Prelude Adhesive System

Product Bulletin: Characteristics and Benefits

Product Description

Prelude Dental Adhesive System is comprised of three components. The water-based Primer that exhibits a pH of 1.7 contains a proprietary methacryl phosphate and a hydrophilic monomer. The Adhesive is an ethanol-based fluoride-releasing 25% nanohybrid-filled light-curable resin. It can be used in total-etch or self-etch mode. The weight-averaged particle size is 250 nm. Due to its low and uniform film thickness obtained by a custom blending process, the adhesive is suitable for direct and indirect techniques using light-cured restoratives or self- and dual-cured restoratives when used with our alcohol-based Dual/Self-Cure Link.

Bond Strength Studies

Bond strengths to etched dentin at 24 hours using direct light cure restoration were confirmed in the lab of Dr. Larry Watanabe (UCSF) by comparison to two marketed brands (6 specimens per set). Shear bond strength testing was performed according to ISO/TS 11405:2003(E), Annex A.3.2.

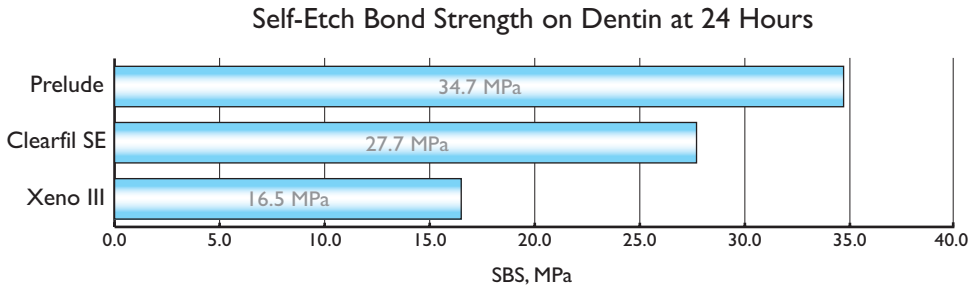
	Shear Bond Strength to Etched Dentin	Coefficient of Variation
Prelude Adhesive (Danville)	40.0 MPa	12.0%
Optibond Solo Plus (Kerr)	28.8 MPa	28.5%
Single Bond (3M/ESPE)	24.6 MPa	20.8%

Bond strengths of Prelude Primer/Adhesive to self-etched dentin and enamel at 24 hours using direct light cure restoration were reported by Dr. John Powers (UTHSC) (8 specimens per set). Macrotensile bond strength testing complies with ISO/TS 11405:2003(E), Annex A.2.1.

	Tensile Bond Strength	Coefficient of Variation
Enamel, Self-etch Mode	24.9 MPa	32.9%
Dentin, Self-etch Mode	27.4 MPa	13.1%

Self-etch bond strengths of Prelude to dentin at 24 hours using direct light cure restoration were confirmed in the lab of Dr. Larry Watanabe (UCSF) by comparison two to marketed brands (6 specimens per set). Shear bond strength testing is performed according to ISO/TS 11405:2003(E), Annex A.3.2.

	Self-Etch Shear Bond Strength to Dentin	Coefficient of Variation
Prelude Adhesive (Danville)	34.7 MPa	5.8%
Clearfil SE (Kuraray)	27.7 MPa	16.4%
Xeno III (Dentsply DeTrey)	16.5 MPa	27.9%

