UTILIZATION OF THE CORROSITEX® TEST METHOD TO EVALUATE A SAMPLE PROVIDED BY APPLIED SPECIALTIES, INC.

Completion Date:

May 25, 1999

Client:

Applied Specialties, Inc. 33555 Pin Oak Parkway Avon Lake, Ohio 44012

Client Contact:

Helvia A. Garcia

Phone Number:

(440) 933-9442

Testing Laboratory:

InVitro International 16632 Millikan Ave

Irvine, CA 92606 Phone: (949) 851-8356 Fax: (949) 851-0563

Study Scientist:

Angels Tang M.S.

Date

Senior Vice President and

General Manager,

Customized Technology Services:

Dennis E. Chenoweth, M.D., Ph.D., M.B.A. Date

EXECUTIVE SUMMARY

A sample provided by Applied Specialties was evaluated with the Corrositex® test method to determine its corrosive potential and to designate its Packing Group classification. The results of this study may be summarized as follows:

| Sample Description | pН | Mean Corrositex * Time (minutes) | Packing Group |
|-----------------------|-------|----------------------------------|------------------|
| AS-9002 | 11.16 | 26,01 ± 0.11 | П |

990160B

EVALUATION OF A SAMPLE PROVIDED BY APPLIED SPECIALTIES, INC. UTILIZING THE CORROSITEX® TEST METHOD

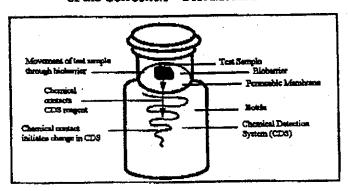
STUDY OBJECTIVE

A sample provided by Applied Specialties 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, >60 min, | | |
| Category 2 | 0 to 3 min. | >3 to 30 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 #: C1659 | Corrositex Time (minutes) | |
|--------------------|---------------------------|--|
| Sample: AS-9002 | Replicate #1: 26.08 | |
| Conc. Tested: Neat | Replicate #2: 26.13 | |
| pH*: 11.16 | Replicate #3: 25.93 | |
| Category: 2 | Replicate #4: 25.90 | |
| Packing Group: II | Mean ± SD: 26.01 ± 0.11 | |

^{*} pH is taken at 10% aqueous solution.

DISCUSSION

A single sample obtained from Applied Specialties 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 26.01 ± 0.11 minutes was required to destroy the synthetic biobarriers. These findings lead to the designation of this sample, AS-9002, as a Packing Group II (moderate corrosivity).