

201-15729B

III Robust Summaries of Existing Data

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Physicochemical End Point: Melting Point

Remark:

Westvaco DIACID® 1550 is a liquid under normal conditions and determination of the melting point is not applicable. Since Westvaco DIACID® 1550 is a complex mixture any attempt to measure the freezing point is not likely to provide a defined freezing point as the product will display freezing behavior over a temperature range. Therefore determination of the freezing point is not considered appropriate.

Physicochemical End Point: Boiling Point

Remark:

Westvaco DIACID® 1550 is a non-volatile liquid at ambient temperatures and will decompose, possibly explosively, if heated to high temperatures. Hence the boiling point has not been determined.

Physicochemical End Point: Vapor Pressure

Remark:

The vapor pressure of Westvaco DIACID® 1550 at ambient temperatures is extremely low, and experimental measurement is inappropriate.

Physicochemical End Point: Water Solubility

Test substance:

The study was carried out using the product Westvaco DIACID® 1550. Westvaco DIACID® 1550 consists of two major components: the C-18 monoacid and the C-21 diacid components. The solubility of each of these components was determined. The results reported here are for both the C18 fatty acid and the C21 dicarboxylic acid.

Chemical Category:

Fatty acid

Method:

OECD Test Guideline 105

GLP:

Yes

Year Study Performed:

2003

Remarks about method:

Preliminary analysis indicated that Westvaco DIACID® 1550 has a solubility of <100 mg/L (<0.1 g/L) in Milli RO water.

The water solubility was assessed using the flask method. Triplicate saturated solutions of Westvaco DIACID® 1550 in Milli RO water were prepared for each successive timepoint (24 h, 48 h & 72 h). Samples were incubated at 30.0 degrees Celsius +/- 0.4 degrees. Upon completion of the incubation period the samples were removed and allowed to equilibrate to 20.0 degrees Celsius +/- 0.4 degrees for 24 hours. The pH was then measured prior to derivatisation of the solutions prior to analysis.

Analysis was performed using gas chromatography with a flame ionisation detector (FID) using internal standardisation.

Results:

The water solubility of the C-18 monoacid is < 1.25 mg/L.

The water solubility of the C-21 diacid = 15.72 mg/L.

Temperature:

20°C (for both components)

Solubility Category:

Slightly soluble (for both components)

pH value:

6 (for both components)

pK_a value:

Not determined (for both components)

Remarks about Results:

The pK_a value was not determined or required according to OECD 105.

Conclusions:

The solubility of the C-18 fatty acid component in Milli RO water was determined at <1.25 mg/L (<0.00125 g/L).

The solubility of the C-21 dicarboxylic acid component in Milli RO water was determined as =15.72 mg/L (=0.01572 g/L).

Reliability:

Klimisch Data Reliability Code 1a

Remarks on Data Reliability:

Study conducted to GLP and a currently accepted guideline OECD Guideline 105.

Reference:

Hogg A (2003): Diacid 1550: Determination of the Water Solubility of Diacid 1550. Inveresk Report No. 23310, Inveresk Research, Tranent Scotland.

Physicochemical End Point: Partition Coefficient

Test substance:

The study was carried out using the product Westvaco DIACID® 1550

Chemical Category:

Fatty acid

Method:

US EPA OPPTS 830.7570

GLP:

Yes

Year Study Performed:

2002

Remarks about method:

The octanol/water partition coefficient of the test material was determined using High Performance Liquid Chromatography (HPLC).

The HPLC conditions were as follows:

HPLC System: HP 1050

Column: Zorbax SB-C18 (Stable Bond), 250 mm x 4.6 mm ID, 5 micron

Mobile phase: 70:15:15 methanol:THF:pH 2 aqueous buffer (phosphate)

Wavelength: 235 nm

Flow rate: 1ml/min.

THF was used as an additive, because the test substance would not come off the column in any methanol:pH2 buffer ratio.

From preliminary work it was determined that the extinction coefficient of the test substance was considerably less than any of the reference materials. Therefore, the test substance was made up approximately 4 times the concentration (ca. 2,000 mg/L) of the reference compounds (ca. 500 mg/L). Even so, the number of area counts of the test substance was much lower than that of the reference compounds.

The test substance showed 2 closely eluting peaks, with the retention time of the test substance being calculated by averaging the 2 peaks.

Although the reference materials are supposed to bracket the material tested, the table of suggested reference materials taken from OPPTS 830.7570 had no materials with a log Kow greater than 6.2, whereas the test substance had a calculated log Kow of 7.09.

Results:

Value of Log Kow = 7.09

Temperature:

Ambient +/-2°C

Remarks about Results:

Surface active: Lipophilic

Dissociative: This substance can be dissociative as the HPLC system was run at pH2

Water solubility: Negligible

Conclusions:

Under the conditions of this study, DIACID 1550 had a calculated log Kow of 7.09.

Reliability:

Klimisch data reliability code 1

Remarks on Data Reliability:

Study conducted to GLP and a currently accepted guideline OPPTS 730.7570, which complies with OECD Guideline 117.

Reference:

Doi, J (2002): WESTVACO DIACID 1550, Determination of the octanol/water partition coefficient using HPLC, US EPA OPPTS 830.7570, Study No. 2002-111-005, MeadWestvaco Corporation, USA, AQUA SURVEY, INC. USA

Environmental Fate and Pathway End Point: Biodegradation

Test substance:

The study was carried out using the product Westvaco DIACID® H-240, the potassium salt of Westvaco DIACID® 1550

Chemical Category:

Fatty acid

Method:

OECD Method 301E

Test Type:

Aerobic

GLP:

Yes

Year Study Performed:

1991

Contact Time:

35 days

Inoculum:

Activated sludge (mixed liquor) obtained from Bergen County Sewage Treatment Plant and soil extract and surface water. The inoculum is not acclimatized to the test materials.

Remarks about method:

Inoculum: mixed culture inoculum: rich top soil, activated sludge from a sewage treatment plant (secondary effluent) and raw surface water, inoculation of test solution with 1 ml/l of the combined inoculum

Concentration of test chemical: 19 ppm as C, aqueous test solution of Westvaco DIACID® H-240 (potassium salt) in nutrient medium

Pre-acclimation conditions: not required by the modified OECD screening test

Temperature of incubation: 20-25°C (in the dark, with shaking)

Dosing procedure: inoculation of each flask with 1 ml/l of combined inoculum

Sampling frequency: 0, 7, 14, 21, 28, 35 days after inoculation

Controls and blank system: aniline as reference, nutrient plus sludge as blank

Analytical method used to measure biodegradation: Acidification of supernatant sample purged with nitrogen and analyzed for DOC

Method of calculating measured concentrations: Arithmetic mean, simplified version of the OECD calculation given in method 301E

Since the product Westvaco DIACID® 1550 is virtually insoluble in water this study was conducted using the potassium salt, which has a higher water solubility.

