VI. Robust Summaries of Data for Tall Oil and Related Substances

PHYSICO-CHEMICAL PROF	PERTY – WATER SOLUBILITY
Test Substance	
Chemical Name	Tall oil
CAS#	8002-26-4
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, "Water Solubility"
Test Type	Water solubility
GLP (Y/N)	Υ
Year (Study Performed)	2003
Test conditions	Tall Oil was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 $^{\circ}$ C \pm 1 $^{\circ}$ C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 $^{\circ}$ C \pm 1 $^{\circ}$ C for 24 h.
	The samples were then passed through scintered glass to remove undissolved material, centrifuged, allowed to sit overnight at ambient laboratory temperature, then re-centrifuged. One replicate appeared cloudy after passing through the glass, hence the settling and recentrifugation. This sample proved to be contaminated and was not reported. 100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatized with trimethylphenylammonium
	hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard.
Results	The water solubility of tall oil, in its entirety as a complex mixture, is 9 mg/l at 20 °C. The water solubility of tall oil based on its 3 major constituents (oleic/elaidic acid, linoleic acid and abietic/dehydroabietic acid) is 1 mg/l at 20 °C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
<u>References</u>	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil and Tall Oil Related Products. Report Number 22709, Inveresk Research, Tranent, Scotland.

Test Substance	
Chemical Name	Tall oil, disproportionated
CAS#	68152-92-1
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, "Water Solubility"
Test Type	Water solubility
GLP (Y/N)	Y
Year (Study Performed)	2003

Test conditions	Tall Oil, disproportionated was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 $^{\circ}$ C \pm 1 $^{\circ}$ C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 $^{\circ}$ C \pm 1 $^{\circ}$ C for 24 h.
	The samples were filtered through a Millipore Millex-HN 0.45 µm filter (previously validated for non-retention of the test material). 100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatised with trimethylphenylammonium hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard.
Results	The water solubility of tall oil, disproportionated in its entirety as a complex mixture, is 11 mg/l at 20 °C. The water solubility of tall oil based on its 3 major constituents (oleic acid, elaidic acid and dehydroabietic acid) is 3 mg/ml at 20 °C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil and Tall Oil Related Products. Report Number 22709, Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Tall oil
CAS #	8002-26-4
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117,
	"Partition Coefficient (n-Octanol/Water) High Performance Liquid
	Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Υ
Year (Study Performed)	2002
Test conditions	Tall oil and 10 reference compounds of known log ₁₀ P _{ow} were
	dissolved in methanol and adjusted to a pH of 2. The solutions
	were analyzed by HPLC with Photodiode Array (PDA) detection
	using a mobile phase of water/methanol [25:75 (v/v) Milli-Q
	Water/Methanol]. All samples showed peaks throughout the
	chromatogram; therefore, a partition coefficient range is reported.
<u>Results</u>	At pH 2, a partition coefficient range of 4.9 to 7.7 was determined
	for tall oil.
<u>Data Quality</u>	Reliable without restrictions – Klimisch Code 1a
<u>References</u>	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002.
	Determination of Partition Coefficient of Tall Oil and Tall Oil Related
	Products. Report Number 20978. Inveresk Research, Tranent,
	Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Tall oil
CAS #	8002-26-4
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117,
	"Partition Coefficient (n-Octanol/Water) High Performance Liquid
	Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Υ
Year (Study Performed)	1993
Test conditions	Tall oil was dissolved in methanol and the solution was analyzed
	by HPLC with UV detection using a mobile phase of
	methanol:buffer (3:1) at pH 2 and pH 7.5. As a reference
	substance, a mixture of seven materials of known log ₁₀ P _{ow} were
	used.
<u>Results</u>	At pH 2, the log P _{ow} [K _{ow}] values of eight components in tall oil
	were 6.1, 6.5, 7.0, 7.4, 7.6, 7.8, 8.1, and 8.2. At pH 7.5, the log
	K _{ow} values of five components in tall oil were 3.5, 4.2, 4.5, 4.7,
	and 5.4.
<u>Data Quality</u>	Reliable without restrictions – Klimisch Code 1a
<u>References</u>	Dybdahl, H.P. 1993. Determination of log Pow for single components
	in distilled tall oil. GLP Study No. 408335/475. Water Quality
	Institute, Horsholm, Denmark.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Tall oil pitch
CAS #	8016-81-7
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, "Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Υ
Year (Study Performed)	2002
Test conditions	Tall oil pitch and 10 reference compounds of known log ₁₀ P _{ow} were dissolved in methanol and adjusted to a pH of 2. The solutions were analyzed by HPLC with Photodiode Array (PDA) detection using a mobile phase of water/methanol [25:75 (v/v) Milli-Q Water/Methanol]. All unbuffered samples showed peaks throughout the chromatogram therefore a partition coefficient range is reported.
Results	In unbuffered media, a partition coefficient range of 3.3 to 6.1 was determined for tall oil pitch; the pH of this sample was measured as <i>ca</i> 7. In media adjusted to pH 2, no peaks were present other than that present in the blank so a partition coefficient value could not be determined.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of Partition Coefficient of Tall Oil and Tall Oil Related Products. Report Number 20978. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Tall oil pitch
CAS #	8016-81-7
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117,
	"Partition Coefficient (n-Octanol/Water) High Performance Liquid
	Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Υ
Year (Study Performed)	1993
Test conditions	Tall oil pitch was dissolved in methanol and the solution was
	analyzed by HPLC with UV detection using a mobile phase of
	methanol:buffer (3:1) at pH 2 and pH 7.5. A mixture of seven
	materials with known K _{ow} values was used as reference.
<u>Results</u>	At pH 2, the log P _{ow} [K _{ow}] values of three components in tall oil
	pitch were 4.3, 6.0, and 6.9. At pH 7.5, the log P _{ow} values of
	three components in tall oil pitch were 2.8, 3.6, and 4.4.
<u>Data Quality</u>	Reliable without restrictions - Klimisch Code 1a
<u>References</u>	Dybdahl, H.P. 1993. Determination of log Pow for single components
	in tall oil pitch. GLP Study No. 408335/473. Water Quality Institute,
	Horsholm, Denmark.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Tall oil pitch, sodium salt
CAS #	68140-16-9
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117,
	"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Υ
Year (Study Performed)	2002
Test conditions	Tall oil pitch, sodium salt and 10 reference compounds of known $\log_{10}P_{ow}$ were dissolved in methanol and adjusted to a pH of 2. The solutions were analyzed by HPLC with Photodiode Array (PDA) detection using a mobile phase of water/methanol [25:75 (v/v) Milli-Q Water/Methanol].
Results	For tall oil pitch, sodium salt, in unbuffered media, a partition coefficient range of 3.1 to 5.7 was determined; the pH of this sample was <i>ca</i> 6-7. In media adjusted to pH 2, because this substance is insoluble in the solvent used, only a small peak was observed suggesting that virtually nothing passed through the column. Consequently, the partition coefficient was 5.8.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of Partition Coefficient of Tall Oil and Tall Oil Related Products. Report Number 20978. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Tall oil, disproportionated
CAS #	68152-92-1
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, "Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Υ
Year (Study Performed)	2002
Test conditions	Tall oil, disproportionated and 10 reference compounds of known $\log_{10}P_{ow}$ were dissolved in methanol and adjusted to a pH of 2. The solutions were analyzed by HPLC with Photodiode Array (PDA) detection using a mobile phase of water/methanol [25:75 (v/v) Milli-Q Water/Methanol]. All samples showed peaks throughout the chromatogram, therefore a partition coefficient range is reported.
<u>Results</u>	At pH 2, a partition coefficient range of 4.4 to 5.9 was determined for tall oil, disproportionated.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of Partition Coefficient of Tall Oil and Tall Oil Related Products. Report Number 20978. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY - OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Tall oil, sodium salt
CAS #	65997-01-5
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, "Partition Coefficient (n-Octanol/Water) High Performance Liquid
	Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Υ
Year (Study Performed)	2002
Test conditions	Tall oil, sodium salt and 10 reference compounds of known $\log_{10}P_{ow}$ were dissolved in methanol and adjusted to a pH of 2. The solutions were analyzed by HPLC with Photodiode Array (PDA) detection using a mobile phase of water/methanol [25:75 (v/v) Milli-Q Water/Methanol]. All samples showed peaks throughout the chromatogram, therefore a partition coefficient range is reported.
Results	At pH 2, a partition coefficient range of 4.9 to 7.6 was determined for tall oil, sodium salt.
<u>Data Quality</u>	Reliable without restrictions – Klimisch Code 1a
<u>References</u>	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of Partition Coefficient of Tall Oil and Tall Oil Related Products. Report Number 20978. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
<u>Test Substance</u>	
Chemical Name	Tall oil, potassium salt
CAS #	68647-71-2
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, "Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Υ
Year (Study Performed)	2002
Test conditions	Tall oil, potassium salt and 10 reference compounds of known $\log_{10}P_{ow}$ were dissolved in methanol and adjusted to a pH of 2. The solutions were analyzed by HPLC with Photodiode Array (PDA) detection using a mobile phase of water/methanol [25:75 (v/v) Milli-Q Water/Methanol]. All samples showed peaks throughout the chromatogram therefore a partition coefficient range is reported.
<u>Results</u>	At pH 2, a partition coefficient range of 4.9 to 7.6 was determined for tall oil, potassium salt.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of Partition Coefficient of Tall Oil and Tall Oil Related Products. Report Number 20978. Inveresk Research, Tranent, Scotland.

