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PRODUCT DIVERSIFICATION AND QUALITY IMPROVEMENT FOR OILS PRODUCED AT ESSEN OILS COMPANY REDEVELOPMENTS (PVT.) LTD., ZIMBABWE

SI/ZIM/94/801/11-53

ZIMBABWE

Technical report: Findings, work performed and recommendations*

Prepared for the Government of Zimbabwe
by the United Nations Industrial Development Organization,
acting as executing agency for the United Nations Development Programme

Based on the work of I. Southwell,
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Vienna

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* This document has not been edited.

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ABSTRACT

The Mission took place from 30th August to 30th September with one day debriefing in Vienna on 11th October 1995. After briefing in Harare by both UNIDO (Mr. Roland Deschamps) and Redevelopments Ltd. (Mr. Craig Naude), the Chemist was relocated to Glen Isla, a tobacco - essential oil farm run by Essen Oils Ltd. (Mr. Chris Tippet). Following inspections of the essential oil operations and discussions with Mr. Tippet, the Chemist spent the remaining time installing and optimising the UNIDO / Essen Oils quality control equipment, demonstrating procedures and protocols to staff, recording standard chromatograms, organising and analysing information and data and compiling this report.

On 13th September Mr. Mike Milchard, Chemical Technologist, arrived to organise the construction and use of the fractionation unit. On Tuesday 26th September a general meeting and field day for the essential oil producers association (EOPA) was held at the Essen Oils Farm, for discussions between the UNIDO Consultants and the wider Zimbabwean essential oil industry. This meeting was attended by Mr. Ian Sinclair (Essential Plant Extract Company), Mr. Mike Jack (Four Seasons Co.), Mr. Brett Payne (Linden Grange Farm Fresh Herbs), Messrs. Chris, Stewart and David Tippet (Essen Oils) and Dr. L.S. Chagonda and three colleagues (Dept. Pharmacy, University of Zimbabwe). The role of gas chromatography in the quality control of oil products was both demonstrated and discussed. Chromatograms of locally produced geranium oils were produced and compared with that obtained from a standard commercial oil. A laboratory scale distillation of *Inulathera nuda*, a native oil bearing species from the Nyanga district in the eastern highlands, was demonstrated. Mr. Mike Milchard explained his progress in the construction of the UNIDO funded pilot scale fractionation unit and discussed the use of fractionation in the improvement of the quality of essential oil products.

The construction of the fractionation unit was not complete when the Chemist departed. Consequently, he was unable to use his optimised GC conditions to evaluate the effectiveness of the fractionation column.

The following report is that of the Quality Control Chemist appointed by UNIDO to study current quality control methods, recommend improvements, demonstrate the use of Gas Chromatography, train counterpart staff and assist and advise in other areas of essential oil production. The job description for this position is attached (Annex 1).

I. INTRODUCTION

A Harare-based marketing company (Redevelopments Ltd.) and Zimbabwe's principal essential oil producer and exporter (Essen Oils Ltd.) have recently recognised the need for assistance in marketing essential oil products of consistently high quality.

In May 1994 Redevelopments (Pvt.) Ltd. and Essen Oils (Pvt.) Ltd. approached UNIDO in Zimbabwe with an application for assistance with the production and marketing of essential oils and value added products.

Essential oils have been produced in Southern Africa for a number of years (Reference 1). For example, South Africa and Swaziland are well known producers of oil from **Eucalyptus smithii**, **E. dives** and **E. radiata** (Reference 2). The potential for the development of new essential oil crops such as **Tagetes**, **Artemesia**, **Eriocephalus**, **Pteronia** and **Salvia** has also been noted (Reference 3). Except for the early production of eucalyptus oil and superficial attempts at geranium oil production, Zimbabwe has only recently entered the world essential oil market.

Zimbabwe (formerly Rhodesia) experienced considerable political and social upheaval some fifteen years ago when the capitalist white Smith regime was replaced by the socialist black Mugabe Government. At present the 1% white minority (approximately 80,000) are vital in maintaining viable industries and preventing the national decline seen in some other newly independent neighbouring countries (e.g. Mozambique). Further boosts to the economy are however urgently needed to slow the devaluation of the Zimbabwean Dollar.

One such area with potential for economic return is the essential oil industry. A small number of farmers are already cultivating exotic (**Eucalyptus**, **Melaleuca**, **Pelargonium**) and native (**Lippia**) species or harvesting weed (**Tagetes**) species for oil production. A market exists for these and other oils provided that a consistent supply of a quality product can be maintained.

The aim of this Mission is to provide input to improve the quality of oil products by (1) optimising quality control procedures and (2) rectifying oils to provide more market-acceptable products. A two man team comprising a Chemist and a Chemical Technologist were respectively assigned these tasks

II. FINDINGS AND ACTIVITIES

Foremost in the push to develop essential oils as viable export commodities is Mr. Chris Tippet of Marondera, some 100 kms south east of Harare. Although Glen Isla is principally a tobacco farm, diversification has seen the cultivation of **Eucalyptus**, **Melaleuca** and **Lippia** for essential oil production in addition to maize, potatoes and hops. During 1995 for example the following areas have been planted:

Maize	**70 ha**
Tobacco	**30 ha**
Hops	**6 ha (1994)**
Eucalyptus	**15 ha**
Tea Tree	**32 ha**
Lippia	**6 ha**
Tagetes	**Variable**

Tagetes is harvested from neighbouring properties where it grows as a weed. The essential oil operations on Glen Isla trade under the name of Essen Oil (Pvt.) Ltd. Rising tobacco prices coupled with falling Eucalyptus Oil prices in recent years have prompted the replanting of land growing **Eucalyptus** with tobacco. Consequently a peak Eucalyptus Oil production of 9 tonne for the **91/92** year when the price was **US$6 per kg** has now fallen to **2½ tonne** at **US$5 per kg** for the year just ended. The fast growing **E. smithii** is the species most utilised.

