Systemp.® desensitizer

Scientific Documentation

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1. Introduction

1.2 What is dentine hypersensitivity?

Patients suffering from hypersensitivity of dentin experience short periods of severe pain triggered by certain types of stimuli. Among such stimuli are physical contact (tactile stimulation), heat or cold (thermal stimulation), contact with osmotically active solutions (e.g. concentrated sugar solutions) or the evaporation of fluid from the dentin surface (Dababneh et al, 1999). The pain usually subsides soon after the stimulus disappears. It is therefore important not to confuse hypersensitivity of dentin with persistent tooth ache, which is usually related to a pathological state of the tooth structure.

1.3 Who is affected?

Depending on the study set-up, it was found that between 5 – 57% of the adult population suffer from hypersensitivity in one way or another (Dababneh et al, 1999). Hypersensitivity of dentin certainly presents a problem for the patient in her/his daily life and for the dentist during dental treatment. We all know the unpleasant sting we experience when our dentist starts rinsing our teeth with cold water or applies air to dry them. The dentin may even remain hypersensitive after new restorations have been placed or indirect restorations incorporated. In daily life, hypersensitivity may occur during the consumption of cold drinks, while eating ice cream, when rinsing the mouth after cleaning teeth, inhaling cold air through the mouth or when eating chocolate.

1.4 How does this type of pain develop? The hydrodynamic theory

The findings of state-of-the art scientific research suggest that hypersensitivity is caused by sudden movements of fluid within the dentinal tubules.

It was mainly Martin Brännström and his co-workers who analyzed the hydrodynamic theory in detail (Brännström et al., 1979; Brännström, 1986). The theory is based on the observation that all stimuli known to provoke dentinal pain accelerate the flow of the dentinal fluid within the tubules. (Brännström et al., 1979).

Fluid movements, for example, are triggered by

- touching dentin with filtering paper,
- applying air to evaporate fluid from the dentinal surface,
- dry heat,
- cold
- covering dentin with osmotically active substances such as calcium chloride or sugar solutions

Examinations with the scanning electron microscope show that nerve fibres and odontoblasts are drawn into the dentinal tubules when dentin has been dried for a long time. The nerve fibres are torn apart and traces of them found in the tubules down to a depth of 200 µm (Brännström, 1986). We can easily imagine that such a process is capable of producing sudden, severe attacks of pain.

Fluid movements involving the pulp, which are induced by stimuli applied to the dentinal surface, will only occur when the tubules are open from the pulp to the surface. This has been confirmed in comparative studies of hypersensitive and non-sensitive dentin. (Absi et al., 1987). SEM images of cervical wear demonstrated that the diameters of tubule apertures in sensitive dentin measured approx. 0.83±0.38 µm, while in non-sensitive dentin they measured approx. 0.43±0.2 µm. In addition, hyersensitive dentin was found to possess 8 times more tubule openings per unit area than non-sensistive dentin (Absi et al., 1987), which makes it much easier to penetrate. Bacteria and their

toxins may easily gain access to the pulp and cause inflammation (Brännström, 1986), a factor that can considerably lower the threshold value for a stimulus that produces dentinal pain.

1.5 How can patients be given relief?

Careful diagnosis is essential when trying to help patients with hypersensitivity. Cusp or tooth fractures, restoration fractures, pulp reactions due to caries or as a result of preceding restorative procedures can cause pain that may be confused with hypersensitivity of dentin (Dowell, et al., 1985). The problem will disappear after repairing the defect in most cases. Treatment involving mechanical sealing of dentinal tubules is indicated if no such clinical reason for hypersensitivity can be found. In the past, mainly cavity varnish was used for this purpose. Desensitizers specifically developed for this indication have been introduced in recent years.