ENVIRONMENTAL FATE – BIODEGRADATION		
Test Substance		
Chemical Name	Tall oil	
CAS #	8002-26-4	
<u>Method</u>		
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 D, "Ready Biodegradability: Closed Bottle Test"	
Test Type (aerobic/anaerobic)	Aerobic	
GLP (Y/N)	Υ	
Year (Study Performed)	1993	
Contact time	28 days	
Inoculum	Secondary effluent from Rungsted Treatment plant	
Test conditions	Inoculum: Secondary effluent was collected from Rungsted Treatment plant in Horsholm.	
	Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes. After determination of the chemical oxygen demand, the solution was used within the same day.	
	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 approximately 9 mg O ₂ /L and inoculated with 1 drop of secondary effluent per liter.	

	The test article was added at 1.96 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 5.01 mg O ₂ /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 O ₂ /L. Both the test and reference articles (1.96 mg/L and 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 8.35 mg O ₂ /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 for the added carbon sources was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds.
Results	
Degradation % after time	43% after 7 days and 60% after 28 days (test article); 63% after 7 days and 77% after 28 days (sodium benzoate)
Conclusions	The biological oxygen demand for tall oil was 43 and 60% of the theoretical oxygen demand after 7 and 28 days, respectively. These data indicate that the material is dominated by readily biodegradable compounds. Tall oil did not inhibit the respiratory activity of the inoculum. The inoculum had satisfactory activity as demonstrated by more than 60% degradation within the 7 days using the reference compound.
<u>Data Quality</u>	Reliable without restrictions- Klimisch Code 1a
<u>References</u>	Madsen, T. 1993. Biodegradation of distilled tall oil. GLP Study No. 308067/475. Water Quality Institute, Horsholm, Denmark.

Test Substance	
Chemical Name	Tall oil
CAS #	8002-26-4
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 F, "Manometric respiratory test for biological degradation"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Υ
Year (Study Performed)	1999
Contact time	28 days
Inoculum	Activated sludge from a municipal sewage treatment plant
Test conditions	Inoculum: Activated sludge from the municipal sewage treatmen plant in Reutlingen was washed twice with dechlorinated tap water and centrifuged at 3000 rpm for one minute. Concentration of test chemical: A stock solution of the test material (102.2 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 deionized 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.
<u>Results</u>	
Degradation % after time	73% after 28 days (test article); 97% after 28 days (sodium benzoate)
<u>Conclusions</u>	Seventy-three percent of tall oil was biodegraded after 28 days indicating that the organic portion of the test material was inherently biodegradable.
Data Quality	Reliable without restrictions- Klimisch Code 1a
References	Aniol. S. 1999. Biological degradation, manometric respirometry test. STZ Project No. 04/99. Steinbeis-Transferzentrum Angewandte und Umwelt-Chemie, Reutungen.