Tea Tree Oil on the other hand is more encouraging as prices have been stable for a number of years. Essen Oil's first plantings (**15 ha**) were of a wrong high cineole, - high terpinolene, chemical variety (Reference 4), thought to be **Melaleuca linariifolia**. Although unacceptable on the international market this oil has found a restricted domestic market. The next planting (**17 ha**) gave a good yield (**750 kg**) of a good quality oil which has been sold to the UK. Plantings of another **30 ha** of this acceptable chemical variety of **M. alternifolia** are planned.

Lippia javanica is an indigenous species giving a low yield of a promising oil. With only around 4% citral, the oil is considerably less lemony than sister species **L. citriodora** (verbena, approximately 10% citral). The major components are linalool and dihydromyrcenone each present at about 20%. This is a new product of which only 21 kgs were produced this year. The oil demands a high price for use in speciality aromatherapy oils.

Tagetes minuta is a weed species distilled in parts of Africa for its perfumery oil. Essen Oils spots infestations from the air and then organises manual harvesting and transport back to the Glen Isla distillery where the plant is processed. Consequently yields are unpredictable and variable with **93/94** yielding **1200 kg** compared with **440 kg** for **94/95**.

A. QUALITY CONTROL

1. CURRENT METHODS - GAS CHROMATOGRAPHY

The Glen Isla quality control laboratory despite its deficiencies is the only producer owned laboratory with a gas chromatograph (GC). Unfortunately this GC is old and obsolete. **The Pye Unicam 104 Chromatograph** is only capable of taking packed columns. Almost all GC quality control of essential oils is now done on capillary columns which give superior resolution, less base line drift and more reproducibility of both retention times and percentage compositions. An injection block-splitter assembly, supposedly ordered by UNIDO did not arrive.

Two new columns purchased by UNIDO were available on arrival. The better quality of the two was a **J & W DB wax 30m x 0.25mm i.d. x 0.15 µ FSOT capillary column**. This column was utterly useless as it will only fit a GC dedicated to the use

of capillary columns. Enquiries were made for converting the Pye Unicam 104 for capillary operation. The construction of a new injector block with splitting capabilities would be necessary at the injection end of the column and modification at the detector end for provision for make up gas would also be required. The cost and effort of such modifications would not be justified given the inadequacies of the GC system particularly the lack of reproducibility. The second column was a new 2.7m glass packed column with 10% PEG 20 m as stationary phase. As this column is about one metre longer than the column in use, it was installed, conditioned and used to optimise GC conditions.

After trials lasting several days GC conditions for the optimum separation of Tea Tree Oil were established as shown in Annex 2.

Although inadequate when compared with results from a capillary column on a modern instrument I believe that these results are the best that can be determined by the 104 with a packed column.

The following inadequacies were highlighted.

1. For the first trace of a morning, the lack of heat in the GC system causes a delay of up to 8 minutes for early components and five minutes for later components.

2. Errors of up to 20% were observed with the first trace of the day when compared with the second (perhaps for the same thermal reasons as in #1). This was seen dramatically with a Tea Tree Oil standard where the same sample gave a 49.4% terpinen-4-ol for the first trace of the day reducing to 41.6% in the second trace of the day.

3. Significant percentage differences were obtained from reference samples determined in Australia on a medium polarity (AT35) capillary column compared to the packed polar (PEG 20m) column. The most significant of these are shown in Table 1. Of the several reasons possible for these differences, co-elution and inadequate resolution provide the best explanations.

TABLE 1

Percentage compositions of the major components of tea tree, eucalyptus and tagetes oils measured on capillary (A) and packed (B) columns:

		A 60 m AT 35	B 2.7 m PEG 20 M
Tea Tree	terpinen-4-ol	36.7	41.6
	γ- terpinene	21.5	22.7
	1,8-cineole	3.9	6.0
Eucalyptus	limonene	6.6	} 76.9
	1,8-cineole	68.2	
	α-terpineol	7.7	9.8
Tagetes	(Z)-β-ocimene	43.8	49.0
	dihydrotagetone	19.2	23.5
	(Z)-tagetone	10.9	11.4

4. The packed polar column did not have the resolving power of capillary intermediate polarity columns. For example key separations of α-pinene from α-thujene, β-pinene from sabinene, limonene from 1,8-cineole and β-phellandrene and sometimes p-cymene from terpinolene could not be achieved on the former column.

5. The Pye Unicam 104 occasionally malfunctioned by skipping the set initial time.

6. Poor sensitivity makes it impossible to analyze the dilute solutions important for assessing the quality of seedling extracts and surveying chemical varieties of promising new species.

The use of helium instead of nitrogen as carrier gas did not seem to enhance either resolution or sensitivity. It's benefit will however be better appreciated when capillary columns are used.

The more recently purchased DAPA software provides computer controlled integration, chromatogram retrieval and data storage facilities that were "state-of-the-art" just a few years ago. Although very recent packages may well be superior, this software provides a facility which far exceeds the capability of the antiquated instrument from which the data is collected.

The DAPA software was used for several days to optimise chromatogram data (Annex 3) and then acquire standard chromatograms and printouts representative of Essen Oils products (Annex 4). Chromatograms were also obtained on oils previously determined in Australia. This enabled a direct comparison of the two quality control facilities (Table 1).

One set back with this system was that the DAPA manual was a different version to that of the software provided. This made driving the software particularly difficult, especially when the inevitable malfunctions occurred.

The use of internal standards is desirable in essential oil quality control when more accurate quantitation is required. Although the absence of an accurate balance discourages this, the use of accurately measured volumes from a micropippette coupled with density data could give such quantitation.

2. CURRENT METHODS - PHYSICAL CONSTANTS

Although a gas chromatogram of a marketable essential oil is a first priority, the measurement of physical constants (refractive index, optical rotation, specific gravity and solubility in alcohol) should not be overlooked especially if the product is to meet specification sheet, national or international standard or pharmacopoeia criteria. These constants are not routinely measured at Essen Oils. Quotations have however been received for the refractometer, polarimeter and balance that are required for such measurements. The purchase of this equipment may not be necessary if it is possible to gain access to it for the measurement of enough constants to formulate a specification sheet and to ensure that the physical constant variation can also be seen as GC variation. The facilities at the university or at private laboratories may be adequate for this purpose.