Results:

Degradation value = 65% within 28 days

Remarks about Results:

Observed inhibition: non-inhibitory at concentrations of $\leq 25\%$

Time required for 10% degradation: 0-7 days (not specified in report), from graphical interpolation 10% degradation requires approximately 2 days

Total degradation at the end of the test: 63.2% degradation after 35 days

Conclusions:

When tested as specified Westvaco DIACID® 1550 potassium salt was not readily biodegradable, showing 65% degradation after 28 days.

Reliability:

Klimisch reliability code 1

Remarks on Data Reliability:

Study conducted to GLP and followed a currently accepted guideline.

Reference:

Drozdowski D et al (1991): Modified OECD Test for Ready Biodegradability, Shake Flask Test of Diacid 1550 Potassium Salt (6339-33), Conducted for: Westvaco Chemical Division, USA, Test Report No. 063576-3B, United States Testing Company, Inc. Biological Services Division USA

Environmental Fate and Pathway End Point: Biodegradation

Test substance:

The study was carried out using the product Westvaco DIACID® H-240, the potassium salt of Westvaco DIACID® 1550

Chemical Category:

Fatty acid

Method:

40CFR 796.3140

Test Type:

Anaerobic

GLP:

Yes

Year Study Performed:

1992

Contact Time:

56 days

Inoculum:

Fresh digester sludge obtained from Bergen County Municipal Utilities Authority

Remarks about method:

Inoculum: anaerobic sludge from a treatment plant, concentration of sludge in nutrient medium used was 10% level (100 ml/l)

Concentration of test chemical: 5, 10 and 20 ppm as C, aqueous solution of Westvaco DIACID® H-240 (potassium salt) in nutrient medium

Pre-acclimation conditions: None mentioned

Temperature of incubation: 35°C (dark)

Dosing procedure: 4 replicates per test level, reference and blank

Sampling frequency: 3, 14, 28, 42 and 55 days from inoculation

Controls and blank system used: ethanol reference and sludge plus nutrient for blank

Analytical method used to measure biodegradation: gas evolution monitoring using a glass manometer

Method of calculating measured concentrations: cumulative arithmetic mean (corrected for blank) and expected theoretical yield

The gas evolution data were confirmed using organic carbon analysis.

Since the product Westvaco DIACID® 1550 is virtually insoluble in water this study was conducted using the potassium salt, which has a higher water solubility.

Results:

Degradation value = 84% within 2 months

Conclusions:

Results indicated that the sample degraded up to 84% under anaerobic conditions, based on the interpretation of both gas evolution and residual carbon analysis.

Reliability:

Klimisch data reliability code 1

Remarks on Data Reliability:

The study was conducted according to GLP and conformed to EPA Method 40 CFR 796.3140, which is equivalent to OPPTS Method 835-3400.

The testing was conducted in a large vessel (1 Litre) which allowed for the low concentrations to be measured with reasonable accuracy.

Reference:

Drozdowski D et al (1992): Anaerobic Biodegradability Testing of DIACID 1550 (6339-33) Potassium Salt, Conducted for: Westvaco Chemical Division USA, Test Report No. 064187, United States Testing Company, Inc. Biological Services USA

Environmental Fate and Pathway End Point: Biodegradation

Test Substance:

Tall oil fatty acid, CAS Number 61790-12-3

Method:

Testing was conducted according to OECD Test Method 301 D, "Ready Biodegradability: Closed Bottle Test".

Test Type:

Aerobic

GLP:

Yes

Year Study Performed:

1993

Contact time:

28 days

Inoculum:

Secondary effluent from Rungsted Treatment plant.

Remarks about method:

Inoculum: Secondary effluent was collected from Rungsted Treatment plant.

Concentration of test chemical: A stock solution of the test material (2 g/l) was prepared in demineralized water by ultrasonication for 5 minutes.

Test Setup: Test medium was prepared by adding 1 ml each of four solutions (potassium phosphate, magnesium sulfate, calcium chloride, ferric chloride) to 1 liter of demineralized water, which was aerated to an initial oxygen concentration of 9 mg O₂/L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 2 mg/l to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 5.03 mg O₂/l. Sodium benzoate, the reference compound, was added at 2 mg/l to another part of the inoculated medium (to assess the activity of the inoculum), equivalent to a theoretical oxygen demand of 3.34 mg O₂/l. Both the test and reference articles (2 mg/l) were added to a third part of the inoculated medium (to assess possible inhibitory effects of the test article), at a theoretical oxygen demand of 8.37 mg O₂/l. Blank controls were prepared using the inoculated medium without test or reference materials. After the samples were prepared, the medium was transferred to calibrated respirometric bottles (BOD bottles), and placed in the dark at 20°C. The study was performed in triplicate.

Sampling frequency: Samples were collected for BOD analysis on days 0, 7, 14, 21, and 28.

Controls: Yes.

Method of calculating oxygen demand: Oxygen demand was calculated as the difference between the measured oxygen concentrations at time t and the start of the test. Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds.

Results:

50% degradation after 7 days and 56% after 28 days (test article); 63% after 7 days and 77% after 28 days (sodium benzoate).

Conclusions:

The biological oxygen demand for tall oil fatty acid was 50 and 56% of the theoretical oxygen demand after 7 and 28 days, respectively. The rapid oxygen consumption in the first week and the total oxygen demand at the termination of the experiment indicate that the test material was dominated by readily biodegradable compounds. Tall oil fatty acid did not inhibit the respiratory activity of the inoculum.

Reliability:

Reliable without restrictions– Klimisch Code 1a

Reference:

Madsen, T. 1993. Biodegradation of tall oil fatty acid. GLP Study No. 308067/472. Water Quality Institute, Horsholm, Denmark.

This robust study summary was provided by the Pine Chemicals Association as part of their HPV commitment for tall oil fatty acids and related substances.

Environmental Fate and Pathway End Point: Biodegradation

Test Substance:

Tall oil fatty acid, CAS Number 61790-12-3

Method:

Testing was conducted according to OECD Test Method OECD Test Method 301 F, "Manometric respiratory test for biological degradation".

