ambient air. Don't inhale explosion and fire gases. In case of accident with respiration of fire gases or decomposition products go to fresh air.

Further indications:

Usual measures of preventive and repelling fire protection.

Burn residues and contaminated extinguishing water have to be disposed according to local regulatory directives. Gather contaminated extinguishing water separately, do not empty into drains.

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6. Accidental Release Measures

Personal precautions:

Take the usual protection measures for handling chemicals. Avoid contact with eyes. Eliminate all ignition sources. Don't smoke. Don't inhale vapors and atomized spray. Provide appropriate ventilation.

Environmental precautions:

Do not empty into waste water, drains, soil or waterbodies.

Methods for absorption / cleaning up:

Cleaning methods for big quantities of spilled material: Embank, scoop up and bring to disposal site in appropriate containers. If bigger quantities of spilled material cannot be embanked, local authorities must be informed.

Cleaning methods for small quantities of spilled material: Absorb mechanically (sand, silica gel, acid-binding agent, universal absorbent, sawdust) and dispose in appropriate containers. Other information:

Further indications see point 8 and 13.

7. Handling and Storage

Handling:

Indications for safe handling:

Use the material only at places where naked light, fire and other ignition sources are kept away. Use only in well ventilated rooms. Don't eat, drink and smoke during use.

Indications against fire and explosions:

The product is combustible, but not highly flammable.

Fire extinguisher: fire class B. Further indications for handling:

Indications for applications that require special precaution measures:

No special precaution measures necessary.

Storage:

Requirements for storage rooms and containers:

Keep container firmly closed and store in a cool place.

Current regulations for water and construction laws have to be respected (WHG Water Resources Act, VAwS Ordinance on installations for handling of substances hazardous to water, regional building law).

Provide leak-proof ground floor resistant to solvents.

Indications for clustering:

Stable under indicated storage conditions. Incompatible with oxidants.

Further indications for storage conditions:

Store at temperatures between +10°C and +30°C. Don't store outside. Protect from heat and direct sunlight. Respect indications on the label.

Storage class according to VCI: 10

<u>Determined use(s) / substitute product(s):</u>

Possibilities for substitution and indications for less dangerous products: This product was develop

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and optimized for a special use. In case of questions about the product or its use, please refer to our sales representatives within the field of customer care or to our technical sales.

8. Exposure controls / Personal protection equipment

Exposure limit values:

Additional indications for limit values:

Recommended monitoring and observation methods:

BG/BGIA-Recommendations and BGIA-Working Folder (Internet:

http://www.hvbg.de/d/pages/index.html)

BG/BGIA-Recommendations for the hazard evaluation according to the Ordinance on hazardous substances (BGI 790)

Calculation method and model building in the field of working analysis (BIA-Report 3/2001)

Practical guidelines for hazard evaluation with recommendations for protection measures during work with substances without working place threshold limits (BGIA-Report 7/2005)

BGIA-Practical guidelines for hazard evaluation during work with hazardous substances

Hazardous substances list 2009 (BGIA-Report 1/2009)

LASI/ALMA-Recommendations (Internet: http://lasi.osha.de/publications):

LASI-publication LV45 – Guidelines for Ordinance on Hazardous Substances

Exposure control and surveillance:

Exposure control and surveillance at the working place:

Arrangement of appropriate working processes and technical control devices, and use of appropriate working equipment (model solutions as approved working methods, working equipment according to the state of technique, working equipment to avoid skin contact, working time models). Indications for the arrangement of technical plants: see point 7.

For the arrangement of working procedures the model solutions in the respective protection guidelines of the BAuA (Occupational Safety and Health) have to be respected. Relevant protection guidelines and packages of measures:

Safety level 1: no. 100,101,110,120 Safety level 2: no. 200,203,213,217,250

Safety level 3: no. 306,308,312

Realisation of collective protection measures at the hazard source and organizational measures (air suction system, technical ventilation, natural ventilation, measures to prevent hazards in case of malfunction, breakdown, emergency, after accidents, first ais measures, measures related to the behavior: operating instructions, instructions, preventive occupational medical care). Take care of good ventilation and extraction at the processing machines. Wherever possible in a rational manner, reach this by a local extraction or good ventilation.