3. CURRENT METHODS - CHEMICAL PARAMETERS

The measurement of constituents by bench chemistry is gradually being replaced by chromatographic procedures. The only bench method employed at Essen Oils is the o-cresol determination of 1,8-cineole. Results were however, not consistent with the GC results. This is easily rationalised on the grounds that the 1,8-cineole peak in the chromatogram is not resolved from the limonene and β-phellandrene peaks. This would mean that for **Eucalyptus radiata** for example, an actual cineole content of **68.2%** (capillary column or o-cresol) would be seen as **76.8%** (packed column).

4. RAW MATERIALS

A judicious choice of raw material is essential to maintain viable essential oil yields and quality.

The first purchase of tea tree seed resulted in the planting of **15 ha** of tea tree of substandard chemical quality. The oil contained approximately **25%** cineole, **40%** terpinolene and only **7%** terpinen-4-ol (**27.4%** cineole and **44.6%** terpinolene as determined on the co-eluting packed column). Such a composition suggests that the seed was from the terpinolene chemical variety of either **Melaleuca alternifolia** or **M. trichostachya** (see Reference 4).

The second acquisition of seed led to the planting of **17 ha** of good quality tea tree giving an oil with less than **3.7%** cineole and **35.0%** terpinen-4-ol. A mix of good/substandard oil in a **5:1** ratio gave a blend with respectable cineole (< 7.7%) and terpinen-4-ol (**32.6%**) concentrations and high terpinolene (**10.0%**).

This tea tree story stresses the need for reliable GC quality checks at different stages of production. If the quality of the oil from the first batch of seedlings had been checked using a leaf extract seedling check method then the planting out of substandard seedlings would have been prevented. In addition the value of GC analysis in the analysis of blends for marketing is clearly seen.

Once a plantation has been established genetic consistency is more certain. Seasonal and plant part variation also need consideration. With **Tagetes minuta**, for example, geographic and plant part variation has been studied for plants from Rwanda and France. (Reference 5). Where plants are harvested from the wild as weeds there is less control of genetic variation as in the Essen Oils tagetes collections.

After several seasons of **Eucalyptus smithii** harvesting chemical consistency should have been achieved. With the harvesting of a new crop such as **Lippia javanica** more work needs to be done to establish oil variation in terms of geographic origin, plant part and season.

5. PROCESSING

The quality of an oil is dependant on the nature and the duration of processing. With tea tree leaf the solvent extracts of flush growth contain precursor oil compounds that are only present in trace amounts in the distilled oil. (Reference 6). Hence a tea tree solvent extract is distinctly different to the steam distilled oil especially at the flush growth stage. In fact, a solvent extract of tea tree flush growth is identical to a majoram extract thus providing an alternative marjoram source. In addition, the differences in flush growth leaf solvent extracts have been found useful in distinguishing **Melaleuca alternifolia** from the other useful commercial tea tree **M. linariifolia** (Reference 7). The distillation of tea tree flush growth however converts these precursor compounds into the same components that are found in the mature leaf. If the distillation time is varied the composition of the distilled oil will also vary. As oils are distilled by a hydrodiffusion process the more polar alcohols distil over before the hydrocarbons (Reference 8). In this way, a tea tree oil with enhanced or reduced terpinen-4-ol content can be produced by collecting respectively either the former or the latter distillation fraction. It may be possible to adjust the quality of **Tagetes** or **Lippia** oils in a similar manner.

6. STORAGE

All essential oils should be treated with care in avoiding excesses of heat, light, water and exposure to air. Tea tree oil is known to produce p-cymene and mentha-1,2,4-triol on oxidation (Reference 8). **Tagetes** and **Lippia** oils seem prone to polymerisation. In some cases this is desirable as a less mobile oil is produced. Some regulatory authorities (e.g. the Therapeutic Goods Administration in Australia) insist on stability studies on products like tea tree oil so that realistic "use by....." dates can be included on labels. Consequently samples of oils produced should be retained and analyzed annually to determine shelf life stability.

Storage procedures at Essen Oils are adequate as lined drums are used and a nitrogen atmosphere used when required.

B. SPECIFICATIONS AND STANDARDS

1. EUCALYPTUS

Of the oils presently produced by Essen Oils eucalyptus oil is the most straight forward from a standardisation view point. The 1995 crop (ES215) on GC gave a **83.9%** cineole + limonene peak suggesting that the oil may fit into a 70-75% British Pharmacopoeia (BP) standard. Hence the o-cresol method is required to determine the real cineole content unless better chromatographic separation was possible. Although International Standards Organisation (ISO) and Zimbabwean Pharmacopoeia (Zimpharm) specifications exist for eucalyptus oil, selling to the BP standard would be the most logical way to go.

2. TEA TREE

Although tea tree oil was listed on the 1949 British Pharmacopoeia Codex and subsequently in Martindale (1972), its prominence was short-lived as it was dropped from the subsequent BP editions. Tea tree oil was sold to Australian Standard (1967; K175) specifications from 1967 and then to revised Australian Standard (1985 - 2782). At the November 1994 Madrid meeting of the ISO TC54 Essential Oil Committee the Draft Standard ISO/DIS 4730E on "Oil of **Melaleuca**, terpinen-4-ol type, was approved as a full standard and should soon be in print. Consequently tea tree oil should be produced to this ISO standard, preliminary copies of which can be obtained from NSW Agriculture or Standards Australia. Moves are being made to have the oil re-listed on the British Pharmacopoeia and listed on the European and German Pharmacopoeias. In the meantime the ISO 4730E Standard is the best available.

3. TAGETES

To my knowledge no standard yet exists for **Tagetes** oil even though an increasing amount of data on chemistry, physical constants and geographic, plant part and seasonal variation is being accumulated (e.g. Reference 5).

4. LIPPIA

Is a new oil source currently being developed and so is not well defined. Some data is available for the already commercial **Lippia citriodora** (verbena) oil but apart from a basic gas chromatography - mass spectrometric (GCMS) analysis little is known about **L. javanica** (Zimbani) oil.

