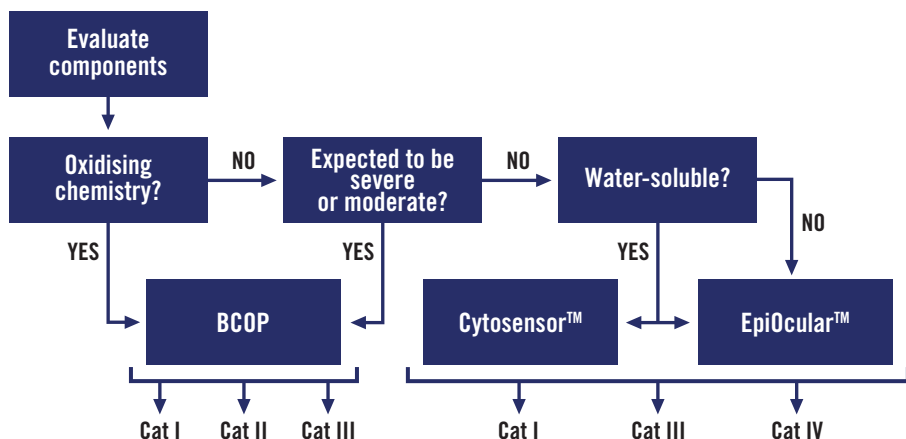


# USE OF AN ALTERNATE TESTING FRAMEWORK FOR CLASSIFICATION OF EYE IRRITATION POTENTIAL OF US ENVIRONMENTAL PROTECTION AGENCY (EPA) PESTICIDE PRODUCTS

## THE STRATEGY

The bovine corneal opacity and permeability (BCOP) assay, Cytosensor™ Microphysiometer, and EpiOcular™ assays are used under this policy to differentiate among the four eye irritation hazard categories currently used by the US EPA.



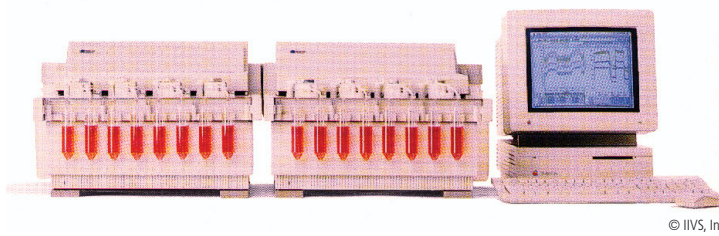
The appropriate assay is selected following test substance evaluation. If the test substance has oxidising chemistry or is expected to be a severe or moderate irritant, the BCOP assay can be used to determine US EPA toxicity category I, II, or III for eye irritation. If a test substance is identified as category III, the manufacturer can choose either to label the product as category III or to conduct the Cytosensor™ or EpiOcular™ assays to differentiate between categories III and IV. Alternatively, if the test substance is expected to be mild or non-irritating, the Cytosensor™ or EpiOcular™ assays can be used to determine US EPA toxicity category I, III, or IV for eye irritation. If the test substance is identified as category I, the manufacturer can choose either to label the product as category I or to conduct the BCOP to distinguish between categories I and II. Thus, while one assay is not sufficient to classify all four EPA eye irritation categories, it is possible to conduct only one assay, assuming that there is some knowledge of the test substance.

The US EPA acknowledges that other *in vitro* assays are available for assessment of eye irritation potential, and as new methods are evaluated for use or as refinements are made to existing methods, the agency will consider incorporating these into the testing scheme as appropriate.

## THE ASSAYS



**BCOP Assay**  
Category I, II, or III



**Cytosensor™ Microphysiometer**  
Category I, III, or IV



**EpiOcular™ (MatTek Corp)**  
Category I, III, or IV

While this strategy was developed for antimicrobial cleaning products, the agency will consider alternative tests on a case-by-case basis for other classes of pesticides and pesticide products, including conventional, biochemical, and other antimicrobial pesticides not within the scope of those with cleaning claims.