Test Type:

Aerobic

GLP:

Yes

Year Study Performed:

1999

Contact time:

28 days

Inoculum:

Activated sludge from a municipal sewage treatment plant.

Remarks about Method:

Inoculum: Activated sludge from the municipal sewage treatment plant in Reutlingen was washed twice with tap water and centrifuged.

Concentration of test chemical: A stock solution of the test material (101.5 mg/l) was prepared.

Test Setup: Mineral medium was prepared by adding 10 ml of a potassium phosphate solution and 1 ml each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to make a total volume of 1 liter in demineralized water. Six flasks were prepared: two of the test article in mineral medium with inoculum (24 mg/l); two of the mineral medium plus the inoculum (24 mg/l); one of the reference substance [sodium benzoate (98.5 mg/l) with inoculum (24 mg/l)]; and one of the test article in water with sterilized medium.

Sampling frequency: Samples were collected for analysis on days 14 and 28.

Controls: Yes.

Method of calculating oxygen demand: Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the flasks containing test and reference compounds.

Results:

84% degradation after 28 days (test article); 97% after 28 days (sodium benzoate).

Conclusions:

Eighty-four percent of tall oil fatty acid was biodegraded after 28 days indicating that the organic portion of the test material was readily biodegradable.

Reliability:

Reliable without restrictions– Klimisch Code 1a

Reference:

Aniol, S. 1999. Biological degradation (Manometric respirometry test). STZ Project No. 03/99. Steinbeis-Transferzentrum Angewandte und Umwelt-Chemie, Reutungen.

This robust study summary was provided by the Pine Chemicals Association as part of their HPV commitment for tall oil fatty acids and related substances.

Environmental Fate and Pathway End Point: Biodegradation

Test Substance:

Tall oil fatty acid, CAS Number 61790-12-3

Method:

Testing was conducted according to the CO₂ Evolution Test (Modified Sturm Test), EPA guideline number OPPTS 853.110, "Ready Biodegradability".

Test Type:

Aerobic

GLP:

No

Year Study Performed:

1994

Contact time:

29 days

Inoculum:

Activated sludge from the Severn Trent Water sewage treatment plant.

Remarks about method:

Inoculum: Activated sludge microorganisms were obtained from the Severn Trent water sewage treatment plant at Belper, Derbyshire. A 1% inoculum was prepared.

Concentration of test chemical: The test material was used at a concentration of 20 mg/l.

Test Setup: Culture medium was prepared by adding 10 ml of a potassium phosphate solution and 1 ml each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with 2400 ml of culture medium and 30 ml of inoculum and aerated over night. On day 0 of the study, the test and reference material (sodium benzoate, 10 mg/l) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The CO₂ absorption bottles were connected to the outlet and were sealed. CO₂-free air was bubbled through the solution and they were stirred continuously. All experiments were performed in the dark at 20 to 22°C.

Sampling frequency: Samples (2 ml) were collected from the first CO₂ absorber vessel on days 0, 1, 2, 3, 6, 8, 10, 14, 16, 18, 20, 22, 24, 27, 28, and 29, and from the second absorber on days 0 and 29.

Controls: Yes.

Analysis: Samples from the CO₂ absorbers were injected into the inorganic carbon channel of the total carbon analyzer for direct analysis of evolved CO₂. The analyses were conducted in triplicate.

Results:

74% degradation after 28 days (test article); 80% after 28 days (sodium benzoate).

Conclusions:

The test article was degraded 74% after 28 days and sodium benzoate was degraded 80% after 28 days. Under the conditions of the OECD guidelines, the test article cannot be considered to be readily biodegradable.

Reliability:

Reliable without restrictions– Klimisch Code 1b

Reference:

Sewell, I.G. 1994. Assessment of ready biodegradability using the CO₂ evolution test (modified Sturm test). Project No. 508/28. SafePharm Laboratories Ltd., Derby, England.

This robust study summary was provided by the Pine Chemicals Association as part of their HPV commitment for tall oil fatty acids and related substances.

Environmental Fate and Pathway End Point: Biodegradation

Test Substance:

Tall oil fatty acids, potassium salt, CAS number 61790-44-1

Method:

Testing was conducted according to a modified OECD test for ready biodegradability, EPA guideline number OPPTS 853.110, "Ready Biodegradability".

Test Type:

Aerobic

GLP:

Yes

Year Study Performed:

1991

Contact time:

28 days

Inoculum:

Activated sludge from Bergen County sewage treatment plant.

Remarks about method:

Inoculum: Activated sludge from Bergen County sewage treatment plant was mixed with soil extract and surface water to prepare the inoculum.

Concentration of test chemical: The test article was tested at a concentration of 20 to 25 ppm.

Test Setup: OECD test medium was used. Aniline was the reference material and was tested at a concentration of 20 to 25 ppm. The experiments were performed in the dark at 20 to 25°C.

Sampling frequency: Samples were collected for analysis on days 0, 7, 14, 21, and 28.

Controls: Yes.

Method of calculating degradation: The mean initial concentration of soluble organic carbon (SOC) in the controls is subtracted from the initial concentration in the test sample. From this is subtracted, the mean initial concentration of SOC in the test and control samples at time t. This value is divided by the mean initial concentration of SOC in the controls subtracted from the initial concentration in the test sample.

Results:

79% degradation after 28 days (test article); 97% after 28 days (aniline)

Conclusions:

The test material degraded 79% and is considered to be readily biodegradable as defined by OECD.

Data Quality:

Reliable without restrictions– Klimisch Code 1b

Reference:

Drozdowski, D. 1991. Modified OECD test for ready biodegradability of [product name deleted] tall oil fatty acid potassium salt. Report No. 063383-1. United States Testing Company, Inc., Hoboken, New Jersey.

This robust study summary was provided by the Pine Chemicals Association as part of their HPV commitment for tall oil fatty acids and related substances.

Environmental Fate and Pathway End Point: Biodegradation

Test Substance:

Fatty acids, Cl 8-unsaturated dimers, CAS number 61788-89-4

Method:

Testing was conducted according to OECD Test Method 301 B "Ready Biodegradability: Modified Sturm Test".

Test Type:

Aerobic

GLP:

Yes

Year Study Performed:

1991

Contact time:

28 days

Inoculum:

Activated sludge from a municipal sewage treatment plant.