5. SPECIFICATION SHEETS

When seeking buyers for an oil product, be it well known or new, it is an advantage to have a specification sheet that describes the product, it's uses and defines it with criteria such as optical rotation, refractive index, specific gravity, solubility in alcohol, a typical gas chromatographic trace and the percentage range of significant constituents. Essen Oils would benefit in the market place by having such a specification sheet for each of it's oil products. A sample specification sheet is shown in Annex 5.

C. CGMP AND SAFETY REQUIREMENTS

Codes for good manufacturing practice (CGMP) and safety requirements are as varied as the countries producing or exporting an oil commodity. Zimbabwe seems to be slower in addressing these issues then most western countries. Never-the-less firm requirements exist for farm safety features such as the storage and use of agricultural chemicals, boiler inspections, etc. All these are well known to the Essen Oils management and every possible step taken to ensure their implementation.

CGMP and safety requirements reach a higher level of importance once the product moves beyond the farm gate. The requirements for tea tree oil value added products in Australia, for example, are well defined by their government's Therapeutic Goods Administration (TGA). Such requirements include the licensing of the manufacture and quality control of therapeutic goods and regular annual inspections of premises thereafter. Further details of these CGMP requirements as practised in Australia are given in Annex 6.

Toxicity studies need to be carried out on new oil products. With tea tree oil, for example, increasing use has necessitated the measurement of data such as LD_{50} values, Ames tests for mutagenicity, skin irritancy and sensitization and the Draize test for eye irritancy.

If a new oil such as Essen Oils' **Lippia javanica** were to become a popular aromatherapy oil, such tests would have to be considered. Toxicity data for many essential oils, including tea tree (Reference 9) and eucalyptus (Reference 10) are published in **Food and Cosmetic Toxicology**

Although not directly responsible for the implementation of such CGMP requirements, Essen Oils and particularly Redevelopments Ltd and other "down-the-line" value adding marketers need to be aware of their implications

An awareness of the implications of pesticide carryover into essential oils is also important. Recently low levels of pesticides have been detected in oils such as tea tree and peppermint. Where chemical sprays are used checks for residues are desirable. When detected, management techniques need to be reviewed and perhaps realistic maximum recommended limits (MRLs) need to be set.

Essen Oils are moving in the right direction by seeking "Organic Product" certification where possible. This minimises the danger of pesticide contamination and gives marketing advantages for their Eucalyptus oil.

D. OIL FRACTIONATION

With the Chemical Technologist arriving some two weeks after the Chemist there was little time available for exploring the effect of fractionation on oil quality. The installation and construction of the pilot scale vacuum fractionation apparatus was difficult and time consuming due to the absence of adequate assembly instructions. Despite this, certain uses for the apparatus were envisaged.

An obvious start would be the removal of isovaleraldehyde from **Eucalyptus smithii** oil. This would serve two purposes. Firstly, it would provide an enhanced cineole oil. Secondly, the removal of the 7% isovaleraldehyde would provide a by-product that has in the past been in some demand by the flavour industry.

The use of fractionation to enhance tea tree oil quality is less likely. The cineole - terpinolene rich chemical variety could be fractionated to remove some of the cineole and terpinolene. The terpinen-4-ol enhanced fraction would certainly lack other important lower boiling ingredients as well.

As ocimene should be easily separated from the ketones, fractionation provides an easy way of reducing or enhancing the ocimene content of tagetes oi . In a similar way, the hydrocarbon/oxygenated ratios in **Lippia** oil could be adjusted.

Along with the delivery of the fractionation column came samples of 19 essential oil isolates (2 x 20 ml). The optimum GC and DAPA software parameters previously determined were now used to measure retention times and percentage purities for each of the isolates. These resultas are shown in Annex 5.

III. CONCLUSIONS AND RECOMMENDATIONS

Summary

Under the circumstances the current methods used for the quality control of essential oils at Essen Oils Ltd. / Redevelopments Ltd. are commendable. In a country where the essential oil industry is still a cottage industry and advanced technology support is limited, the Essen Oils laboratory is making a determined effort to come to grips with adequate quality control. The instruments available have been purchased second hand when suitable opportunities have arisen. Essen Oils have show much initiative in acquiring this equipment and learning through reading the literature and by experimental trial and error the art of obtaining analytical results. They are also very much aware of standards, physical constant and bench chemistry methods used in determining essential oil quality.

Although the most advanced essential oil quality control laboratory in Zimbabwe, on the international marketing scene Essen Oils results have much to be desired especially when compared with the results from modern capillary column instruments. After running the Pye Unicam 104 with the available DAPA software on the recently delivered new packed glass column, conditions are now optimised and much better results can now be obtained. These are however still inadequate as pointed out under number IV - Findings and Observations.

At present, Essen Oils / Redevelopments are at the mercy of the buyers because they cannot claim quality oils of accurately defined composition.

To overcome this, the following is recommended:

1. Purchase of a new gas chromatograph for capillary column analysis.
2. Employment and training of a technician to specialise in essential oil quality control.
3. Liaise with University or commercial laboratories for the use of other instrumentation (e.g. polarimeter, refractometer, gas chromatography - mass spectrometry, etc.).
4. Design and print attractive, scientifically accurate specification sheets for all oil products for market promotion.
5. Using the UNIDO supplied isolates as a basis, build up a collection of essential oils and isolates for reference purposes.
6. Improve the quality of oil products by fractionation where appropriate.
7. Undertake research aimed at improving the biomass, oil yield and quality of existing crops and search for new potentially commercial oil crops
8. Update the DAPA software to the latest version.
9. Obtain the right DAPA manual for the software currently in use.
10. Perform quality stability trials on an annual basis on all oils produced

NOTES:

1. **New Chromatograph**

Gas chromatography is the technique that provides the best "value-for-money" data on essential oils. A capillary column capability is essential. Although this could be provided by using a splitter injector block and make up pneumatics at the detector on the Pye Unicam chromatograph, the machine's other deficiencies (e.g. poor reproducibility) suggest that for little extra outlay a new chromatograph would overcome all deficiencies. In Australia an outlay of around **US$12 000** is sufficient to purchase a basic, "bottom-of-the-range" Shimadzu instrument which would work well. Ideally with extra outlay automatic sampling simultaneous two column - two detector analysis, data analysis software and / or a better quality instrument would be desirable. Justification of the cost for Essen Oils is difficult given the restricted use of the present instrument. If however, other essential oil and herb producers were able to use the machine for both oil and leaf extract analyses and the university was able to locate a postgraduate student on site then the cost would be justified. Given the emerging nature of Zimbabwe's essential oil and herb industries, UNIDO funding for such an instrument is easily justified

2. Technician

Only one of the Essen Oils staff (Chris Tippet, owner) has gained experience in essential oil quality control and even that was self-taught. There is a need for a laboratory assistant to be trained in the operations of essential oil distillation, gas chromatography, polarimetry, refractometry, etc. It may be possible to fund a full time assistant co-operatively from the Essential Oil Producers Association to be shared among all essential oil producers and given non-laboratory duties when there are no laboratory demands. Alternatively such duties would be useful experience for a university postgraduate student who could be jointly funded by the university and the industry.

