CORROSITEX®

CORROSITEX®

CORROSITEX®

CORROSITEX®

CORROSITEX®

The accurate information you need to quickly and cost-effectively determine corrosivity to classify materials in just a few minutes to a few hours.

Accurate information is good business.

InVitro
INTERNATIONAL
17751 Sky Park East, Ste. G. Irvin California 92614

CORROSITEX®

Reference Manual

TABLE OF CONTENTS

NIH NEWS RELEASE

NATIONAL INSTITUTES OF HEALTH

National Institute of Environmental Health Science

FOR IMMEDIATE REALEASE
June 22, 1999
NIEHS PR # 10-99

NIEHS Press Contact: John Peterson
Phone: 919-541-7860

SCIENCE PANEL ENDORSES NEW NON-ANIMAL TEST TO SEE IF CHEMICALS WILL BURN, CORRODE SKIN AND EYES

For the first time, a new federally sponsored panel of scientists has endorsed the use of a non-animal test to determine – for safety and regulatory purposes, and for labeling – whether a chemical is likely to burn or corrode human skin.

The new test can often replace a method in which a chemical or chemical mixture is placed on the intact skin of a laboratory animal.

The results of the review of the new non-animal test were announced today by the National Institute of Environmental Health Sciences, the National Toxicology Program and 13 other federal agencies that support the Interagency Coordination Committee on the Validation of Alternative Methods, an organization established in 1997. this ICCV AM sponsored scientific review, provides a basis for decisions by the regulatory agencies about how the test will be used in their decision making.
The panel said the new method can fully replace the use of animals for testing corrosiveness and irritation in some cases, while in others, only a single animal is required to confirm a chemical's corrosiveness.

William Stokes, D.V.M., the National Institute of Environmental Health Sciences' associate director for animal and alternative resources, said, "Current regulations usually require three animals for each chemical that is evaluated for skin corrosivity and dermal irritation. Since there are more than two thousand chemicals introduced each year, this could result in a considerable reduction in the use of laboratory animals to identify corrosives." Last year, Dr. Stokes was recognized by the Humane Society of the United States under its Russell and Burch Awards program for his leadership in advancing alternative methods of toxicity testing.

Skin corrosiveness testing is conducted to ensure that chemicals and products are properly labeled to alert consumers and workers to take precautions to prevent chemical burns to the skin and eyes.

In the new test, developed under the trade name Corrositex, a chemical or chemical mixture is placed on a collagen matrix barrier that serves as a kind of artificial skin. Once it penetrates the barrier, the chemical causes the color change in a liquid detection system composed of pH indicator dyes. The time it takes for a test chemical to penetrate the barrier and produce a color change in the detection system is compared to a classification chart to determine corrosivity.

In order to develop a scientific consensus on the usefulness and limitations of the new test, panel members evaluated all available information and data to determine the extent to which each of the ICCVAM criteria for validation and acceptance of new test methods was addressed.

Panel chair Robert Scala, Ph.D., said, "We concluded that Corrositex may be used as part of a tiered testing strategy for assessing the dermal corrosive potential of chemicals, or as a stand-alone alternative to the in vivo (live animal) corrosivity test when used in specific testing circumstances for acids and bases. We are also recommending that since false positive or negative test results are possible, there should be ample opportunity for confirmatory testing." Dr. Scala is a former president of the Society of Toxicology.

This is the second expert panel to be convened by ICCVAM for the review of a new toxicological test method. The first review resulted in the validation of a test called the Murine Local Lymph Node Assay that uses one-third to one-half fewer animals to determine the potential of chemicals to cause allergic dermatitis.

Corrositex is sold by In Vitro International of Irvin, Calif.

The National Institute of Environmental Health Sciences
is a component of the National Institutes of Health.
U.S. Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, N.C. 27709

June 18, 1999

W. Richard Ulmer
President and CEO
InVitro International, Inc.
16632 Millikan Avenue
Irvin, CA 92606

Dear Mr. Ulmer:

I am pleased to provide you with the final peer review panel report on the evaluation of the validation status of your proposed test method, Corrositex®. The report, *Corrositex®. An In Vitro Method for Assessing Dermal Corrosivity Potential of Chemicals* (NIH Publication No. 99-4495), has been reviewed and endorsed by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The report will be forwarded to Federal and international agencies for their consideration of Corrositex® for regulatory acceptance and other appropriate non-regulatory applications.

On behalf of ICCVAM and the National Toxicology Program's Interagency Center for the Evaluation of Alternative Toxicological Methods (Center), I want to express our sincere appreciation for your continued cooperation throughout the review process. The information that you and your staff provided greatly facilitated the evaluation.

The independent peer review panel concluded that for specific testing circumstances such as that required by the U.S. Department of Transportation (US DOT), Corrositex® is useful as a stand-alone assay for evaluating the corrosivity or noncorrosivity of acids, bases, and acid derivatives. The current DOT exemption specifies other chemical classes that may be evaluated using Corrositex®; however, the panel did not review data for these classes and therefore did not provide a statement regarding the method's usefulness for these classes.

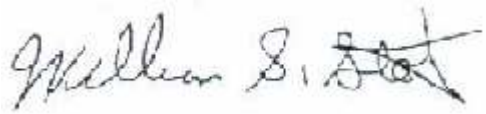
In other testing circumstances, and for other chemical and product classes, the Panel concluded that Corrositex® may be used as part of a tiered assessment strategy, such as the evaluation strategy for dermal irritation/corrosion proposed by the Organization for Economic Co-Operation and Development. In this approach, negative responses must be followed by dermal irritation/corrosion testing, and positive responses require no further testing unless the investigator is concerned about potential false positive responses. The Panel recommended that with either testing outcome, an

investigator may conclude that confirmation testing is necessary based on consideration of supplemental information, such as pH, structure-activity relationships, and other chemical and/or testing information. These conclusions are based on use of the method in accordance with Panel recommendations provide in the report.

The peer review panel concluded that Corrositex® offers advantages with respect to animal welfare considerations. First, , Corrositex®, when used as a stand-alone assay for some testing applications such transportation purposes, can replace the use of animals for corrosivity testing of qualified chemicals in some chemical classes. Secondly, when used as part of a tiered-testing strategy for corrosivity, there is a reduction in the number and when further testing in animals is determined to be necessary, only one animal is required to confirm a corrosive chemical. Lastly, Corrositex® also provides for refinement in that most of the chemicals that are identified as negative by Corrositex® or nonqualifying in the detection system are unlikely to be corrosive when tested in the *in vivo* test for irritation potential.

Again, thank you for your cooperation with ICCVAM and the Center in accomplishing this review of Corrositex®. Please feel free to contact the Center if you would like additional copies of the report or have any question about the evaluation.

Sincerely,



William S. Stokes, D.V.M.
Co-Chair, ICCVAM
NIEHS

Enclosure

CC: ICCVAM
ICCVAM Immunotoxicology Working Group

LAWRENCE W. BIERLEIN
ATTORNEY-AT-LAW

SWIDLER & BERLIN
CHARTERED

DIRECT DIAL
(202) 424-7700

April, 18, 1995

To: InVitro International Customers

From: Lawrence W. Bierlein

Re: Use of DOT-E 10904, First Revision

I understand that you are using the InVitro International Corrositex alternative to animal skin testing to determine corrosivity and Packing Groups under the hazardous materials transportation regulations administered by the U.S. Department of Transportation (DOT) and international dangerous goods codes. As counsel to InVitro International, I have prepared the following summary of the effects of DOT-10904 (First Revision) for those who may have questions about using it. A copy of the revised exemption is attached.

As you know, the DOT regulations and international dangerous goods codes govern the transportation of a wide range of hazardous materials, including research samples, feedstocks, intermediates, products and wastes. One of the nine regulated materials classifications is Class 8, for corrosive liquids and solids, under 49 CFR § 173.136-137. Although the Environmental Protection Agency's corrosivity characteristics for hazardous wastes (40 CFR § 261.22) may be determined by the pH of a material, it also remains necessary for generators to determine the corrosive properties and Packing Group of wastestreams by the DOT criteria as well, in order to meet the DOT/EPA requirements for packaging, marking, labeling, manifesting and vehicle placarding.

The ranking of the severity of corrosivity in transportation is expressed in terms of the Packing Group of the material, with Packing Group I being the most serous hazard rank, Packing Group II describing materials of more moderate risk, and Packing Group III covering materials posing the lowest regulated hazard within Class 8.

Corrosive effects on human skin are reflected within all three transportation Packing Groups for Class 8. By regulation, specified procedures for live animal testing are accepted to replicate the likely effects on human skin. No one favors corrosive materials testing on live animals, however. In addition to other serious concerns, it often has bee noted that live animals, testing is expensive, time-consuming, and difficult to reproduce consistently.

3000, K STREET, N.W. ▪ SUITE 300
WASHINGTON, D.C. 20007-5116
(202) 424-7500 ▪ TELEX 701131 ▪ FACSIMILE (202) 424-7643

Through the original issuance and recent revision of DOT-E 10904 at the request of InVitro International, the U.S. DOT has continued to authorize the first alternative to live animal testing to determine both corrosivity as a hazard classification, and the applicable Packing Groups within that class. Through this exemption, it now is possible to establish the classification and Packing Group of your products and wastes without animal testing or risky guesswork.

In order to take advantage of this positive regulatory alternative, you need not obtain your own DOT exemption or become a party to InVitro's exemption. You may determine your classifications and Packing Groups under InVitro International's exemption, provided you have a copy and meet the conditions DOT has described in the exemption. As a shipper of regulated materials and user of this exemption, you do have certain obligations.

It is important for you to read the attached exemption itself, as well as the test procedures authorized under the DOT exemption. When using this exemption, please note the following binding conditions –

- The exemption is limited to testing:

    a. Acids, inorganic and organic.
    b. Acid derivatives (anhydrides, haloacids, salts etc.), inorganic and organic.
    c. Acyl halides.
    d. Alkylamines and polyalkylamines.
    e. Bases, inorganic and organic.
    f. Chlorosilanes.
    g. Metal halides and oxyhalides.
    h. Any materials containing the materials noted above.

- You need to maintain a current copy of the attached revised exemption in your files where Corrositex testing is performed to determine Class 8 or its Packing Groups and at your initial shipping location. You need not keep a copy at any subsequent distribution centers or shipping points.

- You also need to keep a copy of InVitro International's Corrositex test method, as described in Paragraph 4.4 of InVitro's exemption application, referenced in Paragraph 7 of the exemption, at the location where your testing is performed but not at shipping locations. A copy of the test method is attached.

- DOT-E 10904 (First Revision) has an expiration date of March 1, 1997, unless renewed by DOT upon application by InVitro International. The company will make a timely application for renewal no later than December 1996. In your use of this exemption, it is essential to support InVitro's renewal application on your behalf and on behalf of other Corrositex users, for you to provide InVitro International or DOT with copies of your test results including:
  a. The basic identification of the material tested;
  b. Whether the material was shown to be corrosive or non-corrosive; and,
  c. The packing Group indicated for materials shown to be in Class 8.

  Duplicate data sheets and a self-addressed postage paid envelope are provided with each Corrositex kit. You only need to enclose the copy for all samples tested with the kit, and forward it to InVitro International.

- Please note that DOT also has waived tow requirements usually applicable to their exemptions. You do not need to show the exemption number on packages containing materials classified under the exemption or on your shipping papers. See paragraph 8.c. of the attached exemption.

Please contact your InVitro International representative at 1-800-2-InVitro if you have any questions on this recently revised alternative to live animal testing for the corrosive materials Class 8 and Packing Groups within that class.