1.6 The product: Systemp.desensitizer

Systemp.desensitizer is suitable for dentin desensitization. It can be applied for

- desensitization of dentin after preparation procedures, while the temporary restoration is in place
- desensitization of dentin before indirect restorations are incorporated
- desensitization and rewetting of dentin prior to the application of adhesives
- treatment of exposed tooth necks

System.desensitizer is a new development based on the Syntac System, a product which was very successful clinically and whose success rate in reducing the incidence of post-operative pain was exceptionally high (Cox and O'Neal, 1994).

2. Technical Data

Standard – Composition:	
Polyethylene glycol dimethacrylate	35.0
Maleic acid	< 0.01
Glutaraldehyde (50 %)	10.0
Water	55.0

(in wt.%)

3. How does Systemp.desensitizer work?

3.1 Introduction

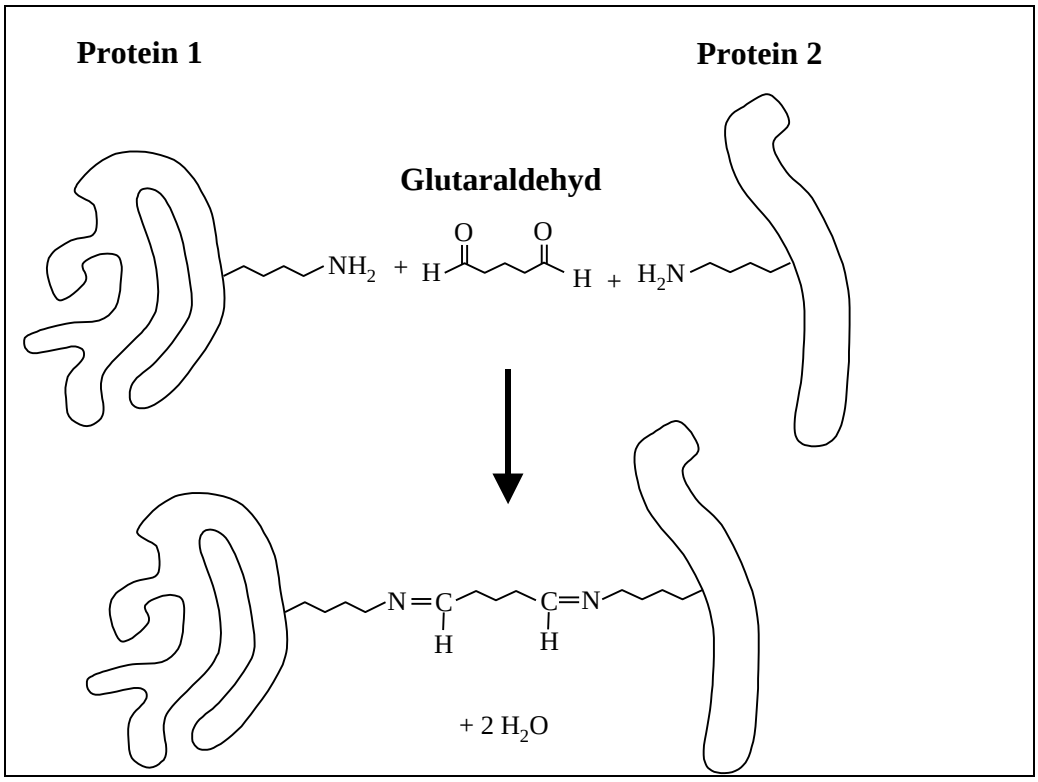
Systemp.desensitizer reduces hypersensitivity of dentin by sealing the dentinal tubules. The desensitizing effect is obtained thanks to two essential components: polyethylene glycol dimethacrylate (PEG-DMA) and glutaraldehyde. Their combined effectiveness ensures optimal sealing of the tubules.

3.2 Polyethylene glycol dimethacrylate

In biochemistry, it is a well-known fact that organic solvents can be used to promote the precipitation of proteins. Mainly acetone, ethanol und polyethylene glycol are used. If increasing amounts of polyethylene glycol are added to protein solutions such as blood plasma, the solubility of proteins will be reduced and some of the proteins will begin to precipitate (Ingham, 1990). To give you an idea of what happens during precipation, imagine a process during which lumps form. We may thus deduce that the polyethylene glycol dimethacrylate in Systemp.desensitizer will also trigger the precipitation of plasma proteins in the dentinal tubules.