3. Other Instrumentation

Ideally it would be good to have a refractometer and a polarimeter in the laboratory so that all the physical constants required for standards can be measured. A four place analytical balance is also required for specific gravity measurements and gas chromatographic internal standard determinations. These instruments although less expensive then a gas chromatograph should take second priority. They would not be used as much once the characteristics of the locally produced oils were defined. Indeed it may be possible to use instruments located at the University of Zimbabwe or commercial analytical laboratories for this purpose. Even though fruitful collaboration with the university has not resulted yet, the potential exists for R. & D. that would benefit both parties and hence the contacts should be maintained.

4. Specification Sheets

For the effective marketing of the presently produced **Eucalyptus**, tea tree, **Lippia** and **Tagetes** oils and any other oils that will be produced in the future, attractively presented specification sheets containing all information relevant to the oil should be produced. Sending such a sheet with a sample of the oil to prospective buyers would greatly enhance market prospects.

5. Reference Isolates and Oils

Essen Oils is building a good reference collection of locally and internationally roduced oils and their individual isolates especially with the recent addition of 19 UNIDO supplied isolates to their collection. These reference samples have been determined chromatographically with the old Pye Unicam 104 GC. Because of the variable retention times and percentage composition on this machine, these reference samples need to be re-analyzed on a capillary column instrument. The collection needs to be maintained by storing it in a stable environment and added to as much as possible. Rather than purchase samples from oil or chemical suppliers it may well be possible to enhance the collection by seeking small reference samples "free-of-charge" from essential oil researchers and dealers.

6. Fractionation

Once the fractionation unit has been constructed and is functioning efficiently it is recommended that **Eucalyptus smithii** oil be distilled in order to enhance the cineole concentration of the oil, remove the offending early odours in the oil and produce an isovaleraldehyde rich fraction which may be sold for flavouring uses. Attempts could also be made to improve the quality of other oils by fractionation.

7. Research

Much could be done to improve the status of the Zimbabwean essential oil industry through research. The biomass yields, oil yields and oil quality of existing crops could be improved and hence increase the value of each crop. Potentially commercial new crops could also be investigated. Research and Development of this nature is expensive. The only way for such research to eventuate would be through the co-operation of the University and the industry. If the University was able to locate students, especially postgraduate students on essential oil farms such as Glen Isla, then research into the agronomy, genetics, harvesting, processing, chemistry, quality control, bioactivity, end use and marketing of oils could be studied. The University would contribute the personnel and the industry the oil crops and other facilities for the project.

8. Data Handling

The DAPA software for the gas chromatographic quality control has undergone many upgradings since the purchase of the present package. Purchasing or upgrading to the latest version would give even better versatility especially when used with capillary column separations.

9. Compatibility of Software

It is recommended that attempts be made to obtain the right manual for the DAPA software in use.

10. Oil Stability

Many oil products in use require stability data so that meaningful "use by" dates can be printed on bottles of oil and value added products. To obtain such data oils need to be analyzed by gas chromatography and physical constants on an annual basis for as long as possible. Ten or even twenty years under normal storage conditions would provide adequate data. This is a long term investigation that needs to be commenced as soon as possible. The results of such stability trials become most important for the introduction of a new oil (e.g. **Lippia javanica**) onto the world market.

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Annex 1

Job Description for Quality Control Chemist.

T. de Silva
10.7.95

TO: Mr. Southwell

REVISED JOB DESCRIPTION.

F. Fernandez

REVISED

UNITED NATIONS INDUSTRIAL DEVELOPMENT ORGANIZATION

Project of the Government of Zimbabwe

JOB DESCRIPTION
SI/ZIM/94/801/11-53/0730DO

Post title	Quality Control Chemist
Duration	1.0 m/m
Date required	June/July 1995
Duty station	Marondera, Zimbabwe
Purpose of project	High level advice for product diversification and the improvement of the quality of essential oils produced at Essen Oils Co./Redevelopments (Pvt.) ltd. in carrying out the following duties:
Duties	The expert will be required to work in collaboration with the Chemical Technologist and counterpart staff at Essen Oils Co./Redevelopments (Pvt.) Ltd. in carrying out the following duties:

1. Study the current methods used in quality control of essential oils and evaluate the quality of oils produced.

2. Recommend methods to improve the quality of oils (eucalyptus, tea tree, Lippia and tagetes oils in particular) and demonstrate the use of equipment in preparing quality protocols and

specifications for raw materials and final products.

3. Demonstrate the use of GLC in quality control and provide standard chromatograms for the essential oils produced.

4. Train counterpart staff in the use of equipment for controlling the quality of raw materials, intermediates and finished products.

5. Assist the Chemical Technologist in the development of process controls.

6. Recommend the equipment needed for the establishment of a fully operational quality control laboratory.

7. Advise on the CGMP and safety requirements.

8. Recommend additional requirements for a good quality assurance system.

9. Advise other companies (Four Seasons Foods Pvt. Ltd., Essential Extracts Company, Nature Products Company and Plant Oils Producers Association) on quality control and processing methods.

Finally, the expert will furnish a report embodying his findings and progress and outlining his recommendations to both UNIDO and Essen Oils Co./Redevelopments (Pvt.) ltd.

Qualifications Chemist/Pharmacist/Technologist with over 10 years of experience in the production and quality control of essential oils and plant based products.

