U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

FEB 25 1998

Mr. L. L. Kerstetter
Hercules Incorporated
Hercules Plaza
1313 North Market Street
Wilmington, DE 19894-0001

Dear Mr. Kerstetter:

This is in response to your letter regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you asked whether Amine D and Amine D Acetate, based on your submitted test report meet the Class 8 corrosivity definition.

The answer is no. Based on the submitted test results, Amine D and Amine D Acetate do not meet the Class 8 corrosivity definition as defined in § 173.136 and, therefore, would not be regulated as a corrosive under the HMR.

I hope this information is helpful. Should you have further questions, do not hesitate to contact us.

Sincerely,

Hattie L. Mitchell

Hattie L. Mitchell, Chief
Regulatory Review and Reinvention
Office of Hazardous Materials Standards

Beth
File Part 173
SC 118, 174

HERCULES

Hercules Incorporated
Hercules Plaza
1313 North Market Street
Wilmington, DE 19894-0001
(302) 594-5000

12/22/97 LeC

HEC 12/16/97

October 17, 1997

Charles Ke, Chief
Sciences, DHM-21
Office of Hazardous Materials Safety
Research & Special Programs Administration
U.S. Department of Transportation
400 Seventh St. SW
Washington, DC 20590-0001

Dear Dr. Ke:

PRODUCT CLASSIFICATION

Hercules Incorporated produces and ships two products identified as Amine D and Amine D Acetate. The Amine D Acetate is a Flammable Liquid, PG III material. Both products were tested per 49 CFR 173.136 for class 8 corrosivity. Although test results show that neither product is corrosive, our toxicologists are not comfortable with shipping these products without recognition of their corrosive properties.

Our problem is that the skin destruction increases slowly and is higher for both test samples after 48 hours. Amine D is greatest one week after application. We are, therefore, requesting your review of the attached test data on both products and advise if the material should be shipped as a Class 8, Corrosive Liquid. We have also attached a copy each product's MSDS.

We that you for your time and cooperation.

Very truly yours,

L. L. Kerstetter
Regulations
Purchasing & Transportation

LLK:ims
W-LLK-Lrs
Attachments

cc: R. W. Hartgrove - 1

OFFICE OF HAZARDOUS MATERIALS STANDARDS
CORRESPONDENCE TRACKING SHEET

DATE	COMPANY	SPECIALIST
10/17/97	HERCULES /FROM: L.L. KERSTETTER	BETTS

RECEIVED:
ASSIGNED: 12/23/97
DUE: 01/26/98
SUBJECT

SIGNED:
COMMENTS:

SUMMARY:

COMPLEXITY: H M L

SIGNATURE:
DRAFTS:

needs writer response -
based on test results + material is
is not regulated under HMR
[if is regulated internationally]
per Cas Time.

HERCULES

MSDS NO.: 856 2181 0100 REV.: 03 ISSUE DATE:
SUPERSEDES: 856 2181 0100 REV.: 02
Hercules Incorporated
Hercules Plaza
1313 North Market Street
Wilmington, DE 19894-0001
(302) 594-5000 (24 hrs)

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: HERCULES AMINE D hydroabietylamine
APPEARANCE: viscous liquid
COLOR: pale amber
ODOR: faint ammonia
CASRN: 61790-47-4
CHEMICAL DESCRIPTION: rosin amine

HMIS Ratings:
Health: 3 SERIOU
Flammability: 1 SLIGHT
Reactivity: 1 SLIGHT

SECTION 2: HAZARDOUS COMPONENT INFORMATION

If this product is used in a manner that could generate a mist, r MSDS Section 8, Recommended Exposure Limits and Personal Protecti Equipment.

If this product is heated or used at temperatures sufficient to p smoke or fumes, refer to MSDS Section 8, Recommended Exposure Lim Personal Protective Equipment.

Hazardous Ingredients	CASRN	
amines, rosin	61790-47-4	1

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: DANGER!
Causes eye burns.
Causes skin burns.
Inhalation of mist may cause respiratory tract irritation.
Ingestion may cause nausea, vomiting, and gastrointestinal irrita

POTENTIAL HEALTH EFFECTS:
Can cause severe slow-healing skin burns and permanent scarring.
May cause eye injury or permanent blindness.
Prolonged exposure to smoke or fumes generated by heating this pr may cause respiratory irritation with throat discomfort, coughing breathing difficulty. Repeated exposure may lead to respiratory sensitization (asthma) in susceptible individuals. Refer to MSDS Section 8, Exposure Controls/Personal Protection, for further information.

Refer to Section 5 for Hazardous Combustion Products, and Section 1 for Hazardous Decomposition/Hazardous Polymerization Products.

SECTION 4: FIRST AID PROCEDURES

EYES: Remove contact lenses. Hold eyelids apart. Immedia flush eyes with plenty of low-pressure water for at minutes. Get immediate medical attention.

SKIN: Wash thoroughly with soap and water. If redness or appears, call a physician. Remove contaminated clot Thoroughly wash clothing before reuse. Discard cont leather articles. See Note to Physician.

INHALATION: Remove to fresh air. Treat any irritation symptomat Get medical attention if irritation develops or pers

INGESTION: If conscious, drink large quantities of water. Do N induce vomiting. Get immediate medical attention. give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: Apply only soap and water to remove from ski Use of solvents may increase skin injury.

This product contains rosin or a rosin deriv Rosin and some of its derivatives have been reported to cause an allergic skin reaction (sensitization) in susceptible individuals a repeated or prolonged skin contact.

SECTION 5: FIRE HAZARDS

FIRE FIGHTING PROCEDURES:

Wear self-contained breathing apparatus pressure-demand, MSHA/NIO approved (or equivalent) and full protective gear when fighting f involving this product.

Use water to keep fire-exposed containers cool.

EXTINGUISHING MEDIA:

Water spray, dry chemical, foam, carbon dioxide or halon may be u on fires involving this product.

CONDITIONS TO AVOID:

None known.

HAZARDOUS COMBUSTION PRODUCTS:

If heated to combustion, the following substances may be formed: carbon monoxide, carbon dioxide, nitrogen oxides, ammonia, hydrog cyanide, smoke, aldehydes and carboxylic acids.

FLASH POINT: 404 F 207 C

Method: Setaflash Closed Cup

AUTOIGNITION TEMPERATURE: 430 F 221 C

SECTION 6: ACCIDENTAL RELEASE MEASURES

Salvage spilled material in steel containers. After removal, was contaminated area with vinegar or dilute acetic acid solution followed by water.

In case of accidental spill or release, refer to Section 8, Perso Protective Equipment and General Hygiene Practices.

SECTION 7: HANDLING AND STORAGE

GENERAL MEASURES:

There are no unusual hazards associated with handling of this pro Store in a cool, dry place: approximately 68 F (20 C).

MATERIALS OR CONDITIONS TO AVOID:

None known

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

GENERAL HYGIENIC PRACTICES:

Avoid contact with eyes, skin, and clothing.
Avoid breathing vapor, fumes or mist.
Wash thoroughly after handling, and before eating, drinking or smoking.
Remove contaminated clothing promptly and clean thoroughly before reuse.

RECOMMENDED EXPOSURE LIMITS:

PARTICULATES (mist): If used under conditions that generate particulates (mist), the OSHA PEL of 5 mg/m3 respirable fraction (15 mg/m3 total), and ACGIH TLV-TWA of 5 mg/m3 respirable fraction (10 mg/m3 total) should be observed.

ROSIN PYROLYSIS FUMES: If this product is heated to temperatures sufficient to produce smoke or fumes, the TLV-TWA of 0.1 mg/m3 (as formaldehyde) for rosin core solder pyrolysis products should be observed.

Hazardous Component	Limit
amines, rosin	Not established

PERSONAL PROTECTIVE EQUIPMENT:

Chemical goggles
Impervious gloves
Full face shield
Appropriate protective clothing
Appropriate respiratory protection is required when exposure to airborne contaminants may exceed acceptable limits. Respirators be selected and used in accordance with OSHA, Subpart I (29 CFR 1 134) and manufacturer's recommendations.
Personnel exposed to hot molten material should wear protective clothing that provides protection against thermal burns. Require Protective Equipment: a) Longsleeved protective shirt, long pant work shoes; b) Hard hat and face shield; c) Long-cuff gloves (Gau type-extending beyond the wrist); d) Lined rainsuit with protecti hood or shoulder shroud or e) Full aluminized or thermal suit wit hood.

WORK PRACTICES AND ENGINEERING CONTROLS:

Eyewash fountains and safety showers should be easily accessible.
Local exhaust ventilation may be necessary to maintain air contam below their recommended exposure limits during the use of this pr Discharge from the ventilation system should comply with applica air pollution control regulations.

PROTECTIVE MEASURES DURING REPAIR AND MAINTENANCE:

Eliminate ignition sources and prevent build-up of static electri charges.
Completely isolate and thoroughly clean all equipment, piping, or vessels before beginning maintenance or repairs.
Keep area clean. Product will burn.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility:	< 0.5 at 100 C
Specific Gravity:	1.00
Vapor Pressure:	< 1 mmHg at 20 C
Evaporation Rate:	slower than butyl acetate
Boiling Point:	671 F 344 C

Freezing Point: Viscosity increases

SECTION 10: STABILITY AND REACTIVITY

GENERAL STABILITY CONSIDERATIONS:
Stable under recommended handling and storage conditions.
INCOMPATIBLE MATERIALS:
None known
HAZARDOUS DECOMPOSITION PRODUCTS:
None known
HAZARDOUS POLYMERIZATION:
Not anticipated under normal or recommended handling and storage conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

REPORTED HUMAN EFFECTS:
PRODUCT/SIMILAR PRODUCT - Contact with neat product for two hours caused skin irritation in human subjects. Contact for short peri (15 minutes or less) did not produce irritation. Prolonged conta (five days) with 2% solution in mineral oil produced irritation i of 200 human subjects. Not a skin sensitizer in human tests.

COMPONENT - Rosin and some rosin derivatives: Reported to cause allergic skin reaction (sensitization) in susceptible individuals after repeated or prolonged contact.
REPORTED ANIMAL EFFECTS:
PRODUCT/SIMILAR PRODUCT - Acute oral LD50 (rats): 2500 mg/kg; ac oral LD50 (guinea pigs): 700 mg/kg. Corrosive to eyes and skin. Skin injury had delayed onset. Not a skin sensitizer in the guin pig maximization test.
CARCINOGENICITY INFORMATION:
PRODUCT/SIMILAR PRODUCT - Not listed as a carcinogen by NTP. Not regulated as a carcinogen by OSHA. Not evaluated by IARC.
MUTAGENICITY/GENOTOXICITY INFORMATION:
PRODUCT/SIMILAR PRODUCT - Not mutagenic in the Ames test.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY:
PRODUCT/SIMILAR PRODUCT - Range-finding studies indicated acute a toxicity to be in the moderate to highly toxic range (0.1-10 mg/L according to U.S. Fish and Wildlife criteria.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:
Incineration in accordance with applicable regulations is the recommended disposal method.

SECTION 14: TRANSPORTATION INFORMATION

For information regarding transportation of this product, please contact Hercules Transportation at (302, 594-7356.

SECTION 15: REGULATORY INFORMATION

CHEMICAL INVENTORIES:
U. S. TSCA : Included on TSCA Inventory.

European EINECS : Included on EINECS list.
Canadian CEPA : Included on DSL Inventory.
Japanese MITI : Included on MITI Gazette.
Australian AICS : Included on AICS Inventory.
Korean KECL : Included on KECL Inventory.