Test Substance	
Chemical Name	Tall oil pitch
CAS #	8016-81-7
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 D, "Ready Biodegradability: Closed Bottle Test"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Υ
Year (Study Performed)	1993
Contact time	28 days
Inoculum	Secondary effluent from Rungsted Treatment plant
Test conditions	Inoculum: Secondary effluent was collected from Rungsted Treatment plant in Horsholm.
	Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes followed by magnetic stirring for 24 hours at 20°C. The solution was filtered and, after determination of the chemical oxygen demand, the solution was used within one day.
	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 approximately 9 mg O_2 /L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 186 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 4.56 mg O_2 /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 O_2 /L. Both the test and reference articles (186 mg/L and 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 7.90 mg O_2 /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 for the added carbon sources was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference

	compounds.
<u>Results</u>	
Degradation % after time	36% after 7 days and 41% after 28 days (test article); 72% after 7 days and 94% after 28 days (sodium benzoate)
Conclusions	The biological oxygen demand for tall oil pitch was 41% of the theoretical oxygen demand after 7 days and did not increase during the 28 days of the experiment. These data indicate that the material contains readily biodegradable and recalcitrant compounds. Tall oil pitch did not inhibit the respiratory activity of the inoculum. The inoculum had satisfactory activity as demonstrated by more than 70% degradation within the 7 days using the reference compound.
Data Quality	Reliable without restrictions - Klimisch Code 1a
References	Madsen, T. 1993. Biodegradation of tall oil pitch. GLP Study No. 308067/473. Water Quality Institute, Horsholm, Denmark.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Tall oil pitch
CAS #	08016-81-7
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD (1992) 301B "Modified Sturm Test"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Υ
Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 3.2 g/l.
	Concentration of test chemical: The test material was used at a concentration of 20 mg DOC/L. Based on the percentage carbon content, a target weight of 49.8 mg of test material was weighed for direct addition to each appropriate bioreactor.
	Test Setup: Each test item bioreactor contained 1980 ml of mineral media, 20 ml of microbial inoculum and the appropriate weight of test item. The reference bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum and 69 ml of reference material (sodium benzoate) stock. The control bioreactors each contained 1980 ml of mineral media and 20 ml of microbial inoculum. The toxicity control bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum, the appropriate weight of test item and 69 ml reference material stock.
	Each bioreactor was connected to three traps, each trap containing 100 ml of 0.0125 M Ba(OH) ₂ . At trap collection, the

	trap closes to the bioreactor was taken for titration, the two remaining traps were moved closer to the bioreactor and a fresh trap was placed third in line from the bioreactor. Trap changes were conducted on days 1, 4, 6, 8, 11, 15, 18, 21, 26, and 29. Each sampled trap was titrated with a few drops of phenolphthalein indicator against 0.05M HCl. The pH was determined in each bioreactor on days 0, 28 and 29; if necessary, the pH on day 0 was adjusted to 7.2-7.8. Calculation of Results: The weight of CO_2 evolved was calculated from the titre. The actual titre for each batch of $Ba(OH)_2$ was used as the background titre. The mean titre for the test, reference and control vessels was calculated according to the following equation: Weight CO_2 produced (mg) = 1.1 x (background titre – ml HCl titrated) The net CO_2 production was then calculated by subtracting the control mean CO_2 production from the test and reference material mean CO_2 production values. The percentage biodegradation was calculated by comparing actual CO_2 evolved in test and reference vessels with the theoretical CO_2 evolution.
	For the test item this was calculated using the DOC addition rate:
Results Degradation % after time Conclusions	9.2% after 28 days (test article); 81.6% after 28 days (sodium benzoate) The test article was degraded 9% after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to be
Data Quality	readily biodegradable. Reliable without restrictions – Klimisch Code 1a
Reference	Kelly, C.R. 2002. Tall oil pitch, CAS No. 08016-81-7; Tall oil, disproportionated CAS No. 68152-92-1 Determination of Ready Biodegradability of Two Tall Oils and Tall Oil Pitch, Sodium Salt by the Modified Sturm Test. Report Number 21628. Inveresk Research, Tranent, Scotland.

Test Substance	
Chemical Name	Tall oil, disproportionated
CAS #	68152-92-1
Method	
Method/Guideline followed	Testing was conducted according to OECD (1992) 301B "Modified Sturm Test"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Υ
Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 3.2 g/l.
	Concentration of test chemical: The test material was used at a concentration of 20 mg DOC/L. Based on the percentage carbon content, a target weight of 51.3 mg of test material was weighed for direct addition to each appropriate bioreactor.
	Test Setup: Each test item bioreactor contained 1980 ml of mineral media, 20 ml of microbial inoculum and the appropriate weight of test item. The reference bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum and 69 ml of reference material (sodium benzoate) stock. The control bioreactors each contained 1980 ml of mineral media and 20 ml of microbial inoculum. The toxicity control bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum, the appropriate weight of test item and 69 ml reference material stock.
	Each bioreactor was connected to three traps, each trap containing 100 ml of 0.0125 M Ba(OH) ₂ . At trap collection, the trap closes to the bioreactor was taken for titration, the two remaining traps were moved closer to the bioreactor and a fresh trap was placed third in line from the bioreactor. Trap changes were conducted on days 1, 4, 6, 8, 11, 15, 18, 21, 26, and 29.
	Each sampled trap was titrated with a few drops of phenolphthalein indicator against 0.05M HCl. The pH was determined in each bioreactor on days 0, 28 and 29; if necessary the pH on day 0 was adjusted to 7.2-7.8.
	Calculation of Results: The weight of CO ₂ evolved was calculated from the titre. The actual titre for each batch of Ba(OH) ₂ was used as the background titre. The mean titre for the test, reference and control vessels was calculated according to the following equation:
	Weight CO ₂ produced (mg) = 1.1 x (background titre – ml HCl