Remarks about method:

Inoculum: Activated sludge microorganisms were obtained from a municipal sewage treatment plant at Wateschap de Aa, Schijndel, the Netherlands.

Concentration of test chemical: The test material was used at concentrations of 10 and 20 mg/l.

Test Setup: Nutrient medium was prepared by adding 2 ml of a potassium phosphate solution, 1 ml each of magnesium sulfate, calcium chloride, and ammonium sulfate solutions, and 4 ml of a ferric chloride solution to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with the nutrient culture medium and 30 ml of inoculum and aerated over night. On day 1 of the study, the test and reference material (sodium benzoate, 20 mg/l) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The CO₂ absorption bottles were connected in series to the exit air line of each bottle. CO₂-free air was bubbled through the solution. All experiments were performed at 20 to 22°C.

Sampling frequency: Samples were collected from the first CO₂ absorber vessel on days 2, 5, 7, 9, 12, 16, 21, and 28.

Controls: Yes.

Analysis: Samples from the CO₂ absorbers were analyzed using a Heraeus CHN-analyzer.

Results:

6.6% degradation at 10 mg/L and 6.3% at 20 mg/L at 28 days (test article); 71% at 28 days (sodium benzoate).

Conclusions:

The test article, at low and high concentrations, was degraded approximately 6% after 28 days and sodium benzoate was degraded 71% after 28 days. Under the conditions of the OECD guidelines, the test article was not readily biodegradable.

Data Quality:

Reliable without restrictions- Klimisch Code 1 a

Reference:

Coenen, T.M.M. 1991. Ready biodegradability: modified Sturm test. RCC NOTOX Project 052559. NOTOX, The Netherlands.

This robust study summary was provided by the Pine Chemicals Association as part of their HPV commitment for fatty acid dimers and trimer.

Environmental Fate and Pathway End Point: Hydrolysis

Remark:

Westvaco DIACID® 1550 does not contain any organic functional groups susceptible to hydrolysis. The very low solubility of Westvaco DIACID® 1550 in water would make any testing technically difficult. Westvaco DIACID® 1550 is anticipated to be stable in water and testing is not therefore considered applicable.

Environmental Fate and Pathway End Point: Photodegradation

Remark:

Westvaco DIACID® 1550 is not volatile and so it will not enter the atmosphere and be subject to photodegradation. Additionally, the chemical structures suggest that the molecules would not be susceptible to breakdown by a photodegradative mechanism. Westvaco DIACID® 1550 is therefore anticipated not to be subject to photodegradation and testing is therefore not considered applicable.

Environmental Fate and Pathway End Point: Transport and Distribution between Environmental Compartments

Remark:

Westvaco DIACID® 1550 is a class 2 substance and modelling to determine transport and distribution between environmental compartments would require the input of multiple parameters and generate multiple outputs for individual constituents of the product. These would not form a reasonable representation of the environmental distribution of the product. For these reasons, it is not considered practical to assess the environmental transport and distribution of this substance.

Ecotoxicity End Point: Acute Toxicity to Fish

Test substance:

The study was carried out using the product Westvaco DIACID® H-240, the potassium salt of Westvaco DIACID® 1550

Chemical Category:

Fatty acid

Method:

40 CFR Part 797.1400

Test type:

Static

GLP:

Unknown

Year Study Performed:

1991

Species:

Pimephales promelas

Analytical method:

Gas chromatography (Flame Ionization Detector)

Exposure Period:

96 hours

Statistical Method:

Graphical interpolation

Remarks about method:

Parameters about organism:

- age: 28-31 days
- length: \leq 18 mm
- weight: not known
- loading: Corrected concentrations: 0, 2.4, 4.9, 9.8, 16.3 and 41.3 ppm
- pretreatment: none, only a screening test to determine the definitive test concentrations

Parameters of Test system:

- Dilution water source: USA EPA moderately-hard reconstituted water
- Dilution water chemistry: hardness - 88 mg/l CaCO₃, alkalinity - 74 mg/l CaCO₃, pH - 7.7, Conductivity - 232 μ mhos, Dissolved oxygen - 8.2 mg/l
- Stock and test solution: stock solution of the analyte Westvaco DIACID® 1550 (potassium salt 39.18% w/v) prepared at a concentration of 1075.1 ppm (activity corrected) in EPA modified hard water. Sequential dilutions were made to produce the test solutions

- Flow-through rate: not applicable as system was static and renewed daily
- Vehicle/solvent and concentrations: diluent in the system was EPA modified hard water, nominal concentrations made were 10.75, 26.75, 53.50, 80.30 and 100.00 ppm of analyte
- Stability of the test chemical solutions: considered to be stable
- Exposure vessel type: 2 L polypropylene test vessels, exposure volume 1 L
- Aeration - mixing test solutions to saturation prior to test if dissolved oxygen falls below 40% during the test oil-free air supplied at 100 +/- 10 bubble per minute
- Lighting - 16:8 hour light/dark cycle fluorescent 50-100 ft candles, 2 vessels per treatment
- Replicates: 2 replicates per treatment, 10 fish per replicate, 20 fish per treatment
- Water chemistry in test: D.O.: control - 8.2 mg/l, 16.3 ppm - 8.0 mg/l, pH: control - 7.7, 16.3 ppm - 7.7
- Test temperature range: 21 +/- 1 °C
- Method of calculating mean measured concentrations: arithmetic mean corrected for activity of product

Since the product Westvaco DIACID® 1550 is highly insoluble in water this study was conducted using the potassium salt, which has a higher water solubility.

Results:

Nominal concentration:

10.75, 26.75, 53.50, 80.30 and 100.00 ppm

Measured concentration:

0, 2.4, 4.9, 9.8, 16.3 and 41.3 ppm

Endpoint:

LC50 = 15 ppm (measured) at 96 hours.

Statistical Results:

95% confidence limits not obtainable

Remarks about Results:

Biological observations: Mortality, reflex loss, erratic swim

Table showing cumulative mortality: no effects seen for concentrations 0-9.8 ppm.