SARA TITLE III

Sections 302 and 304:
This product is not an Extremely Hazardous Substance subject to reporting under 40CFR355.

Sections 311 and 312:
HC-1: Acute health hazard
NPH: Not a physical hazard

Section 313:
This product does not contain any chemicals subject to reporting under Section 313 of Title III of the Superfund Amendments and Reauthorization Act and 40CFR372.

CERCLA

This product does not contain any chemicals subject to reporting CERCLA Hazardous Substance under 40CFR302.4.

RCRA

This product is not a hazardous waste as listed in 40CFR261.33. does not exhibit any of the hazardous characteristics listed in 40CFR261, Subpart C. State or local hazardous waste regulations apply if they are different from the federal regulations.

SECTION 16: OTHER INFORMATION

LIST OF ACRONYMS:

ACGIH: American Conference of Governmental Industrial Hygienists
AICS: Australian Inventory of Chemical Substances
AIHA WEEL American Industrial Hygienists Association Workplace Environmental Exposure Level
ANSI: American National Standards Institute
C: Ceiling
CASRN: Chemical Abstracts Service Registry Number
CERCLA: Comprehensive Emergency Response, Compensation and Liabi Act
DSL: Domestic Substances List (Canadian)
EINECS: European Inventory of Existing Commercial Chemical Subst
HMIS: Hazardous Materials Identification System
IARC: International Agency for Research on Cancer
N/A: Not Applicable
MITI: Ministry of International Trade and Industry (Japanese)
NDSL: Non-Domestic Substances List (Canadian)
NOR: Not Otherwise Regulated
NTP: National Toxicology Program
OSHA: Occupational Safety and Health Administration
PEL: Permissible Exposure Limit (OSHA)
RCRA: Resource Conservation and Recovery Act
RQ: Reportable Quantity
SARA: Superfund Amendment Reauthorization Act
STEL: Short-Term Exposure Limit
TLV: Threshold Limit Values (registered trademark of ACGIH)

TPQ: Threshold Planning Quantity
TSCA: Toxic Substances Control Act
TWA: Time Weighted Average

The information and recommendations contained in this Material Safe Data Sheet have been compiled from sources believed to be reliable represent the most reasonable current opinion on the subject when t MSDS was prepared. No warranty, guaranty or representation is made the correctness or sufficiency of the information. The user of thi product must decide what safety measures are necessary to safely us product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under applicable federal or state laws.

HERCULES

MSDS NO.: 8562185030003 REV.: 1 ISSUE DATE:
SUPERSEDES: 8562185030002 REV.: 0
Hercules Incorporated
Hercules Plaza
1313 North Market Street
Wilmington, DE 19894-0001
(302) 594-5000 (24 hrs)

SECTION 1: PRODUCT IDENTIFICATION

PRODUCT NAME: HERCULES AMINE D ACETATE 50S hydroabietylamine acetat solution

APPEARANCE: liquid
COLOR: yellow
ODOR: vinegar-like
CASRN: mixture
CHEMICAL DESCRIPTION: rosin amine acetate in aqueous-alcoholic so

HMIS Ratings:
Health: 3 SERIOU
Flammability: 2 MODERA
Reactivity: 0 MINIMA

SECTION 2: HAZARDOUS COMPONENT INFORMATION

If this product is used in a manner that could generate a mist, r MSDS Section 8, Recommended Exposure Limits and Personal Protecti Equipment.

If this product is heated or used at temperatures sufficient to p smoke or fumes, refer to MSDS Section 8, Recommended Exposure Lim Personal Protective Equipment.

Hazardous Ingredients	CASRN	Wt
amines, rosin, acetates	068990-26-1	50
isopropanol	000067-63-0	11

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: DANGER!

Causes eye burns.
Causes skin burns.
Inhalation of dust, mist, or vapor may cause respiratory tract irritation.
Inhalation of vapor may cause drowsiness and dizziness.
Ingestion may cause nausea, vomiting, and gastrointestinal irrita
Combustible liquid

POTENTIAL HEALTH EFFECTS:

May cause blindness.
Prolonged exposure to smoke or fumes generated by heating this pr may cause respiratory irritation with throat discomfort, coughing breathing difficulty. Repeated exposure may lead to respiratory sensitization (asthma) in susceptible individuals. Refer to MSDS Section 8, Exposure Controls/Personal Protection, for further information.
Prolonged or repeated exposure may aggravate pre-existing kidney or liver disease.

Refer to Section 5 for [illegible] Products, and Section [illegible] for Hazardous Decomposition/Hazardous Polymerization Products.

SECTION 4: FIRST AID PROCEDURES

EYES: Remove [illegible] lenses. [illegible] eyelids apart. Immedia flush eyes with plenty of low-pressure water for at minutes. Get immediate medical attention.

SKIN: Wash thoroughly with soap and water. Remove contami clothing. Thoroughly wash clothing before reuse. G immediat[illegible] medical attention. Hot molten product: Immediately cool skin burns with water and cold pack least 15 minutes. Do NOT put ice directly on the sk NOT attempt to remove solidified resin from the skin severe tissue damage may result. See Note to Physic

INHALATION: Remove to fresh air. Treat any irritation symptomat Get medical attention if irritation develops or pers

INGESTION: If conscious, drink large quantities of water. Do N induce vomiting. Get immediate medical attention. give anything by mouth to an unconscious person.

NOTE TO PHYSICIAN: This product contains rosin or a rosin deri Rosin and some of its derivatives have been reported to cause an allergic skin reaction (sensitization) in susceptible individuals repeated or prolonged skin contact.

Material should not be forcibly pulled from skin. Mineral oil may be used to loosen an soften the material.

SECTION 5: FIRE HAZARDS

FIRE FIGHTING PROCEDURES:
Wear self-contained breathing apparatus pressure-demand, MSHA/NIO approved (or equivalent) and full protective gear when fighting f involving this product.
Use water to keep fire-exposed containers cool.

EXTINGUISHING MEDIA:
Water spray, dry chemical, foam, carbon dioxide or halon may be u on fires involving this product.

CONDITIONS TO AVOID:
None known.

HAZARDOUS COMBUSTION PRODUCTS:
If heated to combustion, the following substances may be formed: carbon monoxide, carbon dioxide, nitrogen oxides, ammonia, hydrog cyanide, smoke, aldehydes and carboxylic acids.

FLASH POINT: 102 F 39 C
Method: Setaflash Closed Cup
FLAMMABILITY LIMITS - LOWER: 2.5 value is for component
UPPER: 12.0

SECTION 6: ACCIDENTAL RELEASE MEASURES

Extinguish all sources of ignition. Ventilate area. For small spills: Add absorbent, sweep up, and dispose appropriately. For large spills, dike to contain and pump into drums for use or

disposal.
In case of accidental spill or release, refer to Section 8, Perso
Protective Equipment and General Hygiene Practices.

SECTION 7: HANDLING AND STORAGE

GENERAL MEASURES:
There are no unusual hazards associated with handling of this prc
Store in a cool, dry place: approximately 65 F - 80 C .
Store in well ventilated area.
Keep container closed when not in use.
MATERIALS OR CONDITIONS TO AVOID:
Avoid storing product near incompatible materials. See MSDS Sect 10.
Keep away from heat, flame, sparks and other ignition sources.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

GENERAL HYGIENIC PRACTICES:
Avoid contact with eyes, skin, and clothing.
Avoid breathing vapor, fumes or mist.
Wash thoroughly after handling, and before eating, drinking or smoking.
Remove contaminated clothing promptly and clean thoroughly before reuse.
RECOMMENDED EXPOSURE LIMITS:
PARTICULATES (mist): If used under conditions that generate particulates (mist), the OSHA TWA of 5 mg/m3 respirable fraction mg/m3 total), and ACGIH TLV-TWA of 3 mg/m3 respirable fraction (1 mg/m3 total) should be observed.

ROSIN PYROLYSIS FUMES: If this product is heated to temperatures sufficient to produce smoke or fumes, the TLV-TWA of 0.1 mg/m3 (a formaldehyde) for rosin core solder pyrolysis products should be observed.

Hazardous Component	Limit	Basis
amines, rosin, acetates	Not established	
isopropanol	400 ppm; 500 ppm	OSHA TWA; ACGIH

PERSONAL PROTECTIVE EQUIPMENT:
Chemical goggles
Impervious gloves
Full face shield
Appropriate protective clothing
Appropriate respiratory protection is required when exposure to airborne contaminants may exceed acceptable limits. Respirators be selected and used in accordance with OSHA, Subpart I (29 CFR 1 134) and manufacturer's recommendations.
Personnel exposed to hot molten material should wear protective clothing that provides protection against thermal burns. Require Protective Equipment: a) Longsleeved protective shirt, long pant work shoes; b) Hard hat and face shield; c) Long-cuff gloves (Gau type-extending beyond the wrist); d) Lined rainsuit with protecti hood or shoulder shroud or e) Full aluminized or thermal suit wit hood.
WORK PRACTICES AND ENGINEERING CONTROLS:

Eyewash fountains and safety showers should be easily accessible.
Local exhaust ventilation may be necessary to maintain air contam
below their recommended exposure limits during the use of this pr
Discharge from the ventilation system should comply with applica
air pollution control regulations.

PROTECTIVE MEASURES DURING REPAIR AND MAINTENANCE:

Eliminate ignition sources and prevent build-up of static electri
charges.
Completely isolate and thoroughly clean all equipment, piping, or
vessels before beginning maintenance or repairs.
Keep area clean. Product will burn.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

pH:	[illegible]		
Volatile (Wt.), %:	[illegible] (water/isopropanol)		
Water Solubility:	soluble in water		
Specific Gravity:	1.11		
Vapor Density:	lighter than air		
Evaporation Rate:	slower than butyl acetate		
Boiling Point:	[illegible]	F 81	C
Freezing Point:	[illegible]	F -9	C

SECTION 10: STABILITY AND REACTIVITY

GENERAL STABILITY CONSIDERATIONS:

Stable under recommended handling and storage conditions.

INCOMPATIBLE MATERIALS:

Incompatible with: oxidizing agents

HAZARDOUS DECOMPOSITION PRODUCTS:

None known

HAZARDOUS POLYMERIZATION:

Not anticipated under normal or recommended handling and storage conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

REPORTED HUMAN EFFECTS:

PRODUCT/SIMILAR PRODUCT - At 1% solution, marked skin irritancy f repeated or prolonged exposure; nonirritating at 0.1%. No eviden skin sensitization.

COMPONENT - Rosin and some rosin derivatives: Reported to cause allergic skin reaction (sensitization) in susceptible individuals after repeated or prolonged contact.

COMPONENT - isopropanol: Drinking large amounts or prolonged con with occluded skin may aggravate existing liver or kidney disease Vapor may cause eyes, nose and throat irritation, and dizziness. Liquid material may cause severe eye irritation. Repeated skin contact may cause allergic skin sensitization and defatting of sk Swallowing various amounts of liquid reportedly can cause headach drowsiness, severe irritation of the G-I tract, abdominal pain, diarrhea, shock, decreased body temperature and blood pressure, hemolytic anemia, kidney failure, coma and death. Repeated skin contact may lead to coma following absorption to skin. Coma may

irreversible depending upon amount swallowed or absorbed through
REPORTED ANIMAL EFFECTS:
PRODUCT/SIMILAR PRODUCT - Acute oral LD50 (rat) : 0.65 g/kg. Acu oral LD50 (guinea pig : 0.65 g/kg. Severe irritant to rabbit sk when applied as a 70% paste. One percent solution caused severe irritation with prolonged conjunctival and transient corneal dama 500 ppm in water produced no irritation or injury.

