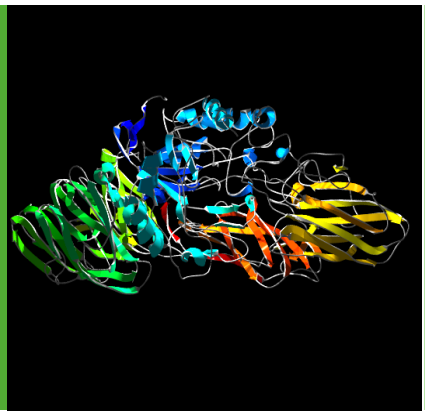
BioTeSys

Genotoxicity testing

In vitro safety tests



Safety tests for chemicals as part of REACH, botanicals (THMP) and cosmetics

The determination of potential genotoxic effects is an essential component of the safety assessment. Applying *in vitro* testing, a combination of tests is usually used to answer this complex question. Available here are a number of recognised protocols, as well as other standard methods for the measurement of DNA damage.

'Test battery' for genotoxicity

BioTeSys offers a specific test package for detecting the endpoints chromosome damage and DNA strand breaks. The test methods complement each other and can detect DNA double strand breaks directly and indirectly.

DNA repair activity

Alongside direct damage to the DNA, genotoxic potential can also be triggered indirectly, e.g. due to the negative influence on DNA repair mechanisms. This important ancillary information can be detected by the γ-H2A.X assay and the automated FADU assay.

	Micronucleus	FADU	γH2A.X
Endpoint	Chromosomal damage	DNA double strand breaks (directly)	DNA double strand breaks (indirectly)
Cell type	e. g. CHO-K1, Jurkat	e. g. Jurkat, BEAS-2B	e. g. Jurkat, BEAS-2B
Techno-logy	Flow cytometry	Automated handling and fluorescence-spectrometry	Flow cytometry
OECD-protocol	TG 487	-	-

▪ Micronucleus Assay according to OECD TG 487

The micronucleus assay is extremely robust and internationally recognised (OECD TG 487). Here, the number of micronuclei in the cytoplasm of dividing cells serves as a marker of induced chromosome breaks or loss. The measurement is based on flow cytometry and is applicable to many different cell types such as lymphocytes, epithelial cells or fibroblasts.

▪ Automated FADU Assay

This procedure is based on the quantitative detection of DNA damage using fluorescence detection, and is a fast and robust alternative to the Comet Assay. The testing protocol is particularly well suited as a screening approach in the early product development process for pharmaceuticals and chemicals, as well as to support the submission of safety dossiers. Suspension cultures, adherent cells and organotypic epidermis models are all equally suitable as test models.

▪ γ-H2A.X Assay

The phosphorylated histone H2A.X (γ-H2A.X) is a well-characterised quantitative marker for DNA double strand breaks. The measurement is performed on the flow cytometer via the detection of a specific anti-phospho-Histone H2A.X (Ser139) fluorescence-conjugated antibody.

Contact information

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