Language English

Annex 2

Optimum conditions for the Determination of Chromatograms on the Pye Unicam 104 Chromatograph.

	Air	H^2	N^{2*}	He
Cylinder Gauge Pressure (kPa)	150	110	300	300
GC Gauge Pressure (kPa)	5.0	15.0	-	-
Flow Rate (ml/min)			40	30

Initial Oven Temperature (°)	80
Programme Rate (° per min)	5
Final Oven Temperature (°)	180
Detector Temperature (°)	250
Ionisation Amplifier	2×10^{-1}
Backing Off Range	Middle Setting
Polarity	A
Recorder Gain	30% VAR
Chart Speed (mm/min)	5

* A cylinder of helium was purchased in an attempt to improve resolution. Although little, if any, improvement was seen, Helium was retained as carrier gas as it (or H2) becomes essential for use with capillary columns.

Annex 3

DAPA parameters used for the determination of standard chromatograms.

Attention 1
Baseline [N]
Calibration [N] Dil: 1 Recal 0
Display Trace Y/N/P[Y]
Exchange or : file 2:
Erase Files : file 3:
Grouping[N]
Hplc/glc cond. file[N]
Integ. action table[N]
Lotus file [N] type [EA4]
Method fileDAPA
Naming (pks) [N]
Offset
Post run & integ. action list
atten [N] bl-sub [Y] clean trace [N]
report [Y] trace [Y] smooth [Y]
Reject area min. 10
Squeeze factor 10
Tg/Pk/Sp/Wth = 20 3 .1 0
Update claib. File Y
View 0 0 to 55.0 min Autoset [Y]
X-Axis time marks 5
Z - change menu

DAPA configured for 640K of RAM Memory: 54448 Bytes
autosampler Varian 8034/5 [N]
board type: HR 18Bit
Batch integration
ChannelA
Drives DataC
SystemC
Frequency2
Gain < 10 > AUTORANGE [N]
Integ [A]rea [H]eight [S]qr (HT) {A}
Output port-Printer LPT:1
L- Calc 1st Derivative of data
Polynomial smoothing [5 pt]
Q - Set relays Low [ ]
** SYSTEM SET UP FOR **
DOTMATRIX PRINTER
Draft Mode
60 dots per inch
RUN TIME ACT. [DEMO] File ID:DEMO
Short report only N
Test errors<needs printer ON>[N]
Z - change menu

Annex 4

Copies of the gas chromatograms for A Essen Oils products, B reference essential oils. C reference isolates (with % purity and retention time) and D previous Essen Oil determinations.

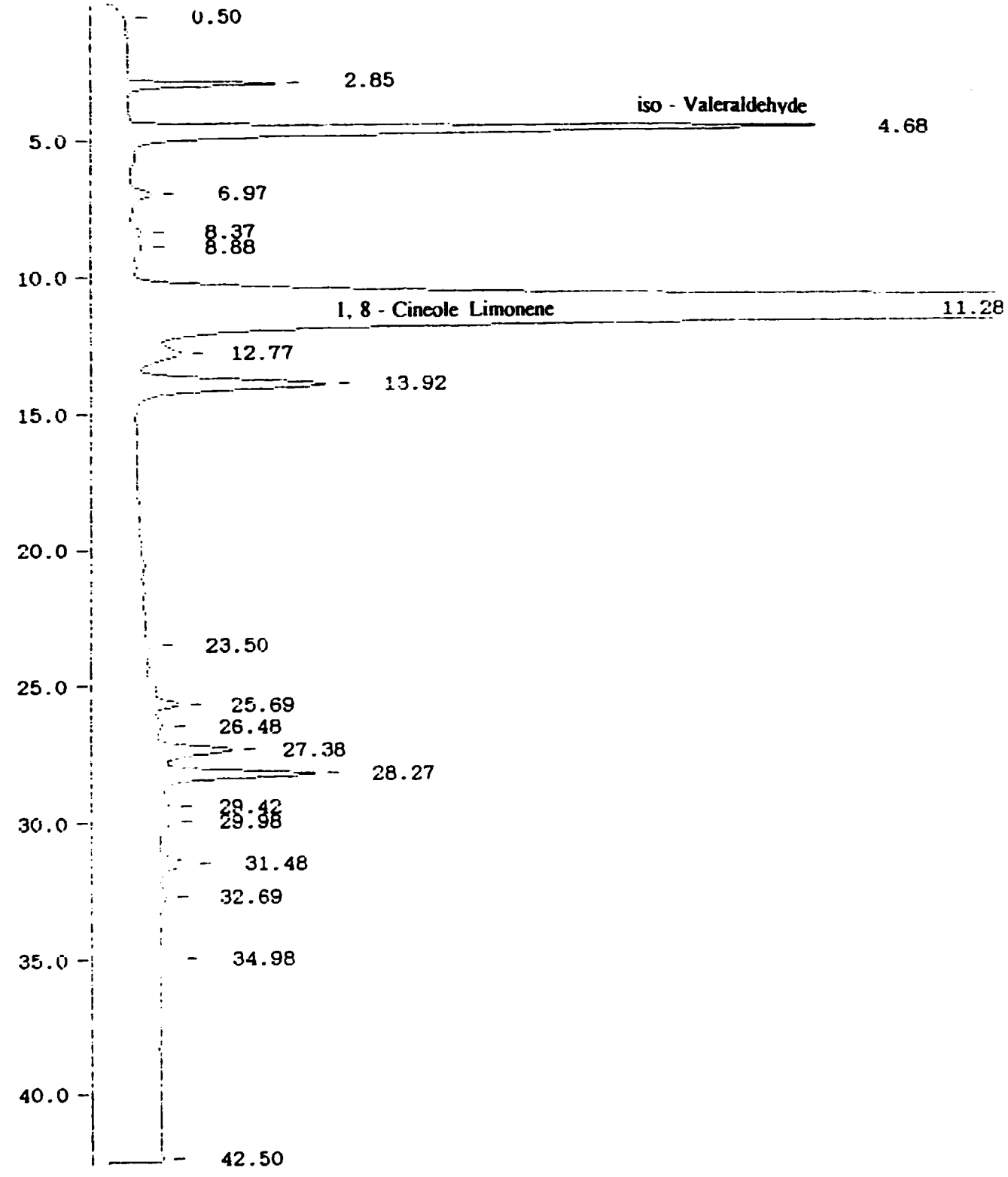
A.	**1.**	Eucalyptus smithii	ES 215
	2.	Melaleuca alternifolia	TTA 197/202 1995
	3.	Melaleuca linariifolia	TTL 207 1995
	4.	Melaleuca blend	TTA-170 blend
	5.	Tagetes minuta	TAG-95 22/06/95
	6.	Lippia javanica	Z 203
	7.	Lippia javanica	Zimbani Oil 6/1/95
B.	**1.**	Eucalyptus radiata	WA1 95564
	2.	Melaleuca alternifolia	WA1 95735
	3.	Tagetes minuta	WA1 93404
	4.	Tagetes minuta	Cav. Freres - Target - 24/2/94