COMPONENT - isopropanol: The following effects by inhalation or ingestion at various multiples of the TLV or equivalent were repo in laboratory animals: slowed heart rate, respiratory difficulti and effects on liver and spleen. Some fetal development effects seen in rats following daily ingestion of large amounts by the mo during most of the pregnancy.
CARCINOGENICITY INFORMATION:
PRODUCT/SIMILAR PRODUCT - Not listed as a carcinogen by NTP. Not regulated as a carcinogen by OSHA. Not evaluated by IARC.

COMPONENT - isopropanol: Not listed as a carcinogen by NTP; not regulated as a carcinogen by OSHA; evaluated by IARC and found to not classifiable for humans.
MUTAGENICITY/GENOTOXICITY INFORMATION:
PRODUCT/SIMILAR PRODUCT - No mutagenicity studies have been carri out with this product.

COMPONENT - isopropanol: Negative in Ames test. No chromosome aberrations in bone marrow cells from rats dosed with material.

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY:
PRODUCT/SIMILAR PRODUCT - Acute aquatic toxicity in a 72-hour tes using Guppies falls in the moderately toxic range of 1-10 mg/L, according to the U.S. Fish and Wildlife criteria. Bluegill fish tolerated 0.2 mg/L in a 12-day test. Signs of toxicity were obse at 0.3 mg/L, with death at 0.6 mg/L. Growth inhibition was obser bacteria and fungi from less than 0.01 mg/L to 1 mg/L, depending species.

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:
Incineration in accordance with applicable regulations is the recommended disposal method.

SECTION 14: TRANSPORTATION INFORMATION

For information regarding transportation of this product, please contact Hercules Transportation at (302) 594-7356.

SECTION 15: REGULATORY INFORMATION

CHEMICAL INVENTORIES:
U. S. TSCA : Included on TSCA Inventory.
SARA TITLE III
Sections 302 and 304:
This product is not an Extremely Hazardous Substance subject to

reporting under 40CFR 35.
Sections 311 and 312:
HC-1: Acute health hazard
HC-3: Fire hazard
Section 313:
This product does not contain any chemicals subject to reportin under Section 313 of Title III of the Superfund Amendments and Reauthorization Act and 40CFR372.

CERCLA
This product does not contain any chemicals subject to reporting CERCLA Hazardous Substance under 40CFR302.4.

RCRA
This product exhibits the following characteristics listed in 40CFR261, Subpart C: ignitability (D-001). Disposal of unused product must comply with the hazardous waste regulations.

SECTION 16: OTHER INFORMATION

LIST OF ACRONYMS:

ACGIH: American Conference of Governmental Industrial Hygienists
AICS: Australian Inventory of Chemical Substances
AIHA WEEL American Industrial Hygienists Association Workplace Environmental Exposure Level
ANSI: American National Standards Institute
C: Ceiling
CASRN: Chemical Abstracts Service Registry Number
CERCLA: Comprehensive Emergency Response, Compensation and Liabi Act
DSL: Domestic Substances List (Canadian)
EINECS: European Inventory of Existing Commercial Chemical Subst
HMIS: Hazardous Materials Identification System
IARC: International Agency for Research on Cancer
N/A: Not Applicable
MITI: Ministry of International Trade and Industry (Japanese)
NDSL: Non-Domestic Substances List (Canadian)
NOR: Not Otherwise Regulated
NTP: National Toxicology Program
OSHA: Occupational Safety and Health Administration
PEL: Permissible Exposure Limit (OSHA)
RCRA: Resource Conservation and Recovery Act
RQ: Reportable Quantity
SARA: Superfund Amendment Reauthorization Act
STEL: Short-Term Exposure Limit
TLV: Threshold Limit Values (registered trademark of ACGIH)
TPQ: Threshold Planning Quantity
TSCA: Toxic Substances Control Act
TWA: Time Weighted Average

The information and recommendations contained in this Material Safe Data Sheet have been compiled from sources believed to be reliable represent the most reasonable current opinion on the subject when t MSDS was prepared. No warranty, guaranty or representation is made the correctness or sufficiency of the information. The user of thi product must decide what safety measures are necessary to safely us

product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under applicable federal or state laws.

HERCULES Interoffice Memo

TOXICOLOGY

cc: G. L. McCallister - Reg. Aff. & Tox
T. J. Zitzelberger - Reg. Affairs

Wilmington, Delaware
October 16, 1997

TO: L. L. Kerstetter - Purchasing/12352 SE

FROM: R. W. Hartgrove - Toxicology/1150 NW RWHartgrove/elm
E. R. Homan - Toxicology/1152 NW ERHoman/elm

DOT LABELING OF ROSIN AMINES

Thanks for the opportunity to discuss anomalies in test results as they pertain to labeling requirements of the rosin amines. One of the outcomes of our meeting was your suggestion that we submit our problem to DOT for a regulatory opinion.

To that end, we attach copies of the studies which generated the anomalous delayed corrosivity data:

Amine D followed by water wash (standard test procedure)
Amine D followed by surgical soap wash
Amine D followed by isopropyl alcohol wash
Amine D followed by mineral oil wash
Amine D Acetate followed by water wash (standard test procedure)

Attached also are two figures summarizing the laboratory findings using the DOT Corrosivity test. Figure 1 shows the mean erythema scores following application of Amine D and Amine D Acetate. Note that in both cases the severity of the injury increases slowly and is higher for both test materials after 48 hours, and with Amine D is greatest one week after application.

In an attempt to determine whether the injury could be alleviated by washing with various solvents and a surgical detergent, these washes were applied in place of the standard water wash in the DOT corrosivity test. Figure 2 shows that all treatments actually increased the severity of damage to the skin as reflected in erythema scores beyond 24 hours. Note also that the injury from Amine D, regardless of the wash used, was greatest one week after treatment. It is not known whether the severity of injury increases beyond this time and whether healing takes place.

RWH/ERH/elm
Attachment
dotlab.doc

Figure 1

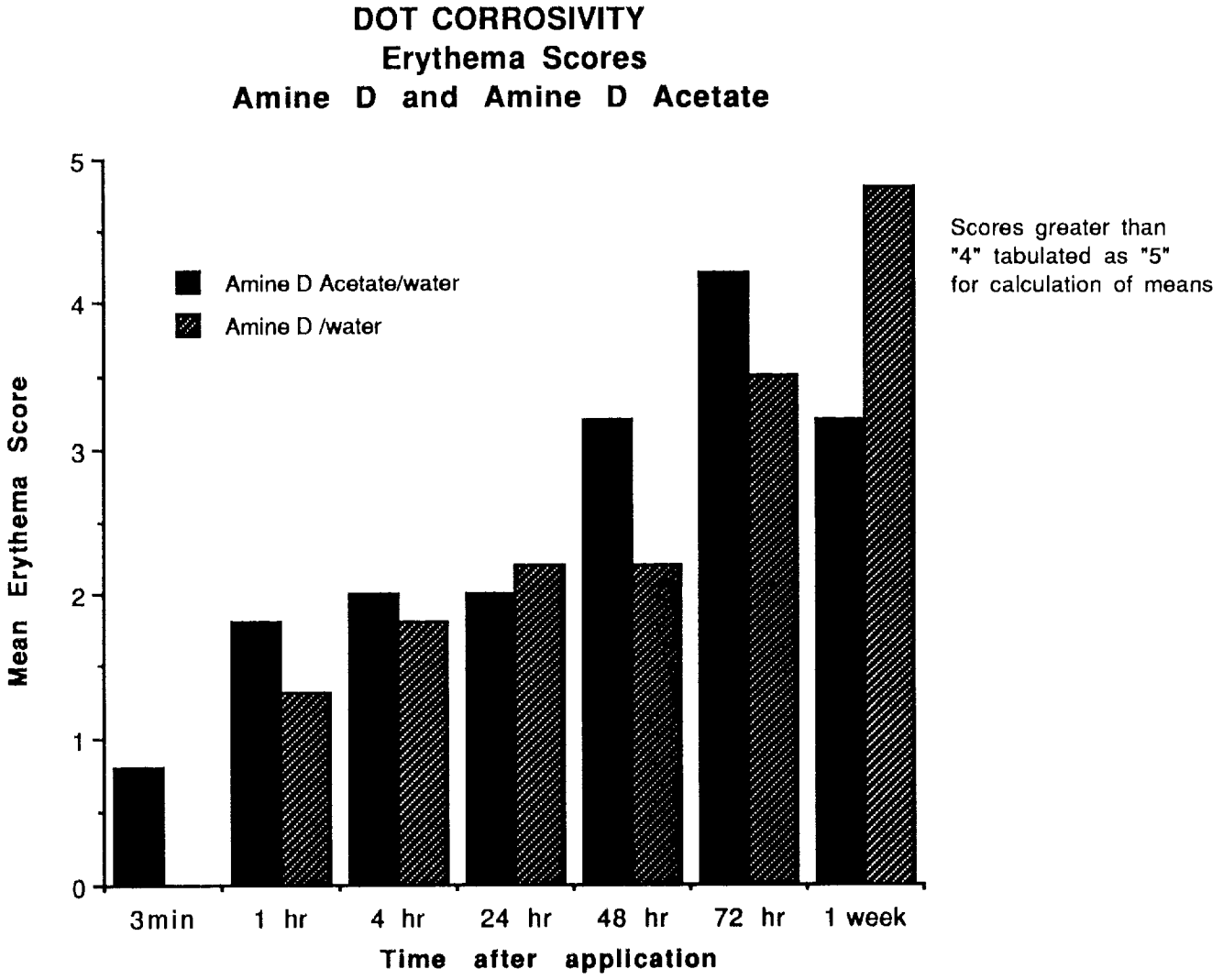
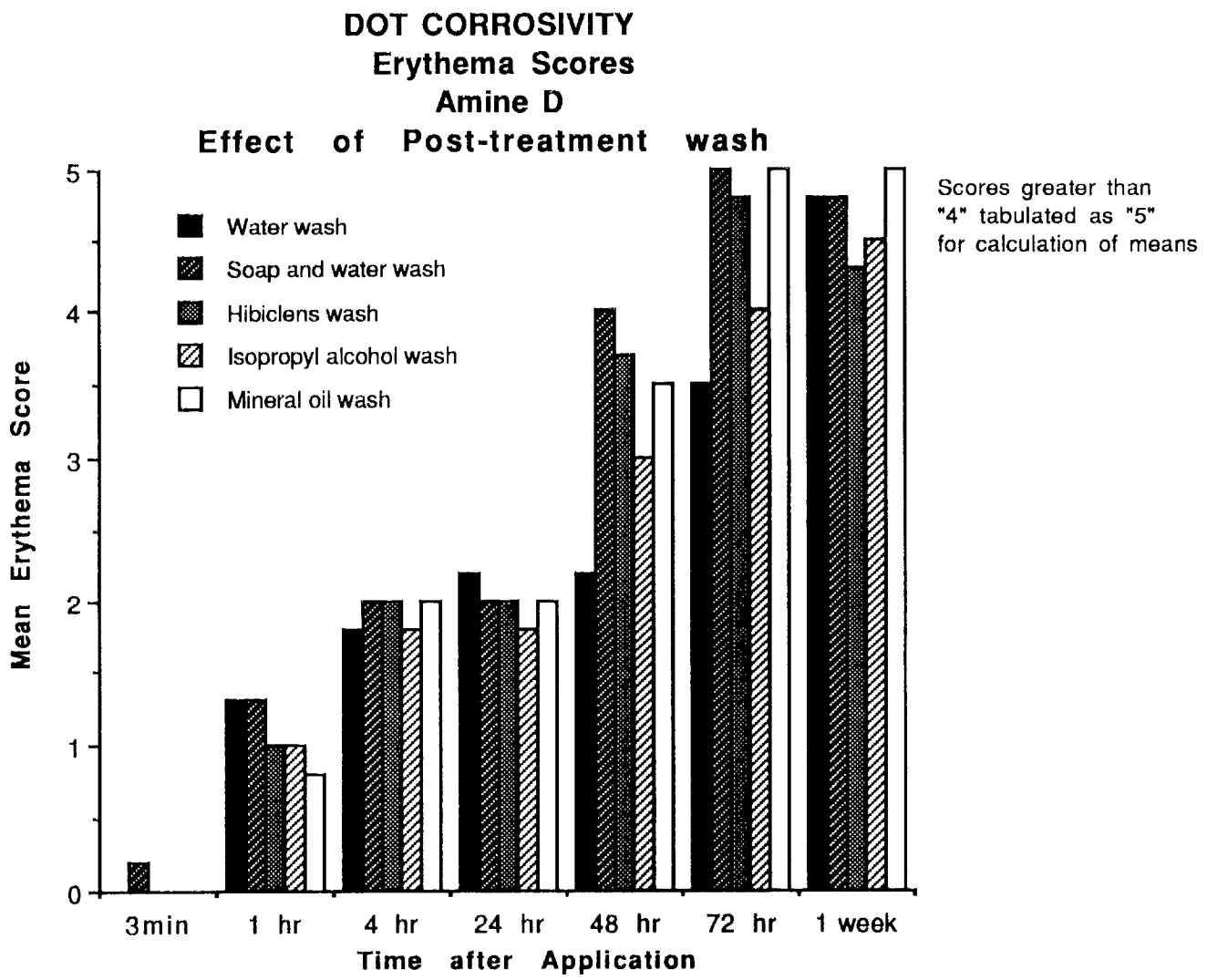

