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

1.1 Product identifier

Trade name: AGC Cem Automix System

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: Auxiliary for dental technology

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60

Further information obtainable from:
Regulatory Affairs
sds@ivoclarvivadent.com

1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Skin Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008
The product is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labelling:
Bis-GMA

Hazard statements
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

Precautionary statements
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
Trade name: AGC Cem Automix System

- vPoB: Not applicable.

SECTION 3: Composition/information on ingredients

- 3.2 Chemical characterisation: Mixtures
  - Description: Mixture of substances listed below with nonhazardous additions.
  - Dangerous components:
    - CAS: 1565-94-2 Bis-GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 25-50%
  - Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures
  - After inhalation: Supply fresh air and to be sure call for a doctor. In case of unconsciousness place patient stably in side position for transportation.
  - After skin contact: Rinse with water.
  - After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
  - After swallowing: Rinse out mouth and then drink plenty of water. If symptoms persist consult doctor.
- 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.

SECTION 5: Firefighting measures

- 5.1 Extinguishing media
  - Suitable extinguishing agents: CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - For safety reasons unsuitable extinguishing agents: Water with full jet
- 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.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures
  - Wear protective equipment. Keep unprotected persons away.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- 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.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling
  - Only adequately trained personnel should handle this product.
Trade name: AGC Cem Automix System

For use in dentistry only.

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

- **7.2 Conditions for safe storage, including any incompatibilities**
  - **Storage:**
    - **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
    - **Information about storage in one common storage facility:** Not required.
    - **Further information about storage conditions:**
      - Keep container tightly sealed.
      - Protect from heat and direct sunlight.

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

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

- **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.
  - **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures:**
      - Usual hygienic measures for dental practice and dental laboratories.
      - Keep away from foodstuffs, beverages and feed.
      - Wash hands before breaks and at the end of work.
      - Avoid contact with the eyes and skin.
    - **Respiratory protection:** Not required.
    - **Protection of hands:**
      - **Protective gloves**
      - After use of gloves apply skin-cleaning agents and skin cosmetics.
      - **Material of gloves**
      - Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
      - **Penetration time of glove material**
      - The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
      - **Not suitable are gloves made of the following materials:**
      - Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
    - **Eye protection:**
      - **Tightly sealed goggles**
SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties
  - General Information
    - Appearance:
      - Form: Pasty
      - Colour: Yellowish
      - Odour: Ester-like
      - Odour threshold: Not determined.
    - pH-value: Not applicable.
    - Change in condition
      - Melting point/freezing point: Undetermined.
      - Initial boiling point and boiling range: >200 °C
    - Flash point: Not applicable.
    - Flammability (solid, gas): Not applicable.
    - Auto-ignition temperature: Product is not selfigniting.
    - Explosive properties:
      - Product does not present an explosion hazard.
    - Explosion limits:
      - Lower: Not determined.
      - Upper: Not determined.
    - Vapour pressure: Not determined.
    - Density at 20 °C: 1.9 g/cm³
    - Relative density: Not determined.
    - Vapour density: Not determined.
    - Evaporation rate: Not determined.
    - Solubility in / Miscibility with water: Nearly insoluble.
    - Partition coefficient: n-octanol/water: Not determined.
    - Viscosity:
      - Dynamic: Not determined.
      - Kinematic: Not determined.
  - 9.2 Other information
    - No further relevant information available.

SECTION 10: Stability and reactivity

- 10.1 Reactivity
  - No further relevant information available.
- 10.2 Chemical stability
  - Stable under normal handling and storage conditions.
- 10.3 Possibility of hazardous reactions
  - No decomposition if used according to specifications.
- 10.4 Conditions to avoid
  - Keep away from heat and direct sunlight.
- 10.5 Incompatible materials
  - No further relevant information available.
- 10.6 Hazardous decomposition products
  - None under normal conditions of storage and use.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity
    - Based on available data, the classification criteria are not met.
SECTION 12: Ecological information

- 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:
    Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
    Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
  - 12.5 Results of PBT and vPvB assessment
    - PBT: Not applicable.
    - vPvB: Not applicable.
  - 12.6 Other adverse effects: No further relevant information available.

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods
  - Recommendation
    Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
  - Uncleaned packaging:
    - Recommendation: Disposal must be made according to official regulations.
    - Recommended cleansing agents: Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR/RID/ADN, ADN, IMDG, IATA: Void
- 14.2 UN proper shipping name
  - ADR/RID/ADN, ADN, IMDG, IATA: Void
- 14.3 Transport hazard class(es)
  - ADR/RID/ADN, ADN, IMDG, IATA: Void
Safety data sheet
according to 1907/2006/EC, Article 31

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- **14.4 Packing group**
  - ADR/RID/ADN, 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.

- **Transport/Additional information:**
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

- **UN "Model Regulation":**
  - Void

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - Directive 2012/18/EU
  - Named dangerous substances - ANNEX I None of the ingredients is listed.
  - REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

- **National regulations:**
  - Other regulations, limitations and prohibitive regulations
    - The product is a medical device according to the Directive 93/42/EEC.

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

**SECTION 16: Other information**

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.

- **Relevant phrases**
  - H315 Causes skin irritation.
  - H317 May cause an allergic skin reaction.
  - H319 Causes serious eye irritation.

- **Classification according to Regulation (EC) No 1272/2008**
  - The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

- **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)
  - vPvB: very Persistent and very Bioaccumulative
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  - Skin Sens. 1: Skin sensitisation – Category 1