



603 B Country Club Drive
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Tel: 800-846-7120
www.AmDental.com

AMERICAN DENTAL PRODUCTS' DENTIN DESENSITIZER SYSTEM (DDS) WITH FLUORIDE

INDICATIONS FOR USE:

General Information: DDS is an aqueous solution which has no photo initiators in it. Therefore it cannot be light cure. DDS is just a desensitizer, not a primer or of adhesion composition. DDS is recommended to be applied to virtually all teeth where dentin is involved placing 2-3 drops on a wet toothbrush. It can be used effectively when applied independently in such cases as conventional amalgams, on crown preps before temporizing, and on areas of cervical sensitivity. When used in conjunction with bonding adhesive systems and C&B luting agents. It is always recommended to follow manufacturer's instructions.

DDS is not a primer, but only an adjunct to help eliminate post-operative sensitivity. DDS contains fluoride and glutaraldehyde, both strong antimicrobial ingredients. At the IADR meeting in 1997, it was revealed that the dry dentin will result in a collapse of the collagen and reduce bond strength. Most dentin bonding systems are hydrophilic and work better in conjunction with moist dentin. DDS is a water solution of well proportionated hydrophilic and hydrophobic composition which will penetrate the collagen and react with it and proteins of the odontoblastic processes eliminating sensitivity. It may be applied to all prepared cavity preps dentin and enamel without removing the smear layer. Glutaraldehyde which is present in DDS reacts with proteins in the tubules, controlling fluid movement. DDS with fluoride should be used to treat sensitive teeth.

1. **COMPOSITE RESTAURATIONS:** most problems occur in posterior restorations, especially Class I and II. The main problems are bulk filling resulting in an exothermic reaction and polymerization shrinkage stress. Placing smaller increments (1.5 mm) is extremely beneficial. Also involving only one wall of the prep at a time helps eliminate pulling on the cusps. Another possible problem is an inadequate curing light with poor polymerization deep in the proximal box. Curing lights should be tested on a routine basis. One of the best methods for posterior composites is using a self-cure composite to cover all dentin followed by a light cure composite. DDS dramatically helps these situations but refining your technique can be a tremendous benefit.
Bonding composites-total etch prep for the appropriate time. After rinsing, partially dry but never desiccate. The dentin should appear slightly moist, then apply 1 generous coat of DDS after etching and before priming. Leaving DDS on the prep for 15 or 20 seconds before applying bonding agents will help elevate the collapsed dentin and facilitate better bonding. All 4th and 5th generation bonding agents work better on a moist tooth. Gently air drying of dentin primers followed by more forceful blasts of air are critical to successful bonding and eliminating sensitivity.
2. **Amalgams:**
 - a. Conventional alloys-apply 2-3 coats of DDS drying between coats. DDS replaces copal varnish and/or Dycal.
 - b. Bonded alloy- If a bonding system is used, follow the basic composite bonding technique of etching, moistening the prep with DDS, and then apply primers and S/C resins.
3. **CROWN AND BRIDGE:**
 - a. Using a glass ionomer cement-since glass ionomer cements are hygroscopic, their use has often resulted in post-operative sensitivity due to the fact that dentinal fluid is being "sucked" out of the



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tubules. By using DDS to moisten the crown prep before cementation, this problem can be eliminated. Note: seating crown should be done with passive pressure not using bite sticks.

- b. Applying DDS before temporizing – this is an excellent technique to keep patient comfortable before cementation of their permanent crowns. Etching is not required, just apply 2 coats of DDS, drying between coats, then cement temporaries.
- c. Conventional cements (zinc phosphate and polycarbonates) – for these cements 2 coats of DDS should be applied and dried before cementation.
- d. Resin cements – when used in conjunction with dentin bonding systems, apply DDS after etching and before priming.

4. CERVICAL SENSITIVITY:

- PUMICE prep, blot gently with a cotton pellet to dry root surface.
- Apply DDS rubbing gently into the area for 10-15 seconds and then gently dry for 10 seconds
- Reapply additional 2-3 coats.

Note: No etching of root surface is necessary unless a bonded restoration is being placed. Careful application near the gingiva is recommended because on occasion, DDS can cause localized tissue irritation to people that are specific sensitive to the ingredients listed..