DOT CORROSIVITY
Erythema Scores
Amine D and Amine D Acetate
Mean Erythema Score
0
1
2
3
4
5
Amine D Acetate/water
Amine D /water
3min
1 hr
4 hr
24 hr
48 hr
72 hr
1 week
Time after application
Scores greater than "4" tabulated as "5" for calculation of means

Figure 2


DOT CORROSIVITY
Erythema Scores
Amine D
Effect of Post-treatment wash
Water wash
Soap and water wash
Hibiclens wash
Isopropyl alcohol wash
Mineral oil wash
Mean Erythema Score
0
1
2
3
4
5
3min
1 hr
4 hr
24 hr
48 hr
72 hr
1 week
Time after Application
Scores greater than "4" tabulated as "5" for calculation of means

PROJECT NUMBER : MB 92-1354 C

TEST ARTICLE : Amine D

SPONSOR : HERCULES INCORPORATED

TITLE : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL # : 108A-01

ABSTRACT

Method Synopsis - Six healthy New Zealand albino rabbits were dosed with Amine D. 0.5 ml/site of the test article was placed on the intact skin of the back. In order to permit dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which were opened to examine the treated site. The test article was kept in contact with the skin for 4 hours. Skin reactions were scored according to the Draize technique during the 4 hour exposure period at 3 minutes post-dose, and again at 1 hour post-dose. The treated sites were scored again at 4, 24, 48 and 72 hours and on day 7 after test article application. The skin was also evaluated for ulceration, necrosis or any evidence of tissue destruction at these time periods. Body weights were recorded pretest.

Summary - Erythema, absent at 3 minutes after application, was absent to well defined at 1 hour and slight to well defined at 4 hours. By 24 hours, erythema was well defined to moderate and by 48 hours, erythema was slight to moderate. Observations at 72 hours revealed moderate to severe erythema which was severe on day 7. In addition, instances of moderate to severe eschar and shiny areas of skin, indicative of injuries in depth, were noted on day 7. Edema, absent at 3 minutes after application, was absent to slight at 1 hour and well defined to moderate at 4 hours. Edema was moderate to severe at 24 and 48 hours. By 72 hours, edema was well defined to severe and by day 7 edema was absent to slight. There were no abnormal systemic signs noted during the observation period.

Conclusion - Although the test article is not a class 8 or DOT corrosive, it did produce delayed corrosive responses by day 7.

MB Res 92-1354C 6-19-92
28.2C

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit (QAU) has reviewed this report and determined that it accurately describes the methods and standard operating procedures used, and that the results contained herein accurately and fully reflect the raw data from this study.

All procedures performed during the conduct of this study were in conformance with the protocol. Applicable Standard Operating Procedures and GLP regulations were followed. There were no discrepancies between the protocol, the raw data, and/or the final report.

The QAU inspected an in-life phase of the study, audited the raw data and reviewed the report on the dates indicated below. QAU findings were reported to management and the Study Director.

Study Inspected	: 3/31/92
Raw Data Audited	: 5/11/92

Final report reviewed:

Oscar M. Moreno 6/18/92
Oscar M. Moreno, Ph.D.

15 Jun 92
Daniel R. Cerven, M.S., Study Director

Bonnie W. Cerven 6/19/92
Bonnie W. Cerven, Quality Assurance

Elizabeth J. Salyer 6/19/92
Elizabeth J. Salyer, Archivist

TITLE OF REPORT : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL NUMBER: 108A-01

OBJECTIVE : To determine whether a material causes irreversible damage as defined in 49 CFR 173.240(a)(1) when applied to rabbit skin. This study was designed to comply with the standards set forth in 49 CFR 173 - Appendix A and also meets the packing group assignment categories of 49 CFR 173.137 as published in the Federal Register, Vol, 55, No. 246, 12/21/90.

TEST ARTICLE

Source : HERCULES INCORPORATED
Date Received : 3/09/92

Test Article Label : Amine D

Storage : The test article was stored at ambient room temperature & humidity.

Test Article Description : Viscous Amber Liquid

Sample Preparation : Used as received

TEST ANIMALS

Six healthy New Zealand Albino rabbits were selected for this test from a larger group which had been quarantined at least one week. The animals were received from Ace Animals on 2/25 and 3/10/92.

Pretest body weight range was 2.2 - 2.8 kg. The animals were identified by cage notation and a uniquely numbered metal eartag. The animals were housed 1/cage in suspended cages. Bedding was placed beneath the cages and changed twice/week. Fresh Purina Rabbit Chow (Diet #5321) and water were available.

The animal room, reserved exclusively for rabbits on acute tests, was temperature controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.

TEST DATES

Study Initiation	(Date Protocol Signed)	:	3/30/92
Experimental Start	(1st Exposure to Test Substance)	:	3/31/92
Experimental Term	(Last date data collected)	:	4/07/92
Draft Report Submitted	(If applicable)	:	5/15/92
Study Completion	(Submission of Final Report)	:	6/24/92

SITE PREPARATION

Prior to application of the test article, the back and sides of each animal were clipped free of hair. The skin was not abraded.

EXPERIMENTAL DESIGN

The test article was used as received and dosed by volume, 0.5 ml/site. The test article was applied to one area on the prepared site on the back of each of six rabbits.

A 1" x 1" gauze patch was placed on the test site. The test article was introduced under the patch and the patches were secured with adhesive tape. In order to aid in maintaining the test patches and to retard evaporation of the test article, the entire trunk of each animal was wrapped with plastic and secured with adhesive tape. In order to permit dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which were opened to examine the test site. The test article was kept in contact with the skin for 4 hours at which time the wrappings were removed. The test sites were washed with distilled water after the 4 hour reading.

TYPE AND FREQUENCY OF OBSERVATIONS

Animals were observed for skin reactions, including ulceration and necrosis, during the 4 hour exposure period at 3 minutes post dose, and again at 1 hour post dose. At 4 hours, the wrappings were removed and the test site was scored for dermal reactions and then washed with water. The treated sites were scored again at 24, 48 and 72 hours and 7 days post-dose. Erythema and edema were scored according to the numerical Draize technique. Additional signs were described.

Body weights were recorded pretest. The general health of the animals was monitored at each observation time.

ANALYSIS OF DATA

Corrosion will be considered to have resulted if the substance in contact with the rabbit skin has caused destruction or irreversible alteration of the tissue. Tissue destruction is considered to have occurred if, at any of the readings, there is ulceration or necrosis. Tissue destruction does not include merely sloughing of the epidermis, or erythema, edema, or fissuring. (49 CFR 173-Appendix A. No. 8).

Packing Group Assignments:

Packing Group I criterion reflects necrosis occurring within a period of three (3) minutes or less following exposure to test substance.

Packing Group II criterion reflects necrosis occurring in more than three (3) minutes but not more than 60 minutes.

Packing Group III criterion reflects necrosis occurring in more than 60 minutes but not more than four hours.

RETENTION OF DATA

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number.

The test article will be returned to the sponsor upon submission of the final report.

GOOD LABORATORY PRACTICES

This study was conducted in accordance with the Good Laboratory Practices Regulations of the FDA - 21 CFR Part 58.

REVISION OF THE PROTOCOL

There were no revisions to the protocol.

RESULTS

INDIVIDUAL SCORES	ANIMAL NUMBERS					
	D2995	D2998	D2996	D3152	D3146	D3148
PRETEST BODY WEIGHT - g:	2.4	2.8	2.4	2.3	2.5	2.2
Erythema & Eschar Formation						
3 Minutes	0	0	0	0	0	0
1 Hour	2	2	0	1	2	1
4 Hours	2	2	1	2	2	2
24 Hours	2	2	2	3	2a	2
48 Hours	2a	2a	1af	3a	3a	2a
72 Hours	3a	3a	4a	4a	4a	3a
7 Days	>4s	>4s	>4s	>4s	4b	>4m
Edema						
3 Minutes	0	0	0	0	0	0
1 Hour	1	1	0	0	1	0
4 Hours	2	3	2	2	2	2
24 Hours	3	3	3	4	3	4
48 Hours	3	3	3	4	4	4
72 Hours	3	2	2	2	4	4
7 Days	1	1	1	0	1	1
SYSTEMIC OBSERVATIONS:						
3 Minutes	A	A	A	A	A	A
1 Hour	A	A	A	A	A	A
4 Hours	A	A	A	A	A	A
24 Hours	A	A	A	A	A	A
48 Hours	A	A	A	A	A	A
72 Hours	A	A	A	A	A	A
7 Days	A	A	A	A	a	A

FOOTNOTES ON PAGE -6-

DRAIZE DERMAL SCORING CODE

ERYTHEMA AND ESCHAR FORMATION:

No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

EDEMA FORMATION:

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm, extending beyond the area of exposure)	4

FOOTNOTES:
A = normal
a = pale areas
b = shiny areas
f = flaking skin
>4s = severe eschar
>4m = moderate eschar
* = animal reclipped

PROJECT NUMBER : MB 92-2150 C

92-13

TEST ARTICLE : Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 (water wash)
Spent Sulfuric Acid (water wash)

SPONSOR : HERCULES INCORPORATED

TITLE : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL # : 108A-02 R/A

ABSTRACT

Method Synopsis - Six healthy New Zealand albino rabbits were dosed on separate sites with Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 (water wash) and Spent Sulfuric Acid (water wash). 0.5 ml of Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 (water wash) was applied to one intact site (Site #1) and 0.5 ml of Spent Sulfuric Acid (water wash) was applied to another intact site (Site #4 - see MB Project 92-2149 C for sites #2 and 3) on the back of each rabbit. In order to facilitate dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which was opened to examine the treated site at 3 minutes and one hour post dose. The test article remained on the skin for 4 hours at which time the wrappings were removed and both sites were washed with water. The sites were scored again at 4, 24, 48 and 72 hours and on day 7. The skin was also evaluated for ulceration, necrosis or any evidence of tissue destruction at these time periods. Body weights were recorded pretest.