Realization of individual and personal protection measures – personal protective equipment.

Measures for safety and hygiene:

The minimal protection measures according to TRGS 500 have to be respected.

Do not eat, drink or smoke during use. Usual measures for working hygiene.

Take the usual protection measures for handling chemicals.

Respiratory protection:

Provide sufficient ventilation, especially in closed spaces.

Hand protection:

Longer or repeated contact with the product can degrease skin. This can lead to a non-allergic contact dermatitis and product absorption by skin. Use only chemical-resistant protective gloves with CE labeling of category III according to EN 374.

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Appropriate materials in case of longer, direct contact (recommended: protection index 6, corresponding to >480 min. permeation time according to EN 374. BGR 195, ZH 1/706)

Butyl rubber / BR-IIR_(BUTOJECT® - Art. Nr. 898) - thickness: 0,7 mm

Nitril rubber / NBR (CAMATRIL VELOURS® - Art. Nr. 730) thickness: 0,4 mm

Appropriate materials in case of short contact or splashes (recommended: protection index 3, corresponding to > 60 min. permeation time according to EN 374, BGR 195, ZH 1/706):

Special Nitril single use protective gloves / NBR (Dermatril®P – Art. Nr. 743) – thickness: 0,2mm Manufacturer:

Kächele-Cama Latex GmbH, Industriepark Röhn, Am Kreuzacker 9, D-36124 Eichenzell Telefon: +49-6659-87-300, Telefax: +49-6659-87-155, Internet: http://www.kcl.de E-Mail: vertrieb@kcl.de

The indications are based on literature and information from manufacturers of protective gloves or are deduced analogically from similar substances. Source: CHEMIKALIEN-MANAGER-KCL-Software for hand protection. Respect the fact that the daily use time of the chemical glove in praxis can be reduced significantly related to calculated permeation time according to EN 374 because of many influencing parameters (e.g. thermic or mechanical load, or special conditions at the working place). Therefore a use of max. 50% of the permeation time is recommended. They relate to the pure solvent as a skin component. To avoid skin problems reduce the wearing of gloves to the necessary extent.

Technical and organizational protection measures are preferable. Wear cotton glove liners if possible. Change gloves every hour or usual special skin protection products for glove wearers, e.g. physioderm® proGlove. Clean gloves with water and soap before taking them off. Dispose protective gloves in case of defect or after the maximum application time. Check protective gloves for their proper state before each use.

Preventive skin protection: Establish skin protection plan. (BGR 197, ZH 1/708)

Before starting work use solvent resistant skin protection products (water soluble O/W Emulsions), e.g. sansibal®, sansibon®, dualin®

Wash hands before breaks and after work, e.g. ecosan®, topscrub® soft / topscrub® extra / tobscrub® nature

After cleaning use fatty skin care, e.g. physioderm® creme, cura soft® / cUrea soft® Manufacturer:

Peter Greven Physioderm GmbH, Procter-&-Gamble-Str. 26, D-53881 Euskirchen

Tel.: +49-(0)2251 77617-61, Fax.: +49-(0)2251 77617-44, Internet: http://www.physioderm.de, E-Mail: info@physioderm.de

Eye protection:

Wear sealed safety goggles with lateral protection. (EN 166, BGR 192, ZH 1/703) Body protection:

Light protective overall (EN 340, BGR 189, ZH 1/700), boots

Monitoring and control of environmental exposure:

Don't drain product into the environment. Further indications see point 6.

