

Alternatives to animal testing



Henkel

A Brand Like a Friend

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Scientists from Henkel and Phenion develop, promote and use alternative methods to animal testing.



Our commitment

Safety and compatibility of all Henkel products

Henkel is responsible for safety, health and environmental matters relating to the production, distribution and use of its products. Customers and consumers can be sure that Henkel products and technologies have been extensively tested for compatibility with human health and the environment and are safe when used as intended.

Henkel systematically evaluates the possible risks of new products during the research and development process. Raw materials and finished products are subjected to the required tests and assessments before they reach the market.

Henkel only commissions animal testing if legislation prescribes this and no alternative test methods are available for obtaining the necessary safety data. Developing test methods that make no use of animals and making these test methods generally available is a top priority at Henkel. Since 2006, Henkel has considerably intensified its research concerning alternatives to animal testing and has concentrated these activities in its research company Phenion. Here, an interdisciplinary team of experts works to develop test methods that are needed worldwide for the replacement of animal tests. At Phenion, these research capabilities are supported by expert knowledge of the effects of raw materials and products on skin and hair.



Our responsibility

Toward humans, animals and the environment

As long as safety data obtained from animal testing are indispensable for an intended purpose, Henkel will take precautions to ensure that the number of tests is kept to a minimum.

The following aspects in particular are carefully examined before commissioning any tests:

- What are the legal requirements for ingredients or products?
- Are applicable safety data available for the intended purpose?
- Are alternatives to animal testing available and can they be used for safety assessments?

If these checks reveal that an animal test cannot be avoided, Henkel ensures that the 3Rs principle will be applied. The 3Rs stand for refine, reduce, and replace. They relate to the development of test methods and the use of animal testing. The aim is to refine animal use so that test animals are subjected to a minimum of stress, to reduce animal use by carrying out testing systematically and referring to already existing information, and – Henkel’s aim – to replace animal use by developing and using alternative research and test methods that make animal testing unnecessary.

Henkel itself does not carry out any animal testing. Before it commissions any necessary tests by an audited external research institute, Henkel always checks whether the institute can carry out the requested tests in a manner that satisfies all legal requirements and is in line with our commitment and responsibility. The key criteria are conformity with recognized protocols, such as the test guidelines of the Organisation for Economic Co-operation and Development (OECD) and the principles of good laboratory practice (GLP), and with the standards and country-specific regulations referred to in the EU Directive on the Protection of Animals.



Our aim

Alternative test methods

For Henkel, the aim of replacing animal testing by alternative test methods is of prime importance. We have been researching alternatives to animal testing methods since the early 1980s, both internally through our research and product safety departments and in cooperation with external research institutions. Although these efforts over the years have produced a number of successful results, a great deal still needs to be done before it will be possible to eliminate animal testing completely. This will require consistent use of the most advanced research methods in the areas of molecular biology and computer technologies.

Henkel has therefore consolidated its activities for developing alternatives to animal testing in the research company Phenion. Henkel aims to develop additional alternative test methods on the basis of, for example, the Phenion® Full Thickness Skin Model (see box). Henkel and Phenion work on alternative methods in joint projects as part of an international network comprising external industrial partners, government agencies and research establishments.



The Phenion® Full Thickness Skin Model

Phenion has developed a robust full thickness skin model based on human cells. It can be produced to a constant and very high level of quality. A test substance is applied to the Phenion® Full Thickness Skin Model so that its effect on the skin tissue can be systematically evaluated. The substance, e.g. a cream for-

mulation, is applied topically using a brush. This can be done several times over a period of at least nine days. In this way, the effect of the substance on the cell layers in the skin can be studied. The standardized production of the model, in combination with its special properties, make it suitable for use as an in-vitro alternative to animal testing.

Our aim

Scientific approaches

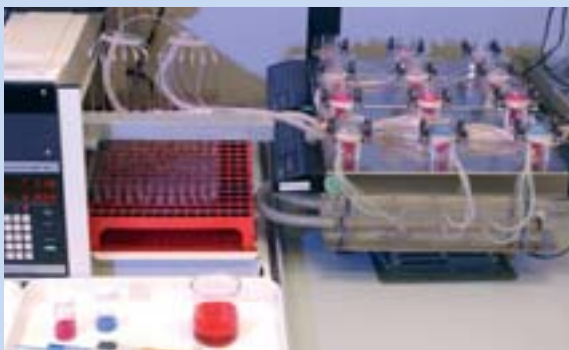
Important approaches include:

- the development of in-vitro (in the glass) methods based on biological materials (for example, skin or other human body cells) that will be suitable for reliably verifying the safety and compatibility of product ingredients;
- the development of in-silico (in the computer) methods to determine the compatibility of substances on the basis of their chemical structure.

In-vitro methods

Instead of using animals, cell and tissue cultures can be used to test product ingredients. Cell culture experiments can show, for example, the lowest concentration at which an ingredient causes damage to cells. The results enable conclusions to be drawn about the ingredient's compatibility with tissue. Cell cultures are now also used routinely to test substances for mutagenic properties.

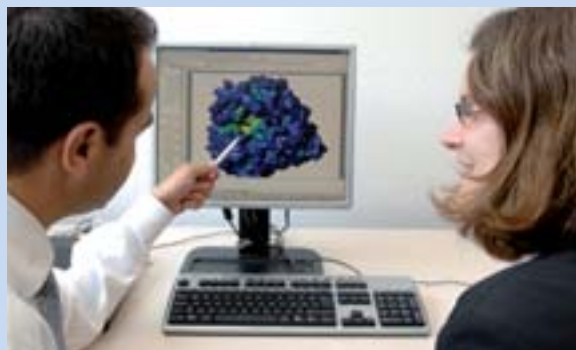
Tissue cultures are additionally used to test substances for compatibility with mucous membranes. A familiar example is the Hen's Egg Test, which Henkel scientists are now further developing so that it can be used to test for mutagenic properties as well.