Sincerely,

Lawrence W. Bierlein

Attachments

May 3, 2006

U.S. Department
Of Transportation

400 Seventh Street, S.W.
Washington, D.C. 20590

**Pipeline and
Hazardous Materials
Safety Administration**

DOT-SP 10904
(SEVENTH REVISION)

EXPIRATION DATE: April 30, 2010

(FOR RENEWAL, SEE 49 CFR §107.109)

1. GRANTEE: InVitro International
   Irvin, CA

2. PURPOSE AND LIMITATIONA:
   a. This special permit authorizes the use of a classification test method for the determination of skin corrosivity as an alternative to a procedure specified in the Hazardous Materials Regulations (HMR). This special permit provides no relief from the HMR other than as specifically stated herein.
   b. The safety analyses performed in development of this special permit only considered the hazards and risks associated with transportation in commerce.
   c. Party status will not be granted to this special permit.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.

4. REGULATIONS FROM WHICH EXEMPTED: The marking requirements of §§ 172.203(a), 172.301(c) and 172.302(b) and (c); and §§173.136(a) and 173.137 in that the use of a non-animal test method is not authorized except as specified herein.

5. BASIS: This special permit is based on the application of InVitro International dated April 26, 2006, submitted in accordance with §107.109.

6. HAZARDOUS MATERIALS:
   The following types of materials may be tested as specified by this special permit:
   a. Acids, inorganic and organic.
   b. Acid derivatives (anhydrides, haloacids, salts etc.), inorganic and organic.
   c. Acyl halides.
   d. Alkylamines and polyalkylamines.
   e. Bases, inorganic and organic.
   f. Chlorosilanes.
   g. Metal halides and oxyhalides.

7. SAFETY CONTROL MEASURES:
   a. As an alternative to the procedure specified in §173.136(a), the corrosivity of a material described in Paragraph 6 above may be determined in accordance with the test method specified in Paragraph 4.4A through 4.4E of InVitro International's application dated September 28, 1992, as amended.
   b. For materials that are determined to be corrosive, packing groups must be assigned according to Paragraph 4.4C of the application.

8. SPECIAL PROVISIONS:
   a. This special permit authorizes the use of an alternative test method for the determination of skin corrosivity by any person or class or persons, in addition to the holder of this special permit, subject to the terms specified herein. However, no person may apply the test method authorized by this special permit unless that person maintains a current copy of this special permit and the test method identified in Paragraph 7 above at each facility where the tests are performed for the purpose of determining the hazard class and packing group of a material for its transportation in commerce.
   b. A current copy of this special permit must be retained by each person initially offering a hazardous material for transportation under this special permit.

c. Packages containing corrosive materials, classed and assigned packing groups as authorized by this special permit, may be offered and reoffered for transportation and transported in the same manner as required for corrosive materials classed according to §173.136(a).
d. The marking requirements of 49 CFR, §§ 172.203(a), 172.301 (c) and 172.302(b) and (c) are waived unless another special permit is involved requiring the display of a special permit number.

9. MODES OF TRANSPORTAION AUTHORIZED: Motor vehicle, rail freight, cargo vessel, cargo aircraft only, passenger carrying aircraft.

10. MODAL REQUIREMENTS: None as a condition of this special permit.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law 49 U.S.C. 5101 et seq.:

- All terms and condition prescribed in this special permit.
- Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- Registration required by §107.601 et seq., when appropriate.

Each "Hazmat employee", as defined in §171.8 who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit when it has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) – 'The Hazardous Materials Safety and Security Reauthorization Act of 2005' (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term 'exemption' to 'special permit' and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 – Immediate notice of certain hazardous materials incidents, and 171.16 – Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:

Robert A. McGuire
Associated Administrator
Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Material Safety, Pipeline and Hazardous Materials Safety Administration, Department of Transportation, Washington, D.C. 20590. Attention: PHH-31.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: GEC/sln

CORROSITEX®

TESTING PROCEDURES

DOT-E 10904

TABLE OF CONTENTS

CORROSITEX® INSTRUCTIONS

I. MATERIALS AND EQUIPMENT

A. **2-Sample Kit**

1) One vial containing one gram of biobarrier matrix and a micro stirbar.
2) One vial containing 10 ml of biobarrier diluent.
3) Two racks of seven vials filled with Chemical Detection System (CDS).
4) One Tray of 12 membrane discs plus one additional membrane disc. **These discs must be stored in the refrigerator at 2-8˚C.**
5) Two Data Sheets.
6) Three Qualify test tubes.
7) Two Categorize tests (two A test tubes, two B test tubes, and one bottle of Confirm Reagent).

B. **4-Sample Kit**

1) One vial containing one gram of biobarrier matrix and a micro stirbar.
2) One vial containing 10 ml of biobarrier diluent.
3) Four racks of seven vials filled with Chemical Detection System (CDS).
4) One Tray of 24 membrane discs plus one additional membrane disc. **These discs must be stored in the refrigerator at 2-8˚C.**
5) Four Data Sheets.
6) Five Qualify test tubes.
7) Four Categorize tests (four A test tubes, four B test tubes, and one bottle of Confirm Reagent).

C. **CORROSITEX Lab** (Contains all equipment necessary to perform the CORROSITEX test method – must be purchased separately)

1) Nuova II stirring hot plate – 110 V (1)
2) Thermometer (1)
3) Digital timers (2)
4) Eppendorf repeat pipettor (1)
5) Eppendorf combitips 2.5 ml (1 case/100)
6) Lab Industries positive displacement pippetor (1)
7) Lab Industries positive displacement pippetor tips (1 case/250)
8) Spatula (1)
9) Forceps (1)
10) Uvex safety goggles (1 pair)
11) Permanent lab marking pens (2)
12) Water bath container (1)
13) Plastic wrap (1 roll)

II. BIOBARRIER PREPARATION[1]

NOTE: Preparation must be completed at least 2 hours prior to running tests.

1) Place the water bath container on the hot plate and insert a thermometer.

2) Fill the water bath container with approximately one inch of water and heat to 68 – 70˚C (turn the heath knob to 7-8). **Do not allow the temperature to exceed 70˚C.**

3) While the water bath is warming, remove the membrane discs from the refrigerator. Remove the tray lid to prevent condensation.

4) Add the entire contents of the biobarrier diluent to the vial of biobarrier matrix powder. Place the vial inside the water bath on the hot plate.

5) Turn the stir knob to medium speed (4-5). Make sure the micro stirbar is rotating smoothly, but not too fast (avoid foaming). Adjust the stir knob if necessary.

   NOTE: DO NOT VORTEX OR SHAKE THE VIAL VIGOROUSLY TO SOLUBILIZE.

6) Allow the biobarrier matrix powder to dissolve completely. This should take approximately 20 minutes.

7) Turn of the stir knob and the heat. Allow the solution to sit for 5 minutes in the water bath to allow any air bubbles to rise to the surface.

   NOTE: To prevent the biobarrier solution from solidifying in the vial, do not remove the vial from the water bath. Immediately proceed to Step 8.

8) Assemble the repeat pipettor with a 2.5 ml combitip and set the pipettor to position four (4), to dispense a total of 200 µl.

---

[1] The instructions detailed below describe the simultaneous preparation of all of the biobarriers. Occasionally, it may be more convenient to analyze only a single sample at one time. If this is the case, prepare only 7 biobarrier membranes with the dissolved biobarrier matrix powder prepared in Step 6. the unused matrix solution may then be stored at 2-8˚C in its tightly sealed original vial for up to 1 month. To prepare the remaining biobarriers at a later date, solubilize the solidified matrix gel by warming it for 3 to 4 minutes without stirring in a 60˚C water bath prior to pipetting it as described in Steps 8 – 12.

Pre-made biobarriers are also available. They may be ordered from InVitro International by calling **(800)-2-INVITRO.**

9) Fill the pipettor tip with biobarrier solution, avoiding air bubbles. Dispense one aliquot to waste to ensure proper subsequent volume delivery. Wipe the pipettor tip to remove excess solution.

10) Pipet 200 µl into each membrane disc, ensuring the entire membrane is covered and no air bubbles have formed. Any air bubbles on the gel will alter the result of the test. If this occurs, the disc should not be used and should be replaced with the spare membrane disc supplied in the kit.

11) Note the preparation and expiration dates of the biobarriers on the tray label. Tightly wrap the filled tray with plastic wrap and immediately store the tray at 2-8˚C.

12) **The tray must be stored at 2-8˚C for 2 hours prior to beginning any testing.** The biobarriers are stable for **7 days** if wrapped with an airtight seal and stored at 2-8˚C. This procedure must be followed as described, as the biobarriers are sensitive and dehydration.

III. CORROSITEX TESTING PROTOCOL

STEP 1 – QUALIFY: This step ensure that your sample is compatible with the CORROSITEX system prior to running the test and may be performed prior to the biobarrier preparation if desired.

1) Fill in the sample information on the CORROSITEX Data Sheet.

2) Add the sample (150 µl if liquid, 100 mg if solid) to the Qualify test tube. Shake to dissolve solids. For immiscible liquids and insoluble solids, shake the vial and let stand for one minute. Observe the color change at the sample/testing fluid interface.

3) If the amber liquid changes color or consistency, check **yes** on the Sample Qualified section of the Data Sheet and proceed to Step 2.

4) If a physical change is not observed, your material is not suitable for the CORROSITEX system. Check **no** on the Sample Qualified section of the Data Sheet and contact your technical representative at **(800)-2-INVITRO.**

STEP 2 – CATEGORIZE: This step establishes the category of cut-off times for your sample.

1) Add the sample (150 µl if liquid, 100 mg if solid) to the tubes labeled Tube A (yellow solution) and Tube B (clear solution). Cap and shake until mixed.

2) If a color change is observed in either tube, match the color to the corresponding color charts on the CORROSITEX Testing Protocol Poster. Assign and record the appropriate category on the Data Sheet and proceed to Step 3.

3) If a color change is not observed in either tube, add two drop of the CONFIRM reagent to **Tube B.** Cap and shake until mixed.

4) Match the resulting color to the color chart on the CORROSITEX Testing Protocol Poster (Step 2B). Assign and record the appropriate category on the Data Sheet and proceed to Step 3.

Note: For immiscible samples, shake the vial and let stand for one minute. Observe the color change at the sample/testing fluid interface.[2]

STEP 3 – CLASSIFY: This step determines the appropriate Packing Group for your sample.

1) Make certain all proper safety procedures are followed for the chemicals being tested. Consult your company's safety procedures prior to proceeding. USE PROPER SAFETY EQUIPMENT – Fume hood, gloves, eye protection, etc.

2) Remove one tray of seven pre-filled CDS vials from the kit box.

3) The CDS vials must be at room temperature (17-25˚C) before using.

---

[2] Occasionally, either intensely colored samples or samples that promote subtle color changes in the Categorize tubes may be encountered. These types of samples may be accurately categorized by performing the following protocol:

1) Measure and record the pH of 10% (v/v or w/v) aqueous solution of the sample.

2) If the pH of the 10% solution is <7.0, utilize Tube A (yellow solution) to perform the categorization test. If the pH of the 10% solution is >7.0, utilize Tube B (clear solution) to perform the categorization test.

3) Add the sample (150 µl if liquid, 100 mg if solid) to the tube that has been selected. Cap and shake until mixed.

4) Measure and record the final pH of the mixture in tube.

5) For measurements performed with Tube A, if the pH is ≤ 5.0, the sample is Category 1. If the pH > 5.0, the sample is Category 2. For measurements performed with Tube B, if the pH ≥ 9.0, the sample is Category 1. If the ph < 9.0, the sample is Category 2.