	titrated)
	The net CO_2 production was then calculated by subtracting the control mean CO_2 production from the test and reference material mean CO_2 production values. The percentage biodegradation was calculated by comparing actual CO_2 evolved in test and reference vessels with the theoretical CO_2 evolution.
	For the test item this was calculated using the DOC addition rate:
	Mg CO ₂ produced
	% degradation = x 100 mg DOC added x 3.67
	* = where 3.67 is the conversion factor (44/12) for carbon to CO_2
Results	
Degradation % after time	33.1% after 28 days (test article); 81.6% after 28 days (sodium benzoate)
Conclusions	The test article was degraded 33% after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to be readily biodegradable, although an appreciable proportion of the test item had degraded by the end of the test.
Data Quality	Reliable without restrictions - Klimisch Code 1a
<u>Reference</u>	Kelly, C.R. 2002. Tall oil pitch, CAS No. 08016-81-7; Tall oil, disproportionated CAS No. 68152-92-1 Determination of Ready Biodegradability of Two Tall Oils and Tall Oil Pitch, Sodium Salt by the Modified Sturm Test. Report Number 21628. Inveresk Research, Tranent, Scotland.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Tall oil pitch, sodium salt
CAS #	68140-16-9
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD (1992) 301B "Modified Sturm Test"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Υ
Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 3.2 g/l.
	Concentration of test chemical: The test material was used at a concentration of 20 mg DOC/L. Based on the percentage carbon content, a target weight of 407.7 mg of test material was weighed for direct addition to each appropriate bioreactor.

Degradation % after time	31.8% after 28 days (test article); 81.6% after 28 days (sodium benzoate)
Results	
	* = where 3.67 is the conversion factor (44/12) for carbon to CO_2
	% degradation = x 100 mg DOC added x 3.67
	For the test item this was calculated using the DOC addition rate: Mg CO ₂ produced
	The net CO ₂ production was then calculated by subtracting the control mean CO ₂ production from the test and reference material mean CO ₂ production values. The percentage biodegradation was calculated by comparing actual CO ₂ evolved in test and reference vessels with the theoretical CO ₂ evolution.
	Weight CO ₂ produced (mg) = 1.1 x (background titre – ml HCl titrated)
	Calculation of Results: The weight of CO ₂ evolved was calculated from the titre. The actual titre for each batch of Ba(OH) ₂ was used as the background titre. The mean titre for the test, reference and control vessels was calculated according to the following equation:
	Each sampled trap was titrated with a few drops of phenolphthalein indicator against 0.05M HCl. The pH was determined in each bioreactor on days 0, 28 and 29; if necessary, the pH on day 0 was adjusted to 7.2-7.8.
	Each bioreactor was connected to three traps, each trap containing 100 ml of 0.0125 M Ba(OH) ₂ . At trap collection, the trap closes to the bioreactor was taken for titration, the two remaining traps were moved closer to the bioreactor and a fresh trap was placed third in line from the bioreactor. Trap changes were conducted on days 1, 4, 6, 8, 11, 15, 18, 21, 26, and 29.
	Test Setup: Each test item bioreactor contained 1980 ml of mineral media, 20 ml of microbial inoculum and the appropriate weight of test item. The reference bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum and 69 ml of reference material (sodium benzoate) stock. The control bioreactors each contained 1980 ml of mineral media and 20 ml of microbial inoculum. The toxicity control bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum, the appropriate weight of test item and 69 ml reference material stock.

Data Quality	Reliable without restrictions - Klimisch Code 1a
Reference	Kelly, C.R. 2002. Tall oil pitch, CAS No. 08016-81-7; Tall oil, disproportionated CAS No. 68152-92-1 Determination of Ready Biodegradability of Two Tall Oils and Tall Oil Pitch, Sodium Salt by the Modified Sturm Test. Report Number 21628. Inveresk Research, Tranent, Scotland.

ENVIRONMENTAL FATE – BIODE	GRADATION
Test Substance	
Chemical Name	Tall oil, sodium salt
CAS#	65997-01-5
Method	
Method/Guideline followed	Testing was conducted according to OECD (1992) 302B
	"Modified Zahn-Wellens Test"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Υ
Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 4.0 g/l.
	Concentration of test chemical: The test material was used at a concentration of 200 mg DOC/L equivalent to 4740 mg of tall oil, sodium salt per 2.5 liter bioreactor based on percentage total carbon content. To prepare the reference material (aniline) 8.09 ml was added to 1000 ml DI water and sonicated for <i>ca</i> 30 min. to aid dissolution; from this stock 125 ml aliquots were added to each appropriate bioreactor at 400 mg/DOC/l equivalent to 125 ml of a 6400 mg/DOC/l solution per 2 liter bioreactor.
	Test Setup: The activated sludge was introduced to the test system at a ratio of 2.5:1 sludge solids/I to test item DOC/I which required the addition of 250 ml of 4 g/I sludge to each bioreactor. A total of six bioreactors were used.
	Each bioreactor had a final volume of 2000 ml; the control bioreactors each contained 250 ml sludge and 1750 ml of mineral medium; the reference bioreactor contained 250 ml sludge, 125 ml of aniline stock solution and 1625 of mineral medium; the test item bioreactors each contained 250 ml sludge, the appropriate weight of test item and 1750 ml of mineral medium; the toxicity control bioreactor contained 250 ml sludge, the appropriate weight of test item, 125 ml aniline stock and 1625 ml mineral medium. The test was conducted over 28 days. DOC measurements were conducted on duplicate samples 3 h after test initiation, and on Days 14 and 28.
	Sampling Procedure: Prior to each sampling point the liquid in each vessel was replenished to its starting level. The pH and