STORAGE AND HANDLING:

DDS Desensitizer with fluoride is designated to be used at room temperature (70-75°F or 20-25°C). Shelf life is 10 years for refrigerated kits. The product should be refrigerated until opened, special for hot area states. Bring to room temperature and shake for 10 seconds before use, and you do not need to place in refrigerator again if the temperature is about 20-25°C or about 68-77°F

WARNING AND PRECAUTIONS:

Avoid contact with eyes, skin and mucous membranes, DDS contains glutaraldehyde that in high concentration and standing a long time without washing with plenty of water might be harmful to the eyes and can cause blindness. We never ever had any report to be harmful, hazardous to eyes in about 20 million applications in dental offices. In case of contact, flush eyes immediately with plenty of water several time and see a physician immediately.

For professional use by dental professional only. Keep away from children!

US Federal Law restricts this device to sale by or on the order of a dentist or dental practitioner. DDS was designed and manufactured by American Dental Products Inc. owned by Dr. George Nicolae, a PhD chemist with more than 50 years' experience in scientific research.

Here is the new format of MSDS, renamed as SDS (Safety Data Sheet), easy to download:

<http://www.amdental.com/documents/ddssds.pdf>

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SAFETY DATA SHEET according with OSHA HCS

AMERICAN DENTAL PRODUCTS DENTIN DESENSITIZING SYSTEM WITH FLUORIDE

Revision date: 04/19/2017

Version 5.1

Printing date: 04/19/2017

1. Identification

Product identifier used on the label

AMERICAN DENTAL PRODUCTS DENTIN DESENSITIZING SYSTEM WITH FLUORIDE

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

Recommended use of the medical device and restriction on use.

Recommended use for medical device by the professional licensed dentists according with Indication for use (instructions for use).

Details of the supplier of the safety data sheet.

Do not use on patients that are specific sensitive to any of the ingredients of the mixtures.

Manufacturer:

Company:

American Dental Products Inc.

603 B Country Club Drive

Bensenville, IL 60106-1329, USA

Information Department: George Nicolae, PhD

E-mail: George@amdental.com Telephone: +1-630-337-5100

Emergency telephone number: 1-800-846-7120 or +1-630-337-5100 ; 1-630-DDS-5100

INFOTRAC EMERGENCY TELEPHONE NUMBER: 1-800-535-5053

Supplier (Distributed by): AMERICAN DENTAL PRODUCTS DENTAL INC.

Other means of identification:

Molecular formula: Mixture of water solution of di-aldehydes and sodium fluoride, may contain poly-acrylic acid that were used in the dental industry for more than 30 years

Chemical family: Di-aldehydes, aqueous solution

Synonyms: Desensitizers used in the dental industry for more than 30 years.

2. Hazard Identification

According to Hazardous Products Regulations (HPR) (SOR/2015-17)

Classification of the product

Met. Corr. 0 Very light Corrosive to metals only if prolonged contact

Acute Tox. 1 (oral) If used in large quantity only

Acute Tox. 1(inhalation) Dentists are using only a few drops for one patient. H334 only for large (55+ gallons) quantities of raw material. If used in large quantities.

Skin Corr./Irrit. 1B H315 Dentists are using gloves anyway by professional regulation. Used in the mouth on the teeth and soft tissues for about 20 million applications for the almost 20 years, never reported a case of an irritation on the soft tissue in the mouth by the dentists. Wash bared hands with plenty with water. A vinegar salad served at restaurant or home is much stronger irritant than the desensitizer that is milder than carbonated juice or carbonated water.

Eyed Dam./Irrit. 1 H318 Serious eye damage/eye irritation for concentrated raw material. If accidental comes in the eyes, wash immediately with plenty of water and see immediately a doctor. The desensitizer is designed to use in the mouth NOT in the eyes.

Resp. Sens. 1 Respiratory sensitization never reported in more than 20 million application used in almost 20 years of successfully use. If a person is specifically sensitive to this product, than do not use on him or her.

Skin Sens. 1 1B H317 Dentists are using gloves anyway by professional regulation. Used in the mouth for more than 20 million applications for the almost 20 years, never reported an irritation on the soft issue in the mouth by the dentists. Wash bared hands with plenty with water it is recommended any way by professional regulations.