4) Vials 1 – 4 are to be utilized for sample replicate testing. The vial labeled (+) is to be utilized for a positive control sample, the vial labeled (-) is for a negative control sample and the vial labeled C serves as a CDS color control.

Note: Label each vial cap with the corresponding test material for appropriate disposal purposes.

The following table lists several chemicals which may be used as positive and negative controls, or you may establish your own controls. If the control falls outside the designated range, please contact your technical representative at **800-2-INVITRO.**

CORROSITEX POSITIVE AND NEGATIVE CONTROLS

	Chemical	Conc. (wt. %)	CORROSITEX Time (min.)
Positive Control	Nitric Acid	68-73	0.5 – 2.0
	Sulfuric Acid	95-98	0.5 – 2.0
Negative Control	Citric Acid	10	>60
	Propionic Acid	6	>60

5) One timer may be used for the sample replicates and one timer may be used for the controls. Place the timers in front of the rack. Make certain they are set to zero and are ready to time the test.

6) Add a biobarrier disc to the top of the first vial. Do not allow the discs to be in the vial for longer than two minutes before adding the test sample.

NOTE: The tray of biobarrier discs should be kept on crushed ice when not in the refrigerator. Immediately re-wrap and place the tray of unused discs back into a 2-8˚C refrigerator after completion of the test.

7) Evenly apply 500 µl or 500 mg of the test sample onto the top of the biobarrier disc and start the timer the instant the sample is added.

Repeat Steps 6 and 7 for the remaining vials, staggering each start time by one minute. The start time difference for each vial will be subtracted from the final time to determine the net response time. Staggering allows more accurate time recording if exact reaction times are desired.

DO NOT CAP THE VIALS WHILE THE TEST IS IN PROGRESS DUE TO POSSIBLE PRESSURE BUILD UP WITH SOME REACTIVE CHEMICALS.

8) The first indication of the presence of a chemical in the CDS will be a narrow stream of color change produced beneath the center of each biobarrier disc. As soon as this reaction is observed, record the detection time on the Data Sheet.

   If exact reaction times are not required, observe the CDS vials for the first 5 minutes after each start time and for 5 minutes before and after each Packing Group cut-off time. For example, if you have a Category 1 sample the CDS vials would be observed for the first 5 minutes, and then again at the 55 to 65 minute interval and the 235 to 245 minute interval for each vial.

   NOTE: Changes in the CDS may include various color changes (red, orange, or lightening) and flaking or precipitation.

9) When the test has been completed, remove the biobarrier discs and cap each vial. Use caution when handling vials. Follow your lab protocol for proper chemical disposal.

10) Repeat Steps III.1, 2 and 3 for each sample to be tested.

11) Calculate the CORROSITEX Time and the mean of the four sample replicates. (CORROSITEX Time = Detection Time – Start Time).

12) Using the table below, assign the appropriate Packing Group by sample category and CORROSITEX time.

PACKING GROUP DESIGNATION

	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	Non-corrosive

CORROSITEX®

A How-To Guide to the

Convenient and Cost-Effective

Identification of Corrosive

and Non-Corrosive Materials.

CORROSITEX® BIOBARRIER PREPARATION

a Add entire contents of Diluent to the vial of Biobarrier Matrix powder.

b Stir and warm to 68 - 70°C in a water bath until the Biobarrier Matrix powder has completely dissolved (approximately 20 min.).

c Pipet 200 µl into each membrane disc, ensuring the entire membrane is covered and no air bubbles have formed.

d Note the preparation/expiration dates, seal the tray with plastic wrap and refrigerate (2 - 8°C) immediately. Do not freeze.

Caution: Wear and use safety equipment and conduct test under approved fume hood for corrosive materials.

Pre-made biobarriers available from InVitro.
Ask for details when ordering.

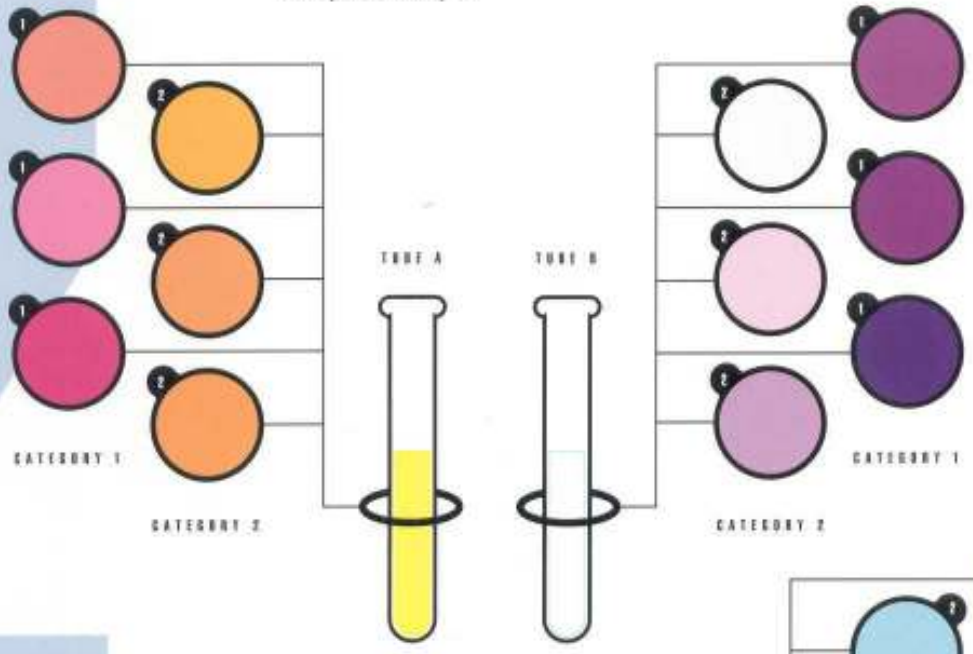
CORROSITEX® TESTING PROTOCOL

STEP 1- QUALIFY

Add your sample (150 µl if liquid, 100 mg if solid) to the Qualify test tube. If the amber liquid changes consistency or color, proceed to Step 2. If a physical change is not observed, your material is not suitable for the Corrositex system. Please call your technical representative at 1-800-2-INVITRO.

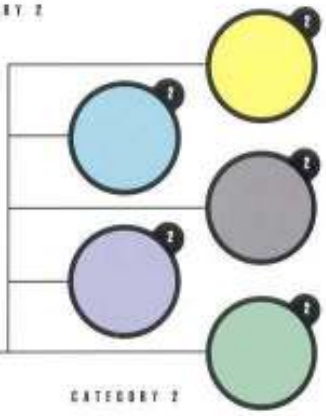
STEP 2- CATEGORIZE

Add your sample* (150 µl if liquid, 100 mg if solid) to Tube A and Tube B. Cap and shake until mixed. If a color change is observed in either tube, match the color to the corresponding color chart. Assign the appropriate category and proceed to Step 3. If a color change is *not* observed in either tube, proceed to Step 2B.



STEP 2B

Add two drops of the CONFIRM reagent to Tube B. Cap and shake until mixed. Match the resulting color to the color charts at right. Assign the appropriate category and proceed to Step 3.



*For intensely colored samples, please refer to the instruction manual.

INVITRO INTERNATIONAL

STEP 3- CLASSIFY

a Place one (prepared and refrigerated) Biobarrier Disc in the top of each vial. Begin test immediately (no later than 2 minutes).

b Add 500 µl (liquid) or 500 mg (solid) of your test sample and control chemicals into Biobarrier Discs in each of the 6 vials and start timers. *Caution: Do not cap the vials during the test due to possible pressure build up.*

c As soon as a reaction is observed in the Chemical Detection System, record the detection time.

d Remove each Biobarrier Disc, cap and dispose of vials using your lab protocol for proper chemical disposal.

Use the category determined in Step 2 and the reaction time determined in Step 3 to assign the proper Packing Group as shown in the table to the right.

U.N. PACKING GROUP ASSIGNMENT TABLE

Category	Time Required for CDS change (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**	**Non-corrosive**

Note: Full compliance with DOT regulations requires metal corrosivity data before packaging as a non-corrosive.

CORROSITEX®

CORROSITEX is an *in vitro* testing system that mimics the effect of corrosives on living skin and classifies the level of corrosivity in chemicals, formulations and waste.

CORROSITEX can save your business time and money by enabling you to accurately and efficiently package and ship hazardous materials.

Ensures Compliance - New regulations stipulate that all corrosives in commerce be classified prior to shipment into United Nations (U.N.) Packing Groups according to DOT and international requirements. CORROSITEX accurately assigns U.N. Packing Groups I, II, III, or verifies non-corrosivity.

Lower Costs - CORROSITEX costs up to 80% less than *in vivo* testing.

Quicker Results - CORROSITEX delivers results in as little as 3 minutes to 4 hours.

Greater Accuracy - Because CORROSITEX is more accurate than pH testing and is packing group specific, it prevents costly over-packing and eliminates any potential risk of under-packing corrosive materials.

Reduces Risk - CORROSITEX provides important information on potential dangers in the workplace and the type of emergency response required in case of an accident.

Government Approved - Government approved and internationally accepted, CORROSITEX is recommended by and/or meets the requirements of:

- *U.S. Department of Transportation (DOT): DOT-E 10904*
- *Environmental Protection Agency (EPA): SW-846 Method 1120*
- *International Air Transport Association (IATA)*
- *Occupational Safety and Health Administration (OSHA)*
- *Transport Canada*
- *United Nations Packing Groups*
- *European Community*

Faster Product Development -
CORROSITEX accelerates product development by allowing you to:

- Inexpensively pre-screen and modify new formulations
- Determine the toxic impact of formulations
- Rapidly bring to market better, safer brands

CORROSITEX can be purchased and performed on-site, or you may send your samples off-site to a private laboratory for testing. For more information on how CORROSITEX can benefit your company, contact InVitro International at **1-800-2-INVITRO**.

InVitro International's CUSTOMIZED TECHNOLOGY SERVICES is dedicated to ensuring that our products and services meet your specific requirements.

WE FULLY GUARANTEE YOUR SATISFACTION.

16632 Millikan Ave. • Irvine, CA 92606 • 1-800-2-INVITRO • Fax: 714-851-0563
http://www.invitrointl.com

INVITRO INTERNATIONAL

CORROSITEX Y2K UPDATE

I. On Jun 22nd, 1999 the National Institute of Environmental Health Sciences (NIEHS), the National Toxicology Program and 13 other federal agencies that support the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) announced their endorsement of the Corrositex test method.

II. When volatile test samples give off vapors, this can stimulate overestimated test results in the Corrositex system; please refer to Chapter 5 for resolution.

III. The Corrositex test correlates very well with the *in vivo* test except for aqueous compounds whose pH is in the range of 5 to 8.5. This phenomenon does not endanger public safety because these neutral solutions are found to be noncorrosive about 85% of the time using more traditional animal testing methods. We (In Vitro) need samples with pH in this range previously tested corrosive via *in vivo* methods. Such samples are needed for our research purposes and we will pay for them. Please call us toll free @ (800) 246-8487.

IV. We have approximately 2000 Corrositex test results in our database. These are used in a consulting way today and may be available through our web site within the next year. Please call us at the above listed number if this is of interest to you.

V. The most frequently asked question about Corrositex testing involves the categorization step. Please refer to Chapter 3, page 4 for a "trouble shooting" approach to categorizing a sample which does not change color clearly, or if the sample has an intense color. In these instances we will categorize the sample by the pH test.