Summary

Amine D Acetate 50S (sites washed with water) - Erythema, absent to slight at 3 minutes after test article application, was slight to well defined at 1 hour, well defined at 4 and 24 hours, and well defined to severe at 48 and 72 hours and on day 7. Pale areas were noted at 24 hours. Moderate eschar, necrosis of tissue, shiny areas and poor hair regrowth, indicative of injuries in depth, were noted at 48 and 72 hours and on day 7. Edema absent at 3 minutes after test article application, was slight at 1 hour, well defined to moderate at 4 hours and moderate at 24 hours. Edema was well defined to moderate at 48 and 72 hours, and absent to slight on day 7.

Spent Sulfuric Acid (sites washed with water) - Erythema, absent to slight at 3 minutes, 1, 4, 24, 48 and 72 hours after test article application, was absent on day 7. Edema was absent at all observation periods.

Systemic - Mucoid diarrhea, noted in one animal, was the only abnormal physical signs noted during the observation period.

Conclusion

Amine D Acetate 50S - Since only one animal presented evidence of irreversible changes, characterized by necrosis of tissues at 48 hours, the test article is not considered to be a DOT or Class 8 corrosive as defined in 49 CFR 173.136 and does not require a packing group assignment. However, the presence of moderate to severe eschar and necrosis of tissue at 72 hours and on day 7, indicates that the test article has the potential to produce a delayed corrosive response.

Spent Sulfuric Acid - Since there was no evidence of irreversible changes at 48 hours after test article application, the test article is not a DOT or Class 8 corrosive as defined in 49 CFR 173.136 and does not require a packing group assignment.

MB Rev 92-2150C 2-7-94

28-2C

GOOD LABORATORY PRACTICES

This study was conducted in accordance with the Good Laboratory Practices Regulations of the FDA - 21 CFR Part 58.

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit (QAU) has reviewed this report and determined that it accurately describes the methods and standard operating procedures used, and that the results contained herein accurately and fully reflect the raw data from this study.

All procedures performed during the conduct of this study were in conformance with the protocol. Applicable Standard Operating Procedures and GLP regulations were followed. There were no discrepancies between the protocol, the raw data, and/or the final report. The Revision/Addendum (R/A) applicable to this study was made and fully documented in accordance with the GLP requirements and is fully described in this report.

The QAU inspected an in-life phase of the study, audited the raw data and reviewed the report on the dates indicated below. QAU findings were reported to management and the Study Director.

Study Inspected	: 12/08/92
Raw Data Audited	: 01/22/93

Final report reviewed:

Oscar M. Moreno, Ph.D. 2/4/94

Lori Kieffer, B.A., Study Director 2/7/94

Bonnie W. Cerven, Quality Assurance 2/7/94

Elizabeth J. Salyer, Archivist 2/7/94

TITLE OF REPORT : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL NUMBER: 108A-02 R/A

OBJECTIVE : To determine whether a material causes irreversible damage as defined in 49 CFR 173.240(a)(1) when applied to rabbit skin. This study was designed to comply with the standards set forth in 49 CFR 173 - Appendix A and also meets the packing group assignment categories of 49 CFR 173.137 as published in the Federal Register, Vol, 55, No. 246, 12/21/90.

TEST ARTICLE

Source : HERCULES INCORPORATED
Date Received : 11/17/92

Test Article Label : Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 and Spent Sulfuric Acid

Storage : The test articles were stored at room temperature and humidity.

Test Article Description : Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 (Amber Liquid)
: Spent Sulfuric Acid (Clear Liquid)

Sample Preparation : Both test articles were used as received

TEST ANIMALS

Animals were received from Ace Animals on 11/10 and 11/17/92. Six healthy New Zealand Albino rabbits which had been quarantined for at least one week were selected for this test from a larger group.

Pretest body weight range was 2.2 - 2.9 kg. The animals were identified by cage notation and a uniquely numbered metal eartag. The animals were housed 1/cage in suspended cages. Bedding was placed beneath the cages and changed twice/week. Fresh Purina Rabbit Chow (Diet #5321) was provided daily. Water was available ad libitum.

The animal room, reserved exclusively for rabbits on acute tests, was temperature controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.

TEST DATES

Study Initiation	(Date Protocol Signed)	:	12/03 and 12/08/92
Experimental Start	(1st Exposure to Test Substance)	:	12/08/92
Experimental Term	(Last date data collected)	:	12/15/92
Draft Report Submitted	(If applicable)	:	2/9/93
Study Completion	(Submission of Final Report)	:	2/7/94

SITE PREPARATION

Prior to application of the test article, the back and sides of each animal were clipped free of hair. The skin was not abraded.

EXPERIMENTAL DESIGN

0.5 ml of each test article was applied to each of two sites on the prepared area on the back of of six rabbits.

A 1" x 1" gauze patch was placed on each test site. The test articles were introduced under the patch and the patches were secured with adhesive tape. In order to aid in maintaining the test patches and to retard evaporation of the test articles, the entire trunk of each animal was wrapped with plastic and secured with adhesive tape. In order to permit dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which was opened to examine the test sites. The test article was kept in contact with the skin for 4 hours at which time the wrappings were removed and both sites were washed with distilled water.

TYPE AND FREQUENCY OF OBSERVATIONS

Animals were observed for skin reactions, including ulceration and necrosis, during the 4 hour exposure period at 3 minutes post dose, and again at 1 hour post dose. At 4 hours, the wrappings were removed and the test sites were scored for dermal reactions and then washed with water. The treated sites were scored again at 24, 48 and 72 hours and on day 7 post-dose. Erythema and edema were scored according to the numerical Draize technique. Additional signs were described.

Body weights were recorded pretest. The general health of the animals was monitored at each observation time.

ANALYSIS OF DATA

Corrosion will be considered to have resulted if the substance in contact with the rabbit skin has caused destruction or irreversible alteration of the tissue. Tissue destruction is considered to have occurred if, at any of the readings, there is ulceration or necrosis. Tissue destruction does not include merely sloughing of the epidermis, or erythema, edema, or fissuring. (49 CFR 173-Appendix A. No. 8).

Packing Group Assignments:

Packing Group I criterion reflects necrosis occurring within a period of three (3) minutes or less following exposure to test substance.

Packing Group II criterion reflects necrosis occurring in more than three (3) minutes but not more than 60 minutes.

Packing Group III criterion reflects necrosis occurring in more than 60 minutes but not more than four hours.

RETENTION OF DATA

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number.

The test article will be returned to the sponsor upon submission of the final report.

REVISION OF THE PROTOCOL

Per sponsor's instructions, four test sites/animal were used (Refer to MB 92-2149 C for results of Sites 2 and 3).

RESULTS

SITE 1: Amine D Acetate 50S (washed with water)

ANIMAL NUMBERS/SEX

	D5212 F	D5162 M	D5217 F	D5163 M	D5219 M	D5165 M
PRETEST BODY WEIGHT (kg):	2.3	2.2	2.3	2.9	2.4	2.8
Erythema & Eschar Formation						
3 Minutes	1	1	1	1	1	0
1 Hour	2	2	2	2	1	2
4 Hours	2	2	2	2	2	2
24 Hours	2p	2p	2	2	2p	2p
48 Hours	4pa	>4n,pac	2p	2p	4p	2p
72 Hours	>4n,pa	>4n,pa	>4n,p	2p	4p	>4ms,pe
7 Days	>4m,gh	>4n,gh	2fgh	2fgh	1fgh	>4m
Edema						
3 Minutes	0	0	0	0	0	0
1 Hour	1	1	1	1	1	1
4 Hours	2	2	3	3	2	3
24 Hours	3	3	3	3	3	3
48 Hours	2	2	2	3	2	3
72 Hours	2	2	2	2	2	3
7 Days	1	1	1	0	0	1
SYSTEMIC OBSERVATIONS:						
3 Minutes	A	A	A	A	A	A
1 Hour	A	A	A	A	A	A
4 Hours	A	A	A	A	A	A
24 Hours	A	A	A	A	A	A
48 Hours	A	A	A	D,1	A	A
72 Hours	A	A	A	A	A	A
7 Days	A	A	A	A	A	A

SYSTEMIC CODE:
- A = normal
- D = diarrhea
- 1 = mucoid diarrhea

DERMAL FOOTNOTES:
- a = upper dermis peeling away
- c = white discharge
- e = dermis cracking
- f = flaking skin
- g = shiny areas
- h = areas of poor hair regrowth
- p = pale areas

DRAIZE DERMAL SCORES: See page -8- for dermal scoring codes.

R E S U L T S (cont'd):

SITE 4: Spent Sulfuric Acid (washed with water)

	ANIMAL NUMBERS/SEX					
	D5212 F	D5162 M	D5217 F	D5163 M	D5219 M	D5165 M
PRETEST BODY WEIGHT - kg:	2.3	2.2	2.3	2.9	2.4	2.8
Erythema & Eschar Formation						
3 Minutes	1b	0	0	0	0	0
1 Hour	1b	0	0	0	0	0
4 Hours	1b	1	0	1	0	1
24 Hours	1b	0	0	1	0	0
48 Hours	1b	0	0	0	0	0
72 Hours	1b	0	0	0	0	0
7 Days	0	0	0	0	0	0
Edema						
3 Minutes	0	0	0	0	0	0
1 Hour	0	0	0	0	0	0
4 Hours	0	0	0	0	0	0
24 Hours	0	0	0	0	0	0
48 Hours	0	0	0	0	0	0
72 Hours	0	0	0	0	0	0
7 Days	0	0	0	0	0	0
SYSTEMIC OBSERVATIONS:						
3 Minutes	A	A	A	A	A	A
1 Hour	A	A	A	A	A	A
4 Hours	A	A	A	A	A	A
24 Hours	A	A	A	A	A	A
48 Hours	A	A	A	D,1	A	A
72 Hours	A	A	A	A	A	A
7 Days	A	A	A	A	A	A

SYSTEMIC CODE:
A = normal
D = diarrhea
1 = mucoid diarrhea

DERMAL FOOTNOTES:
b = brown areas on fur

DRAIZE DERMAL SCORES: See page -8- for dermal scoring codes.

DRAIZE DERMAL SCORING CODE

ERYTHEMA AND ESCHAR FORMATION:

No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Severe eschar formation	>4s
Necrosis	>4n
Moderate to severe eschar formation	>4ms
Moderate eschar formation	>4m

EDEMA FORMATION:

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm, extending beyond the area of exposure)	4

PROJECT NUMBER : MB 92-2149 C

TEST ARTICLE : Amine D, Lot #HBD-059, Sample #92-2617 (soap and water or mineral oil wash)

SPONSOR : HERCULES INCORPORATED

TITLE : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL # : 108A-02 R/A

ABSTRACT

Method Synopsis - Six healthy New Zealand albino rabbits were dosed with Amine D, Lot #HBD-059, Sample #92-2617. 0.5 ml of the test article was placed on the two intact sites (#'s 2 and 3; See MB Project 92-2150 C for sites #1 and 4) of the back of each rabbit. In order to facilitate dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which was opened to examine the treated site at 3 minutes and one hour post dose. The test article remained on the skin for 4 hours at which time the wrappings were removed and site 2 was washed with soap and water, and site 3 was washed with mineral oil. The sites were scored again at 4, 24, 48 and 72 hours and on day 7. The skin was also evaluated for ulceration, necrosis or any evidence of tissue destruction at these time periods. Body weights were recorded pretest.

