Nicole Senn
artimetl; CH-Sursee

NO SIMPLE SUBSTRATE: HUMAN SKIN-KEY CONSIDERATIONS FOR HMPSAs IN MEDICAL DEVICES

ABSTRACT
Hot-melt adhesives for medical applications involving direct skin contact must be tailored to a substrate that differs fundamentally from conventional technical surfaces. Human skin is a dynamic, heterogeneous system whose properties are influenced by a variety of factors. This variability has a decisive impact on adhesion, cohesion, and debonding behavior of adhesive systems.

At the same time, such systems are subject to stringent regulatory requirements in the context of medical devices, particularly with respect to biocompatibility, skin compatibility, and risk assessment. Consequently, adhesive design must not only ensure functional performance but also be robustly justified from a regulatory perspective.

Using selected examples, this contribution illustrates how functional requirements for skin adhesives can be aligned with regulatory constraints. In addition, different product concepts and applications are comparatively evaluated to discuss their specific requirements, advantages, and limitations in terms of skin adhesion, wearing comfort, and regulatory assessment.

The central focus is on how the unique properties of human skin can be effectively addressed in the development of medical hot-melt adhesives. Based on this analysis, practical conclusions are derived for the selection, design, and evaluation of suitable adhesive systems.