BULLETIN: COT004-080594
REVISED: 05/11/95

FOR FURTHER INFORMATION:
U.S. Technical Service (800) 2-INVITRO

TECHNICAL REPORT: DEALING WITH OVERESTIMATED RESULTS IN CORROSITEX® DUE TO SAMPLE VAPORS

Volatile test samples giving off vapors or fumes can potentially generate overestimated test results in the CORROZITEX® system. The problem is caused by sample vapors seeping down into the Chemical Detection System (CDS) between the vial wall and the biobarrier prior to an actual membrane breakthrough taking place.

The problem is characterized by extremely fast detection times, discoloration of the CDS at the top of the vial only or the presence of two color streams moving down the sides of the biobarrier disc and joining together just below the biobarrier membrane.

This problem is easily remedied through the use of a silicone sealant or petroleum jelly such as Vaseline. If you suspect a vapor problem, coat the entire outside upper surface of the biobarrier disc, just under the lip, with a liberal amount of sealant. Seat the disc in the top of the vial insuring that an airtight seal is established. Make sure that the sealant does not come into contact with the lower surface of the biobarrier disc, the biobarrier membrane or the CDS.

This procedure will insure that vapors do not come into contact with the CDS before the test sample has actually broken through the biobarrier membrane. If you have any questions regarding this procedure, call InVitro International's technical support group at the phone number given above.

BULLETIN: COT 003-040194
REVISED: 05/05/95

FOR FURTHER INFORMATION:
U.S. Technical Service (800) 2-INVITRO

TECHNICAL REPORT: pH VALUES CANNOT BE EMPLOYED TO ASSIGN PACKING GROUPS

EPA regulations (40 C.F.R. §261.22) define a substance to be corrosive if it "is aqueous and has a pH less than or equal to 2 [≤ 2.0] or greater than or equal to 12.5 [≥ 12.5]." However, this definition has at least three important limitations. First, scientific studies have shown that there are many substances whose pH falls within the presumably noncorrosive range of 2.0 to 12.5 that actually **are corrosive.** Second, it is impossible to use pH value, by itself, to permit accurate assignment of Packing Groups as required by DOT regulations for Class 8 corrosive materials. Third, this definition refers to aqueous solutions and is not applicable for solids. Consequently, reliable testing procedures, other than the measurement of pH, are required in order to accurately identify and classify corrosives.

The failure of pH to predict corrosivity has been demonstrated in two ways. Initially, an examination of information published in 49 C.F.R. §172.10 was conducted. This study revealed that 32% of all compounds whose pH was in the range 2.0 to 12.5 were considered to be corrosive as judged by either *in vivo* testing or DOT assignment. Subsequently, the CORROSITEX test was employed to characterize the corrosivity of 442 chemicals and chemical formulations to known pH. The results of these studies are summarized in Table 1 and Figure 1.

TABLE 1. Relationship Between pH and Packing Group: Results of Corrositex Testing

	pH ≤ 2.0		**2.0 < pH < 12.5**		**pH ≥ 12.5**	
Packing Group	**N**	**%**	**N**	**%**	**N**	**%**
I	15	11.8	1	0.4	0	0.0
II	91	71.7	49	22.1	60	64.5
III	9	7.1	25	11.3	17	18.3
Non-Corrosive	12	9.4	147	66.2	16	17.2
Total	127	100.0	222	100.0	93	100.0

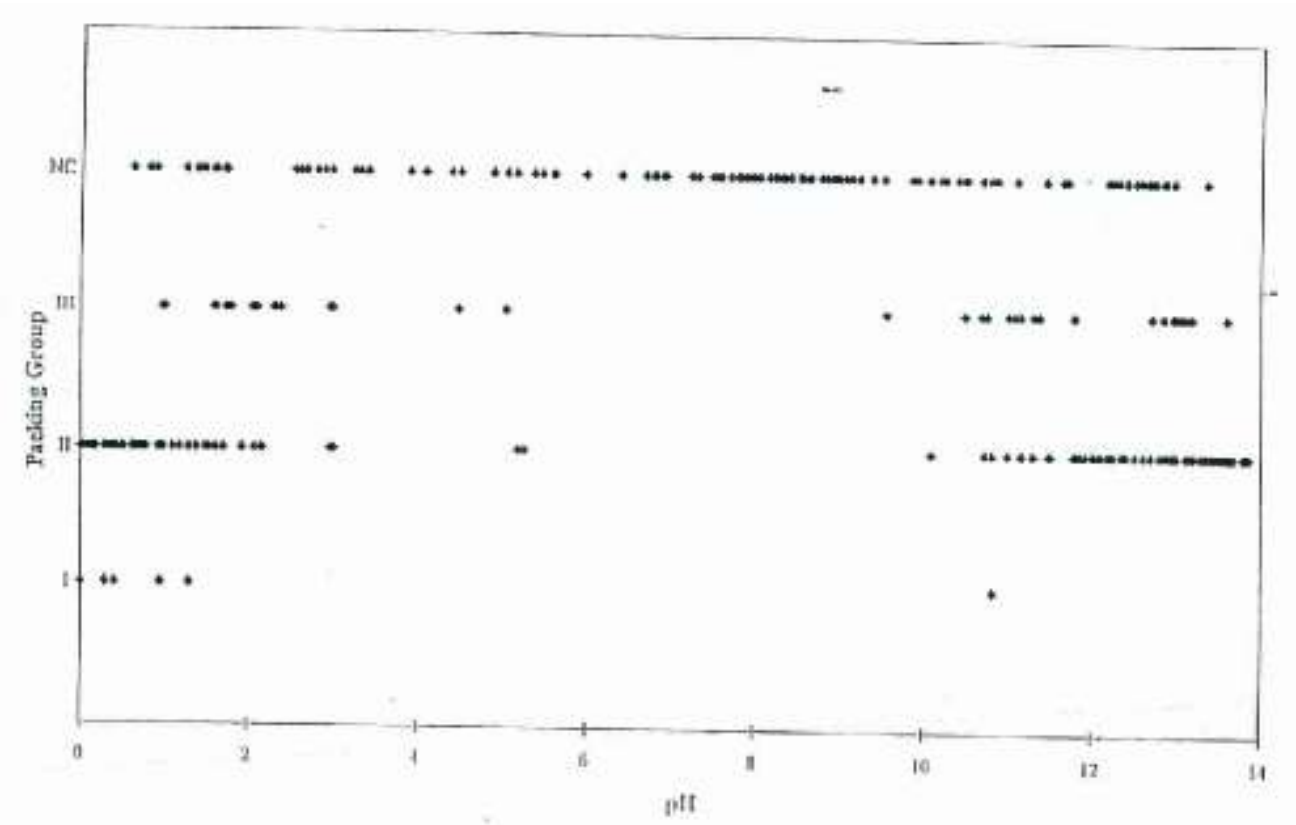
These findings demonstrated, as expected, that most very acidic compounds were found to be corrosive. However, somewhat unexpectedly, the results, of CORROSITEX testing also indicated that nearly 1 in 10 of the compounds whose pH was less than or equal to 2.0 could be considered to be noncorrosive. When chemicals whose pH was in the range of 2.0 to 12.5 were evaluated, the results of the CORROSITEX test were nearly identical to those previously observed for *in vivo* testing, i.e., one third of all tested compounds were found to be corrosive rather than noncorrosive. When very alkaline materials were examined, the CORROSITEX test demonstrated that only 83% of these materials were corrosive. Taken together, these findings provided clear evidence that the measurement of pH alone did not provide an adequate description of the corrosivity of many common chemicals and chemical formulations.

While the measurement of pH does not permit assignment of Class 8 Packing Groups, the CORROSITEX test has been specifically designed to provide the information. As shown in Table 1 and Figure 1, the results of CORROSITEX testing clearly demonstrated that only 16 of the 442 tested compounds (3.6%) should be classified as Packing Group I corrosive materials. With only one exception, all of these compounds were very acidic in nature. Packing Group II materials were observed to be the most frequently encountered type of corrosive material, with 200 of the 442 tested chemicals (45.2%) being classified in this manner. As would be expected, Packing Group II materials were most often found to be strongly acidic or strongly basic. However, a surprising number of compounds (22.1%) that would have been considered to be noncorrosive as judged strictly by their pH were found to be classified as Packing Group II materials when evaluated with the CORROSITEX test. Interestingly, materials classified in Packing Group III were essentially equally distributed among highly acidic, neutral and extremely alkaline compounds.

The CORROSITEX test provides an additional benefit when compared to the measurement of pH, i.e., the CORROSITEX test has been specifically constructed to determine the corrosivity of either liquids or solids. By contrast, pH measurement can only be conducted an aqueous solutions.

These investigations have clearly demonstrated that the measurement of pH is an inadequate means of establishing the corrosivity of chemical compounds and this test is not suited for the designation of corrosive materials Packing Groups. By contrast, the CORROSITEX test provides a simple, accurate and reproducible method for identifying both corrosive liquids and solids and assigning them to the appropriate Packing Group. This is particularly important to both the manufacturers and transporters of all types of chemical formulations because, for the first time, it is now possible to utilize a simple *in vitro* test to eliminate the excessive costs of over-packaging improperly classified materials as well as avoiding the risks of under-packaging misclassified corrosive materials.

Figure 1. Relationship Between pH and Corrosivity



BULLETIN: C-004-080796
REVISED: 07/28/2003

FOR FURTHER INFORMATION:
U.S. Technical Service (800) 2-INVITRO

TECHNICAL REPORT: ASSESSING CORROSIVITY WITH THE CORRISITEX®

EXECUTIVE SUMMARY

In Vitro International's Corrositex® test is an U.S. Department of Transportation-approved (DOT E-10904) laboratory alternative to the *in vivo* methods that are commonly employed to assess dermal corrosivity. As reported here, ongoing investigations have clearly demonstrated that this *in vitro* method is a satisfactory means of defining the corrosivity of Class 8 hazardous materials. Specifically, a complete review of our existing data suggested the following conclusions:

- With regard to the ability to assess the corrosivity of well-defined inorganic and organic acids and bases, the results obtained with the Corrositex test are quite comparable to those obtained with standard *in vivo* test methods.

- With regard to the ability to assess the corrosivity of complex mixture of inorganic and organic acids and bases, the results obtained with the Corrositex test are quite comparable to those obtained with standard *in vivo* test methods.

- As judged by sensitivity, specificity, false positive rates, and false negative rates, the Corrositex test tends to "err on the side of safety".

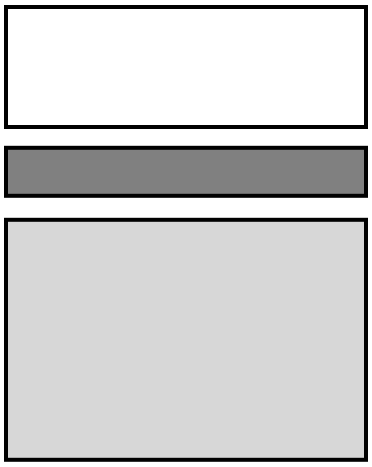
- Aqueous compounds whose pH is within the range of 5 to 8.5 frequently fail to qualify for the Corrositex test. This phenomenon does not endanger public safety because these neutral solutions are almost universally found to be noncorrosive.

- The Corrositex test method has been shown to produce false positive results when testing formulations combining some (but not all) surfactants and wetting agents. The frequency of such results may be as high as 30%. Currently, In Vitro International has only fourteen pieces of data, among its several thousand test results, to suggest this overestimation. We are very interested in working with any company to further our information base for the cause of testing on fewer animals, and are willing to pay for such cooperation while testing.