	dissolved oxygen concentration were recorded. If necessary the pH was adjusted to 6.5-8.0 using H ₂ SO ₄ as appropriate. A <i>ca</i> 25 ml sample was extracted from each vessel using a syringe and allowed to settle after which it was passed through a 0.45um filter for DOC analysis. Determination of DOC, total organic carbon (TOC), total carbon (TC) and inorganic carbon (IC) were determined. Calculation of Results: All measurements were conducted on duplicate samples. Dissolved organic carbon (DOC) values were calculated as follows:
	DOC = TC - IC
	The percentage degradation (Dt) at each timepoint was calculated using mean DOC measurements from the duplicate samples, using the following equation:
	(Ct -Cb) Dt = (1) x 100 (Ca - Cba)
	Where:
	Ct = mean DOC concentration in test/reference at time t Cb = mean DOC concentration in controls at time t Ca = mean DOC concentration in test/reference at $3 \text{ h} \pm 0.5 \text{ h}$ Cba = mean DOC concentration in controls at $3 \text{ h} \pm 0.5 \text{ h}$
Results Degradation % after time	The test material reached 78 % degradation by Day 28; the reference material reached 97.3% degradation by Day 14. Based on total carbon content this was equivalent to 21.7% of the whole test item. Initial solubility trials demonstrated that the majority of the component fractions are poorly soluble. Absorption to the sludge was not apparent.
<u>Conclusions</u>	The test article was degraded 78% after 28 days under the conditions of the test.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Kelly, C.R. 2002. Tall oil pitch, sodium salt, CAS No. 68140-16-9; Tall oil, sodium salt, CAS No. 65997-01-5; Tall oil, potassium salt, CAS No. 68647-71-2, Determination of Inherent Biodegradability by the Modified Zahn-Wellens Test. Report Number 21628. Inveresk Research, Tranent, Scotland.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Tall oil, potassium salt
CAS #	68647-71-2
<u>Method</u>	
Method/Guideline followed	Testing was conducted according to OECD (1992) 302B "Modified Zahn-Wellens Test"
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Υ

Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 4.0 g/l.
	Concentration of test chemical: The test material was used at a concentration of 200 mg DOC/L equivalent to 5026 mg of tall oil, potassium salt per 2.5 liter bioreactor based on percentage total carbon content. To prepare the reference material (aniline) 8.09 ml was added to 1000 ml DI water and sonicated for <i>ca</i> 30 min. to aid dissolution; from this stock 125 ml aliquots were added to each appropriate bioreactor at 400 mg/DOC/l equivalent to 125 ml of a 6400 mg/DOC/l solution per 2 liter bioreactor.
	Test Setup: The activated sludge was introduced to the test system at a ratio of 2.5:1 sludge solids/I to test item DOC/I which required the addition of 250 ml of 4 g/I sludge to each bioreactor. A total of six bioreactors were used.
	Each bioreactor had a final volume of 2000 ml; the control bioreactors each contained 250 ml sludge and 1750 ml of mineral medium; the reference bioreactor contained 250 ml sludge, 125 ml of aniline stock solution and 1625 of mineral medium; the test item bioreactors each contained 250 ml sludge, the appropriate weight of test item and 1750 ml of mineral medium; the toxicity control bioreactor contained 250 ml sludge, the appropriate weight of test item, 125 ml aniline stock and 1625 ml mineral medium. The test was conducted over 28 days. DOC measurements were conducted on duplicate samples 3 h after test initiation, and on Days 14 and 28.
	Sampling Procedure: Prior to each sampling point the liquid in each vessel was replenished to its starting level. The pH and dissolved oxygen concentration were recorded. If necessary the pH was adjusted to 6.5-8.0 using H ₂ SO ₄ as appropriate. A <i>ca</i> 25 ml sample was extracted from each vessel using a syringe and allowed to settle after which it was passed through a 0.45um filter for DOC analysis. Determination of DOC, total organic carbon (TOC), total carbon (TC) and inorganic carbon (IC) were determined.
	Calculation of Results: All measurements were conducted on duplicate samples. Dissolved organic carbon (DOC) values were calculated as follows:
	DOC = TC - IC
	The percentage degradation (Dt) at each timepoint was calculated using mean DOC measurements from the duplicate samples, using the following equation:
	(Ct -Cb) Dt = (1) x 100

	(Ca – Cba)
	Where:
	Ct = mean DOC concentration in test/reference at time t Cb = mean DOC concentration in controls at time t Ca = mean DOC concentration in test/reference at 3 h \pm 0.5 h Cba = mean DOC concentration in controls at 3 h \pm 0.5 h
<u>Results</u>	
Degradation % after time	The test material reached 71.5% degradation by Day 14 and 95.9 % degradation by Day 28; the reference material reached 97.3% degradation by Day 14. Based on total carbon content this was equivalent to 23.9% of the whole test item. Initial solubility trials demonstrated that the majority of the component fractions are poorly soluble. Absorption to the sludge was not apparent.
<u>Conclusions</u>	The test article was degraded 78% after 28 days under the conditions of the test.
Data Quality	Reliable without restrictions - Klimisch Code 1a
<u>Reference</u>	Kelly, C.R. 2002. Tall oil pitch, sodium salt, CAS No. 68140-16-9; Tall oil, sodium salt, CAS No. 65997-01-5; Tall oil, potassium salt, CAS No. 68647-71-2, Determination of Inherent Biodegradability by the Modified Zahn-Wellens Test. Report Number 21628. Inveresk Research, Tranent, Scotland.