3.3 Glutaraldehyde

Glutaraldehyde is a cross-linking reagent capable of bonding to amine groups of proteins. Figure 3.1 illustrates how glutaraldehyde forms covalent bonds to two proteins. In this way, highly cross-linked, insoluble protein aggregates are formed (Faber, 1995).



Diagrammatic representation of two proteins cross-linked by glutaraldehyde. The amine groups of lysyl residues bond to glutaraldehyde.

Even glutaraldehyde alone could seal dentin. In a study on permeability, root dentin was examined. Radiolabeled glutaraldehyde was placed in freshly extracted teeth and its diffusion towards the exterior was measured. Within 72 hours, no diffusion of glutaraldehyde towards the exterior could be observed. In contrast to these findings, Formocresol, a substance used for comparison in the same test procedure, quickly diffused towards the exterior. If the root canal was rinsed with a glutaraldehyde solution prior to the application of Formocresol, diffusion was avoided as well (Wemes et. al. 1982).

SEM analyses also demonstrated that a 2%-glutaraldehyde solution is capable of fixing the smear layer on prepared dentin. While some open tubules were visible on SEM images of untreated dentin, they remained sealed after the pretreatment with glutaraldehyde (2.%). While etching of untreated dentin with the complexing agent EDTA (ethylenediamine tetraacetic acid) completely removed the smear layer and opened the tubules, the same procedure, when applied on dentin that had been treated with glutaraldehyde, only partially opened the tubules (Dijkman et al., 1994).

3.4 The combination of PEG-DMA and glutaraldehyde and their effect

The studies indicated above show that glutaraldehyde reduces the permeability of dentinal tubules. The combination of polyethylene glycol dimethacrylate, which precipitates proteins and thus leads to local concentrations, and glutaraldehyde, which establishes stable, covalent bonds to proteins, results in the formation of firm plugs of protein that seal the tubules. These plugs considerably reduce permeability and the incidence of dentinal sensitivity.

In a simple *in vitro* experiment, Systemp.desensitizer was shown to precipitate serum proteins. In this experiment, 1 mL of horse serum was mixed with 200 µL of desensitizer preparations of different manufacturers in a centrifuge tube. The precipitated proteins were subsequently separated by centrifuging, dried and weighed. The following table shows the weight of the protein precipitates.

Product	**Manufacturer**	**Precipitate (mg)**
Systemp.desensitizer	Ivoclar Vivadent	91
Gluma Desensitizer	Heraeus Kulzer	85
SuperSeal	Phoenix Dental	0.2
Health-Dent Desensitizer	Healthdent	8
HurrySeal	Beutlich Pharmaceutical	6
MicroPrime	Danville Materials	7
Sensodyne Desensitizer	Block Drug Co.	27
MS Coat	Sun Medical	8
D/sense	Centrix	10
Hemaseal & Cide	Advantage Dental Products	21

Internal investigation, R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

The results show that Systemp.desensitizer and Gluma Desensitizer are the only products that are capable of precipitating large amounts of protein from horse serum. This information indicates that Systemp.desensitizer and Gluma Desensitizer relieve postoperative pain in similar ways.

4. In vitro tests with Systemp.desensitizer

4.1 Sealing of dentinal tubules

Systemp.desensitizer needs to penetrate dentinal tubules in order to seal them properly. The dentist may decide to use Systemp.desensitizer either before or after etching the dentin. In both cases, it is essential that enough active ingredient penentrate the tubules. Freshly extracted teeth were used to test this in vitro.