- The Corrositex test tends to exhibit an increased false negative rate for petrochemicals and for compounds designated as agrochemicals, the concordance of the *in vitro* and *in vivo* tests is marginal. Consequently, neither of these types of materials is included in the current DOT exemption.

SCIENTIFIC BACKGROUND

The mechanism of action of the Corrositex test is briefly described in Figures 1 and 2 below.

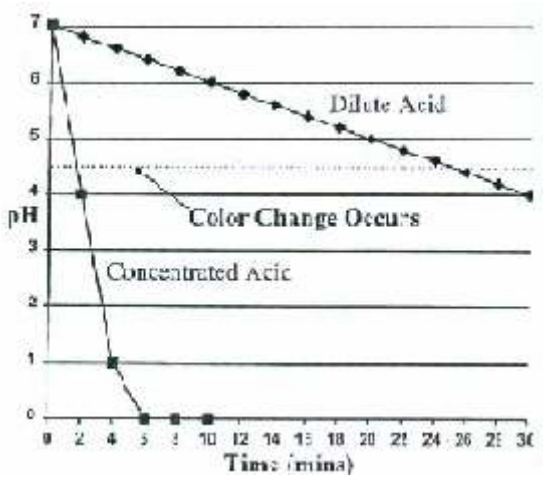


Collagen gel is predominantly composed of **water,** with small amounts of dissolved protein. Most test materials actually **diffuse** through the aqueous phase of this gel. Only the most corrosive materials (Packing Group I) will destroy this portion of the biobarrier.

Porous *Cellulose membrane* permits free **diffusion** of chemicals whose molecular weight is <12,000. only the most corrosive substances actually burn a hole in the membrane.

Chemical Detection System is composed of water and two pH indicator dyes. The pH of the CDS is 7. The acid indicator dye changes color when the pH of the solution drops below 4.5. The basic indicator dye changes color when the pH rises above 8.5. Therefore, acids and bases that enter the CDS are detected because they promote a visible change in the color of these indicator dyes. **NOTE:** Chemicals that do not cause the pH to change appreciably will **not qualify** for the assay because they fail to provoke a color change.

Figure 1. Detailed Description of the Components of the Corrositex® Test



When a test material diffuses through the biobarrier, it mixes with and alters the pH of the CDS. A color change occurs when the pH of the CDS falls below 4.5 or rises above 8.5. The **Time** that is required to cause this change in pH is governed by three factors:

1. the **strength** of the acid or base,
2. the **rate of diffusion** of the test material and,
3. for very corrosive substances, the **rate of destruction** of the biobarrier.

These mechanisms are depicted in the graph shown at the left. In this example, concentrated and dilute hydrochloric acid (HCl) were analyzed with the Corrositex® test. Because the rate of diffusion is proportional to concentration, the concentrated acid diffused through the biobarrier more rapidly than the dilute acid solution. Additionally, the concentrated HCl reacted chemically with (hydrolyzed) the collagen and cellulose to cause destruction of the biobarrier. As a result, the concentrated acid entered the CDS and caused a color change in less than 2 minutes. By contrast, the dilute acid required 25 minutes to diffuse through the biobarrier and induce a visible color change. Accordingly, the concentrated acid was considered to be a Packing Group I material and the dilute acid was a Packing Group II substance.

Figure 2. Diffusion Times and Acid/Base Strength Govern "Breakthrough" Times

Based on this understanding, it is clear that this *in vitro* test method would be best suited for the determination of the corrosivity of acidic and alkaline compounds. Consequently, manufacturers and shippers of these types of products, typically referred to as Class 8 corrosives, would be expected to benefit most from use of this *in vitro* alternative to the *in vivo* tests of corrosivity.

METHODS

During the past few years, In Vitro International's scientists have collected information on more than 1000 potentially corrosive compounds. In May, 1994 this data was summarized and submitted to the US Department of Transportation in an Application for Renewal of Exemption DOT E-10904. Subsequently, as outlined in Figure 3, this data was examined and duplicated samples, diluted solutions of the same material, and non-qualifying samples were eliminated from consideration. In addition, all data was re-examined and, when necessary, corrected to insure that the results were consistent with the requirements of the Corrositex test protocol that was approved by the DOT in its exemption dated March 22, 1995. The resulting edited database, which contained a description of 419 distinct samples, was subsequently employed as the primary source of information for this report.

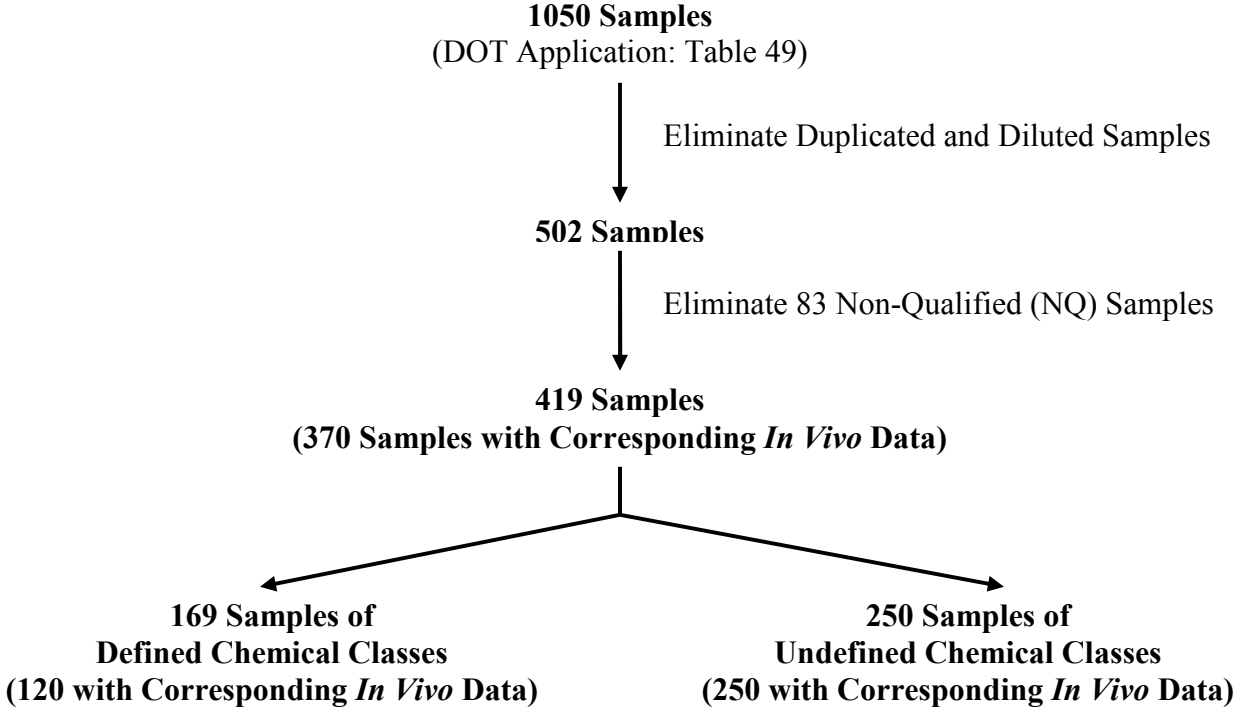


Figure 3. Schematic Diagram Depicting Refinement of the Corrositex Data Originally Submitted to the DOT on May 24, 1994.

RESULTS

Comparison of Corrositex and Published Results

Examination of the In Vitro International data base demonstrated that 83 of the 419 chemicals listed there could also be found in the DOT Hazardous Materials Table (49 CFR 172.101). For these 83 compounds, the results obtained with the Corrositex test were then compared to those listed in this published table. These findings are summarized in Table 1.

		DOT Results		
		Corrosive	**Noncorrosive**	**Total**
Corrositex Results	**Corrosive**	76	Not Applicable	76
	Noncorrosive	7	Not Applicable	7
	Total	83	Not Applicable	83

Table 1. Comparison of Corrositex Results with Results Predicted from DOT List Of Corrosive Chemicals (49 CFR 172.101).

These observations demonstrate that the equivalence of the Corrositex method and the DOT designation is 91.6% and the false negative rate of the Corrositex test is 8.4%.

Interestingly, the information contained in the In Vitro International data base also permitted a comparison of *in vivo* results with the information contained in the DOT table found in 49 CFR 172.101. Specifically, the data base contained 34 chemicals that were found in 49 CFR 172.101 and had corresponding *in vivo* data. The findings for these 34 chemicals are summarized in the 2X2 contingency table shown below.

		DOT Results		
		Corrosive	**Noncorrosive**	**Total**
***In Vivo* Results**	**Corrosive**	24	Not Applicable	24
	Noncorrosive	10	Not Applicable	10
	Total	34	Not Applicable	34

Table 2. Comparison of *In Vivo* Results with Results Predicted from DOT List Of Corrosive Chemicals (49 CFR 172.101).

These observations suggest that the equivalence of the *in vivo* method and the DOT designation is 70.6% and, if the DOT results are considered to be the acceptable standard, the false negative rate of the *in vivo* test is 29.4%. Alternatively, this data could be interpreted as indicating that the DOT table tends to over-estimate corrosivity, displaying a false positive rate of 29.4% when compared to the *in vivo* data.

Comparison of the results contained in Tables 1 and 2 above indicates that the Corrositex test correlates more closely with the corrosivity designations found in the DOT table than the *in vivo* test results do. This observation is consistent with the knowledge that In Vitro International's scientists originally set out to develop a laboratory test that could substitute for the measures of corrosivity embodied in the DOT regulations.

Comparison of Corrositex and *In Vivo* Results

Another method that was employed to assess the performance of the Corrositex test consisted of comparing *in vitro* and *in vivo* test results. These studies demonstrated that 370 of the 419 chemicals and compounds found in the data base had corresponding Corrositex and *in vivo* data. These findings are summarized in Tables 3 and 4 shown below.

		***In Vivo* Results**		
		Corrosive	**Noncorrosive**	**Total**
Corrositex Results	**Corrosive**	144	40	184
	Noncorrosive	15	171	186
	Total	159	211	370

Table 3. Comparison of Corrositex Results with *In Vivo* Results.

Parameter	Formula	Results
Equivalence=	Number of Compounds Correctly Identified / Total Number of Compounds Tested	**=315/370=85.1%**
Sensitivity=	Number of Corrosives Correctly Identified / Total Number of Corrosives	**=144/159=90.6%**
Specificity=	Number of Noncorrosives Correctly Identified / Total Number of Noncorrosives	**=171/211=81.0%**
Predictive Value= (Corrosives)	Number of Corrosives Correctly Identified / Total Number of Corrosive Results	**=144/184=78.3%**
Predictive Value= (Noncorrosives)	Number of Noncorrosives Classified as Corrosive / Total Number of Noncorrosive Results	**=171/186=91.9%**
False Positive Rate=	Number of Noncorrosives Classified as Corrosive / Total Number of Compounds Tested	**=40/370=10.8%**
False Negative Rate=	Number of Corrosives Classified as Noncorrosive / Total Number of Compounds Tested	**=15/370=4.0%**

Table 4. Summary of the Performance of the Corrositex Test Compared to *In vivo* Findings

These findings demonstrate that the Corrositex test correlates well with the accepted *in vivo* method of assessing dermal corrosivity. The sensitivity and specificity of the laboratory test favors identification of corrosive substances. This observation is also substantiated by noting that the false positive rage is approximately tow and one-half times greater than the false negative rate. All of

these observations are consistent with the stated developmental objective of providing an *in vitro* test that tends to "err on the side of safety".