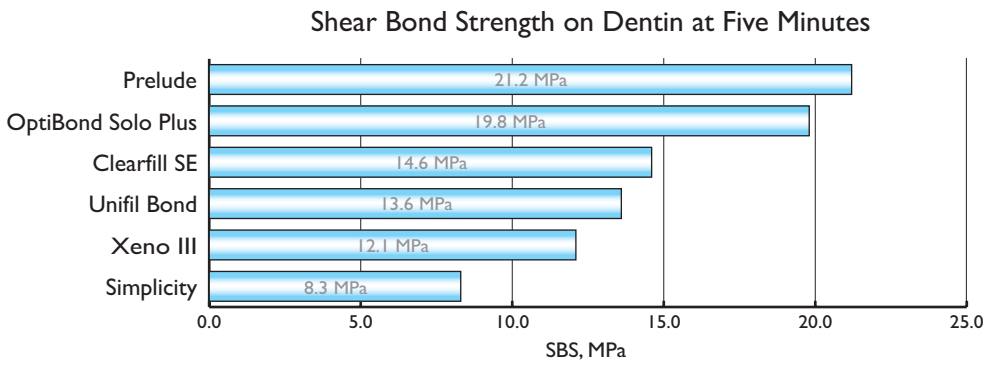


Dr. Larry Watanabe (UCSF) verified self-etch bond strengths of Prelude to dentin at 24 hours using direct auto-cure restoration in comparison to marketed brands (6 specimens per set). Shear bond strength testing is performed according to ISO/TS 11405:2003(E), Annex A.3.2.

	Self-Etch Shear Bond Strength to Dentin	Coefficient of Variation
Prelude (Danville)	29.4 MPa	17.2%
Prelude (Danville) with BondLink (Den-Mat)	17.6 MPa	26.4%
Xeno III (Dentsply DeTrey)	2.8 MPa	51.9%

Prelude also exhibits excellent early self-etch bond strengths. Our internal study measured shear bond strength to dentin according to ISO/TS 11405:2003(E), Annex A.3.2, except that the specimens are stressed to failure 5 minutes after light curing of the composite begins instead of at a 24 hour age. We compared Prelude to several marketed brands (5 specimens per set). Mean values with the same superscript were not significantly different (P>0.05). Two advantages we have over these competitors are superior early strength and low coefficient of variation. We believe that early strength may prevent gap formation due to restorative polymerization shrinkage stress. The low CV may indicate a user-friendly product with less likelihood of occasional early bond failures. Shown in graphical form below.

	Self-Etch Shear Bond Strength to Dentin	Coefficient of Variation
Prelude (Danville)	21.1 MPa [c]	2.6%
Optibond Solo Plus (Kerr)	19.8 MPa [b, c]	18.6%
Clearfil SE Bond (Kuraray)	14.6 MPa [a, b]	25.9%
Unifil Bond	13.6 MPa [a, b]	17.3%
Xeno III	12.1 MPa [a, b]	20.2%
Simplicity	8.3 MPa [a]	48.0%



Shear bond strengths of Prelude Primer/Adhesive and Clearfil SE Prime/Bond to ozonated and untreated dentin using direct light cure restoration were determined at 24 hours in an internal study (6 specimens per set). After surface preparation, teeth in the treatment group received ozone from a Healozone Unit (Curozone USA) for 40 seconds with bonding completed immediately after. Shear bond strength testing is performed according to ISO/TS 11405:2003(E), Annex A.3.2.

	Self-Etch Shear Bond Strength to Untreated Dentin (Coefficient of Variation)	Self-Etch Shear Bond Strength to Ozonated Dentin (Coefficient of Variation)
Prelude Adhesive (Danville)	33.4 MPa (2.1%)	31.7 MPa (16.7%)
Clearfil SE (Kuraray)	27.7 MPa (16.4%)	26.6 MPa (26.8%)

Microleakage

Class V preparations including one margin in cementum and one in enamel were restored using Prelude Adhesive in total-etch mode and using StarFlow light-cured composite. The teeth were submitted to thermal cycling between baths of 5°C and 55°C for at least 1000 cycles, stained with methylene blue, and sectioned apical-occlusal through the restoration. Three independent, blinded evaluators scored our adhesive better than OptiBond Solo plus and Clearfil SE Bond in each of seven separate internal studies. The resistance to microleakage persisted even after the product had been stored in unit dose compoules at 37°C for 4 months.