9. Physical and Chemical Properties

General indications:

Aggregate state: liquid
Colour: colourless
Odour: characteristic

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Important indications for health, environmental protection and safety:

pH:

not applicable

Changes of state

Boiling point/ range: > 250°C (literature) Flash point: > 160°C (EN ISO 2719)

Danger of explosion: not applicable

Lower explosion limit: --Upper explosion limit: ---

Vapour pressure at 20°C: < 0,1 hPa (literature)
Density at 20°C: 0,95 g/cm³ (DIN 51757)
Solubility in water at 20°C: < 0,1g/L (literature)

Solubility in other solvents: soluble in most other organical solvents

Distribution coefficient: not applicable

Kin. viscosity at 23°C: $> 7mm^2/s$ (3 EN ISO 2431) Flow time at 23°C: > 30s (3 EN ISO 2431)

Solvent separation test: not applicable

Other indications:

Ignition temperature: > 250°C (literature)

10. Stability and Reactivity:

Conditions to avoid:

None if used according to determinations.

Substances to avoid:

None if used according to determinations. Incompatible with oxidants.

<u>Dangerous decomposition products:</u>

Stable under normal conditions.

11. Toxicological Information:

Toxicological tests:

Acute Toxicity:

No data available. Preparation not tested.

The classification was realized according to the conventional method (calculation method of the new preparations directive 1999/45/CE).

Further indications about tests:

About the product itself no data are available, the description of possible harmful consequences is based on experiences in praxis and / or toxicological characteristics of single components. Acute toxicity, skin irritation, mucosa irritation, mutagenic potential and skin sensitization of the substance were evaluated by the manufacturer on basis of data available for the main components. Data gaps partly exist for single main components. According to the experience of the manufacturer other dangers than the indicated don't have to be expected.

Experiences from praxis:

Observations relevant for classification

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Acute toxicity:

The following statements are deducted from the characteristics of the single components.

 LD50 oral (rat)
 2000mg/kg

 LD50 dermal (rat)
 2000mg/kg

 LD50 inhalation (4h, rat)
 20mg/l

Irritation and corrosivity:

On skin: Can cause skin irritation for sensible persons.

At the eye: Eye contact can cause irritation.

Sensitization:

After inhalation:

After skin contact:

not known
not known
Sub-acute to chronic toxicity:

not known
not known

Cancer-causing, mutagenic or toxicity for reproduction: not known

If used according to determinations no damages to health are known nor have to be expected.

Further observations:

Longer or repeated contact with the product can degrease the skin. This can lead to a non-allergic contact dermatitis and product absorption by skin.

Primary irritation:

Skin: Corrosive Eye: Corrosive

Respiratory organs: No data available. Sensitization: No data available.

12. Ecological Information:

Ecotoxicity:

No ecotoxical data available. Preparation not tested. The classification was realized according to the conventional method (calculation method of the new preparations directive 1999/45/EG).

Aquatic toxicity (fish toxicity, alga toxicity, daphnia toxicity):

The following statements are deducted from the characteristics of the single components.

LC50 (96h, guppy): 100mg/l EC50 (72h, alga): 100ml/l EC50 (48h, daphnia): 100mg/l

Terrestrial toxicity (bird toxicity, beneficial insect toxicity, earthworm toxicity):

No data available. Plant toxicity:
No data available.

Behavior in purification plants:

No data available.

Mobility:

Surface tension: No data available.

Transport ground-water (adsorption, desorption): The product floats on water and

doesn't dissolve.

Transport water-air (volatility rate, Henry constant):

The product evaporates slowly.

The product evaporates slowly.

The product evaporates slowly.

Persistence and degradability:

Abiotic decomposition (hydrolysis, photolysis):

Physicochemical elimination (oxidation, hydrolysis):

No data available.

No data available.

No data available.

Biodegradation:

No data available.

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Bioaccumulation potential:

Distribution coefficient n-Octanol / water (log pO/W): Not applicable (preparation). Bioconcentration factor (BCF): Not applicable (preparation).

Other damaging effects:

Ozone-depleting potential (ODP):

Photochemical ozone-building potential (OBP):

Global warming potential (GWP):

No data available.

No data available.

Product doesn't contain any organic halogens. (AOX)

Further indications:

Result of the determination of the PBT-properties: No data available.