For 16.3 ppm the cumulative mortality was as follows: 24 hr- 6, 48 hr- 9, 72 hr- 12, 96 hr- 15 (% mortality = 75)

For 41.3 ppm the cumulative mortality was as follows: 24 hr- 20, 48 hr - 20, 72 hr- 20, 96 hr -20 (% mortality = 100)

Lowest test substance concentration causing 100% mortality: 41.3 ppm only concentration to cause 100% mortality

Mortality of controls: controls were healthy and swam actively

Abnormal responses: none

Reference substances: none used

Any observations, such as precipitation that might cause a difference between measured and nominal values: none recorded

Additional data outside the longest end-point:

24 hr LC50 = 18.5 ppm

48 hr LC50 = 17 ppm

72 hr LC50 = 16 ppm

Conclusions:

The acute toxicity of DIACID 1550 (as potassium salt) to the freshwater minnow, *Pimephales promelas*, was found to be: 96 hour LC50 = 15 ppm (95% confidence limit not obtainable)

The No Observed Effect Concentration (NOEC) was 9.8 ppm

Reliability:

Klimisch data reliability code 2

Remarks on Data Reliability:

The study conformed to EPA Method 40 CFR 797.1400 which is equivalent to OPPTS Method 850.1075. Although there is not a GLP Compliance statement in the report, the test plan (Addendum # 3) indicate that the study was conducted according to GLP.

Reference:

Cooke D (1991): Aquatic Toxicity Tests versus *Pimephales promelas* and *Daphnia pulex* DIACID 1550, Conducted for: Westvaco Chemical Division USA, Test Report No.: 063576-2, United States Testing Company, Inc., Biological Services Division USA.

Ecotoxicity End Point: Acute Toxicity to Daphnia

Test substance:

The study was carried out using the product Westvaco DIACID® H-240, the potassium salt of Westvaco DIACID® 1550

Chemical Category:

Fatty Acid

Method:

40CFR Part 797.1300

Test type:

static

GLP:

Unknown

Year Study Performed:

1991

Species:

Daphnia pulex

Analytical method:

Gas chromatography (Flame Ionization Detector)

Exposure Period:

48 hours

Statistical Method:

Graphical interpolation

Remarks about method:

Test organisms

- USTC stock cultures
- Age at study initiation: \leq 48 hours
- Control group: diluent only

Test conditions:

- Stock solutions: vehicle/solvent: EPA moderately-hard reconstituted water, stock solution was prepared at a concentration of 1075.1 ppm (activity corrected). Sequential dilutions were made to achieve nominal concentrations of 10.75, 26.75, 53.50, 80.30 and 100.00 ppm
- Test temperature range: 22-23 °C
- Exposure vessel type: test vessel: 18 x 150 mm glass test tubes capped, exposure volume: 15 ml

- Aeration: aerate by mixing test solutions to saturation prior to test no aeration during test, 4 vessels per treatment.
- Dilution water source: EPA moderately-hard reconstituted water
- Dilution water chemistry: hardness: 90 mg/l CaCO₃, alkalinity: 80 mg/l CaCO₃, pH: 7.7, Conductivity: 233 µmhos, D.O.: 8.4 mg/l
- Lighting: 16:8 hour light/dark cycle, fluorescent, 50-100 ft candles (lab ambient)
- Water chemistry: D.O.: control - 8.4, 16.3 ppm - 8.4, pH: control - 7.7, 16.3 ppm - 7.8
- Endpoints assessed: immobilization
- Test design: 4 replicates per treatment, 5 daphnia per replicate, 5 concentrations (measured) 2.4, 4.9, 9.8, 16.3 and 41.3 ppm
- Method of calculating mean measured concentrations arithmetic mean corrected for activity

Since the product Westvaco DIACID® 1550 is highly insoluble in water this study was conducted using the potassium salt, which has a higher water solubility.

Results:

Nominal concentration:

10.75, 26.75, 53.50, 80.30 and 100.00 ppm

Measured concentration:

2.4, 4.9, 9.8, 16.3 and 41.3 ppm

Endpoint:

LC50 = 22.5 ppm (measured) at 48 hours.

Statistical Results:

95% confidence limits not obtainable

Remarks about Results:

Biological observations

- Number immobilized as compared to the number exposed: 0/20 for 2.4, 4.9 & 9.8 ppm, 07/20 at 16.3 ppm, 18/20 at 41.3 ppm
- Concentration response with 95% confidence limits: not obtainable
- Cumulative immobilization: 16.3 ppm: 24 hr - 2, 48 hr - 5 (% mortality 25), 41.3 ppm: 24 hr - 7, 48 hr - 18 (% mortality 90)
- Control response: satisfactory

Additional data outside the longest end-point:

24hr LC50 = >41.3 ppm (95% C.L. not obtainable)

Conclusions:

The acute toxicity of Westvaco DIACID® 1550 (as potassium salt) to the water flea, *Daphnia pulex*, was found to be:

48 hour LC50 = 22.5 ppm (95% confidence limit was not obtainable)

The No Observed Effect Concentration (NOEC) was 9.8 ppm

Reliability:

Klimisch data reliability code 2

Remarks on Data Reliability:

The study conformed to EPA Method 40 CFR 797.1300 which is equivalent to OPPTS Method 850.1010. Although there is not a GLP Compliance statement in the report, the test plan (Addendum # 3) indicates that the study was conducted according to GLP.

Reference:

Cooke D (1991): Aquatic Toxicity Tests versus *Pimephales promelas* and *Daphnia pulex* DIACID 1550, Conducted for: Westvaco Chemical Division, USA, Test Report No. 063576-2, United States Testing Company, Inc. Biological Services Division, USA

Ecotoxicity End Point: Acute Toxicity to Algae**Test substance:**

The study was carried out using the product Westvaco DIACID® H-240, the potassium salt of Westvaco DIACID® 1550.

Chemical Category:

Fatty Acid

Method:

40CFR Part 797.1050

Test type:

static

GLP:

Yes

Year Study Performed:

1991

Species:

Selenastrum capricornutum

Endpoint:

Growth rate, cell count by hemocytometer

Analytical method:

Total organic carbon analysis (Ionics 1555)

Exposure Period:

96 hours

Statistical Method:

Probit analysis

Remarks about method:

Test organisms

- Laboratory culture: USTC Stock Culture, origin EPA, Cincinnati, Ohio
- Method of cultivation: incubation in appropriate media, at 20 +/- 2 °C under 400 +/- 50 ft. candles using a 16:8 light/dark photoperiod, with manual shaking periodically
- Controls: vessels containing algal medium were inoculated and then incubated as for test vessels

Test Conditions

- Test temperature range: 24 +/- 2 °C
- Growth/test medium chemistry: pH: 7.4, alkalinity: 30 mg/l CaCO₃, hardness: 50 mg/l CaCO₃, conductivity: 130µmhos