Class V preparations including one margin in cementum and one in enamel were restored using Prelude Primer and Adhesive in self-etch mode and using Accolade light-cured flowable composite. The teeth were submitted to thermal cycling between baths of 5°C and 55°C for 1000 cycles, stained with methylene blue, and sectioned apical-occlusal through the restoration. Three independent, blinded evaluators ranked our adhesive equal to Clearfil SE Bond and better than OptiBond Solo plus.

Nonoleakage

Dr. Franklin Tay assessed Prelude using two electron microscopy methods. First he examined stained, demineralized dentin TEM sections for ultrastructure. He also used tracer-immersed, unstained, undemineralized dentin TEM sections for evaluation of potential interface voids (nanoleakage). In this method the tracer solution consists of ammoniacal silver nitrate that prevents inadvertent artifactual dentin demineralization during the course of tracer penetration into resin-dentin interfaces. Voids show up as dark areas in sharp contrast to dentin and resins.

Using the total-etch technique Dr. Tay concludes that for Prelude "the extent of nanoleakage is either comparable or less than that observed in commercial two-step total-etch adhesives." Figure 1 shows an ultrastructure TEM after application of Prelude Adhesive (A) to acid etched dentin. A 4-6 micron hybrid layer (H) is present with extension of the resin tags (pointer) into dentin (D) tubules.

Figure 1

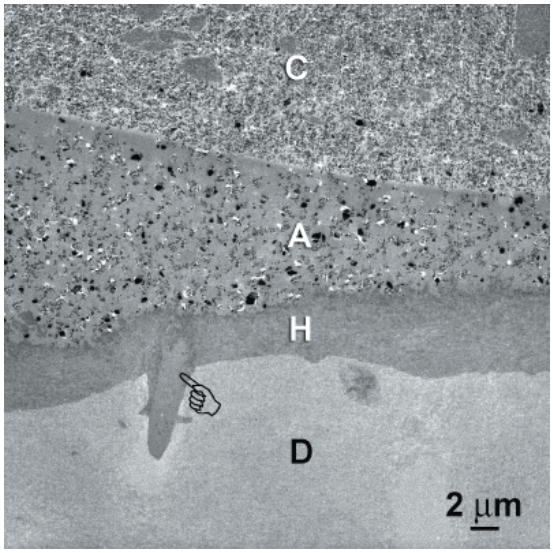
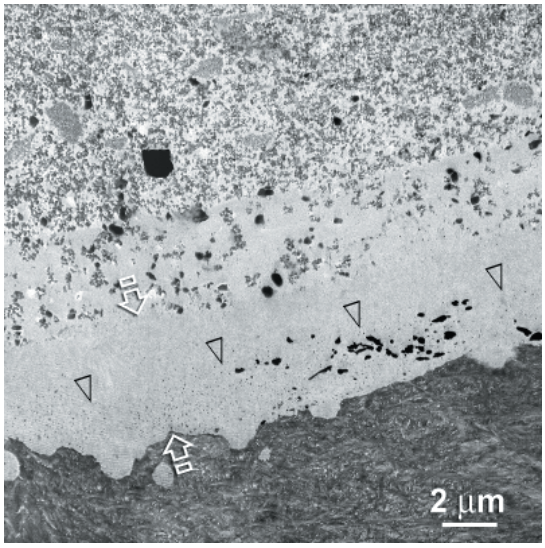


Figure 2 shows an "interface voids" TEM after application of Prelude Adhesive (A) to acid etched dentin. This view of the resin-dentin interface shows that the minimal nanoleakage observed is localized to the basal half (open arrowheads) of the hybrid layer (between open arrows). Both reticular (large black spots) and isolated (small black dots) modes of nanoleakage are shown.