13. Disposal Considerations:

Recommendation:

Disposal according to current legal regulations. Don't empty into drains or surface water. Mustn't be disposed and stored with household waste. Pack or close and mark product waste and non-cleaned empty packages and bring to appropriate disposal site respecting local and official regulation.

The assignment of the waste codes according to the EC waste-catalogue (EWC) has to be realized according to the AVV (2000/532/EC) specifically for industries and processes. The waste producer is responsible for the correct assignment of the designations of his waste. In case of small quantities (< 20 kg/L) contact the nearest temporary storage for special waste or visit the mobile harmful substances collection. Before introduction into the public drainage (e.g. rests of wash and rinse liquids) relevant rules on national and communal level have to be respected (WHG, AbwAG, AbwV, communal waste water charter, introduction permission, etc.). For further questions please relate to your assignee for waste and environment or to the competent local authority.

Non-binding proposal list for waste codes and waste designations according to AVV (2000/532/EC): Waste code for product

070215 waste of organic-chemical processes; waste of HZVA of plastics, synthetic rubber

and fibre; waste of additional ingredients except those who belong to 07 02 14.

Waste code for product rests

070215 waste of organic-chemical processes; waste of HZVA of plastics, synthetic rubber

and fibre; waste of additional ingredients except those who belong to 07 02 14.

Waste code for uncleaned packages

package waste, absorption materials, wiping clothes, filter materials and protective

clothes (a. n. g.); packages (including separately collected communal package

waste); mixed packages

Disposal of uncleaned packages:

Contaminated packages have tob e emptied completely (non-drip, non-trickling, scraper clean). Non-cleanable packages have to be disposed as the product. Cleaned packages can be introduced to the local recovered substances cycle.

Recommended detergents: Clean with detergents. Avoid solvents. Dispose washing water as waste water. Don't pollute water bodies.

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14. Transport Information:

Transport by land ADR/RID and GGVS/GGVE (international/ domestic)

No dangerous good according to transport regulations.

Transport by sea IMDG/GGVSea:

No dangerous good according to transport regulations.

Transport by air ICAO-TI and IATA-DGR:

No dangerous good according to transport regulations.

15. Regulatory Information:

Specification:

Specifications for classification:

According to CE directives or the respective national law no labelling is required for this product.

Preparations directive 1999/45/CE. European Community directives:

Indications for VOC-guideline: content of volatile organic compounds (VOC) = 0%w/w.

VOC-value (25°C) = 0g/L

<u>Further indications:</u>

Restrictions to bringing into circulation and use of certain compounds (VO (CE) no. 552/2009): Not relevant.

Indications for directive 2004/42CE – realized by ChemVOCFarbV: Not applicable.

CE Chemical Inventories: All ingredients are listed in EINECS/ELINCS or excluded from the listing (polymers, No-longer-polymer / NLP – 92/32/EWG). The substitutes (monomers) of the polymers are listed.

A safety classification of the substance (or for one substance of the preparation) was not executed. National regulations:

Ordinance on industrial accidents:

Appendix I: not implied

Catalogue no. according to Ordinance on industrial accidents:

Classification according to VbF: Not subject to the Ordinance on

flammable liquids

Technical instruction Air I: 5.2.5.I: organic substances at m

>=0,10kg/h: conc. 20mg/m³

Proportion: ---

Technical instruction Air II: 5.2.5.II: organic substances at m

>=0,50kg/h: conc. 0,10mg/m³

Proportion: --

Technical instruction Air III: 5.2.5. organic substances, indicated

as total carbon at $m \ge 0.50 \text{kg/h}$: conc.

50mg/m³

Proportion: <85%

Water hazard class: 1 - slightly hazardous to water Status: mixing rule according to VwVwS

mixing rule according to v

appendix 4, no. 3

Additional indications:

International Chemical Inventories (registration status for substances):

No data available.

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European Product Inventories (registration status for preparations):

The product was not registered.