- Dilution water source: OECD test medium
- Exposure vessel type: 125ml Erlenmeyer Flasks, 50 ml solution volume
- Aeration: mixing test solutions to saturation prior to test no aeration during test, 3 replicates per treatment
- Water chemistry in test: 32 ppm - pH 7.3/7.5 (0/96 hrs), 63 ppm - pH 7.3/7.4 (0/96 hrs), 125 ppm - pH 7.2/7.3 (0/96 hrs), 250 ppm - 7.1/7.2 (0/96 hrs), 500 ppm - 7.1/7.2 (0/96 hrs)
- Stock solutions preparation: 5 g/195 ml test material in test medium, 10,000 and 1,000 ppm, serial dilutions to: 32, 63, 125, 250 and 500 ppm
- Light levels and quality during exposure: continuous light, fluorescent 400-450 ft candles

Test design: 3 replicates per treatment, inoculum density 10,000 cell per ml

Test concentrations: 32, 63, 125, 250 and 500 ppm

Method of calculating mean measured concentrations: Total organic carbon count

Since the product Westvaco DIACID® 1550 is highly insoluble in water this study was conducted using the potassium salt, which has a higher water solubility.

Results:

Nominal concentration:

32, 63, 125, 250, 500 ppm

Measured concentration:

32, 50, 500 ppm confirmed, 63, 125 ppm variable

Endpoint:

EC50-CD = 88 ppm (nominal) at 96 hours

NOEC <= 32 ppm (nominal) based on growth inhibition

LOEC = 40 ppm (nominal) based on growth inhibition.

Statistical Results:

At 96 hours EC point 95% confidence limits upper/lower: EC1- 2.5/39, EC5- 6.7/52, EC10- 11/62, EC15- 16/69, EC50- 55/137, EC85- 112/463, EC90- 126/647, EC95 - 149/1076, EC100- 201/2850

Remarks about Results:

Response of control group satisfactory

Biological observations

- Cell density (per ml of x 10-E4) at each flask at each measuring point: control - 23, 25, 26 (48 hrs) 118, 130, 125 (72 hrs) 180, 194, 200 (96 hrs), 32 ppm- 23, 23, 20 (48 hrs) 95, 97, 80 (72 hrs) 202, 210, 212 (96 hrs), 63 ppm - 22, 19, 18 (48 hrs) 65, 70, 73 (48 hrs) 120, 125, 120 (96 hrs), 125 ppm - 16, 19, 14 (48 hrs) 23, 24, 24 (72 hrs) 45, 37, 38 (96 hrs), 250 ppm 13, 13, 13 (48 hrs) 12, 14, 15 (72 hrs) 20, 19, 18 (96 hrs), 500 ppm < inoculum at each time point

- Growth curves: log plot of cell number vs hrs for each concentration, showed reduced growth at all levels, lower levels produced smaller % inhibition

growth rate inhibition per concentration 48/72/96 hrs: 32 ppm - 12/27/0%, 63 ppm - 20/44/36%, 125 ppm - 36/81/79%, 250 ppm - 48/89/79%, 500 ppm - 100/100/100%

- Observations: Cell growth was insufficient at 24 and 48 hours to establish concentration-effect relationships for all concentrations. Subculturing of cells from exposure concentrations recovered viable cells, demonstrated by resumption of growth where previously retarded. Test concentrations up to 500 ppm were thus algistatic rather than algicidal. Morphological changes, as smaller cell size were seen at 250 and 500 ppm. It was possible that sample degradation occurred under test conditions, thus exposure to the test material should not be considered to be uniform throughout the 96 hr test period, but only to concentrations established at the onset of testing.

Conclusions:

For Westvaco DIACID® 1550 (as potassium salt) on the basis of 100% active sample.

96 hr EC50 = 87.6 ppm (95% C.L. = 54.5-137.4 ppm)

96 hr EC10 = 39.9 ppm

96 hr EC90 = 192.6 ppm

NOEC approximately 32 ppm.

Test concentrations up to 500 ppm proved that test material was algistatic.

Reliability:

Klimisch data reliability code 1

Remarks on Data Reliability:

The study was conducted according to GLP and conformed to EPA CFR 40 Part 797.1050 which is equivalent to currently accepted OPPTS Method 850.5400 (which follows the general principles of OECD Method 201)

Reference:

Drozdowski D (1991): Algal Acute Toxicity Test of DIACID 1550 Potassium salt (6339-33), Conducted for: Westvaco Chemical Division USA, Test Report No. 063576-3A, United States Testing Company, Inc., Biological Services Division, USA.

Toxicity End Point: Acute Toxicity

Test substance:

The study was carried out using the product Westvaco DIACID® 1550

Chemical Category:

Fatty acid

Method:

No specific guideline is quoted

GLP:

No

Year Study Performed:

1973

Species:

rat

Strain:

Sprague-Dawley

Sex:

Both

Number of males per dose:

2

Number of females per dose:

2

Vehicle:

corn oil, 25% w/v/ suspension

Route of administration:

Oral – by intubation syringe

Remarks about method:

The animals used were classed as 'young'

There were 4 dose groups and animals received a single dose

Concentration administered: 3038; 4556; 6834 and 10250 mg/kg

There was a 14 day post dose observation period

End Point:

Acute lethal value = 6176 mg/kg bw

Deaths per dose:

Deaths occurred in 0/4, 0/4, 3/4 and 4/4 rats treated at 3038, 4556, 6834 & 10250 mg/kg respectively

Remarks about Results:

Rats dosed at 6834 mg/kg died between 6-22 hours and 2 days after dosing; 1 female rat 6-22 hours after dosing and 1 male and 1 female rat died 2 days after dosing.

Rats dosed at 10250 mg/kg died between 6-22 hours and 2-3 days after dosing; both females died 6-22 hours after dosing and 1 male died 2 days after dosing and the remaining male died 3 days after dosing.

Clinical signs at 3038 mg/kg: hypoactivity and ruffed fur which onset 1 hour after dosing with a duration of 1 day.

Clinical signs at 4556 mg/kg: hypoactivity and ruffed fur which onset 1 hour after dosing with a duration of 2 days, laboured breathing onset after 3 hours with a duration of 6-22 hours.

Clinical signs at 6834 mg/kg: hypoactivity and ruffed fur which onset 1 hour after dosing with a duration of 5 days, laboured breathing onset after 2 hours with a duration of 2 days. Muscular weakness onset 3 hours after dosing with a duration of 2 days. Diuresis onset 6-22 hours after dosing with a duration of 2 days.