Test set-up: The pulp was removed from freshly extracted teeth. Subsequently, the teeth were attached apically to an apparatus simulating natural pulp pressure by means of horse serum. The next step was to reduce the buccal cusps to expose dentin surfaces large enough for the intended purpose. The test specimens were then divided into two groups and treated with Systemp.desensitizer in the following manner:

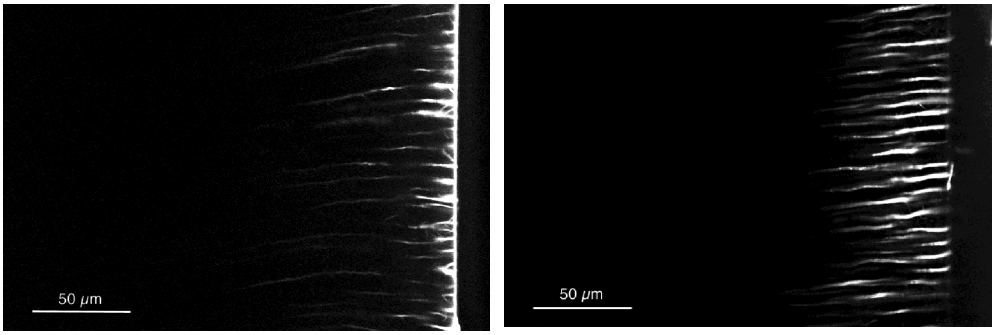
Group 1 smear layer left untreated. Systemp.desensitizer was brushed into the dentin for 10 sec and carefully dried with the air gun for 20 sec. This type of treatment is recommended in the case of sensitive tooth necks.

Group 2 etched dentin. The dentin was etched for 15 sec using Email Preparator, rinsed and dried slightly. Subsequently, Systemp. desensitizer was applied as indicated above.

The test specimens were then analyzed using confocal laser microscopy.

The figures below show images of dentin after having been treated with Systemp.desensitizer. Systemp.desensitizer is able to infiltrate prepared, unetched dentin down to a depth of approx. 10-25 µm, forming tags. The smear layer is fixed at the same time. Systemp.desensitizer is able to penetrate into the tubules twice as deeply, forming both lamellas and tags, if the dentin is etched prior to its application. Even when subjected to artificial pulp pressure for 48 hours, the fluorescent tags are not extruded.

Without etching: Etched:



Confocal laser micrograph of dentin treated with Systemp.desensitizer. Systemp.desensitizer was mixed with 0.1% of the fluorescent dye rhodamine. Above: unetched dentin with smear layer, below: etched dentin without smear layer. Picture: Dr. Peter Schüpbach, Microphot, Horgen, Switzerland.

Conclusion: The results show that Systemp.desensitizer firmly seals etched as well as unetched dentin.

4.2 Bonding values when used with dentin adhesives – application as a rewetting agent

If dentin is desensitized before the adhesive cementation of direct and indirect restorations, the desensitizer must not impair the bond strength of the dentin adhesive. For this purpose, Systemp.desensitizer was tested with Excite/Tetric Ceram (Ivoclar Vivadent), Prime & Bond NT/TPH (Dentsply) and Optibond Solo Plus/Point 4 (Kerr).

Investigator: Prof. Dr. Steven E. Duke
Indiana School of Dentistry, Dept. of Restorative Dentistry, Indianapolis, USA

Test set-up: Shear bond strengths were measured when the dentin adhesive was used with and without Systemp.desensitizer. Twelve measurements were taken for each test group.

Control 1: The dentin adhesive was used according to the instructions and the principles of **wet bonding**.

Control 2: The dentin adhesive was used according to the instructions. However, the dentin was thoroughly dried after the etchant was rinsed off (**dry bonding**).

Test group: Following the etching, rinsing and drying of the prepared dentin, Systemp.**desensitizer** was applied. Subsequently, the adhesive was used.

Results:

Adhesive	Group	Bonding value	Type of failure	
		MPa	Cohesive	Adhesive
Excite	Wet Bonding	13.8 ± 1.6	12	0
	Dry Bonding	10.5 ± 2.0	12	0
	Desensitizer	13.0 ± 1.2	12	0
P&B NT	Wet Bonding	12.2 ± 1.3	5	7
	Dry Bonding	10.1 ± 2.6	1	11
	Desensitizer	13.1 ± 2.2	3	9
Optibond SP	Wet Bonding	10.8 ± 1.7	12	0
	Dry Bonding	11.5 ± 1.5	12	0
	Desensitizer	11.4 ± 1.6	12	0

Conclusion: Systemp.desensitzier does not impair the dentin bond strength in the least when it is used together with Excite, P&B NT and Optibond Solo Plus.

