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Hydrocolloid Adhesion Study

Clearly, the ability to adhere well to the skin defines a necessary ingredient of an effective skin barrier, especially as it relates to its absorptive capacity; in other words, having high absorptive capacity may be irrelevant if the barrier doesn't stay on the skin! Having formulated **XenMed 18** to have the properties required by ostomy EndUser's Company management felt compelled to demonstrate that its product meets this need well.

Conclusion

XenMed 18 demonstrated no significant improvements over most competitive samples, although all samples demonstrated superior results over samples y50 and z95 for the different reasons outlined above.

Results of Adhesion Study

All products had significant initial tack. Samples designated as z95 and z33 maintained a lesser tack at one hour, and both left a significant residue upon removal. The peel of sample y50 was approaching a dangerous tack level of 240g per inch at one hour; in fact, subject's arm still has a red imprint of y50 HCD two days after removal, and it was the only one demonstrating that problem. The sample z95 disintegrated and had to be removed in clumps. As the hydrocolloids absorb over time in general, the adhesion levels fall, regressing as a group to around 200 grams by the third hour.

Test Conditions. All testing was carried out at a temperature of 20° C ± 1° C and 40% - 60% relative humidity.

Procedure for "Dry Tack" Study

A test sample of each hydrocolloid under study was created. The samples were all one-inch by one-inch strips. Their thickness was a function of what we acquired for ostomy applications. Xennovate Medical promotes the use of its ostomy skin barrier at a thickness of 25 mils (0.635 mm) versus the industry standard of 40 mils (~1 mm) because it provides a lower cost to our customers based on weight and a lower profile to the EndUser, while lasting as long or longer than competitive brands. This study validates this marketing claim. Where needed to maintain the tensile integrity of the sample, a 3M 1776 acrylic backed woven material was applied to one side of the hydrocolloid sample. The test subject's forearm was prepared by wiping with a saline moistened cloth and allowed to air dry. After application onto forearm, a 5 pound weight was applied perpendicular to the sample on the arm for 5 seconds.

At each respect time point, one edge of each hydrocolloid sample was lifted and a strain gauge (American Weigh®) with a gram scale was attached using an alligator clip. A pull direction of 90 degrees to the arm was maintained while peeling each sample and the resulting removal force was measured by the strain gauge. The tabulated removal forces by respective sample are depicted nearby.