Clinical signs at 10250 mg/kg: hypoactivity and ruffed fur which onset 1 hour after dosing and laboured breathing and muscular weakness onset after 2 hours Diuresis onset 6-22 hours after dosing with a duration for all signs until death.

All animals that died underwent necropsy examination and revealed gastroenteritis. No gross pathologic alterations were noted among the animals sacrificed at the end of the 14 day observation period.

Conclusions:

The LD50 is 6176 mg/kg bw for acute oral toxicity to rats.

Reliability:

Klimisch data reliability code 2

Remarks on Data Reliability:

The study was not conducted according to any recognised guideline and only 4 animals per dose group were administered the compound. The observation period was appropriate for an acute study and generally recognised procedures appear to have been followed. Although the study does not comply with any acceptable guidelines (past or current) in the interests of animal welfare, these results should be considered acceptable.

Reference:

Hintz C *et al.* (1973): Report to Westvaco: Acute toxicity studies with DIACID 1550, P.O. No. S-10590, IBT No. 601-04128, Industrial BIO-TEST Laboratories, Inc.

Toxicity End Point: Combined Repeat Dose Toxicity with Reproductive/Developmental Toxicity and Neurotoxicity Screening Tests

Test substance:

The study was carried out using the product Westvaco DIACID® 1550

Chemical Category:

Fatty acid

Method:

OECD Test Guideline 422

GLP:

Yes

Year Study Performed:

2003

Species:

rat

Strain:

Sprague-Dawley

Sex:

Both

Number of males per dose:

10

Number of females per dose:

10

Route of administration:

Oral

Exposure period:

The males were treated for 2 weeks prior to mating, through until necropsy after at least 4 weeks of treatment. Females were treated for 2 weeks prior to mating, then through mating, gestation until at least Day 4 of lactation.

Frequency of treatment:

Continuous via diet

Dose levels:

0, 500 ppm, 3000 ppm and 15000 ppm

Duration of test:

4 weeks minimum

Control group:

Yes

Statistical method:

Selected neurotoxicity, body weight, food consumption, haematology and clinical chemistry data were subjected to analysis of variance or the Kruskal-Wallis non-parametric analysis.

Organ weights were analysed as above and by one-way analysis of covariance (ANCOVA) using the terminal kill body weight as covariate.

Histological incidence data were analysed using Fisher's Exact Probability test.

Pairwise comparisons were made using Fisher's F protected LSD method via Student's t-test, or by chi squared protected z-test (the non-parametric equivalent of Student's t-test), and were only performed against the Control group.

All statistical tests were two-sided and performed at the 5% significance level.

Remarks about method:

Animals were ca. 8 weeks of age at study initiation.

Test item was dissolved in acetone and the solution was added to untreated diet 100 ml solvent/kg of pre-mix

Observations:

The animals were monitored daily for any signs of ill health or reaction to treatment. Detailed functional observations were performed weekly, with additional functional observations performed on 5 males and 5 females per group on two occasions, the first occasion was during pretrial and the second was during Week 4 for males and during lactation for females.

Blood samples were also taken from 5 males and 5 females per group for laboratory investigations. Males were sampled during Week 4 and females were sampled during lactation.

All adult animals were killed and subjected to a detailed necropsy examination after completion of treatment. Representative samples were taken from all adult animals and fixed in 10% neutral buffered formalin unless stated otherwise, with a selection of tissues being weighed. Histopathology was conducted on tissues from 5 males and 5 females from Control and High dose groups; the same animals that were used for laboratory investigations. Pups were examined externally. The table below indicated which organs were examined macro- and microscopically.

Tissues to be collected	Weighed	Examined
Abnormal Tissue	-	X
Adrenal x 2	X	X
Aorta	-	X
Brain	X	X
Epididymis x 2	X	X
Eye x 2	-	X
Gastro intestinal Tract:		
Stomach	-	X
Duodenum	-	X
Jejunum	-	X
Ileum	-	X
Caecum	-	X
Colon	-	X
Rectum	-	X
Heart	X	X
Optic Nerve x 2	-	X
Implant(s)	-	-
Kidney x 2	X	X
Liver	X	X
Lung	X	X
Marrow Smear	-	-
Mesenteric Lymph Node	-	X
Oesophagus	-	X
Ovary x 2	X	X
Pancreas	-	X
Pituitary	X	X
Prostate	X	X
Sciatic Nerve	-	X
Seminal Vesicle	-	X
Skin + Mammary Gland	-	X
Spinal Cord	-	X
Spleen	X	X
Sternum	-	X
Submandibular Lymph Node	-	X
Submaxillary Salivary Gland	X	X
Testis x 2	X	X
Thigh muscle	-	X
Thymus	X	X
Thyroid with Parathyroid x 2	X	X
Trachea	-	X
Urinary Bladder	-	X
Uterus	X	X
Vagina	-	X

Results:

Parental NOEL. None established as toxicity was exhibited at all dose levels.
Reproductive NOEL 15000 ppm

Remarks about Results:

At 15000 ppm, there was an increase in liver weights that was associated with an increase in centrilobular hepatocyte hypertrophy which was observed in 2/5 males and 4/5 females examined. Changes in liver function were demonstrated with an increase in alkaline phosphatase. Clinical chemistry at this level also revealed an increase in albumin in both sexes, a reduction in cholesterol and an increase in phosphate in females. In females, kidney weight was markedly increased and spleen weight was markedly decreased, haematology showed a decrease in haemoglobin and haematocrit. A decrease in thymus weights of females was also evident at this level.

At 3000 ppm, liver weight was also increased, although statistical significance was not attained. An increase in the levels of alkaline phosphatase was also seen in both sexes. In females, there was an increase in albumin and a slight increase in phosphate.

At 500 ppm there was an increase in alkaline phosphatase in males, and reduced cholesterol in females. The biological significance of these findings alone is unknown.

There were no obvious effects of treatment noted during neurotoxicity observations or on the mating performance.

Conclusions:

Under the conditions of this study, toxicity was exhibited at all dose levels. Therefore, no parental NOEL (No Observed Effect Level) was established. For reproductive parameters the NOEL was considered to be 15000 ppm.

Reliability:

Klimisch data reliability code 1a

Reference:

S Clubb 2004. Diacid 1550 Combined Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity and Neurotoxicity Screening Tests. Report number 23551. Inveresk Research, Tranent, Scotland.