The table also shows that in cases where overdrying of the dentin has led to a reduction in the bonding strength, Systemp.desensitizer functions as a rewetting agent. Systemp.desensitizer therefore is capable of restoring the optimal moisture content in the etched dentin surface and loosening the collapsed collagen fibres. Thus the adhesive, which is applied later, can optimally permeate the exposed collagen network.

4.3 Application sequence in conjunction with dentin adhesives

Most dental professionals will want to know if they can safely introduce a desensitizing step between the etching and bonding procedure when using a one-bottle adhesive or if they should rather apply the desensitizer prior to etching in order to avoid influencing the bonding procedure. To answer this question, the bonding values of Excite adhesive were investigated as a function of the application sequence.

Investigator: Applied Testing Laboratory, Ivoclar North America Inc.

Results:

Sequence	**Bonding value (MPa)**
Etching-Excite (control)	24.1 ± 4.7
Etching-Desensitizer-Excite (as indicated)	31.6 ± 10.5
Desensitizer-Etching-Excite	19.8 ± 4.4

Conclusion: If Systemp.desensitizer is applied after etching, the bond strength of Excite tends to increase, while it decreases if the desensitizer is applied before the etching procedure. This reaction may be attributed to the fact that glutaraldehyde is capable of fixing the smear layer of prepared dentin (Dijkman et al., 1994), which impairs the etchability of dentin.

4.4 Compatibility with temporary and permanent dental restoratives

Since Systemp.desensitizer is often used in conjunction with other temporary and permanent dental restoratives, we had to ascertain that Systemp.desensitizer is compatible with these materials and does not cause unintended adherence of temporaries or affect the retention of permanent cements.

Investigators: Dr. Roland Frankenberger
Friedrich-Alexander – University of Erlangen-Nuremberg, Germany

Test set-up: The coronal part of freshly extracted third molars was cut into sections with a circumferential enamel border. Tapered finishing diamonds were used to prepare cavities in the center of the sections. The test specimens were then positioned in a holding device and attached using self-curing resin. The cavities were pretreated as shown and filled with temporary restorative material. After one week’s immersion in water, the bond strength of the temporary restorative material in the cone-shaped cavity was determined by subjecting the test specimen to an extrusion test. After that, the same cavities were filled with permanent restorative material as described in table 4.1. The test specimen were immersed in water for another week and the bond strength was measured again by means of extrusion tests.

Results:

experiments	group 1	control	group 2	control	group 3	control
treatment	S.des.	none	S.des.	none	S.des.	none
temporary	Provilink		Systemp.inlay		Tempbond	
incubation	Immersion in water for 7 days					
1st mmt	**2.4 ± 0.8**	**2.8 ± 0.8**	**3.2 ± 1.0**	**2.5 ± 1.1**	**3.1 ± 0.9**	**3.5 ± 1.7**
treatment	none	none	S.des.	none	S.des.	none
cementation	Excite		Harvard cement		Ketac Cem	
restoration	Variolink		gold		gold	
incubation	Immersion in water for 7 days					
2nd mmt	**15 ± 3**	**14 ± 2**	**5.2 ± 1.3**	**5.4 ± 1.4**	**6.8 ± 1.9**	**7.3 ± 1.5**

Bond strength of temporary and permanent dental restoratives to dentin measured with the extrusion test method. S.des.= Systemp.desensitizer.

Conclusion: Test results demonstrate that pretreatment of dentin with Systemp.desensitizer will neither reduce nor increase adhesion to dentin to any significant degree.