ECOTOXICITY – ACUTE TOXICITY TO FISH	
Test substance	
Chemical Name	Tall oil
CAS#	8002-26-4
<u>Method</u>	
Method/Guideline followed	OECD Test Method 203, "Testing of Chemicals, Fish Acute
	Toxicity Test" and following procedures in OECD (2000) Series
	on Testing and Assessment, No. 23, "Guidance Document on
	Aquatic Toxicity Testing of Difficult Substances and Mixtures."
Year	2002
GLP (Y/N)	Υ
System of testing	Fathead minnows (<i>Pimephales promelas</i>) under static conditions.
Concentration	0, 1, 10, 100 and 1000 mg/l
<u>Results</u>	The 96 hr LL ₅₀ was > 1000 mg/l the highest loading rate tested.
	The No Observed Effect Loading Rate (NOEL) was 1000 mg/l.
<u>Detailed Summary</u>	Tall oil was tested in fathead minnows under static conditions to
	determine the acute toxicity. Water accommodated fractions
	(WAF) were prepared using the same conditions as those used
	to determine the water solubility of this substance. Appropriate
	weights of tall oil were added to a stirring medium in glass
	vessels which were sealed to avoid loss of volatile fractions.
	Using magnetic stirrers, the stirring speed was adjusted to give a
	stirring vortex 5-10% of the water column. After a stirring period
	of approximately 48 hr. the test solutions were allowed to settle
	for ca hour. The WAF was then removed via a glass siphon
	taking care not to remove undissolved material at the top of
	bottom of the water column. The test organisms were exposed
	to this WAF. This procedure was adopted to maximize the
	solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble
	but to reduce exposure to the test organisms to insoluble

	fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test using the highest loading rate (i.e., 1000 mg/l). Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. The 96 hr LL $_{50}$ was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate (NOEL $_{r}$) was 1000 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
<u>Reference</u>	Kelly, C. 2002. Tall oil, CAS No. 8002-26-4 Determination of
	Acute Toxicity (LL ₅₀) to Fathead Minnows (96 h, Static). Report
	Number 20787. Inveresk Research, Tranent, Scotland.

ECOTOXICITY – ACUTE TOXICIT	Y TO DAPHNIA
Test substance	
Chemical Name	Tall oil
CAS#	8002-26-4
<u>Method</u>	
Method/Guideline followed	OECD Test Method 202, Part 1 "Testing of Chemicals, Daphnia sp. Acute Immobilization Test" and following procedures in OECD (2000) Series on Testing and Assessment, No. 23, "Guidance Document on Aquatic Toxicity Testing of Difficult
	Substances and Mixtures."
Year	2002
GLP (Y/N)	Υ
System of testing	Daphnia magna (water fleas) under static conditions.
Concentration	0, 1, 10, 100 and 1000 mg/l
Results	The 48 hr EL ₅₀ was > 1000 mg/l the highest loading rate tested. The No Observed Effect Loading Rate (NOEL _r) was 1000 mg/l.
Detailed Summary	Tall oil was tested in daphnia under static conditions to determine the acute toxicity. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of TOFA were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. The 48 hr EL ₅₀ was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate (NOEL _r) was 1000 mg/l.

Data Quality	Valid without restriction – Klimisch Code 1a
<u>Reference</u>	Kelly, C. 2002. Tall oil, CAS No. 8002-26-4 Determination of
	Acute Toxicity (EL ₅₀) to Daphnia (48 h, Static). Report Number
	21015. Inveresk Research, Tranent, Scotland.

ECOTOXICITY - ALGA, GROWTH	INHIBITION
Test substance	-
Chemical Name	Tall oil
CAS #	8002-26-4
Method	
Method/Guideline followed	OECD Test Method 201, "Testing of Chemicals, Alga, Growth Inhibition Test" and following procedures in OECD (2000) Series on Testing and Assessment, No. 23, "Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures."
Year	2002
GLP (Y/N)	Υ
System of testing	Green alga (Selenastrum capriconutum) growth inhibition.
Concentration	0, 125, 250, 500 and 1000 mg/l (range finding test) 1.6, 8, 40, 200, 1000 mg/l (definitive test)
<u>Results</u>	The 72 hr EL ₅₀ for area under growth curve (AUC) and Average Specific Growth Rate (0-72h) was > 1000 mg/l. The No Observed Effect Loading Rate (NOEL _r) for Average Specific Growth Rate and AUC was > 1000 mg/l.
Detailed Summary	Tall oil was tested in alga to determine the median effective loading (EL ₅₀) for growth inhibition. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of TOFA were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test at the highest loading rate. In the range finding test there was a 44%, 32%, 21% and 35% inhibition of growth at 1000, 100, 10 and mg/l, respectively. Based on the results of the range-finding test a definitive test was conducted at loading rates of 0, 1.6, 8, 40, 200 and 1000 mg/l. This test was conducted using an unfiltered WAF with no pH adjustment. As no effects or inhibition was observed the 72 hr EL ₅₀ was > 1000 mg/l for area under growth curve (AUC) and Average Specific Growth Rate (0-72h). Consequently, the No Observed Effect Loading Rate (NOEL _f) for AUC and Average Specific Growth Rate is 1000 mg/l.

Data Quality	Valid without restriction – Klimisch Code 1a
<u>Reference</u>	Kelly, C. 2002. Tall oil, CAS No. 8002-26-4 Alga, Growth
	Inhibition Test (72 h, EL ₅₀). Report Number 20829. Inveresk
	Research, Tranent, Scotland.

ACUTE TOXICITY - ORAL	
Test substance	
Chemical Name	Tall oil
CAS#	8002-26-4
<u>Method</u>	
Method/Guideline followed	Test procedure was similar to OECD Test Method 401, "Acute Oral Toxicity."
GLP (Y/N)	N
Year (Study Performed)	1986
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	5000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
<u>Result</u>	
Acute Oral LD ₅₀	>5000 mg/kg
Detailed Summary	Crude tall oil (CAS #8002-26-4) was administered orally (via gavage) to Sprague-Dawley rats (n = 5/sex/study) at 5000 mg/kg and the animals were observed for 14 days. The study was performed two times. Parameters evaluated included mortality, clinical signs, body weight gain, and gross pathology. In the first test, one male died on day 1 and a second male died on day 7. For the females, one death occurred on day 1 and a second on day 3. The overall mortality was 40%. No body weight effects were noted. Animals surviving the treatment appeared normal and exhibited no effects at gross pathological examination. In comparison, rats dying on study exhibited erosion of the stomach epithelium and hyperemia of the intestinal tract. When the study was repeated using the same dose level, no deaths occurred, the rats appeared normal throughout, no body weight effects occurred, and there were no gross pathological findings. Based on these data, the oral LD ₅₀ was greater than 5000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1b
Reference	Prince, H.N. 1986. Acute toxicity report: oral toxicity. Report No. GBL 30373. Gibraltar Biological Laboratories, Inc., Fairfield, New Jersey.