Toxicity End Point: Bacterial Gene Mutation

Test substance:

The study was carried out using the product Westvaco DIACID® 1550

Chemical Category:

Fatty acid

Method:

Method used followed all procedures outlined by Ames – Ames test

GLP:

Yes

Year Study Performed:

1991

Species:

Salmonella typhimurium Strains used were TA 98, 100, 1535, 1537 and 1538

Metabolic Activation:

activator mammalian liver S-9, with or without

Concentration:

10 mg/ml, 100 mg/ml in Dimethylsulfoxide

Statistical Method:

The average number of revertant colonies (+/- SD)

Remarks about method:

Test Design

- Number of replicates: 2 plates for 10 mg/ml and 3 plates for 100 mg/ml, plus 1 solvent and 1 positive control, with activation and the same without activation per strain
- Frequency of Dosing: one dosing only, followed by a 48 hour incubation period
- Positive and negative control groups and treatment: 1 positive and 1 negative control group and two treatment groups with and without activation per strain

Solvent/vehicle: solvent used was dimethylsulfoxide a concentration of 10 and 100 mg/ml of test material

Criteria for evaluating results: spontaneous reversion frequency is measured. A test material producing a consistent bacterial response twice that of the solvent or spontaneous reversion count is indicated as positive for TA 98 and 100, a three times response is indicated as positive for TA 1535, 1537 and 1538

Results:

Negative

Cytotoxic concentration:

100 mg/l

Genotoxic Effects:

Unconfirmed

Statistical Results:

None, average (+/- SD) revertant colony counts for all strains at both concentrations and with or without activation were comparable to the solvent control in all cases.

Remarks about Results:

The test material had a maximum solubility in dimethylsulfoxide of 100 mg/ml and is sparingly soluble in water

Conclusions:

When tested as specified Westvaco DIACID® 1550 did not exhibit mutagenicity versus test strains TA 98, 100, 1535, 1537 and 1538 in the presence or absence of activation at maximum solubility and cytotoxicity.

Reliability:

Klimisch reliability code 1

Remarks on Data Reliability:

The test was not carried out according to currently accepted guidelines, but it was conducted to GLP and followed a method which is still referenced in current guidelines.

References:

Tong C C (1991): Ames Mutagenicity Testing of DIACID 1550, Conducted for: Westvaco Chemical Division, USA, Test Report No. 063576-1B, United States Testing Company, Inc, Biological Services Division, USA,

Ames et al (1975): Methods for Detecting Carcinogens and Mutagens with the Salmonella/Mammalian Microsome Mutagenicity test, Mutation Research, 31, 347-364

Toxicity End Point: In vitro gene Mutation**Test substance:**

The study was carried out using the product Westvaco DIACID® 1550

Chemical Category:

Fatty acid

Method:

OECD 473 Chromosomal aberration in cultured Chinese hamster ovary cells

GLP:

Yes

Year Study Performed:

1991

Species:

Chinese Hamster Ovary cells

Metabolic Activation:

S-9 activation system 7.5 ml/100 ml (S-9 to culture medium)

Concentration:

non-activated: 13, 25, 50, 75, 100, 150 µg/ml, activated: 6.3, 13, 25, 50, 75, 100 µg/ml

Statistical Method:

Chi-square test for positive controls only

Remarks about method:

Test Design

- Number of replicates: 4 per dose level, 2 for cytotoxicity test and 2 for chromosome aberration assay
- Frequency of Dosing: 1 dose, exposure to test material for 2 hours with activation and 16 hours without activation followed in both cases by incubation and additional harvesting time
- Positive controls - triethylenemelamine (0.5 µg/ml) non-activation and cyclophosphamide (30 µg/ml) activation
- Number of metaphases analyzed for chromosomal studies: 100 metaphases at each dose level (50 per duplicate group). Only cells showing 18-20 chromosomes were scored.

Solvent used was dimethylsulfoxide (DMSO), at a maximum of 1% of the volume of the culture medium

This main study was preceded by a range-finding study with concentrations from 0.1-5000 µg/ml (10 levels)

Number of metaphases analyzed for chromosomal studies: 100 metaphases at each dose level (50 per duplicate group). Only cells showing 18-20 chromosomes were scored

Results:

Negative

Cytotoxic Concentration:

At 100 µg/ml the Relative Cell Growth (RCG) was reduced to 54% (non-activated) and 13% (activated)

Genotoxic Effects:

Unconfirmed

Statistical results:

Chi-square test was used on positive controls, results were considered significant if p is ≤ 0.05 . There were no statistically significant results in the test doses.

Remarks about Results:

Miscibility was tested during the range-finding test and indicated the test article formed a turbid suspension with water. There was precipitate in the medium in the test flasks at concentrations of 500, 1000 and 5000 µg/ml in DMSO, indicating miscibility limitations at this level. However, since cells did not survive at these doses, thus these levels were not used in the main study. Osmolality values were determined during the range-finding test, again at levels 500, 1000 and 5000 µg/ml precipitate was visible in the medium. However, none of the doses tested showed an osmolality beyond 427 (mOsmol/kg water) which was below the range that may cause damage to the cells.

There were no dose-related effects seen. In the non-activated system there were no scorable metaphases at 150 µg/ml, chromosome aberrations were scored from controls and 25, 50, 75 and 100 µg/ml. In the activated system there were insufficient scorable metaphases at 100 µg/ml, chromosome aberrations were scored from 13, 25, 50 and 75 µg/ml.

No. of aberrations per cell (non-activated) 0.01-0.03 for 25-100 µg/ml, \leq to solvent values.

No. of aberrations per cell (activated) 0.01-0.02 for 13-75 µg/ml, < solvent values

Conclusions:

Under the conditions of this study, Westvaco DIACID® 1550 did not induce a significant increase in chromosome aberrations nor was there any indication of a positive dose trend in either the non-activated or activated systems. Therefore the test article is considered to be negative in the in-vitro CHO chromosome aberration assay.

Reliability:

Klimisch reliability code 1

Remarks on Data Reliability:

Study conducted to GLP and accepted guideline.

Reference:

Kumaroo, P V (1991): Test for Chemical Induction of Chromosome Aberration in Cultured Chinese Hamster Ovary (CHO) Cells With and Without Metabolic Activation, Westvaco Chemical Division, USA, Study No. 0172-3110, Sitek Research Laboratories, USA