Comparison of Corrositex and *In Vivo* Results for Acids and Bases

As noted previously, the Corrositex test was specifically designed to assess the corrosivity of Class 8 corrosives. Consequently, the types of chemicals that have been assessed to date have predominantly been those that are thought to be consistent with this designation.

Selected information was obtained for specific categories of defined compounds by compiling the data for 169 materials of known chemical composition. This data was then utilized to develop the 2X2 contingency tables and performance analysis for each chemical class as shown below.

When **inorganic and organic acids** as well as **acid mixtures** were delineated within the data base, the following results were obtained:

Contingency Table:

		***In Vivo* Results**		
		Corrosive	**Noncorrosive**	**Total**
Corrositex Results	**Corrosive**	21	2	23
	Noncorrosive	1	1	2
	Total	22	3	25

Table 5. Comparison of Corrositex Results with *In Vivo* Results for **Inorganic and Organic Acids** and **Acid Mixtures.**

Performance summary:

Parameter	Results
Equivalence	**22/25 = 88.0%**
Sensitivity	**21/22 = 95.5%**
Specificity	**1/3 = 33.3%**
Predictive Value (Corrosives)	**21/23 = 91.3%**
Predictive Value (Noncorrosives)	**1/2 = 50.0%**
False Positive Rate	**2/25 = 8.0%**
False Negative Rate	**1/25 = 4.0%**

Table 6. Summary of the Performance of the Corrositex Test Compared to *In Vivo* Findings for **Inorganic and Organic Acids** and **Acid Mixtures.**

When **inorganic and acid derivatives** were delineated within the data base, the following results were obtained:

Contingency Table:

		***In Vivo* Results**		
		Corrosive	**Noncorrosive**	**Total**
Corrositex Results	**Corrosive**	10	2	12
	Noncorrosive	1	13	14
	Total	11	15	26

Table 7. Comparison of Corrositex Results with *In Vivo* Results for **Acid Derivatives.**

Performance summary:

Parameter	Results
Equivalence	**23/26 = 88.5%**
Sensitivity	**10/11 = 90.9%**
Specificity	**13/15 = 86.7%**
Predictive Value (Corrosives)	**10/12 = 83.3%**
Predictive Value (Noncorrosives)	**13/14 = 92.9%**
False Positive Rate	**2/26 = 7.7%**
False Negative Rate	**1/26 = 3.9%**

Table 8. Summary of the Performance of the Corrositex Test Compared to *In Vivo* Findings for **Acid Derivatives.**

When **alkylamines and polyalkylamines** were delineated within the data base found in Appendix VII, the following results were obtained:

Contingency Table:

		***In Vivo* Results**		
		Corrosive	**Noncorrosive**	**Total**
Corrositex Results	**Corrosive**	17	2	19
	Noncorrosive	10	3	3
	Total	17	5	22

Table 9. Comparison of Corrositex Results with *In Vivo* Results for **Alkylamines and Polyalkylamines.**

Performance summary:

Parameter	Results
Equivalence	**20/22 = 90.9%**
Sensitivity	**17/17 = 100.0%**
Specificity	**3/5 = 60.0%**
Predictive Value (Corrosives)	**17/19 = 89.5%**
Predictive Value (Noncorrosives)	**3/3 = 100.0%**
False Positive Rate	**2/22 = 9.1%**
False Negative Rate	**0/22 = 0.0%**

Table 10. Summary of the Performance of the Corrositex Test Compared to *In Vivo* Findings for **Alkylamines and Polyalkylamines.**

When **inorganic and organic bases** were delineated within the data base, the following results were obtained:

Contingency Table:

		***In Vivo* Results**		
		Corrosive	**Noncorrosive**	**Total**
Corrositex Results	**Corrosive**	7	0	7
	Noncorrosive	1	0	1
	Total	8	0	8

Table11. Comparison of Corrositex Results with *In Vivo* Results for **Inorganic and Organic Bases.**

Performance summary:

Parameter	Results
Equivalence	**7/8 = 87.5%**
Sensitivity	**7/8 = 87.5%**
Specificity	**N/A**
Predictive Value (Corrosives)	**7/7 = 100.0%**
Predictive Value (Noncorrosives)	**N/A**
False Positive Rate	**0/8 = 0.0%**
False Negative Rate	**1/8 = 12.5%**

Table 12. Summary of the Performance of the Corrositex Test Compared to *In Vivo* Findings for **Inorganic and Organic Bases.**

An interesting way of summarizing this data is suggested by the knowledge that the Corrositex Chemical Solution is composed of an aqueous solution of an acidic indicator dye (methyl orange) and a basic indicator dye (phenyl red). As a result, the Corrositex test would be expected to perform most reliably as a means of characterizing the dermal corrosivity of acids and bases. Therefore, the acid and base data from Tables 5, 7, 9, and 11 presented above have been compiled and are presented below in Table 13.

		***In Vivo* Results**		
		Corrosive	**Noncorrosive**	**Total**
Corrositex Results	**Corrosive**	55	6	61
	Noncorrosive	3	17	20
	Total	58	23	81

Table13. Comparison of Corrositex Results with *In Vivo* Results for **Organic and Inorganic Acids and Bases.**

The performance of the Corrositex test for organic and inorganic acids and bases may then be calculated as follow:

Parameter	Results
Equivalence	**72/81 = 88.9%**
Sensitivity	**55/58 = 94.8%**
Specificity	**17/23 = 73.9%**
Predictive Value (Corrosives)	**55/61 = 90.2%**
Predictive Value (Noncorrosives)	**17/20 = 85.0%**
False Positive Rate	**6/81 = 7.4%**
False Negative Rate	**3/81 = 3.7%**

Table 14. Summary of the Performance of the Corrositex Test Compared to *In Vivo* Findings for **Inorganic and Organic Acids** and **Bases.**

The results reported here suggest that, for acids and bases, the Corrositex test is very comparable to the *in vivo* test of dermal corrosivity. In addition, with regard to corrosive materials, the Corrositex test displays excellent sensitivity and predictivity. The false positive rate of the Corrositex test is twice the false negative rate. In these regards, the results obtained with acids and bases alone are very consistent with those reported for all of the different types of compounds found in the current data base (see Table 4).

Comparison of Corrositex and *In Vivo* Results for Other Chemical Classes

As shown below in Table 15, the Corrositex test has been employed to characterize the corrosivity of several other classes of chemicals and chemical formulations.

Product Category	N	Equivalence	Sensitivity	Specificity	Corrosive Predictivity	Noncorrosive Predictivity	False Positive	False Negative
Agrochemical	24	45.8%	85.7%	88.0%	75.0%	93.8%	8.3%	4.2%
Biocide	10	100%	N/A	100%	N/A	100%	0%	N/A
Cleaner	114	79.8%	96.1%	66.1%	70.4%	95.3%	18.4%	1.8%
Petrochemical	27	77.8%	62.5%	84.2%	62.5%	84.2%	11.1%	11.1%
Surfactant	34	88.0%	95.5%	33.3%	91.3%	50.0%	8.0%	4.0%
Surfactant Blend	49	89.8%	100%	83.3%	79.2%	100%	10.2%	0%
Textile Dye	7	85.7%	N/A	85.7%	N/A	100%	14.3%	N/A

Table 15 Summary of Performance of the Corrositex Test when Compared to *In Vivo* Test Results for Classes of Chemicals of Unknown Composition (Data from Appendix XI).

The findings obtained during these studies suggested that "industrial cleaners" tend to give an elevated false positive response rate in the Corrositex test. Initial investigations indicate that most of these formulations appear to be composed of a mixture of dilute (0.5 – 2.0%) alkali, dilute (0.5 – 5.0%) sodium metasilicate, and a surfactant. Further studies aimed at gaining a better understanding of these phenomena and developing a more reliable version of the Corrositex test that is specifically designed for these types of compounds are currently underway.

It was also noted that the Corrositex test did not appear to be highly concordant with the *in vivo* test for materials classed as "agrochemicals". Similarly, materials designated to be "petrochemicals" appear to display the greatest false negative rate.

Finally, as summarized in Table 16 found on the next page, evaluation of the available data suggested that about 16% of the tested materials failed to qualify for the Corrositex test, i.e., failed to produce a measurable change in the Qualify reagent provided with the test kit. Examination of the characteristics of 502 samples revealed that 83 of them failed to qualify in the initial step of the Corrositex test. Of these 83 non-qualifying samples, 32 had recorded pH measurements. Of these 32 samples, 26 (81%) exhibited pH value within the range of 5 to 8.5. Additionally, it was observed that samples that were characterized as surfactants or surfactant blends and hydrocarbons or petrochemicals also displayed a tendency to fail to qualify.

Description	N	Percent of Total Samples	Percent of NQ Samples
Total Samples	502	100.0	N/A
Total Non-Qualifying (NQ) Samples	83	16.5	100.0
Total NQ Samples with pH measurements	32	6.4	38.6
Total NQ Samples with pH between 5 and 8.5	26	5.2	31.3
Total NQ Samples that were Surfactant/Surfactant Blends	26	5.2	31.3
Total NQ Samples that were Hydrocarbon/Petrochemicals	22	4.4	26.5

Table 16. Summary of the Characteristics of Common Non-Qualifying Materials

The observation that samples that have a pH in the range of 5.0 to 8.5 display a significant rate of non-qualification in the Corrositex test is consistent with the knowledge that the CDS indicator solution does not exhibit a color change in this pH range.

SUMMARY

In Vitro International's Corrositex test has been specifically designed to assess the corrosivity of Class 8 corrosive substances. The components of the test include a proprietary biobarrier that mimics the dermis and Chemical Detection System that provides a sensitive means of detecting acidic or basic substances.

The Corrositex test has been validated by comparing its performance to that of the accepted *in vivo* test method. These studies have demonstrated that the two test methods display an equivalence of 85.1%. Of equal importance, the Corrositex test displayed a sensitivity of 90.6%, specificity of 81.0%, and false negative rate of only 4.0%, indicating that the laboratory method was unlikely to misclassify a truly corrosive substance.

Studies performed with specific types of materials demonstrated that the Corrositex test most reliably classified acids and bases as well as acidic and basic mixtures of chemicals. Compounds whose pH was within the range of 5.0 to 8.5 frequently failed to qualify for the Corrositex test because they did not produce a color change in the indicator dyes found in the CDS reagent. However, this was not deemed to be a significant limitation of the *in vitro* test method because neutral compounds are seldom found to be corrosive. Additionally, the Corrositex test tended to over-estimate the corrosivity of industrial cleaners composed of a mixture of dilute alkali, sodium metasilicate, and a surfactant. However, these results were judged to be acceptable because the laboratory test method tended to "err on the side of safety" rather than underestimate the corrosivity of these common cleaning products.

REFERENCES

V.C. Gordon, J.D. Harvell, and H.I. Maibach, Dermal Corrosion, The CORROSITEX System: A DOT Accepted Method to Predict Corrosivity Potential of Test Materials, *In Vitro* Skin Toxicology, ed. Andre Rougier, V10: 37-45.

V.C. Gordon, S. Mirhashemi, R. Wei and V. Harutunian, A New *In Vitro* Method to Determine the Corrosivity Potential of Surfactants and Surfactant-Based Formulations, communicaciones – Presentadas a la XXV Jornadas Del Comite Espanol De La Detergencia.

BULLETIN: C005-95102
REVISED: 07/28/2003

FOR FURTHER INFORMATION:
U.S. Technical Service (800) 2-INVITRO

TECHNICAL REPORT: SUMMARY OF CORROSITEX® PAST AND PRESENT

The 1993, original Corrositex® technology authorized by DOT was recently refined; it is now an even more expedient and effective alternative animal tests when determining corrosivity and U.N. Packing Groups. This information is relevant to the OSHA hazard communication program under 29 CFR 1910.1200, and to the EPA hazardous waste program under 40 CFR Part 262.

