

FRAUNHOFER INSTITUTE FOR SILICATE RESEARCH ISC WÜRZBURG

PRESS RELEASE

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Fraunhofer TLZ-RT ensures availability of epiCS® epidermis models for OECD 439 tests

The Fraunhofer Translational Center for Regenerative Therapies (TLC-RT) is taking over the epiCS® technology from Henkel AG & Co. KGaA, thereby ensuring the continued availability of internationally standardized epidermis models. These OECD-validated tissue models offer a reliable alternative for evaluating the skin reactions of chemical substances and contribute to the safety of cosmetics and pharmaceuticals.

Three-dimensional tissue models of the human epidermis can be used to evaluate chemical substances, cosmetics, or pharmaceuticals in terms of their irritation or damage potential, as well as for dermatological, pharmaceutical, and cosmetic research. The Fraunhofer Translational Center for Regenerative Therapies (TLC-RT) at the Fraunhofer Institute for Silicate Research ISC has long been active in research and development for functional, three-dimensional tissue models.

Such models must be approved in order to be used for toxicological evaluation in accordance with the internationally applicable OECD guidelines. The epiCS® technology provides a system of epidermis models and test protocols for determining the skin irritation and skin corrosion potential of active substances, which has been validated according to internationally recognized standards. The protocols are part of OECD Test Guidelines 431 (in vitro skin corrosion testing) and 439 (in vitro skin irritation testing) and thus offer a validated alternative to animal testing.

The epiCS® technology previously offered by Henkel AG & Co. KGaA is now being taken over by Fraunhofer TLC-RT. "This step is the result of many years of cooperation and intensive knowledge transfer between Henkel AG & Co. KGaA and Fraunhofer TLC-RT," says Prof. Florian Groeber-Becker, head of TLC-RT. "While the validated epiCS® epidermis model is indispensable for regulatory safety testing, we are simultaneously developing advanced in-house skin models for specific research questions. In this way, we are creating a broad testing platform, from standard approval to complex skin models for individual research questions," Groeber-Becker continues.

The success of the method transfer was verified with extensive testing to ensure the high quality of the tissue and the test procedures based on it at the new production site. Dr. Dieter Groneberg, Group Leader of the "Skin" working group at Fraunhofer TLC-RT, confirms: "The epiCS® epidermis models will thus continue to be available for research projects and industrial applications. This preserves one of the most powerful epidermis models 'Made in Germany'." The tissues, which are produced entirely in the



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laboratory, enable precise, reproducible tests and thus make an important contribution to product safety. Fraunhofer TLC-RT is thus underlining its commitment to innovative technologies that promote ethical standards in research and support the scientific use of skin models as an alternative to animal testing (New Approach Technologies).

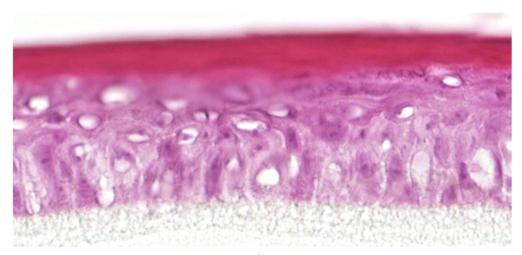
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Image material



epiCS® - human epidermis, reconstructed from primary human keratinocytes® Fraunhofer ISC/TLZ-RT

The Fraunhofer Society, based in Germany, is the world's leading organization for applied research. By prioritizing key technologies for the future and exploiting its findings in business and industry, it plays an important role in the innovation process. As a pioneer and trendsetter for innovative developments and cutting-edge research, it helps shape our society and our future. Founded in 1949, the Fraunhofer Society currently operates 76 institutes and research facilities throughout Germany. Around 30,800 employees, mainly scientists and engineers, work with an annual research volume of around €3.0 billion, of which €2.6 billion is for contract research.

The **Fraunhofer Institute for Silicate Research ISC** is one of the leading R&D centers for materials-based research and development in the fields of resource efficiency, energy, environment, and health. With 340 scientists and technicians, the institute works to develop innovative functional materials and technologies for more sustainable and resource-efficient products and to make significant contributions to solving the major global issues and challenges of the future. The Fraunhofer Translational Center for Regenerative Therapies, located at Fraunhofer ISC, develops new cell-based tissue models and test systems, scalable production processes, and biological vascularized implants.

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