Figure 2



Using the self-etch technique concerning Prelude Tay states, "nanoleakage is minimal within the hybridized complex. However, like some of the commercially available self-etch adhesives, (it) exhibits the problem of continuous etching beneath the hybridized complex creating a porous zone in the mineralized intact dentin." Figure 3 is an ultrastructure TEM showing light-cured composite (C), filled adhesive (A), a 1-1.5 µm thick hybridized complex (H), and intertubular dentin (D).

Figure 3

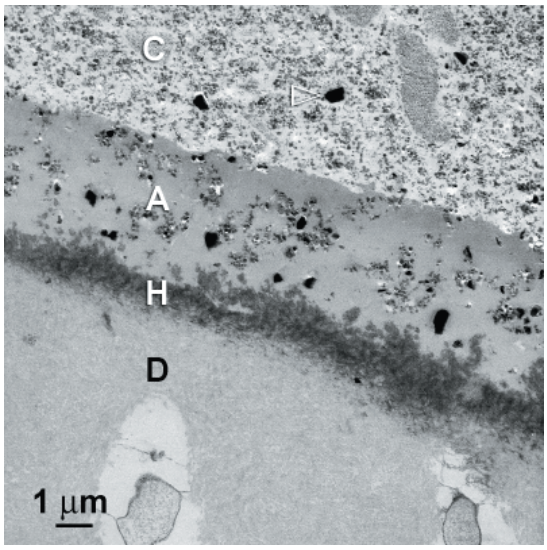


Figure 4 is a low magnification, overall view of the resin-dentin interface showing areas of no nanoleakage and an isolated area where continuous etching is identified by the presence of silver deposits in the underlying mineralized dentin (pointer). Also shown is partially demineralized dentin (between arrowheads), composite (C), adhesive (A), dentin (D), and peritubular dentin (P). Figure 5 shows a very high magnification showing a smear plug (SP) and apatite crystallites within the zone of partially demineralized dentin (between open arrows). Very fine isolated silver grains (open arrowheads) probably represent bound water that is associated with the hydrophilic domains of the resin monomers.

Figure 4

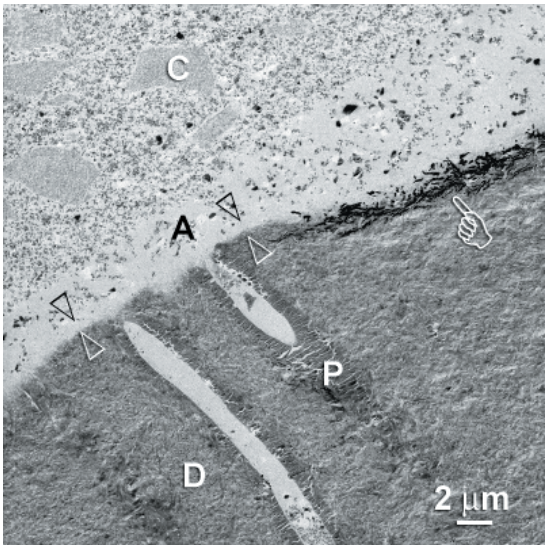
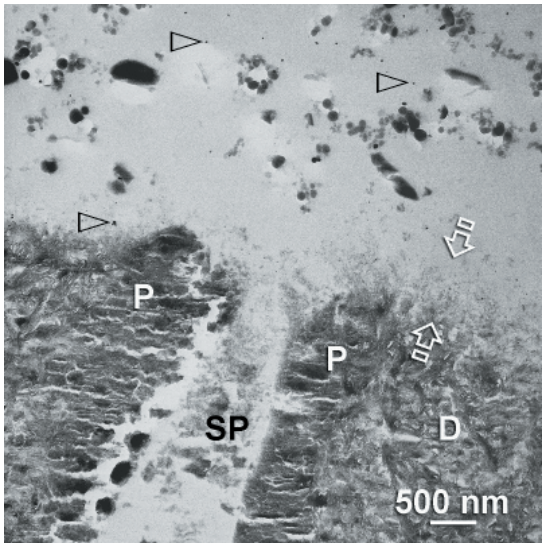


Figure 5



Figures 6 and 7 are additional "interface voids" TEMs showing various degrees of continuous etching beneath mineralized dentin caused by self-etch Prelude. Figures 8 and 9 show similar but stronger continuous etch patterns when using Xeno III and one year old iBond, respectively.