5. Clinical studies

Systemp.desensitizer is specifically indicated for desensitizing freshly prepared dentin. Since weeks or months may pass before a permanent restoration can be fabricated, tried in and finally incorporated, dentin may often be protected insufficiently by temporary cements, filling materials or restorations. It is one of the characteristics of temporary materials that they do not provide strong adhesion, since they have to be removed again. Therefore, ingress of microorganisms into freshly prepared dentin, which may lead to pulp reaction, cannot always been excluded. A desensitizer such as Systemp.desensitizer, which mechanically seals dentinal tubules, can provide additional protection. The clinical effectiveness of Systemp.desensitizer has been tested.

5.1 Desensitization during temporary procedures

The desensitizing effect of Systemp.desensitizer on tooth stumps was examined while the temporary restoration was in place and after permanent cementation of the final restoration.

Investigator: Dr. Carlo Pati, University of Bologna, Italy

Test set-up: After the administration of a local anesthetic, shoulder preparations for crowns were performed. Systemp.desensitizer was applied to the dentin of the test group before the temporary crowns were bonded using TempBond NE (Kerr) and once again before the permanent crown was cemented. The control group did not receive treatment with Systemp.desensitizer. No anesthetic was used during the final cementation of the permanent restoration. Patients themselves were asked to indicate the extent of post-operative pain with the help of a “visual analog scale” (VAS). The scale grades pain from 0 to 100, with 0 being no pain at all and 100 very severe pain. Post-operative pain was either stimulated by air-drying or eating ice-cream. Post-operative sensitivity was measured

1. after removing the temporary crown when the fit of the permanent crown was checked
2. after removing the temporary crown before the final restoration was cemented
3. immediately after cementation of the final restoration
4. one day after the final restoration had been incorporated
5. seven days after the final restoration had been incorporated

Results:

Group (N)	1	2	3	4	5
Test	Air gun	Air gun	Air gun	Ice-cream	Ice-cream
S.des. (18)	28 ± 17	50 ± 9	14 ± 3	7 ± 5	7 ± 3
Control (14)	65.9 ± 25	57 ± 7	7 ± 10	4 ± 0	0 ± 0

Post-operative pain experienced after crown preparation and cementing of permanent crowns. The severity of the pain was determined by means of a “Visual Analog Scale” ranging from **no pain** (0) to very severe pain (100). Values below 30 indicate that the patient feels the restoration but does not feel pain.

Conclusion: In the temporary phase (1st measurement), Systemp.desensitizer reduces post-operative pain by half. If the temporary crown has to be cemented again after checking the fit of the final restoration, a second application of Systemp.desensitizer is required to prevent post-operative pain in the period that follows until the permanent restoration is incorporated. Post-operative pain did not occur either in the test group or in the control group during final cementation.

5.2 Desensitization of onlay preparations

Systemp.desensitizer is indicated to reduce pain while temporary restorations are in place. Therefore, it is specially recommended for use with the provisional restorative materials Systemp.inlay and Systemp.onlay. For this purpose, the desensitizing action of Systemp.desensitizer was tested in conjunction with Systemp.onlay.

Investigator: Dr. Carlo Pati, University of Bologna, Italy

Test set-up: In the study, in which 22 people participated, two teeth per patient were prepared to receive onlays under local anaesthesia. According to the split mouth principle Systemp.desensitizer was applied to the dentin of the test teeth while the application of Systemp.desensitizer was omitted in control teeth. Then both, test and control teeth were temporarily restored with Systemp.onlay. Patients were asked to quantify the pain they were experiencing at different times. These recordings were conducted in the dental practice (clinical test with cold air) as well as by the patients themselves at home (drinking refrigerated water). The pain was recorded with the help of a visual analog scale, which grades pain from 0 (no pain) to 100 (severe pain). When the permanent restoration was placed, Systemp.desensitizer was used on the test group again, while it was omitted on the control group. The results were statistically evaluated with the Student T Test.