Aquatic Acute 1 Hazardous to the aquatic environment- acute for large quantities in high concentration.

Aquatic Chronic 1 Hazardous to the aquatic environment –chronic for large quantities in high concentration.

Label elements

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



GHS 05



GHS 08

· Signal word *Danger*

· Hazard-determining components of labeling: For concentrated raw materials.

Glutaraldehyde modified

Sodium Fluoride

· Hazard statements

Causes skin irritation by high concentrated raw materials. Never ever reported skin irritation.

Causes serious eye damage by high concentrated raw materials. Never ever reported any eyes damage or irritation by DDS.

May cause allergy or asthma symptoms or breathing difficulties if inhaled high volume.

May cause an allergic skin reaction by the high concentrated raw materials.

· Precautionary statements

In case of inadequate ventilation wear respiratory protection if handle very large quantities.

Avoid breathing dust/fume/gas/mist/vapors/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

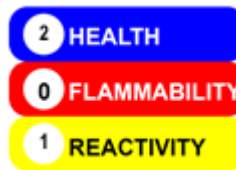
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. See immediately a physician.

Specific treatment (see on this label).

Dispose of contents/container in accordance with local/regional/national/international regulations.

Classification system

- **NFPA ratings for USA (scale 0-4) HMIS-Ratings (Scale 0-4)**



- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3. Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description: -**

- **Dangerous components (only if are concentrated):**

111-30-8	glutaraldehyde modified diluted	less than 10%
7681-49-4	Sodium Fluoride (water solution)	less than 5%

4. FIRST AID MEASURES:

Description of first aid measures

- **General information**

Symptoms of poisoning may even occur after several hours after handling very large quantities; therefore medical observation for at least 48 hours after the accident.

- **After skin contact** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact**

Rinse opened eye for several minutes with running water. Then consult immediately a doctor.

- **After swallowing large quantities** Immediately call a doctor.

- **Most important symptoms and effects, both acute and delayed**

No further relevant information available.

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5. Fire-fighting measures

- **Extinguishing**

The desensitizer by itself it is not flammable and would not burn.

Extinguishing media

- **Suitable extinguishing agents**

CO2, extinguishing powder or water spray. Fight larger fires with water spray or foam.

- **Special hazards arising from the substance or mixture in large quantities**

Formation of toxic gases is possible during heating or in case of fire.

- **Advice for firefighters**

*· **Protective equipment:** Mount respiratory protective autonomy device for any fire where are involved other chemicals.*

- **Additional information –**

6. Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** *Not required.*

- **Environmental precautions:** *No special measures required.*

- **Methods and material for containment and cleaning up:**

Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).

Dispose contaminated material as waste according to item 13.

Send for recovery or disposal in suitable receptacles.

- **Reference to other sections**

See Section 13 for disposal information.

See Section 8 for information on personal protection equipment.

7. Handling and storage

- **Precautions for safe handling**

Keep receptacles tightly sealed.

Wear protective equipment. Keep unprotected persons away.

Ensure good ventilation/exhaustion at the workplace if handle large quantities.

- **Information about protection against explosions and fires:** *No special measures required.*

- **Conditions for safe storage, including any incompatibilities.**

Storage

- **Requirements to be met by storerooms and receptacles:** *No special requirements.*

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

- **Further information about storage conditions:** *None.*

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

8. Exposure controls/personal protection

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

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

111-30-8 glutaraldehyde if handling large quantities

REL () Short-term value: C 0.8 mg/m³, C 0.2 ppm

TLV () Short-term value: C 0.2 mg/m³, C 0.05 ppm

SEN

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

· **Breathing equipment:**

Not necessary with efficient local exhaust if used in large quantities. If exposure to vapors from large quantities is possible, use breathing protective mask (filter A).

· **Protection of hands:**

If skin contact cannot be avoided, protective solvent resistant gloves are recommended to avoid possible sensitization.

Selection of the glove material has to be impermeable and resistant to the product, the substances, the preparation and in consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **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.

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Butyl rubber, BR

· **Eye protection:**

Before use, put on the protective goggles and cover the patient's eyes to protect against splashes of material. Wash with plain water will remove any irritation.