Federal Office for Health – BAG / Registration Office Chemicals / Information System for dangerous and environmentally relevant substances – IGS:

The product was not registered.

BG-Chemistry-Instructions of the M-series (dangerous substances):

M 053 – general work protection measures for the handling of dangerous substances (BGI 660, ZH 1/471)

Relevant professional and occupational medicine regulations and rules (BGVR):

Protection measures concept for spray painting works – paint aerosols (BGR 231)

Electrostatic coating (BGI 764, ZH 1/160)

Occupational medicinal preventive examinations: It is recommended to check the necessity in the context of the hazards analysis respecting the following professional principles. These indications are only indications typical for use without direct relation to the product and its ingredients with the function of support:

G24 - skin disease

Dangerous substances regulation (GefStoffV, appendix IV – production and application prohibitions): Not relevant.

Chemicals prohibition regulation (ChemVerbotsV): Not relevant.

Relevant technical rule for dangerous substances (TRGS):

TRGS 400 - Hazard classification for activities with dangerous substances (§7 GefStoffV) and

TRGS 401 – Danger by skin contact – Evaluation, rating, measures

TRGS 500 – protective measures (§§8-11 GefStoffV)

TRGS 507 - Surface treatment in rooms and containers

TRGS 555 – Operating instructions and information for employees (§14 GefStoffV)

Other regulations, restrictions and prohibitive ordinances:

FDA- / BfR-Status: The product mustn't be use in direct contact to food in compliance with the existing regulations.

H1- / NSF-listing of food compatible substances: Not applicable.

16. Other Information:

Further indications:

Training indications:

Annual briefing and instruction of employees with the help of operating instructions according to Art. 8 guideline 98/24CE and GefStoffV.

Recommended restriction of use:

The product is allowed only for industrial and commercial use – no product for general public. Indications for use have to be learned from a separated product information.

Sources of the most important data that were used for the creation of this Safety Data Sheet:

The classification corresponds to the actual CE lists, but is completed by indications from literature and by company indications.

Other public sources:

Regulation (CE) Nr. 1907/2006 (REACH) in the respective valid version Regulation (CE) Nr. 1272/2008 (GHS/CLP) in the respective valid version

Substance regulation 67/548/EWG in the respective valid version – changed by regulation

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Preparation regulation 1999/45/CE in the respective valid version – changed by regulation 2006/8/CE

European Agency for Security and Health at the working place – national air threshold limits of the European member states

(http://osha.europa.eu/good_practice/topics/dangerous_substances/oel/members.stm)

European Chemical Substances Information System – ESIS (http://ecb. Jrc.ec.europa.eu/esis)

MERCK Chemical Databases - MERCK Chemicals (http://www.merck-chemicals.com)

GESTIS-substance data base of HVBG (http://www.dguv.de/bgia/de/gestis/stoffdb/index.jsp)

Further information and practical help in the internet (written and electronical sources):

European Agency for Chemical Substances _ ECHA (http://ec.europa.eu/echa)

Access to CE law – EUR-Lex (http://eur-lex.europa.eu)

Federal Institute for Occupational Safety and Health BAuA (http://www.baua.de)

Federal Environment Office – UBA (http://www.umeltbundesamt.de)

Federation of German Industries - BDI Helpdesk - BDI-Support about Reach (http://reach.bdi.info)

Chemical Industry Association – VCI (http://www.vci.de)

BGVR-Data base of HVBG (http://www.arbeitssicherheit.de)

Industry-specific regulations for dangerous substances – Universum – Verlag

(http://www.branchenregelungen.de)

Dangerous substances portal for small and medium.sized companies (http://www.gefahrstoffe-im-griff.de)

Closing conditions:

The information in this safety data sheet describe the security requirements of our product. Thus the indications don't have the meaning of garanties on properties nor establish a contractual legal relationship. They should give you clues for the handling of the product mentioned in this Safety Data Sheet, for storage, processing, transport and disposal. The user is responsible for respecting all current laws and legal regulations.

All indications are guidelines and are not supposed to be used for specifications.

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