Figure 6

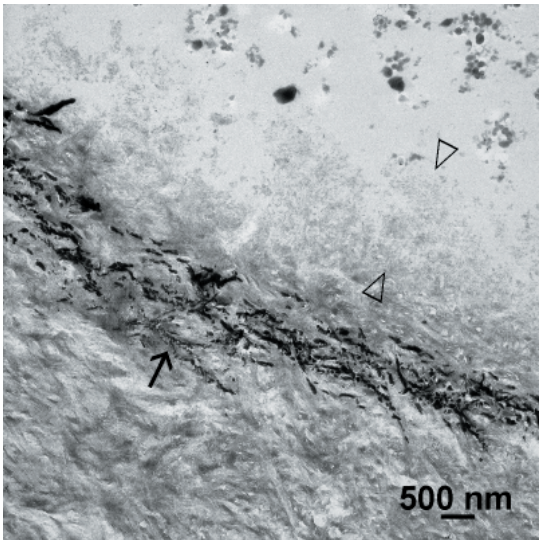


Figure 7

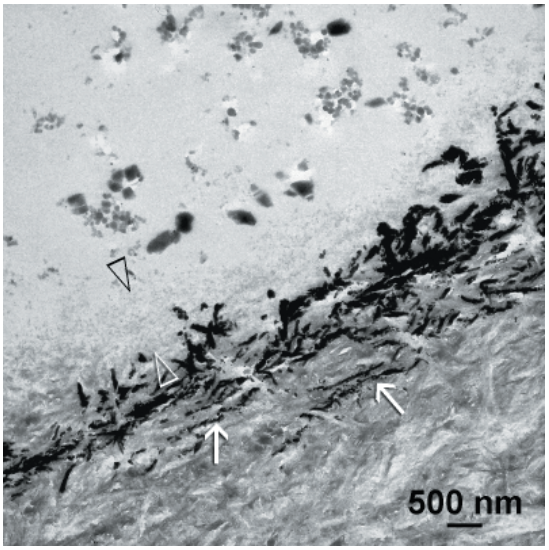


Figure 8

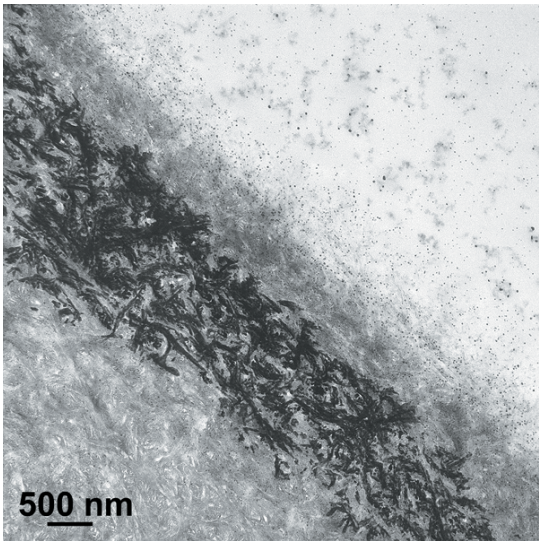
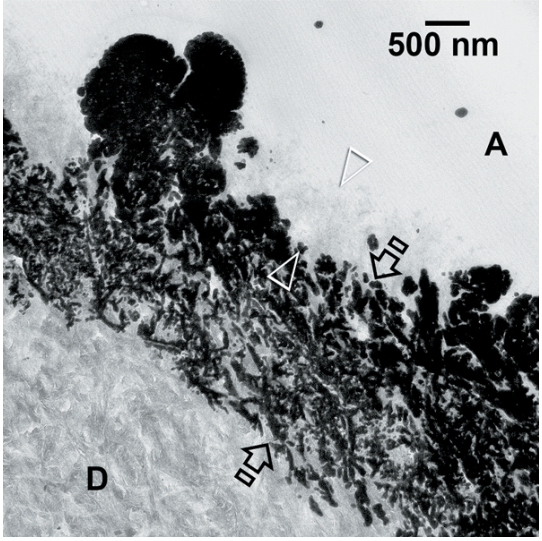