Summary -

Amine D washed soap and water - Erythema, absent to slight at 3 minutes after test article application, was slight to well defined at 1 hour, well defined at 4 and 24 hours, well defined to severe at 48 hours and severe at 72 hours and on day 7. Pale areas were noted at 24 hours. Moderate eschar, necrosis of tissue, shiny areas and poor hair regrowth, indicative of injuries in depth, were noted at 48 and 72 hours and on day 7. Although the sites were washed, the test article remained on the dose site in 6/6 animals through 72 hours. Edema, absent at 3 minutes after test article application, was absent to slight at 1 hour, slight to moderate at 4 hours and moderate to severe at 24 hours. Edema was well defined to moderate at 48 hours, slight to moderate at 72 hours and absent to slight on day 7.

Amine D washed with mineral oil - Erythema, absent at 3 minutes after test article application, was absent to well defined at 1 hour, well defined at 4 and 24 hours, well defined to severe at 48 hours and severe at 72 hours and on day 7. Pale areas were noted at 24 hours. Moderate eschar, necrosis of tissue, shiny areas and poor hair regrowth, indicative of injuries in depth, were noted at 48 and 72 hours and on day 7. One animal had a white discharge from the dose site at 48 hours. Edema, absent at 3 minutes after test article application, was absent to slight at 1 hour, well defined to moderate at 4 hours, and severe at 24 and 48 hours. Edema was well defined to severe at 72 hours and absent to slight on day 7.

Systemic - Mucoid diarrhea, noted in one animal, was the only abnormal physical signs noted during the observation period.

Conclusion - Evidence of irreversible changes, characterized by moderate eschar and necrotic tissue at 48 hours, indicates that the test article is a DOT, but not a class 8 corrosive as defined in 49 CFR 173.136 and does not require a packing group assignment. However, the presence of moderate eschar and necrotic tissue at 72 hours and on day 7 indicates that the test article has the potential to produce a delayed corrosive response. Soap and water proved ineffective in removing the test article. Mineral oil was an effective solvent, but appeared to spread the test article and resulting irritating effects over a larger area, as indicated by the severity of edema at 24, 48 and 72 hours.

MB Res 92-2149 2-7-94

28-2C

GOOD LABORATORY PRACTICES

This study was conducted in accordance with the Good Laboratory Practices Regulations of the FDA - 21 CFR Part 58.

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit (QAU) has reviewed this report and determined that it accurately describes the methods and standard operating procedures used, and that the results contained herein accurately and fully reflect the raw data from this study.

All procedures performed during the conduct of this study were in conformance with the protocol. Applicable Standard Operating Procedures and GLP regulations were followed. There were no discrepancies between the protocol, the raw data, and/or the final report. The Revision/Addendum (R/A) applicable to this study was made and fully documented in accordance with the GLP requirements and is fully described in this report.

The QAU inspected an in-life phase of the study, audited the raw data and reviewed the report on the dates indicated below. QAU findings were reported to management and the Study Director.

Study Inspected	: 12/08/92
Raw Data Audited	: 01/22/93

Final report reviewed:

Oscar M. Moreno, Ph.D. 2/4/94

Lori Kieffer, B.A., Study Director 2/7/94

Bonnie W. Cerven, Quality Assurance 2/7/94

Elizabeth J. Salyer, Archivist 2/7/94

TITLE OF REPORT : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL NUMBER: 108A-02 R/A

OBJECTIVE : To determine whether a material causes irreversible damage as defined in 49 CFR 173.240(a)(1) when applied to rabbit skin. This study was designed to comply with the standards set forth in 49 CFR 173 - Appendix A and also meets the packing group assignment categories of 49 CFR 173.137 as published in the Federal Register, Vol, 55, No. 246, 12/21/90.

TEST ARTICLE

Source : HERCULES INCORPORATED
Date Received : 11/17/92

Test Article Label : Amine D, Lot #HBD-059, Sample #92-2617

Storage : The test article was stored at room temperature and humidity.

Test Article Description : Viscous Amber Liquid

Sample Preparation : Used as received

TEST ANIMALS

Animals were received from Ace Animals on 11/10 and 11/17/92. Six healthy New Zealand Albino rabbits which had been quarantined for at least one week were selected for this test from a larger group.

Pretest body weight range was 2.2 - 2.9 kg. The animals were identified by cage notation and a uniquely numbered metal eartag. The animals were housed 1/cage in suspended cages. Bedding was placed beneath the cages and changed twice/week. Fresh Purina Rabbit Chow (Diet #5321) was provided daily. Water was available ad libitum.

The animal room, reserved exclusively for rabbits on acute tests, was temperature controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.

TEST DATES

Study Initiation	(Date Protocol Signed)	:	12/03/92
Experimental Start	(1st Exposure to Test Substance)	:	12/08/92
Experimental Term	(Last date data collected)	:	12/11/92
Draft Report Submitted	(If applicable)	:	2/9/93
Study Completion	(Submission of Final Report)	:	2/7/94

SITE PREPARATION

Prior to application of the test article, the back and sides of each animal were clipped free of hair. The skin was not abraded.

EXPERIMENTAL DESIGN

0.5 ml of the test article was applied to each of two sites on the prepared area on the back of each of six rabbits.

A 1" x 1" gauze patch was placed on each test site. The test article was introduced under the patch and the patches were secured with adhesive tape. In order to aid in maintaining the test patches and to retard evaporation of the test article, the entire trunk of each animal was wrapped with plastic and secured with adhesive tape. In order to permit dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which was opened to examine the test sites. The test article was kept in contact with the skin for 4 hours at which time the wrappings were removed. Site 2 was washed with soap and water, and site 3 was washed with mineral oil.

TYPE AND FREQUENCY OF OBSERVATIONS

Animals were observed for skin reactions, including ulceration and necrosis, during the 4 hour exposure period at 3 minutes post dose, and again at 1 hour post dose. At 4 hours, the wrappings were removed and the test sites were scored for dermal reactions and then washed with water. The treated sites were scored again at 24, 48 and 72 hours and on day 7 post-dose. Erythema and edema were scored according to the numerical Draize technique. Additional signs were described.

Body weights were recorded pretest. The general health of the animals was monitored at each observation time.

ANALYSIS OF DATA

Corrosion will be considered to have resulted if the substance in contact with the rabbit skin has caused destruction or irreversible alteration of the tissue. Tissue destruction is considered to have occurred if, at any of the readings, there is ulceration or necrosis. Tissue destruction does not include merely sloughing of the epidermis, or erythema, edema, or fissuring. (49 CFR 173-Appendix A. No. 8).

Packing Group Assignments:

Packing Group I criterion reflects necrosis occurring within a period of three (3) minutes or less following exposure to test substance.

Packing Group II criterion reflects necrosis occurring in more than three (3) minutes but not more than 60 minutes.

Packing Group III criterion reflects necrosis occurring in more than 60 minutes but not more than four hours.

RETENTION OF DATA

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number.

The test article will be returned to the sponsor upon submission of the final report.

REVISION OF THE PROTOCOL

Per sponsor's instructions, four test sites/animal were used (Refer to MB 92-2150 C for results of Sites 1 and 4).

RESULTS

SITE 2: Amine D
(washed with soap & water)

ANIMAL NUMBERS/SEX

	D5212 F	D5162 M	D5217 F	D5163 M	D5219 M	D5165 M
PRETEST BODY WEIGHT (kg):	2.3	2.2	2.3	2.9	2.4	2.8
Erythema & Eschar Formation						
3 Minutes	1	0	0	0	0	0
1 Hour	2	2	1	1	1	1
4 Hours	2	2	2	2	2	2
24 Hours	2p	2p	2p	2p	2p	2p
48 Hours	>4m,pd	>4m,pd	2pd	>4m,pd	>4m,pd	2pd
72 Hours	>4n,pd	>4n,pd	>4n,pd	>4n,pda	>4n,pd	>4n,pd
7 Days	>4m,gh	>4m,fgh	4gh	>4m,gh	>4m,fgh	>4ms,d
Edema						
3 Minutes	0	0	0	0	0	0
1 Hour	0	1	1	1	0	0
4 Hours	1	3	3	2	2	2
24 Hours	3	3	3	3	4	3
48 Hours	2	3	2	3	2	3
72 Hours	1	2	2	2	2	3
7 Days	0	1	0	1	1	0
SYSTEMIC OBSERVATIONS:						
3 Minutes	A	A	A	A	A	A
1 Hour	A	A	A	A	A	A
4 Hours	A	A	A	A	A	A
24 Hours	A	A	A	A	A	A
48 Hours	A	A	A	D,1	A	A
72 Hours	A	A	A	A	A	A
7 Days	A	A	A	A	A	A

SYSTEMIC CODE:
A = normal
D = diarrhea
1 = mucoid diarrhea

DERMAL FOOTNOTES:
a = upper dermis peeling off
d = test article remaining on dose site
f = flaking skin
g = shiny area
h = areas of poor hair regrowth
p = pale areas

DRAIZE DERMAL SCORES: See page -8- for dermal scoring codes.

R E S U L T S (cont'd)

SITE 3: Amine D
(washed with mineral oil)

ANIMAL NUMBERS/SEX

	D5212 F	D5162 M	D5217 F	D5163 M	D5219 M	D5165 M
PRETEST BODY WEIGHT (kg):	2.3	2.2	2.3	2.9	2.4	2.8
Erythema & Eschar Formation						
3 Minutes	0	0	0	0	0	0
1 Hour	1	2	1	1	0	0
4 Hours	2	2	2	2	2	2
24 Hours	2p	2p	2p	2p	2p	2p
48 Hours	>4n,apc	>4m,p	2p	2p	>4m,pe	2p
72 Hours	>4n,ap	>4n,ape	>4n,p	>4n,ap	>4n,pe	>4n,pe
7 Days	>4ms,gh	>4n	>4n,cgh	>4m,fgh	>4n,c	>4n
Edema						
3 Minutes	0	0	0	0	0	0
1 Hour	0	1	1	1	0	0
4 Hours	2	3	2	2	2	3
24 Hours	4	4	4	4	4	4
48 Hours	4	4	4	4	4	4
72 Hours	2	3	4	3	4	4
7 Days	1	1	1	1	1	0
SYSTEMIC OBSERVATIONS:						
3 Minutes	A	A	A	A	A	A
1 Hour	A	A	A	A	A	A
4 Hours	A	A	A	A	A	A
24 Hours	A	A	A	A	A	A
48 Hours	A	A	A	D,1	A	A
72 Hours	A	A	A	A	A	A
7 Days	A	A	A	A	A	A

SYSTEMIC CODE:
A = normal
D = diarrhea
1 = mucoid diarrhea

DERMAL FOOTNOTES:
a = upper dermis peeling off
c = white discharge
e = dermis cracking
f = flaking skin
g = shiny areas
h = areas of poor hair regrowth
p = pale areas

DRAIZE DERMAL SCORES: See page -8- for dermal scoring codes.

DRAIZE DERMAL SCORING CODE

ERYTHEMA AND ESCHAR FORMATION:

No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Severe eschar formation	>4s
Necrosis	>4n
Moderate to severe eschar formation	>4ms
Moderate eschar formation	>4m

EDEMA FORMATION:

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm, extending beyond the area of exposure)	4

PROJECT NUMBER : MB 92-1987 C

TEST ARTICLE : Amine D

19-93

SPONSOR : HERCULES INCORPORATED

TITLE : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL # : 108A-02 R/A

ABSTRACT

Method Synopsis - Six healthy New Zealand albino rabbits were dosed with Amine D. 0.5 ml of the test article was placed on the two intact sites of the back of each rabbit. In order to facilitate dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which was opened to examine the treated site at 3 minutes and one hour post dose. The test article remained on the skin for 4 hours at which time the wrappings were removed and site 1 was washed with Hibiclens and site 2 was washed with Isopropyl alcohol. The sites were scored again at 4, 24, 48 and 72 hours and on day 7. The skin was also evaluated for ulceration, necrosis or any evidence of tissue destruction at these time periods. Body weights were recorded pretest.