· **Body protection:** Light weight protective clothing

Highly trained educated professional chemists would know the best exactly if they need any of this kind of protection during the manufacture of the Desensitizer up to 55 gallons.

9. Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

· **Form:** Fluid

· **Color:** Colorless or slight yellow

· **Odor:** light specific

· **pH-value at 20 °C (68 °F):** Acid less than 5-6

· Change in condition

· **Melting point/Melting range:** undetermined

· **Boiling point/Boiling range:** 100 °C (212 °F)

· **Flash point:** Not applicable

· **Ignition temperature:** Not applicable

· **Auto igniting:** Product is not self-igniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Vapor pressure at 20 °C (68 °F):** Approx. 17 torr

· **Density at 20 °C (68 °F):** 1.01 g/cm³ (8.36 lbs/gal)

· Solubility in / Miscibility with

· **Water:** Miscible in any proportion

· **Water:**

· **Other information** No further relevant information available.

Possibility of hazardous reactions No dangerous reactions known

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** none

10 Stability and reactivity

· **Possibility of hazardous reactions** No dangerous reactions known

· **Conditions to avoid** No further relevant information available.

· **Incompatible materials:** No further relevant information available.

· **Hazardous decomposition products:** none

11 Toxicological information

· Information on toxicological effects

· Acute toxicity:

· **LD/LC50 values that are relevant for classification:**

Oral LD50 > 2000 mg/kg (rat)

· Primary irritant effect:

· **on the skin:** Irritant to skin and mucous membranes for specific sensitive people.

· **on the eye:** Strong irritant with the danger of severe eye injury for concentrated ingredients.

· **Sensitization:**

Sensitization possible through inhalation of large quantities.

Sensitization possible through skin contact for long time for specific sensitive people.

· **Additional toxicological information: For concentrated raw materials**

Harmful

Irritant

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12. Ecological information

· **Toxicity**

· **Aquatic toxicity:** No further relevant information available.

· **Persistence and degradability** No further relevant information available.

· **Bio accumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Additional ecological information:**

· **General notes:**

Do not allow large quantities of product to reach ground water, water course.

Danger to drinking water leak large quantities into the ground.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Other adverse effects** No further relevant

13 Disposal considerations

· **Waste treatment methods**

· **Recommendation:** it is expected to be auto-neutralized by the sewage system

14. Transport information

· **UN-Number**

· **DOT, ADR, ADN, IMDG, IATA** Void

· **UN proper shipping name**

- **DOT, ADR, ADN, IMDG, IATA Void**
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class Void**
- **Packing group**
- **DOT, ADR, IMDG, IATA Void**
- **Environmental hazards:**
- **Marine pollutant: No**
- **Special precautions for user** Not applicable for small packages in small plastic bottles designed to be in the patients' mouth.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **Transport/Additional information: -**
- **UN "Model Regulation":**

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **SARA Section 355 (extremely hazardous substances)**
None of the ingredients is listed.
- **Carcinogenicity categories**
- **TLV (Threshold Limit Value established by ACGIH)**
111-30-8 glutaraldehyde A4 concentrated ingredients
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms For starting concentrated raw materials**



GHS 05



GHS08

- **Signal word** Danger
- **Hazard-determining components of labeling:**
Glutaraldehyde in high concentration
- **Hazard statements**
Causes skin irritation for specific sensitive people. Never ever reported from DDS
Causes serious eye damage for long time contact of high concentration of raw materials, and not washed with plain water. Never ever reported any damage of eyes due from DDS.
May cause allergy or asthma symptoms or breathing difficulties if inhaled large quantities.
May cause an allergic skin reaction from high concentration of raw materials.

· **Precautionary statements**

In case of inadequate ventilation wear respiratory protection if used in large quantities.

Avoid breathing dust/fume/gas/mist/vapors/spray.

Wear protective gloves/protective clothing/eye protection/face protection if use large quantities. Highly skilled professional chemists would know the best if they need any special means of protections when handling such mixtures.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Specific treatment (see on this label).

Dispose of contents/container in accordance with local/regional/national/international regulations.

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

16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 21/01/2016 / -

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

*** Data compared to the previous version altered.**