Evaluation of a Sample
Provided by

Regulatory Compliance Services

Utilizing the
CORROSITEX®
Test Method

March 7, 2006

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March 7, 2006

Robert J. Reynolds
Regulatory Compliance Services
2312 Colony Woods Drive
Apex, NC 27523

Dear Mr. Reynolds:

Enclosed is a copy of the final report detailing the results of our study of the material that was sent to us for analysis by the Corrositex® test method.

We are delighted that you have selected InVitro International to perform this analysis for you. We look forward to being able to provide additional services for you in the future.

Sincerely,

W. Richard Ulmer

W. Richard Ulmer

President & CEO of InVitro International

EVALUATION OF A SAMPLE PROVIDED BY REGULATORY COMPLIANCE SERVICES UTILIZING THE CORROSITEX® TEST METHOD

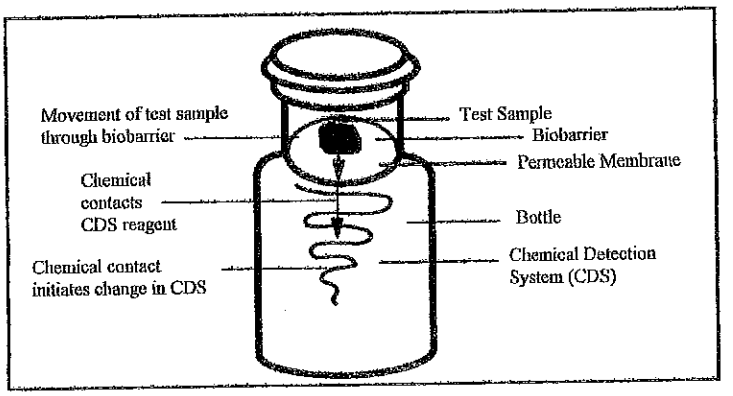
STUDY OBJECTIVE

A single sample provided by Regulatory Compliance Services was evaluated with the Corrositex® test method to determine its corrosive potential and to designate its Packing Group classification. To achieve this objective, the sample was subjected to a three-step testing process as described under Materials and Methods.

BACKGROUND

The Corrositex test is a standardized and reproducible method that can be employed to determine the potential corrosivity and determine the Packing Group classification of specified categories of chemical compounds under the hazardous materials transportation regulations administered by the U.S. Department of Transportation (DOT) and international dangerous goods codes. The Corrositex test predicts the *in vivo* corrosive potential of a chemical compound or mixture by using as an endpoint the time it takes for the chemical to permeate through or destroy a synthetic biobarrier. When the chemical has passed through this biobarrier, a visual change is produced in a proprietary Chemical Detection System (CDS). This assay system is depicted in Figure 1.

Figure 1. A Schematic Diagram Depicting the Biobarrier and Chemical Detection System of the Corrositex® Test Method



MATERIALS/METHODS

The Corrositex test is performed in three steps. First, a qualification test is done to insure that the test sample and the CDS reagent are compatible. This is achieved by placing either 150 µl of a liquid or 100 mg of a solid into an aliquot of the CDS reagent and observing it for the presence of any detectable change. If a physical or color change is observed, the sample is judged to be compatible with the detection solution and the remainder of the test is performed. The second step of the Corrositex test utilizes appropriate indicator solutions to permit categorization of the test sample as either a Category 1 or Category 2 material. Category 1 materials are typically strong acids/bases,

while Category 2 materials are typically weak acids/bases. The third step in the test is performed by applying the test sample to the biobarrier. When the chemical permeates through or destroys the full thickness of this biobarrier, it comes into contact with the CDS which then undergoes a simple color change. This color change is visually observed and the time required for the color change to occur is recorded. As summarized in Table 2 below, the time required to destroy the biobarrier is recorded for four sample replicates and the mean of these replicates is utilized to designate the UN Packing Group classification as I (severe corrosivity), II (moderate corrosivity), III (mild corrosivity), or Noncorrosive (NC). Positive and negative controls are analyzed concurrently to confirm the test's validity.

Table 1. Designation of UN Packing Groups

	Corrositex Time (minutes)			
Category 1	0 to 3 min.	>3 to 60 min.	>60 to 240 min.	>240 min.
Category 2	0 to 3 min.	>3 to 30 min.	>30 to 60 min.	>60 min.
	Packing Group I	Packing Group II	Packing Group III	Noncorrosive

RESULTS

A summary of the results obtained after evaluating the test sample is presented in Table 2.

Table 2. Summary of Corrositex® Test Results

IVI #: C2951	**Corrositex Time (minutes)**
Sample: Easy Prime-Part B	**Replicate #1:** > 60
Conc. Tested: Neat	**Replicate #2:** > 60
pH[a]: 10.07	**Replicate #3:** > 60
Category: 2	**Replicate #4:** > 60
Packing Group: NC	**Mean ± SD:** > 60

[a] pH is taken at 10% aqueous solution.

DISCUSSION

A single sample obtained from Regulatory Compliance Services was analyzed by the Corrositex method to determine its corrosive potential and Packing Group designation.

The results of this study indicated that the sample was compatible with the Corrositex system and was classified as a Category 2 material. The results obtained from the evaluation of four replicate samples were highly reproducible, demonstrating that a mean time of > 60 minutes required to destroy the synthetic biobarriers. These findings lead to the designation of this sample, Easy Prime-Part B, as a non-corrosive.