Figure 9



Stability

Prelude Adhesive showed excellent stability in unit dose packaging (not yet available for market) in an accelerated (37°C) stability study that also included OptiBond Solo plus in its marketed unit dose package. Specimens were monitored for weight loss, appearance of polymer, pH, refractive index, microleakage, and shear bond strength (Bencor Method, ISO/TS 11405:2003(E), Annex A2.2) to etched dentin restored with StarFlow (5 specimens per set). Shear bond strengths are:

Months at 37°C	1	2	3	4	6	14
Prelude Adhesive	30.5 MPa	15.1 MPa	20.5 MPa	17.3 MPa	15.1 MPa	5.5 MPa
OptiBond Solo Plus	25.3 MPa	14.2 MPa	17.1 MPa	11.5 MPa	8.0 MPa	0 MPa

Stability of Prelude Primer was tested in treated polyethylene dropper bottles using shear bond strength (Watanabe Method, ISO/TS 11405:2003(E), Annex A3.2) to self-etched dentin and enamel restored with Accolade (5 specimens per set).

Months at 37°C	0	0.5	1	2	4	6
Dentin at 5 minutes	18.8 MPa	18.5 MPa	19.7 MPa	19.5 MPa	14.3 MPa	19.4 MPa
Enamel at 24 hours	26.1 MPa	20.3 MPa	25.4 MPa	26.3 MPa	27.1 MPa	33.6 MPa

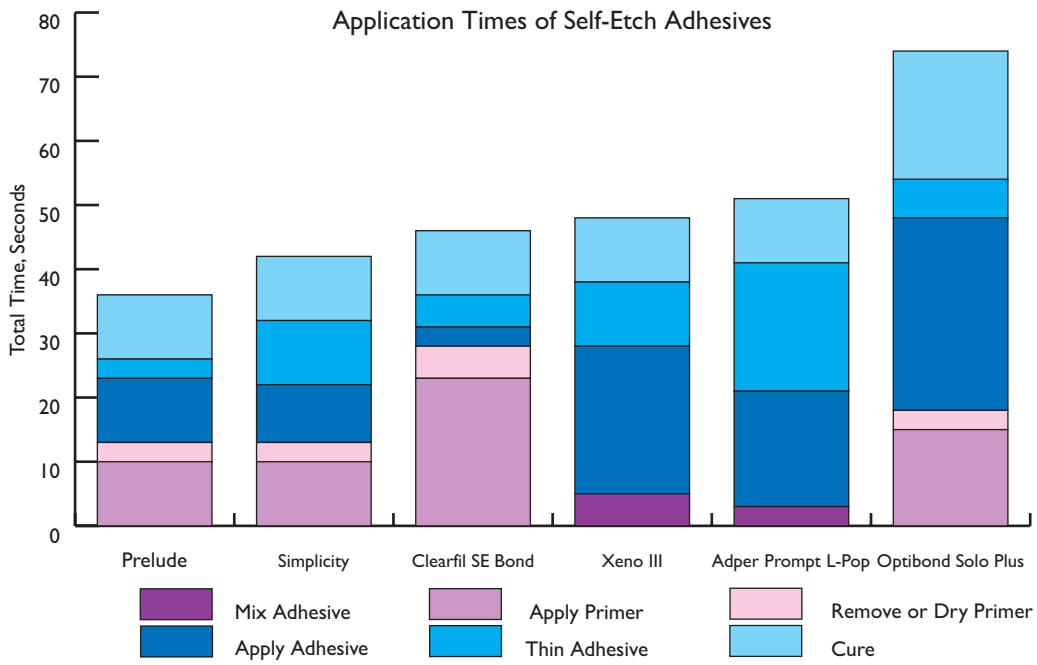
Stability of Prelude Dual/Self Cure Link was tested in treated polyethylene dropper bottles using shear bond strength (Watanabe Method, ISO/TS 11405:2003(E), Annex A3.2) to self-etched dentin restored with Core paste (Den-Mat), an auto-cure resin-based restorative (5 specimens per set).