On March 22, 1995, DOT issued "DOT-E 10904 (First Revision)" incorporating all of IVI's requested changes. Thus, the Corrositex testing protocol, as amended, may be used for the same materials covered by the initial exemption:

1. To determine corrosivity and Packaging Groups for strong acids and bases, and for weak acids and bases.
2. To use only four of the six available test units, thereby leaving two for use as controls.
3. To determine that a material is not regulated as a skin-corrosive, without having to resort to animal testing.

The exemption, as revised, has bee extended until March 1, 1997. At least 60 days before that expiration date, IVI will apply once again for renewal. Under DOT regulations, when a timely application for renewal has been filed, the exemption remains in effect until the agency acts on the application.

Background. Hazardous materials are regulated as products and waste in the workplace, transportation and in disposal by the Occupation Safety & Health Administration (OSHA), the Department of Transportation (DOT), and the Environmental Protection Agency (EPA), respectively. Parallel regulatory organizations exist at the international as well as the local level. Most materials are subject to the rules for all three types of agencies as those materials move to and from production and use locations, and ultimately to disposal or treatment facilities.

All of these regulatory bodies include corrosive materials within the scope of their regulations. The most common hazard of corrosive materials is their impact on human skin, as illustrated by their effect on the skin of test animals such as rabbits.

Within the United Nations system for classification, as implemented in the United States through DOT's Docket No. HM-181, corrosive materials are in "Class 8". The degree of corrosivity is expressed by the "Packing Group" of the material, with Packing Group I being the most severely corrosive, Packing Group II being moderately corrosive, and Packing Group III covering materials that are less corrosive but still within the scope of the transportation regulations. Use of this system of classifications became mandatory on October 1, 1993. It is recognized worldwide, through the International Maritime Organizations' Dangerous Goods Code, the International Civil Aviation Organization's Technical Instructions on the Air Transport of Dangerous Goods, the rules of Transport Canada and those being developed by Mexico, and within Europe under the codes administered by RID, ADR, and AND.

U.S. Department of Transportation Exemption

IVI's Corrositex Technology. Corrositex offers a recognized alternative to animal testing to determine whether a material is skin-corrosive, and t rank the severity of that corrosivity.

DOT-E 10904. In 1993, the U.S. Department of Transportation pioneered the federal recognition of the Corrsitex alternative to animal testing by issuing DOT Exemption 10904. This exemption authorized shippers to determine whether a material falls within the corrosive materials class (Class 8) and, if so, the appropriate Packing Group for that material. The following types of materials were authorized to be tested under the exemption:

a) Acids, both inorganic and organic.
b) Acid derivatives (anhydrides, haloacids, salts, etc.), both inorganic and organic.
c) Acyl halides
d) Alkylamines and polyalkylamines.
e) Bases, both inorganic and organic.
f) Chlorosilanes.
g) Metal halides and oxyhalides.

Subsequently, OSHA indicated that for purposes of their hazard communication system of Material Safety Data Sheets, etc/ (29 CFR 1910.1200), the DOT-authorized corrosive determinations could be utilized. Classification and Packing Groups as determined in accordance with DOT authorizations also must be shown on the Uniform Hazardous Waste Manifest, and must be used in the selection of appropriate packaging for hazardous wastes shipped off-site (40 CFR Part 262).

The initial DOT exemption contained a provision which required performance of animal tests if the Corrositex results did not show a material to be a corrosive, i.e., a Noncorrosive reading under the exemption still compelled animal testing. As DOT explained at the time, more experience with the technology was required before DOT would authorize its use to declare a material to be unregulated.

DOT-E Renewal and Expansion

DOT-E 10904 (First Revision). DOT's authority is limited by statue to grants of exemptions for a maximum of a 2 year term. Thereafter the exemption may be renewed for another 2 years, etc. When IVI applied for renewal of DOT-E 10904, certain important revisions to be exemption also were requested – First, the Company had found that certain weak acids and bases could give false positive readings under the original testing protocol. In other words, the test results for certain materials prompted a more stringent level of regulation than animal tests showed to be necessary. Accordingly, IVI's application for renewal asked DOT to authorize a modification to the test protocol for weak acids and bases, with different observations times than those for strong acids and bases. Data for over 1,000 materials were provided to support the application, showing the modified protocol to be more accurate than the original protocol for alal material and Packing Groups. Second, the testing protocol originally authorized by DOT under the exemption involved preparation of six test samples. Experience under the exemption showed that only four sample replicates were necessary. IVI requested a reduction in the required number of test samples, so the additional test units could be used as controls in good laboratory practices. Third, data developed by IVI and many users to exemption confirmed that Corrositex could determine noncorrosivity at least as accurately as animal tests. IVI asked DOT to remove the paragraph compelling animal testing upon a finding of noncorrosivity.

InVitro

INTERNATIONAL

Corporate Office
17751 Sky Park East, Suite G
Irvin, California 92614
800-2-INVITRO
FAX: 949-851-4985
http://www.invitrointl.com

Date: 08/05 Revision: 5

MATERIAL SAFETY DATA SHEET 10000

InVitro International
17751 Sky Park East, Ste. G
Irvin, CA 92614
Telephone: (714) 851-8356
Fax: (714) 851-0563

FOR EMERGENCY INFORMATION CALL:
1-800-535-5053

Section I: PRODUCT IDENTIFICATION

Product Name: CRROSITEX® Quality Test
SPECIFIC CONTENTS ARE TRADE SECRET

Section II: HAZARDOUS COMPONENTS

To our knowledge this product contains no hazardous component.

Section III: TOXICITY HAZARDS

Irritation Data: NA
Toxicity Data: NA

Section IV: PHYSICAL DATA

Appearance: Yellow/orange liquid.
Odor: No distinctive odor.

Section V: FIRE AND EXPLOSION HAZARD

Fire Hazards: None.
Explosion Hazards: None.
Extinguishing Media: NA.
Special Firefighting Procedure: None.

Section VI: HEALTH HAZARD DATA

Acute Effects: Harmful if swallowed. May be harmful if inhaled or absorbed through skin. Causes eye and skin irritation

First Aid: In case of contact, flush eyes or skin with copious amount of water.

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

If swallowed, wash out mouth with water, provided person is conscious.

Call a physician.

Section VII: REACTIVITY DATA

Stability: Stable

Incompatibles: Alkaline Metals.

Hazardous Combustion or Decomposition Product: None known.

Conditions Leading to Hazardous Polymerization: Will not occur.

Section VIII: SPILL OR LEAK PROCEDURES

Steps to be taken if material is released or spilled: Wipe spilled material with a dry cloth or absorb in sand. Place in a container for later disposal. Wash spill site after material pick up is complete.

Waste Disposal Method: The substance can be disposed of as regular waste.

Section IX: PROTECTIVE EQUIPMENT AND CONTROL MEASURES

Wear chemical resistant gloves, safety goggles and other protective clothing. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Section X: HANDLING AND STORAGE

Store in cool, dry place
Protect from Light.
Keep tightly closed.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. In Vitro International shall not be held liable for any damage resulting from handling or from contact with the above product. The information contained herein is furnished without warranty of any kind and is intended for the use only by persons having adequate related technical skills and at their own discretion and risk. Users should consider these data only as a supplement to other information gathered by them and must make independent

InVitro

INTERNATIONAL

Corporate Office
17751 Sky Park East, Suite G
Irvin, California 92614
800-2-INVITRO
FAX: 949-851-4985
http://www.invitrointl.com

Date: 08/05 Revision: 5

MATERIAL SAFETY DATA SHEET 10001

InVitro International
17751 Sky Park East, Ste. G
Irvin, CA 92614
Telephone: (714) 851-8356
Fax: (714) 851-0563

FOR EMERGENCY INFORMATION CALL:
1-800-535-5053

Section I: PRODUCT IDENTIFICATION

Product Name: Corrositex® Biobarrier Matrix

SPECIFIC CONTENTS ARE TRADE SECRET

Section II: HAZARDOUS COMPONENTS

To our knowledge this product contains no hazardous component.

Section III: TOXICITY HAZARDS

Irritation Data: NA

Toxicity Data: NA

Section IV: PHYSICAL DATA

Appearance: Tan crystals.

Odor: No distinctive odor.

Section V: FIRE AND EXPLOSION HAZARD

Fire Hazards: None known.

Explosion Hazards: None Known

Extinguishing Media: Water Spray, Carbon Dioxide, Dry Chemical Powder or appropriate foam.

Special Firefighting Procedure: Wear self contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

Section VI: HEALTH HAZARD DATA

Acute Effects: May be harmful by inhalation, ingestion or skin absorption.

Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

The toxicological properties have not been thoroughly investigated.

First Aid: In case of contact, immediately wash affected area with soap and copious amount of water.

In case of eye contact, immediately flush eyes with copious amount of water for at least fifteen (15) minutes.

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, call a physician.

Section VII: REACTIVITY DATA

Stability: Stable

Incompatibles: Anionic agents and nitrates.

Hazardous Combustion or Decomposition Product: Nature of decomposition products not known.

Conditions Leading to Hazardous Polymerization: Will not occur.

Section VIII: SPILL OR LEAK PROCEDURES

Steps to be taken if material is released or spilled: Sweep up, place in bag and hold for waste disposal. Avoid raising dust.

Waste Disposal Method: The substance can be disposed of as regular waste.

Section IX: PROTECTIVE EQUIPMENT AND CONTROL MEASURES

Persons who exhibit allergic reactions should observe the following precautions in handling this product:

Respiratory Protection: NIOSH or MSHA approved respiratory protection.

Section X: HANDLING AND STORAGE

Store in cool, dry place
Protect from Light.
Keep tightly closed.

Persons who exhibit allergic reactions should observe the following precautions in handling this product:
Use safety goggles or glasses, gloves and approved respiratory equipment.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. In Vitro International shall not be held liable for any damage resulting from handling or from contact with the above product. The information contained herein is furnished without warranty of any kind and is intended for the use only by persons having adequate related technical skills and at their own discretion and risk. Users should consider these data only as a supplement to other information gathered by them and must make independent

InVitro
INTERNATIONAL

Corporate Office
17751 Sky Park East, Suite G
Irvin, California 92614
800-2-INVITRO
FAX: 949-851-4985
http://www.invitrointl.com

Date: 08/05 Revision: 5

MATERIAL SAFETY DATA SHEET 10002

InVitro International
17751 Sky Park East, Ste. G
Irvin, CA 92614
Telephone: (714) 851-8356
Fax: (714) 851-0563

FOR EMERGENCY INFORMATION CALL:
1-800-535-5053

Section I: PRODUCT IDENTIFICATION

Product Name: Corrositex® Diluent
SPECIFIC CONTENTS ARE TRADE SECRET

Section II: HAZARDOUS COMPONENTS

A dilute solution of organic poly-ol, slightly acidic to litmus.

Section III: TOXICITY HAZARDS

Irritation Data: NA
Toxicity Data: NA

Section IV: PHYSICAL DATA

Appearance: Colorless, sweet-tasting liquid.
Odor: No distinctive odor.

Section V: FIRE AND EXPLOSION HAZARD

Fire Hazards: None.
Explosion Hazards: None.
Extinguishing Media: NA.
Special Firefighting Procedure: None.

Section VI: HEALTH HAZARD DATA

Acute Effects: Harmful if swallowed. May be harmful if inhaled or absorbed through skin. Causes eye and skin irritation

First Aid: In case of contact, flush eyes or skin with copious amount of water.