C.	**1.**	Iso-valeraldehyde	99.8% (3.92')
	2.	Limonene	99.4% (14.16')
	3.	Cineole, 1.8 -	99.7% (16.11')
	4.	Phellandrene	96.9% (13.65')
	5.	Piperitone	47.8% (33.70')
	6.	Terpinen-4-ol	99.5% (32.07')
	7.	Terpinene	94.2% (11.98')
	8.	**alpha** - Pinene	96.4% (7.23')
	9.	**beta** - Pinene	99.9% (10.01')
	10.	Ocimene	73.2% (15.68')
	11.	**iso** - Tagetone	97.3% (17.97')
	12.	Citronellol	54.0% (31.62')
	13.	Linalool	99.9% (27.78')
	14.	Dihyromyrcenol	99.3% (25.98')
	15.	Terpineol	82.5% (33.69')
	16.	Geraniol	99.5% (46.71')
	17.	Citral (neral/geranial)	32.1/65.4% (34.7'/37.4')
	18.	Nonan-2-one	99.8% (23.68')
	19.	Undecan-2-one	99.1% (35.31')

D.	**1.**	Eucalyptus smithii	ES 1/2/3/4/5
	2.	Tea Tree Oil	Bodycare sample
	3.	Tagetes	TG 145
	4.	Lippia javanica	March 95

SAMPLE ID = E-SMITHI
Sampling Frequency [2] Hz
DATE 09-14-1995
TEXT:EUCALYPTUS SMITHII ES-215

PLOT Squeeze = 8 times ATTEN = 2
Tg/Pk/Sp/Wth= 20 3 .1 0
TIME 09:39:52

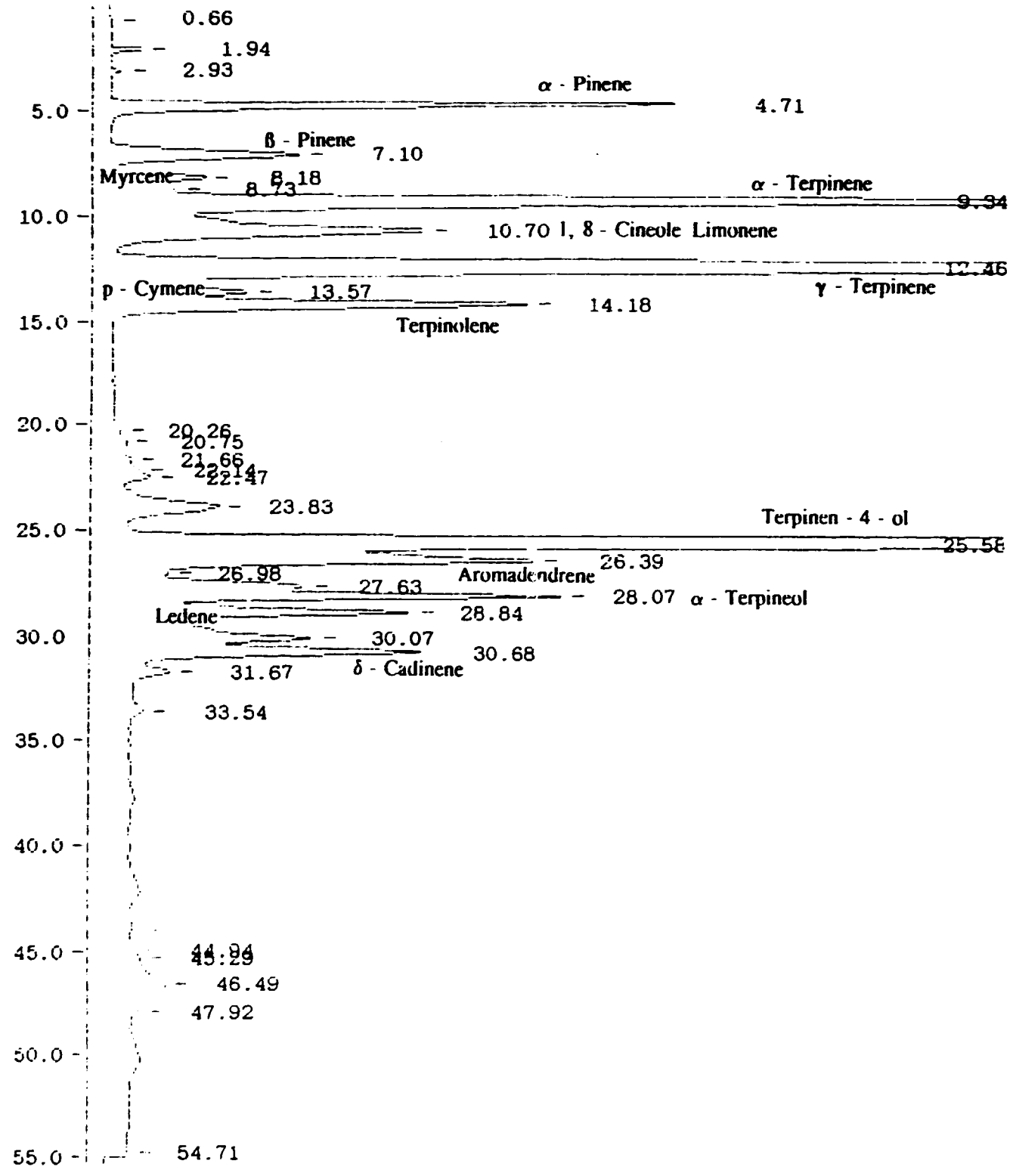


SAMPLE ID = E-SMITHI PLOT Squeeze = 8 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-14-1995 TIME 09:39:52
TEXT:EUCALYPTUS SMITHII ES-215