ACUTE TOXICITY – ORAL	ACUTE TOXICITY – ORAL	
Test substance		
Chemical Name	Tall oil	
CAS#	8002-26-4	
<u>Method</u>		
Method/Guideline followed	Test procedure was similar to OECD Test Method 401, "Acute	
	Oral Toxicity"	
GLP (Y/N)	N	
Year (Study Performed)	1986	
Species	Rat	
Strain	Sprague-Dawley	
Route of administration	Oral	
Dose levels	6000 mg/kg	
Sex and number/group	5 male and 5 female rats	
Frequency of treatment	Single oral gavage	
Duration of test	14 day observation post-treatment	
Control group (Y/N)	N	
<u>Result</u>		
Acute Oral LD ₅₀	>6000 mg/kg	
<u>Detailed Summary</u>	Crude tall oil (CAS #8002-26-4) was administered orally (via	
	gavage) to Sprague-Dawley rats (n = 5/sex) at 6000 mg/kg and	
	the animals were observed for 14 days. Parameters evaluated	
	included mortality, clinical signs, body weight gain, and gross	
	pathology. One female rat died on day 3; no other deaths	
	occurred. All surviving animals appeared normal throughout the	
	course of the study, and no body weight changes were observed.	
	At gross pathology, no abnormalities were reported in the	
	surviving animals; data for the animal dying on study were not	
Data Quality	presented. The oral LD ₅₀ was greater than 6000 mg/kg. Valid without restriction – Klimisch Code 1b	
Data Quality		
<u>Reference</u>	Prince, H.N. 1986. Acute toxicity report: oral toxicity. Report No. GBL 30371. Gibraltar Biological Laboratories, Inc., Fairfield,	
	New Jersey.	
	ivew delacy.	

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Tall oil pitch
CAS #	8016-81-7
<u>Method</u>	
Method/Guideline followed	OECD Test Method 425, "Acute Oral Toxicity – Up-and-Down Procedure."
GLP (Y/N)	Υ
Year (Study Performed)	2002
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	2000 mg/kg
Sex and number/group	5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N

<u>Result</u>	
Acute Oral LD ₅₀	>2000 mg/kg
Detailed Summary	Tall oil pitch (CAS # 008016-81-7) was administered to one female animal at 2000 mg/kg. As this animal survived, 4 additional animals were dosed sequentially at 2000 mg/kg so that a total of 5 animals were tested. The test item was dissolved in corn oil and administered orally in a single dose, by means of a gavage, followed by a 14 day observation period. A constant dose volume of 4 ml/kg was used. The formulations were magnetically stirred and warmed prior to dosing. The dose was calculated based on the weight of the animal on the day of dosing.
	Clinical observations were conducted frequently after dosing on Day 1 (at approximately ½½, 1 -1½, 2 -2½, 3½ -3½, and 4½5½h) and daily the reafter until Day 15. There were no mortalities during the observation period. No adverse clinical signs were noted during the observation period. Under the conditions of the study, following a single oral administration of Tall Oil Pitch to Sprague-Dawley rats, the median lethal dose (LD ₅₀) was estimated to be > 2000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Hutchinson, A.M.K. 2002. Tall Oil Pitch (CAS No. 008016-81-7) Acute Oral Toxicity (Up-and-Down Procedure) Test in Rats. Report Number 22039. Inveresk Research, Tranent, Scotland.

REPEAT DOSE TOXICITY WITH REPRODUCTIVE/DEVELOPMENTAL TOXICITY SCREENING TEST	
Test substance	
Chemical Name	Tall oil
CAS#	8002-26-4
Method	
Method/Guideline followed	OECD Test Guideline 422, "Combined Repeated Dose Toxicity
	Study with the Reproduction/Developmental Toxicity Screening Test."
GLP (Y/N)	Υ
Year (Study Performed)	2002
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral via diet
Dose levels	0, 1000, 5000 and 20000 p.p.m.
Sex and number/group	40 males and 40 females
Frequency of treatment	Males were treated for at least 4 weeks overall, starting from 2 weeks prior to mating until termination; females were treated for 2 weeks prior to mating, then through mating until termination after Day 4 of lactation.
Duration of test	4 weeks
Control group (Y/N)	Υ
<u>Result</u>	
Parental NOEL	1000 ppm
Reproductive/developmental	
NOEL	5000 ppm
Detailed Summary	Four groups of 10 male and 10 female Sprague-Dawley rats received the tall oil <i>via</i> the diet at concentrations of 0, 1000, 5000