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

If swallowed, wash out mouth with water, provided person is conscious.

Call a physician.

Section VII: REACTIVITY DATA

Stability: Stable

Incompatibles: Strong oxidizing agents and bases.

Hazardous Combustion or Decomposition Product: Toxic fumes of carbon dioxide, carbon monoxide.

Conditions Leading to Hazardous Polymerization: Will not occur.

Section VIII: SPILL OR LEAK PROCEDURES

Steps to be taken if material is released or spilled: Wipe spilled material with a dry cloth or absorb in sand. Place in a container for later disposal. Wash spill site after material pick up is complete.

Waste Disposal Method: The substance can be disposed of as regular waste.

Section IX: PROTECTIVE EQUIPMENT AND CONTROL MEASURES

Wear chemical resistant gloves, safety goggles and other protective clothing. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Section X: HANDLING AND STORAGE

Store in cool, dry place
Protect from Light.
Keep tightly closed.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. In Vitro International shall not be held liable for any damage resulting from handling or from contact with the above product. The information contained herein is furnished without warranty of any kind and is intended for the use only by persons having adequate related technical skills and at their own discretion and risk. Users should consider these data only as a supplement to other information gathered by them and must make independent

InVitro

INTERNATIONAL

Corporate Office
17751 Sky Park East, Suite G
Irvin, California 92614
800-2-INVITRO
FAX: 949-851-4985
http://www.invitrointl.com

Date: 08/05 Revision: 5

MATERIAL SAFETY DATA SHEET 10003

InVitro International
17751 Sky Park East, Ste. G
Irvin, CA 92614
Telephone: (714) 851-8356
Fax: (714) 851-0563

FOR EMERGENCY INFORMATION CALL:
1-800-535-5053

Section I: PRODUCT IDENTIFICATION

Product Name: CRROSITEX®
Chemical Detection System

SPECIFIC CONTENTS ARE TRADE SECRET

Section II: HAZARDOUS COMPONENTS

To our knowledge this product contains no hazardous component.

Section III: TOXICITY HAZARDS

Irritation Data: NA

Toxicity Data: NA

Section IV: PHYSICAL DATA

Appearance: Yellow/orange liquid.

Odor: No distinctive odor.

Section V: FIRE AND EXPLOSION HAZARD

Fire Hazards: None.

Explosion Hazards: None.

Extinguishing Media: NA.

Special Firefighting Procedure: None.

Section VI: HEALTH HAZARD DATA

Acute Effects: Harmful if swallowed. May be harmful if inhaled or absorbed through skin. Causes eye and skin irritation

First Aid: In case of contact, flush eyes or skin with copious amount of water.

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

If swallowed, wash out mouth with water, provided person is conscious.

Call a physician.

Section VII: REACTIVITY DATA

Stability: Stable

Incompatibles: Alkaline Metals.

Hazardous Combustion or Decomposition Product: None known.

Conditions Leading to Hazardous Polymerization: Will not occur.

Section VIII: SPILL OR LEAK PROCEDURES

Steps to be taken if material is released or spilled: Wipe spilled material with a dry cloth or absorb in sand. Place in a container for later disposal. Wash spill site after material pick up is complete.

Waste Disposal Method: The substance can be disposed of as regular waste.

Section IX: PROTECTIVE EQUIPMENT AND CONTROL MEASURES

Wear chemical resistant gloves, safety goggles and other protective clothing. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Section X: HANDLING AND STORAGE

Store in cool, dry place
Protect from Light.
Keep tightly closed.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. In Vitro International shall not be held liable for any damage resulting from handling or from contact with the above product. The information contained herein is furnished without warranty of any kind and is intended for the use only by persons having adequate related technical skills and at their own discretion and risk. Users should consider these data only as a supplement to other information gathered by them and must make independent

InVitro
INTERNATIONAL

Corporate Office
17751 Sky Park East, Suite G
Irvin, California 92614
800-2-INVITRO
FAX: 949-851-4985
http://www.invitrointl.com

Date: 08/05 Revision: 5

MATERIAL SAFETY DATA SHEET 10004

InVitro International
17751 Sky Park East, Ste. G
Irvin, CA 92614
Telephone: (714) 851-8356
Fax: (714) 851-0563

FOR EMERGENCY INFORMATION CALL:
1-800-535-5053

Section I: PRODUCT IDENTIFICATION

Product Name: CRROSITEX®
Categorize Test, Tube A

SPECIFIC CONTENTS ARE TRADE SECRET

Section II: HAZARDOUS COMPONENTS

A biological buffer solution with pH adjusted to 7.0 ± 0.1.

Section III: TOXICITY HAZARDS

Irritation Data: NA

Toxicity Data: NA

Section IV: PHYSICAL DATA

Appearance: Clear yellow liquid.

Odor: No distinctive odor.

Section V: FIRE AND EXPLOSION HAZARD

Fire Hazards: None.

Explosion Hazards: None.

Extinguishing Media: NA.

Special Firefighting Procedure: None.

Section VI: HEALTH HAZARD DATA

Acute Effects: Harmful if swallowed or inhaled.

First Aid: In case of contact, flush eyes or skin with copious amount of water.

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

If swallowed, wash out mouth with water, provided person is conscious.

Call a physician.

Section VII: REACTIVITY DATA

Stability: Stable

Incompatibles: Reactive alkaline metals (e.g. lithium and sodium).

Hazardous Combustion or Decomposition Product: None.

Conditions Leading to Hazardous Polymerization: Will not occur.

Section VIII: SPILL OR LEAK PROCEDURES

Steps to be taken if material is released or spilled: Wipe spilled material with a dry cloth or absorb in sand. Place in a container for later disposal. Wash spill site after material pick up is complete.

Waste Disposal Method: The substance can be disposed of as regular waste.

Section IX: PROTECTIVE EQUIPMENT AND CONTROL MEASURES

Wear chemical resistant gloves, safety goggles and other protective clothing.

MATERIAL SAFETY DATA SHEET 10004
CORRSOTEX® Categorize Test, Tube A

Section X: HANDLING AND STORAGE

Store in cool, dry place
Protect from Light.
Keep tightly closed.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. In Vitro International shall not be held liable for any damage resulting from handling or from contact with the above product. The information contained herein is furnished without warranty of any kind and is intended for the use only by persons having adequate related technical skills and at their own discretion and risk. Users should consider these data only as a supplement to other information gathered by them and must make independent

InVitro

INTERNATIONAL

Corporate Office
17751 Sky Park East, Suite G
Irvin, California 92614
800-2-INVITRO
FAX: 949-851-4985
http://www.invitrointl.com

Date: 08/05 Revision: 5

MATERIAL SAFETY DATA SHEET 10005

InVitro International
17751 Sky Park East, Ste. G
Irvin, CA 92614
Telephone: (714) 851-8356
Fax: (714) 851-0563

FOR EMERGENCY INFORMATION CALL:
1-800-535-5053

Section I: PRODUCT IDENTIFICATION

Product Name: CRROSITEX®
Categorize Test, Tube B

SPECIFIC CONTENTS ARE TRADE SECRET

Section II: HAZARDOUS COMPONENTS

A biological buffer solution with pH adjusted to 7.0 ± 0.1.

Section III: TOXICITY HAZARDS

Irritation Data: NA

Toxicity Data: NA

Section IV: PHYSICAL DATA

Appearance: Colorless liquid.

Odor: No distinctive odor or taste.

Section V: FIRE AND EXPLOSION HAZARD

Fire Hazards: None.

Explosion Hazards: None.

Extinguishing Media: NA.

Special Firefighting Procedure: None.

Section VI: HEALTH HAZARD DATA

Acute Effects: Harmful if swallowed or inhaled.

First Aid: In case of contact, flush eyes or skin with copious amount of water.

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

If swallowed, wash out mouth with water, provided person is conscious.

Call a physician.

Section VII: REACTIVITY DATA

Stability: Stable

Incompatibles: Reactive alkaline metals (e.g. lithium and sodium).

Hazardous Combustion or Decomposition Product: None.

Conditions Leading to Hazardous Polymerization: Will not occur.

Section VIII: SPILL OR LEAK PROCEDURES

Steps to be taken if material is released or spilled: Wipe spilled material with a dry cloth or absorb in sand. Place in a container for later disposal. Wash spill site after material pick up is complete.

Waste Disposal Method: The substance can be disposed of as regular waste.

Section IX: PROTECTIVE EQUIPMENT AND CONTROL MEASURES

Wear chemical resistant gloves, safety goggles and other protective clothing.

Section X: HANDLING AND STORAGE

Store in cool, dry place
Protect from Light.
Keep tightly closed.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. In Vitro International shall not be held liable for any damage resulting from handling or from contact with the above product. The information contained herein is furnished without warranty of any kind and is intended for the use only by persons having adequate related technical skills and at their own discretion and risk. Users should consider these data only as a supplement to other information gathered by them and must make independent

InVitro

INTERNATIONAL

Corporate Office
17751 Sky Park East, Suite G
Irvin, California 92614
800-2-INVITRO
FAX: 949-851-4985
http://www.invitrointl.com

Date: 08/05 Revision: 5

MATERIAL SAFETY DATA SHEET 10006

InVitro International
17751 Sky Park East, Ste. G
Irvin, CA 92614
Telephone: (714) 851-8356
Fax: (714) 851-0563

FOR EMERGENCY INFORMATION CALL:
1-800-535-5053

Section I: PRODUCT IDENTIFICATION

Product Name: CRROSITEX®
Categorize Test, Confirm

SPECIFIC CONTENTS ARE TRADE SECRET

Section II: HAZARDOUS COMPONENTS

A dilute aqueous solution of organic compounds.

Section III: TOXICITY HAZARDS

Irritation Data: NA

Toxicity Data: NA

Section IV: PHYSICAL DATA

Appearance: Dark amber liquid.

Odor: No distinctive odor or taste.

Section V: FIRE AND EXPLOSION HAZARD

Fire Hazards: None.

Explosion Hazards: None.

Extinguishing Media: NA.

Special Firefighting Procedure: None.

Section VI: HEALTH HAZARD DATA

Acute Effects: Harmful if swallowed or inhaled. May cause eye and skin irritation.

First Aid: In case of contact, flush eyes or skin with copious amount of water.

If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

If swallowed, wash out mouth with water, provided person is conscious.

Call a physician.

Section VII: REACTIVITY DATA

Stability: Stable

Incompatibles: Reactive alkaline metals (e.g. lithium and sodium).

Hazardous Combustion or Decomposition Product: None.

Conditions Leading to Hazardous Polymerization: Will not occur.

Section VIII: SPILL OR LEAK PROCEDURES

Steps to be taken if material is released or spilled: Wipe spilled material with a dry cloth or absorb in sand. Place in a container for later disposal. Wash spill site after material pick up is complete.

Waste Disposal Method: The substance can be disposed of as regular waste.

Section IX: PROTECTIVE EQUIPMENT AND CONTROL MEASURES

Wear chemical resistant gloves, safety goggles and other protective clothing. Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

MATERIAL SAFETY DATA SHEET 10006
CORRSOTEX® Categorize Test, Confirm

Section X: HANDLING AND STORAGE

Store in cool, dry place
Protect from Light.
Keep tightly closed.

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. In Vitro International shall not be held liable for any damage resulting from handling or from contact with the above product. The information contained herein is furnished without warranty of any kind and is intended for the use only by persons having adequate related technical skills and at their own discretion and risk. Users should consider these data only as a supplement to other information gathered by them and must make independent