Summary -

Amine D washed with Hibiclens - Erythema, absent at 3 minutes after test article application, was absent to well defined at 1 hour, well defined at 4 and 24 hours and well defined to severe at 48 hours. Erythema was severe at 72 hours and slight to severe on day 7. The test article remained on the dose site in 5/6 animals through 72 hours. In addition, pale areas were noted at 24 hours, areas of hair loss, cracking of the skin into the dermis and white discharge were evident at 48 hours, and moderate eschar appeared at 72 hours and on day 7. Edema, absent at 3 minutes and 1 hour after test article application, was well defined at 4 hours and well defined to severe at 24 and 48 hours. Edema was slight to well defined at 72 hours and absent to slight on day 7.

Amine D washed with Isopropyl Alcohol - Erythema, absent at 3 minutes after test article application, was absent to well defined at 1 hour and slight to well defined at 4 and 24 hours. Erythema was well defined to severe at 48 hours, moderate to severe at 72 hours and severe on day 7. In addition, pale areas were noted at 24 hours, cracking of the skin into the dermis was noted at 48 hours and moderate eschar was noted at 72 hours and on day 7. Edema, absent at 3 minutes and 1 hour after test article application, was well defined at 4 hours and moderate to severe at 24 hours. Edema was well defined to severe at 48 hours, well defined at 72 hours and absent to slight on day 7. The area of edema was greater in 5/6 animals at 24 hours than that of the sites washed with Hibiclens. This may have been due to the spreading of the test article during the alcohol wash.

Systemic - There were no abnormal systemic signs noted during the observation period.

Conclusion - Since there was no evidence of irreversible changes at 48 hours after test article application, the test article is not considered to be a class 8 or DOT corrosive. However, the presence of moderate eschar at 72 hours and on day 7 indicates that the test article has the potential to produce a delayed corrosive response. The Hibiclens proved ineffective in removing the test article. Isopropyl alcohol was an effective solvent, but appeared to spread the test article and resulting irritation effects over a larger area.

28-2C

GOOD LABORATORY PRACTICES

This study was conducted in accordance with the Good Laboratory Practices Regulations of the FDA - 21 CFR Part 58.

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit (QAU) has reviewed this report and determined that it accurately describes the methods and standard operating procedures used, and that the results contained herein accurately and fully reflect the raw data from this study.

All procedures performed during the conduct of this study were in conformance with the protocol. Applicable Standard Operating Procedures and GLP regulations were followed. There were no discrepancies between the protocol, the raw data, and/or the final report.

The QAU inspected an in-life phase of the study, audited the raw data and reviewed the report on the dates indicated below. QAU findings were reported to management and the Study Director.

Study Inspected	: 09/29/92
Raw Data Audited	: 12/01/92

Final report reviewed:

Oscar M. Moreno 1/7/93
Oscar M. Moreno, Ph.D.

Lori Kieffer 1/7/93
Lori Kieffer, B.A., Study Director

Bonnie W. Cerven 1/7/93
Bonnie W. Cerven, Quality Assurance

Elizabeth J. Salyer 1/7
Elizabeth J. Salyer, Archivist

steinsburg & wentz roads, p.o. box 178, spinnerstown, pa 18968
phone: (215)536-4110 fax: (215)536-1816

TITLE OF REPORT : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL NUMBER: 108A-02 R/A

OBJECTIVE : To determine whether a material causes irreversible damage as defined in 49 CFR 173.240(a)(1) when applied to rabbit skin. This study was designed to comply with the standards set forth in 49 CFR 173 - Appendix A and also meets the packing group assignment categories of 49 CFR 173.137 as published in the Federal Register, Vol, 55, No. 246, 12/21/90.

TEST ARTICLE

Source : HERCULES INCORPORATED
Date Received : 9/24/92

Test Article Label : Amine D

Storage : The test article was stored at room temperature and humidity.

Test Article Description : Yellow Viscous Liquid

Sample Preparation : Used as received

TEST ANIMALS

Animals were received from Ace Animals on 8/04, 8/11 and 8/25/92. Six healthy New Zealand Albino rabbits which had been quarantined for at least one week were selected for this test from a larger group.

Pretest body weight range was 2.2 - 2.9 kg. The animals were identified by cage notation and a uniquely numbered metal eartag. The animals were housed 1/cage in suspended cages. Bedding was placed beneath the cages and changed twice/week. Fresh Purina Rabbit Chow (Diet #5321) was provided daily. Water was available ad libitum.

The animal room, reserved exclusively for rabbits on acute tests, was temperature controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.

TEST DATES

Study Initiation	(Date Protocol Signed)	:	9/28/92
Experimental Start	(1st Exposure to Test Substance)	:	9/29/92
Experimental Term	(Last date data collected)	:	10/06/92
Draft Report Submitted	(If applicable)	:	12/11/92
Study Completion	(Submission of Final Report)	:	01/07/93

SITE PREPARATION

Prior to application of the test article, the back and sides of each animal were clipped free of hair. The skin was not abraded.

EXPERIMENTAL DESIGN

0.5 ml of the test article was applied to each of two sites on the prepared area on the back of each of six rabbits.

A 1" x 1" gauze patch was placed on each test site. The test article was introduced under the patch and the patches were secured with adhesive tape. In order to aid in maintaining the test patches and to retard evaporation of the test article, the entire trunk of each animal was wrapped with plastic and secured with adhesive tape. In order to permit dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which was opened to examine the test sites. The test article was kept in contact with the skin for 4 hours at which time the wrappings were removed. Site 1 was washed with Hibiclens and site 2 was washed with Isopropyl Alcohol. Both sites were then rinsed with distilled water prior to dermal observations.

TYPE AND FREQUENCY OF OBSERVATIONS

Animals were observed for skin reactions, including ulceration and necrosis, during the 4 hour exposure period at 3 minutes post dose, and again at 1 hour post dose. At 4 hours, the wrappings were removed and the test sites were scored for dermal reactions and then washed with water. The treated sites were scored again at 24, 48 and 72 hours and on day 7 post-dose. Erythema and edema were scored according to the numerical Draize technique. Additional signs were described.

Body weights were recorded pretest. The general health of the animals was monitored at each observation time.

ANALYSIS OF DATA

Corrosion will be considered to have resulted if the substance in contact with the rabbit skin has caused destruction or irreversible alteration of the tissue. Tissue destruction is considered to have occurred if, at any of the readings, there is ulceration or necrosis. Tissue destruction does not include merely sloughing of the epidermis, or erythema, edema, or fissuring. (49 CFR 173-Appendix A. No. 8).

Packing Group Assignments:

Packing Group I criterion reflects necrosis occurring within a period of three (3) minutes or less following exposure to test substance.

Packing Group II criterion reflects necrosis occurring in more than three (3) minutes but not more than 60 minutes.

Packing Group III criterion reflects necrosis occurring in more than 60 minutes but not more than four hours.

RETENTION OF DATA

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number.

The test article will be returned to the sponsor upon submission of the final report.

REVISION OF THE PROTOCOL

Per sponsor's instructions, the animals were dosed on two sites. After the 4 hour exposure, one site was washed with Hibiclens and one site was washed with Isopropyl Alcohol.

RESULTS

SITE 1 (Hibiciens Wash)	ANIMAL NUMBERS/SEX					
	D4421	D4482	D4484	D4517	D4352	D4521
	F	M	M	F	F	F
PRETEST BODY WEIGHT - kg:	2.6	2.9	2.5	2.3	2.2	2.4
Erythema & Eschar Formation						
3 Minutes	0	0	0	0	0	0
1 Hour	1	1	0	2	1	1
4 Hours	2	2	2	2	2	2
24 Hours	2p	2p	2a	2a	2p	2
48 Hours	4pcde	2pe	4ga	4aedc	4aedc	4ped
72 Hours	>4m,ep	4ped	>4m	>4m,e	>4m,ec	>4m,e
7 Days	>4ms,e	>4ms,ed	>4ms,e	>4m,es	1sf	>4ms,e
Edema						
3 Minutes	0	0	0	0	0	0
1 Hour	0	0	0	0	0	0
4 Hours	2	2	2	2	2	2
24 Hours	3	3	3	4	4	2
48 Hours	2	2	2	2	4	2
72 Hours	2	2	2	1	2	1
7 Days	1	0	1	0	0	0

SITE 2 (Isopropyl Alcohol Wash)	ANIMAL NUMBERS/SEX					
	D4421	D4482	D4484	D4517	D4352	D4521
	F	M	M	F	F	F
Erythema & Eschar Formation						
3 Minutes	0	0	0	0	0	0
1 Hour	1	1	0	2	1	1
4 Hours	2	2	1	2	2	2
24 Hours	1p	2p	2a	2p	2	2
48 Hours	4pd	2pd	4p	2p	4dp	2p
72 Hours	4d	4pd	4pd	4pd	>4m,d	3pd
7 Days	>4m	4df	>4ms,ds	>4m,dsf	4sf	4df
Edema						
3 Minutes	0	0	0	0	0	0
1 Hour	0	0	0	0	0	0
4 Hours	2	2	2	2	2	2
24 Hours	3	3b	4b	4b	4b	4b
48 Hours	2	2	2b	2b	4b	3b
72 Hours	2	2	2b	2	2p	2b
7 Days	1	1	1b	1	0	1
SYSTEMIC OBSERVATIONS:						
3 Minutes	A	A	A	A	A	A
1 Hour	A	A	A	A	A	A
4 Hours	A	A	A	A	A	A
24 Hours	A	A	A	A	A	A
48 Hours	A	A	A	A	A	A
72 Hours	A	A	A	A	A	A
7 Days	A	A	A	A	A	A

FOOTNOTES ON PAGE -7-

DRAIZE DERMAL SCORING CODE

ERYTHEMA AND ESCHAR FORMATION:

No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Severe eschar formation	>4s
Necrosis	>4n
Moderate to severe eschar formation	>4ms
Moderate eschar formation	>4m

EDEMA FORMATION:

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm, extending beyond the area of exposure)	4

FOOTNOTES:
A = normal
a = pale areas
b = area of edema larger, apparently due to wash
c = white discharge
d = skin cracking into dermis
e = test article remaining
f = flaking skin
g = areas of hair loss
p = entire dose site pale, areas around dose site scored for erythema
s = shiny areas

MB RESEARCH LABORATORIES, INC.