Results: Sensitivity to air (conducted in the clinic)

Time	**Desensitizer**	**Control**	**Statistics**
1 day after preparation	55± 12	78 ± 7	$p < 0.05$
1 day after the placement of the permanent restoration	23 ± 6	44 ± 12	$p < 0.01$
1 week after the placement of the permanent restoration	25 ± 9	39 ± 8	$p < 0.06$

Evaluation of sensitivity to cold water recorded by the patient at home

Time	**Desensitizer**	**Control**	**Statistics**
1 day after preparation	16 ± 5	30 ± 10	$p < 0.01$
Temporary phase	15 ± 7	25 ± 70	$p < 0.01$
1 day after the placement of the permanent restoration	6 ± 5	16 ± 9	$p < 0.005$
1 week after the placement of the permanent restoration	3 ± 2	15 ± 13	$p < 0.001$

Conclusion: During the temporary phase as well as during the period immediately following the placement of the permanent restoration, Systemp.desensitizer reduces post-operative pain by half. The differences are statistically significant.

6. Toxicology

6.1 Introduction

Systemp.desensitizer consists of 5% glutaraldehyde and 35% polyethylene glycol dimethacrylate in an aqueous solution. Depending on the procedure, Systemp.desensitizer is applied to prepared/unetched, prepared/etched or unprepared dentin. Per application, one drop (10-20 µL) of desensitizer is used. The toxicity of an adhesive containing 5% glutaraldehyde and 35% polyethylene glycol dimethacrylate was evalutated by experts (Leimgruber, 1990), who reported that the toxicity can almost exclusively be attributed to the glutaraldehyde component.

6.2 Toxicity of glutaraldehyde

Reports on the acute oral toxicity of glutaraldehyde for rats indicate amounts between 100 - 2400 mg/kg (Beauchamp et al., 1992). The reason for this wide range of variation is the fact that glutaraldehyde is particularly agressive in the alkaline range (pH > 7.5), while it exhibits much lower toxicity when the slightly acidic range is analyzed. The formulation that has to be evaluated here shows a pH-value of 3.0, which means that the upper LD-50 range (lower toxicity) is applicable.

If used as directed, System.desensitizer is applied to prepared/unetched, prepared/etched or unprepared dentin. Glutaraldehyde will bond to both the amino groups of serum proteins in the dentinal tubules and exposed collagen fibres. Protein fixation by glutaraldehyde is irreversible (Hopwood, 1990) and a detrimental effect of chemically bonded glutaraldehyde can thus be exluded. Wether or not the precipitation reaction involves all the glutaraldehyde molecules, cannot be judged. The amount of glutaraldehyde employed, however, is inferior. Per application, only 20 mg of Systemp.desensitizer are used, which corresponds to a maximum of 1 mg glutaraldehyde. Glutaraldehyde molecules diffuse very slowly into dentinal tissue (diffusion of a 2%-glutaraldehyde solution needs more than a week to cover a distance of 200 µm) (Wemes et al., 1982). Possible free glutaraldehyde molecules diffuse very slowly through the dentin to the pulp, where they might have a mutagenic effect on living cells. On their way to the pulp, the diffusing molecules are considerably diluted. We can thus proceed on the assumption that the amount of glutaraldehyde that eventually reaches the pulp is small and has no toxic effect.

If Systemp.desensitizer is used incorrectly, the solution may be brought into contact with the oral mucosa. The tissue will suffer no damage if rinsed with copious amounts of water immediately after contact has occurred (any concentration of glutaraldehyde is soluble in water). Unintended contamination of mucous membranes can however go unnoticed and provoke local tissue lesions.

6.3 Conclusions

When used as directed, the toxicity of the Vivadent Desensitizer is very low because:

1. The quantities used are small.
2. Glutaraldehyde quickly bonds to the available potein reducing mobility and availability
3. Any remaining molecules are slow to diffuse, thus a toxic effect on the pulp is improbable. A histological study confirmed pulp compatibility of the material (Farmer et al., 1992).

The product, however, can have an irritating effect on gingival tissue.

6.4 Literature on toxicity

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