In-vitro test system for the investigation of substance penetration through the skin.

In-silico methods

Substances with similar chemical structures often have similar properties. In these cases, therefore, a knowledge of the properties of a few representative substances is sufficient to be able to deduce the properties of a series of similar substances. By analogy, certain properties of these representative substances can also be assumed to be properties of the other substances in the series. The required calculations are performed using specially developed computer programs. It is anticipated that combinations of such calculations will make it possible to narrow down the number of substances to be tested. Only these selected substances will then have to be tested according to the legally prescribed test methods.



In-silico methods gain more and more relevance for the development of alternatives to animal testing.

Research into alternative test methods has so far resulted in the incorporation of a range of new cell and tissue culture systems into the repertoire of alternative methods. These methods are used to investigate the behavior of a substance in the body or its effect on skin and mucous membranes. A single-layer epidermis skin model was included in the OECD guidelines several years ago as a method for testing skin irritating properties (see “Alternative test methods” box). Recently, a similar skin model has been approved by the European Centre for the Validation of Alternative Methods (ECVAM) for testing for inflammatory properties.

Henkel, Phenion and other companies and institutions are working intensively to speed up the development of additional valid alternative methods and intelligent test strategies for reducing and replacing animal testing.

Alternative test methods

At present there are only seven alternative methods that can replace legally required tests on animals. The following have been validated and given regulatory approval:

- tests for corrosive properties (OECD 430 and 431),
- tests for acute phototoxicity or irritation (OECD 432),
- tests for skin absorption (OECD 428), and
- in-vitro methods for determining potentially mutagenic effects (OECD 471, 473, 476).

Further methods are in the validation phase (see www.ecvam.jrc.it.com).

The Local Lymph Node Assay (LLNA), which has been approved by the OECD as a test for skin-sensitizing properties (OECD 429), makes an important contribution to refinement and reduction. The number of animals needed for certain tests was also reduced by the harmonization of test requirements and the development of new test methods, such as the Acute Toxic Class Method (OECD 423) and the Fixed Dose Method (OECD 420) for testing for acute oral toxicity. The industry played a decisive role in the development of the test protocols.

Our aim

Official approval

When an alternative method is developed, it must undergo an internationally recognized validation process before being officially approved. This procedure is very complicated and usually takes more than ten years.

The alternative methods developed must first be subjected to comparative tests in a number of laboratories (round-robin studies) to demonstrate that the results obtained carry as much weight as those of in-vivo studies, so that the alternative method provides an equivalent level of safety. The results of these studies are submitted to the responsible scientific committee of the European Centre for the Validation of Alternative Methods (ECVAM) for evaluation. Once the validity of the method has been recognized by ECVAM, the Organisation for Economic Co-operation and Development (OECD) can then officially approve the alternative method and incorporate it into an OECD guideline.



Selected non-animal screening and alternative methods used in Henkel laboratories:

- Neutral red cytotoxicity assay for determining cell toxicity potential,
- Organotypical skin models for studying irritation of the skin,
- Hen's Egg Test for mucous membrane compatibility (Hen's Egg Test on the Chorionallantoic Membrane, HET-CAM Test),
- In-vitro testing of skin absorption (OECD 428),
- Photohemolysis test for determining phototoxic potential,
- Dendritic cells for determining sensitizing potential,
- In-silico methods: quantitative structure-activity relationships using chemical informatics systems

Our activities

Cooperation with external partners – development, validation and approval of alternative test methods

Henkel and Phenion actively promote and participate in cross-industry programs for developing non-animal test methods. Henkel is a member of the European Partnership for Alternative Approaches to Animal Testing (EPAA, see below) and of various committees of the European Cosmetic Toiletry and Perfumery Association (COLIPA) focusing on alternatives to animal testing. In addition, Henkel collaborates with partner companies and government agencies in carrying out validation projects to smooth the way for official acceptance of newly developed methods. Henkel also plays a role in organizations that promote alternative methods, such as the German Foundation for the Promotion of Alternative and Complementary Methods to Reduce Animal Testing (SET), and represents the chemical industry on the Commission of the German Centre for Documentation and Evaluation of Alternatives to Animal Experiments (ZEBET).

European Partnership for Alternative Approaches to Animal Testing

In November 2005, the European Partnership for Alternative Approaches to Animal Testing (EPAA) was launched by the European Commission and industry. The chemical, plant protection, pharmaceutical, cosmetics, detergent and household cleaner, and biotechnology sectors are represented in the initiative.



Our activities

Cooperation with external partners – development, validation and approval of alternative test methods

In the Brussels 3Rs Declaration Henkel, together with the other partners, has committed to refining, reducing and ultimately replacing the use of animals. In early 2006, the European Partnership formulated an action program which is now being implemented by the participating parties. Henkel and its research company Phenion have been actively involved in developing and implementing the activities of the European Partnership from the very beginning. The Partnership announces the results of its joint research work in a progress report at its annual conference.

Legal requirements in the European Union

Under the 7th Amendment to the Cosmetics Directive 76/768/EEC, the sale of cosmetic products whose ingredients have been tested on animals for certain toxic effects will be prohibited in the Member States of the European Union after 2009. For other damaging effects the prohibition is valid from the year 2013. It is therefore important that more alternatives to animal testing are approved in time by the OECD.

With its new chemicals legislation REACH, the European Union requires all chemicals to be newly registered, evaluated and – where necessary – authorized (REACH = Registration, Evaluation, and Authorization of Chemicals). To prevent that this registration process leads to a dramatic increase in the number of tests on animals, suitable alternative methods must soon be made available and officially approved.



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