TRANSMITTAL FORM

DATE : January 11, 1993

TO : Dr. Elton R. Homan

COMPANY : HERCULES INCORPORATED

FROM : John Schugard

Transmitted herewith are the following:

( )DRAFT REPORT(s) (X)FINAL REPORT(s) (X)TEST ARTICLE (under separate cover)

( )RAW DATA ( )PROTOCOL SIGNATURE PAGE ( )INVOICE

( )OTHER

PROTOCOL #	STUDY TITLE	TEST ARTICLE	MB PROJECT #
108A-02	DOT Corrosivity	Amine D	92-1987 C

steinsburg & wentz roads, p.o.box 178, spinnerstown, pa 18968
phone: (215)536-4110 fax: (215)536-1816

PROJECT NUMBER : MB 92-2150 C

92-13

TEST ARTICLE : Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 (water wash)
Spent Sulfuric Acid (water wash)

SPONSOR : HERCULES INCORPORATED

TITLE : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL # : 108A-02 R/A

ABSTRACT

Method Synopsis - Six healthy New Zealand albino rabbits were dosed on separate sites with Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 (water wash) and Spent Sulfuric Acid (water wash). 0.5 ml of Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 (water wash) was applied to one intact site (Site #1) and 0.5 ml of Spent Sulfuric Acid (water wash) was applied to another intact site (Site #4 - see MB Project 92-2149 C for sites #2 and 3) on the back of each rabbit. In order to facilitate dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which was opened to examine the treated site at 3 minutes and one hour post dose. The test article remained on the skin for 4 hours at which time the wrappings were removed and both sites were washed with water. The sites were scored again at 4, 24, 48 and 72 hours and on day 7. The skin was also evaluated for ulceration, necrosis or any evidence of tissue destruction at these time periods. Body weights were recorded pretest.

Summary

Amine D Acetate 50S (sites washed with water) - Erythema, absent to slight at 3 minutes after test article application, was slight to well defined at 1 hour, well defined at 4 and 24 hours, and well defined to severe at 48 and 72 hours and on day 7. Pale areas were noted at 24 hours. Moderate eschar, necrosis of tissue, shiny areas and poor hair regrowth, indicative of injuries in depth, were noted at 48 and 72 hours and on day 7. Edema absent at 3 minutes after test article application, was slight at 1 hour, well defined to moderate at 4 hours and moderate at 24 hours. Edema was well defined to moderate at 48 and 72 hours, and absent to slight on day 7.

Spent Sulfuric Acid (sites washed with water) - Erythema, absent to slight at 3 minutes, 1, 4, 24, 48 and 72 hours after test article application, was absent on day 7. Edema was absent at all observation periods.

Systemic - Mucoid diarrhea, noted in one animal, was the only abnormal physical signs noted during the observation period.

Conclusion

Amine D Acetate 50S - Since only one animal presented evidence of irreversible changes, characterized by necrosis of tissues at 48 hours, the test article is not considered to be a DOT or Class 8 corrosive as defined in 49 CFR 173.136 and does not require a packing group assignment. However, the presence of moderate to severe eschar and necrosis of tissue at 72 hours and on day 7, indicates that the test article has the potential to produce a delayed corrosive response.

Spent Sulfuric Acid - Since there was no evidence of irreversible changes at 48 hours after test article application, the test article is not a DOT or Class 8 corrosive as defined in 49 CFR 173.136 and does not require a packing group assignment.

MB Rea 92-2150C 2-7-94

28-2C

GOOD LABORATORY PRACTICES

This study was conducted in accordance with the Good Laboratory Practices Regulations of the FDA - 21 CFR Part 58.

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit (QAU) has reviewed this report and determined that it accurately describes the methods and standard operating procedures used, and that the results contained herein accurately and fully reflect the raw data from this study.

All procedures performed during the conduct of this study were in conformance with the protocol. Applicable Standard Operating Procedures and GLP regulations were followed. There were no discrepancies between the protocol, the raw data, and/or the final report. The Revision/Addendum (R/A) applicable to this study was made and fully documented in accordance with the GLP requirements and is fully described in this report.

The QAU inspected an in-life phase of the study, audited the raw data and reviewed the report on the dates indicated below. QAU findings were reported to management and the Study Director.

Study Inspected	: 12/08/92
Raw Data Audited	: 01/22/93

Final report reviewed:

Oscar M. Moreno, Ph.D. 2/4/94

Lori Kieffer, B.A., Study Director 2/7/94

Bonnie W. Cerven 2/7/94

Elizabeth J. Salyer 2/7/94

TITLE OF REPORT : DOT TEST FOR SKIN CORROSIVITY

PROTOCOL NUMBER: 108A-02 R/A

OBJECTIVE : To determine whether a material causes irreversible damage as defined in 49 CFR 173.240(a)(1) when applied to rabbit skin. This study was designed to comply with the standards set forth in 49 CFR 173 - Appendix A and also meets the packing group assignment categories of 49 CFR 173.137 as published in the Federal Register, Vol, 55, No. 246, 12/21/90.

TEST ARTICLE

Source : HERCULES INCORPORATED
Date Received : 11/17/92

Test Article Label : Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 and Spent Sulfuric Acid

Storage : The test articles were stored at room temperature and humidity.

Test Article Description : Amine D Acetate 50S, Lot #HHS-080, Sample #92-2618 (Amber Liquid)
: Spent Sulfuric Acid (Clear Liquid)

Sample Preparation : Both test articles were used as received

TEST ANIMALS

Animals were received from Ace Animals on 11/10 and 11/17/92. Six healthy New Zealand Albino rabbits which had been quarantined for at least one week were selected for this test from a larger group.

Pretest body weight range was 2.2 - 2.9 kg. The animals were identified by cage notation and a uniquely numbered metal eartag. The animals were housed 1/cage in suspended cages. Bedding was placed beneath the cages and changed twice/week. Fresh Purina Rabbit Chow (Diet #5321) was provided daily. Water was available ad libitum.

The animal room, reserved exclusively for rabbits on acute tests, was temperature controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.

TEST DATES

Study Initiation	(Date Protocol Signed)	:	12/03 and 12/08/92
Experimental Start	(1st Exposure to Test Substance)	:	12/08/92
Experimental Term	(Last date data collected)	:	12/15/92
Draft Report Submitted	(If applicable)	:	2/9/93
Study Completion	(Submission of Final Report)	:	2/7/94

SITE PREPARATION

Prior to application of the test article, the back and sides of each animal were clipped free of hair. The skin was not abraded.

EXPERIMENTAL DESIGN

0.5 ml of each test article was applied to each of two sites on the prepared area on the back of of six rabbits.

A 1" x 1" gauze patch was placed on each test site. The test articles were introduced under the patch and the patches were secured with adhesive tape. In order to aid in maintaining the test patches and to retard evaporation of the test articles, the entire trunk of each animal was wrapped with plastic and secured with adhesive tape. In order to permit dermal observations during the 4 hour exposure period, the wrappings were fitted with a window which was opened to examine the test sites. The test article was kept in contact with the skin for 4 hours at which time the wrappings were removed and both sites were washed with distilled water.

TYPE AND FREQUENCY OF OBSERVATIONS

Animals were observed for skin reactions, including ulceration and necrosis, during the 4 hour exposure period at 3 minutes post dose, and again at 1 hour post dose. At 4 hours, the wrappings were removed and the test sites were scored for dermal reactions and then washed with water. The treated sites were scored again at 24, 48 and 72 hours and on day 7 post-dose. Erythema and edema were scored according to the numerical Draize technique. Additional signs were described.

Body weights were recorded pretest. The general health of the animals was monitored at each observation time.

ANALYSIS OF DATA

Corrosion will be considered to have resulted if the substance in contact with the rabbit skin has caused destruction or irreversible alteration of the tissue. Tissue destruction is considered to have occurred if, at any of the readings, there is ulceration or necrosis. Tissue destruction does not include merely sloughing of the epidermis, or erythema, edema, or fissuring. (49 CFR 173-Appendix A. No. 8).

Packing Group Assignments:

Packing Group I criterion reflects necrosis occurring within a period of three (3) minutes or less following exposure to test substance.

Packing Group II criterion reflects necrosis occurring in more than three (3) minutes but not more than 60 minutes.

Packing Group III criterion reflects necrosis occurring in more than 60 minutes but not more than four hours.

RETENTION OF DATA

The raw data is filed at MB Research by project number. The final report is filed at MB Research by sponsor name and MB project number.

The test article will be returned to the sponsor upon submission of the final report.

REVISION OF THE PROTOCOL

Per sponsor's instructions, four test sites/animal were used (Refer to MB 92-2149 C for results of Sites 2 and 3).

RESULTS

SITE 1: Amine D Acetate 50S (washed with water)

ANIMAL NUMBERS/SEX

	D5212 F	D5162 M	D5217 F	D5163 M	D5219 M	D5165 M
PRETEST BODY WEIGHT (kg):	2.3	2.2	2.3	2.9	2.4	2.8
Erythema & Eschar Formation						
3 Minutes	1	1	1	1	1	0
1 Hour	2	2	2	2	1	2
4 Hours	2	2	2	2	2	2
24 Hours	2p	2p	2	2	2p	2p
48 Hours	4pa	>4n,pac	2p	2p	4p	2p
72 Hours	>4n,pa	>4n,pa	>4n,p	2p	4p	>4ms,pe
7 Days	>4m,gh	>4n,gh	2fgh	2fgh	1fgh	>4m
Edema						
3 Minutes	0	0	0	0	0	0
1 Hour	1	1	1	1	1	1
4 Hours	2	2	3	3	2	3
24 Hours	3	3	3	3	3	3
48 Hours	2	2	2	3	2	3
72 Hours	2	2	2	2	2	3
7 Days	1	1	1	0	0	1
SYSTEMIC OBSERVATIONS:						
3 Minutes	A	A	A	A	A	A
1 Hour	A	A	A	A	A	A
4 Hours	A	A	A	A	A	A
24 Hours	A	A	A	A	A	A
48 Hours	A	A	A	D,1	A	A
72 Hours	A	A	A	A	A	A
7 Days	A	A	A	A	A	A

SYSTEMIC CODE:
- A = normal
- D = diarrhea
- 1 = mucoid diarrhea

DERMAL FOOTNOTES:
- a = upper dermis peeling away
- c = white discharge
- e = dermis cracking
- f = flaking skin
- g = shiny areas
- h = areas of poor hair regrowth
- p = pale areas

DRAIZE DERMAL SCORES: See page -8- for dermal scoring codes.

R E S U L T S (cont'd):

SITE 4: Spent Sulfuric Acid (washed with water)

	ANIMAL NUMBERS/SEX					
	D5212 F	D5162 M	D5217 F	D5163 M	D5219 M	D5165 M
PRETEST BODY WEIGHT - kg:	2.3	2.2	2.3	2.9	2.4	2.8
Erythema & Eschar Formation						
3 Minutes	1b	0	0	0	0	0
1 Hour	1b	0	0	0	0	0
4 Hours	1b	1	0	1	0	1
24 Hours	1b	0	0	1	0	0
48 Hours	1b	0	0	0	0	0
72 Hours	1b	0	0	0	0	0
7 Days	0	0	0	0	0	0
Edema						
3 Minutes	0	0	0	0	0	0
1 Hour	0	0	0	0	0	0
4 Hours	0	0	0	0	0	0
24 Hours	0	0	0	0	0	0
48 Hours	0	0	0	0	0	0
72 Hours	0	0	0	0	0	0
7 Days	0	0	0	0	0	0
SYSTEMIC OBSERVATIONS:						
3 Minutes	A	A	A	A	A	A
1 Hour	A	A	A	A	A	A
4 Hours	A	A	A	A	A	A
24 Hours	A	A	A	A	A	A
48 Hours	A	A	A	D,1	A	A
72 Hours	A	A	A	A	A	A
7 Days	A	A	A	A	A	A

SYSTEMIC CODE:
A = normal
D = diarrhea
1 = mucoid diarrhea

DERMAL FOOTNOTES:
b = brown areas on fur

DRAIZE DERMAL SCORES: See page -8- for dermal scoring codes.

DRAIZE DERMAL SCORING CODE

ERYTHEMA AND ESCHAR FORMATION:

No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4
Severe eschar formation	>4s
Necrosis	>4n
Moderate to severe eschar formation	>4ms
Moderate eschar formation	>4m

EDEMA FORMATION:

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm, extending beyond the area of exposure)	4