and 20000 ppm. The males were dosed for at least 4 weeks, starting from 2 weeks prior to mating. The females were dosed from 2 weeks prior to mating until at least Day 6 of lactation. The animals were monitored for clinical signs, body weight, food consumption, mating and litter performance. Blood samples were taken from 5 males and 5 females per group for laboratory investigations. Males were sampled during Week 5: females were sampled on Day 6 of lactation. All animals were subjected to necropsy, which included weighing of major organs. Histopathology was conducted on tissues from 5 males from Control and High dose, and 7 females from the Control and 8 females from the High dose. At 20000 ppm in-life observations included decreased weight gain and food consumption in both sexes. Increased male liver weight following covariance analysis, and increases in bilirubin and alkaline phosphatase were noted in both sexes. In addition, small decreases were noted in adrenal gland weight in both sexes, and in albumin, white blood cell count and ovary weight in females; spleen weight and cholesterol were slightly increased in males. At 5000 ppm liver weight in males and alkaline phosphatase in both sexes were increased. Female adrenal gland weight was reduced. The only indication of reproductive toxicity was a decrease in implant sites at 20000 ppm. Alkaline phosphatase levels were significantly increased in females at 5000 and 20000 ppm and in males at 20000 ppm. In males there was a non significant increase in levels at 5000 ppm and in females at 1000 ppm there was an equivocal increase, but given the small group size it was considered that the difference was too small to reflect an effect of treatment. At 20000 ppm total bilirubin was increased in both sexes and cholesterol levels were increased in males; albumin (and consequently total protein) were reduced in females. There were no histology findings attributed to treatment. All histology findings were typical of spontaneously arising background findings in rats of this strain and age. Under the conditions of this study, toxicity was exhibited at levels of 5000 and 20000 ppm, but there were no clear effects of toxicity at 1000 ppm. Therefore, the parental NOEL was considered to be 1000 ppm while for reproductive parameters the NOEL was considered to be 5000 ppm. Data Quality Valid without restriction - Klimisch Code 1a Clubb, S. 2002. Tall Oil (CAS No. 8002-26-4) Combined Reference Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Test. Report Number 21553. Inveresk

IN VITRO GENETIC TOXICITY	
<u>Test substance</u>	
Chemical Name	Tall oil
CAS #	8002-26-4

Research, Tranent, Scotland.

<u>Method</u>	
Method/Guideline followed	OECD Test Method 471, "Bacterial Reverse Mutation Test"
Year	2001
GLP (Y/N)	Υ
System of testing	S. typhimurium strains TA98, TA100, TA1535 and TA1537 E. coli WP2uvrA
Concentration	
Metabolic activation	With and without addition of S-9 fraction from Aroclor 1254
IVICIADORIC ACTIVATION	treated Sprague-Dawley rats.
Results	Non-mutagenic with or without metabolic activation
Detailed Summary	Tall oil was tested in <i>S. typhimurium</i> strains TA98, TA100, TA102, TA1535 and TA1537 and <i>E. coli</i> WP2 <i>uvr</i> A for mutagenic activity. The test article was tested at concentrations of 17, 50, 167, 500, 1667, and 5000 μg/plate with and without metabolic activation with S9 fraction from Aroclor 1254-treated adult male Fisher rats. Positive controls not requiring metabolic activation included N-ethyl-N-nitro-N-nitrosoguanidine (EENG), 9-aminoacridine, 2-nitrofluorene, and sodium azide; the positive control requiring metabolic activation was 2-aminoanthracene. No increases in mutation frequency were reported at any concentration of tall oil with or without metabolic activation. Tall oil was not mutagenic in this assay to <i>S. thyphimurium</i> or <i>E. coli</i> either with or without metabolic activation to a maximum limit of 5000 μg/plate.
Data Quality	Valid without restriction – Klimisch Code 1a
<u>Reference</u>	Stevenson, F.M. 2001. Tall Oil, CAS No. 8002-26-4 Testing for Mutagenic Activity with <i>Salmonella Typhimurium</i> TA 1535, TA 1537, TA 98 and TA 100 and <i>Escherichia coli</i> WP2 <i>uvr</i> A. Report Number 20338. Inveresk Research, Tranent, Scotland.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Tall oil
CAS#	8002-26-4
<u>Method</u>	
Method/Guideline followed	OECD Test Method 473, "Chromosomal Aberration Assay with Chinese Hamster Ovary Cells in vitro."
Year	2001
GLP (Y/N)	Υ
System of testing	Chinese Hamster Ovary (CHO) cells in vitro
Concentrations of test material	Test 1: With S9 mix: 10, 20 and 40 ug/ml
selected for assessment of	Test 2: With S9 mix: 10, 20 and 30 ug/ml
chromosomal aberrations	Test 1: Without S9 mix: 20, 39, and 78 ug/ml Test 2: Without S0 mix: 65, 76.5 and 70 ug/ml
Metabolic activation	With and without addition of S9 fraction from Aroclor 1254-treated adult male Fisher rats.
Results	Clastogenic with S9 mix only at a concentration level that was deemed overtly toxic to the cells.
Detailed Summary	Tall oil was tested in Chinese hamster ovary (CHO) cells for clastogenic activity both with and with metabolic activation with rat liver S9 mix. The test article was tested with metabolic activation with S9 mix at concentrations of 10, 20, 40, and 80 ug/ml (Test 1) and in Test 2 at 5, 10, 20, 30, 40, 50 and 60 ug/ml

	and without metabolic activation with S9 mix at concentrations of 50, 55, 60, 62.5, 65, 67.5 and 70 ug/ml. The positive controls requiring and not requiring metabolic activation were cyclophosphamide (CPH) and methanesulphonate (MMS), respectively. Treatments with test item or controls were performed on duplicate cell cultures. Two slides per culture up to 50 metaphase cells per slide were examined. A dose level was considered to be toxic if the cell count was reduced to less than 50% of the mean vehicle control values or if consistent evidence of changes to cell morphology was observed. In the presence of S9 mix, positive levels of structural aberrations were observed in the cultures treated with 30 ug/ml. In the absence of S9 mix all cultures had structural aberrations within the 95% confidence limits of the historical negative control data, even when assessed into the toxic range. It was concluded that tall oil was weakly
	clastogenic in CHO cells <i>in vitro</i> in the presence of S9 mix, but only at concentrations judged overtly toxic to the cultures.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Murie, E. 2001. Tall Oil, CAS No. 8002-26-4 Chromosomal
	Aberration Assay with Chinese Hamster Ovary Cells in vitro
	(Complying with EC (Annex V) and OECD 473 Guidelines).
	Report Number 20748. Inveresk Research, Tranent, Scotland.