Months at 37°C	0	0.5	1	2	4	6
Dentin at 1 hour	23.1 MPa	23.4 MPa	26.2 MPa	33.3 MPa	26.9 MPa	24.4 MPa

All Prelude products can be stored in a freezer with no ill effects.

Ease of Use

We have found that use of our adhesive in total-etch mode is affected by when the dentin surface is over-dried after the etchant is rinsed away. However, blotting excess moisture from the surface using a brush or paper point rather than air stream drying can easily control dentin moisture levels. The fact that total-etch adhesion to enamel is quite strong suggests this 25%-filled product could be used as a fissure seal. In self-etch mode adhesion is not much influenced by the moisture level. The system can be cured with all types of curing units. We know of no simpler to use product than Dual/Self Cure Link to allow a light-cured adhesive to be effective with auto-cured composites...just apply to cured adhesive layer and air dry. Also, the number of steps and overall application time compare well to the best of the systems reported recently by CRA (volume 27, Issue 11/12, 2004). The graph below shows that the application time for self-etch Prelude is among the fastest of all competitors.



Safety

Prelude Adhesive was tested for cytotoxicity side-by-side with Optibond Solo plus. The 1X MEM Test Article extract (37°C for 24 hours) was incubated with L-929 mouse fibroblast cells (37°C, 5% CO2, 48 hours) and then examined microscopically to estimate % lysis. Prelude produced moderate toxicity while Optibond Solo plus scored severe toxicity.

Prelude Primer and Adhesive on Accolade composite disks were tested for cytotoxicity side-by-side with Clearfil SE Bond. Both products produced slight toxicity.

Prelude Adhesive with Dual/Self Cure Link on StarFill 2B composite disks was tested for cytotoxicity side-by-side with Prelude Adhesive/BondLink/StarFill 2B. Both products produced no toxicity.

A full risk analysis of the Prelude Adhesive System concluded that with controls in place (labeling, warnings, and instructions to the user) its benefits outweigh potential risks.

Kit Confgurations

Prelude is available in a variety of configurations to meet the needs of various clinics. One kit is specially suited for those that prefer the self-etch technique while the other is suited to the total-etch technique. A plastic tackle box holds the kit components in a tray formed to securely hold each and allow the bottles to stand upright. The bottles have caps in colors that match their label colors. Labels are high-quality commercial stock that resists solvent smearing. The instruction sheet is laminated for chairside use and includes instruction for both self-etch and total-etch techniques as well as for use of the Dual/Self-Cure Link.

Prelude Primer, Adhesive, and Dual/Self Cure Link are available individually as refills. The Primer and Adhesive are packaged together in a Two-Pak.

Part Numbers

Prelude Self-Etch Kit 5ml each Prelude Primer, Adhesive & Dual/Self-Cure Link, 40 Microbrushes & 10 Mixing Wells	90990
Prelude Total-Etch Kit 5ml each Prelude Adhesive & MicroPrime, 5gm SureEtch, 40 Microbrushes & 10 Mixing Wells	90994
Prelude Primer/Adhesive 2/pk 5ml ea.	91024
Prelude Primer 5ml	90971
Prelude Adhesive 5ml	90973
Prelude Dual/Self-Cure Link 5ml	90975