PLOTTING IS FROM 0.00 to 42.60 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.50	1622	32	BV	-5	32	0.3175
2	2.85	4885	218	BB	32	40	0.9563
3	4.68	37057	973	BB	35	67	7.2540
4	6.97	1220	28	BB	33	50	0.2388
5	8.37	190	6	BB	38	25	0.0371
6	8.88	63	3	BB	44	23	0.0123
7	11.28	430705	5209	BV	40	148	84.3112
8	12.78	1814	36	BV	84	54	0.3551
9	13.92	14383	266	VB	50	79	2.8156
10	23.50	108	5	BB	60	20	0.0211
11	25.69	1360	39	BB	69	40	0.2663
12	26.48	76	3	BV	79	19	0.0149
13	27.38	4810	104	BV	78	50	0.9415
14	28.27	8237	212	VB	88	60	1.6123
15	29.42	250	8	BV	83	30	0.0489
16	29.98	102	4	BB	82	20	0.0200
17	31.48	1963	40	BV	78	58	0.3842
18	32.69	176	7	BV	78	23	0.0345
19	34.98	1122	20	BB	77	56	0.2197
20	42.50	708	21	BB	78	10	0.1386

SAMPLE ID = A12 PLOT Squeeze = 10.4 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-13-1995 TIME 13:41:00
TEXT:TEA TREE OIL STANDARD TTA 197/202 1995

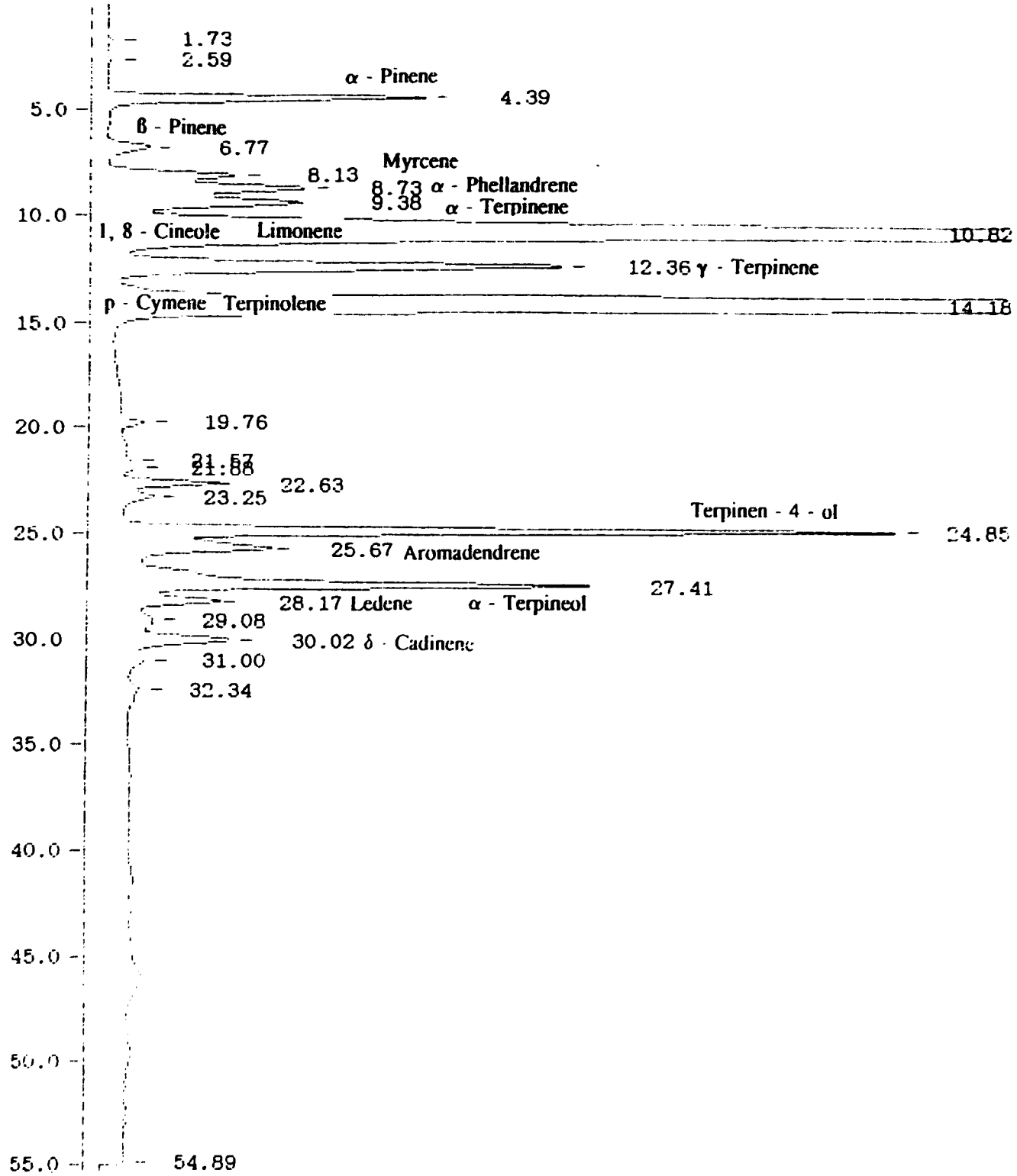


SAMPLE ID = A12 PLOT Squeeze = 10.4 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-13-1995 TIME 13:41:00
TEXT:TEA TREE OIL STANDARD TTA 197/202 1995

PLOTTING IS FROM 0.00 to 55.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.66	54	6	BV	3	10	0.0076
2	1.94	1059	64	BB	5	29	0.1492
3	2.93	375	17	BV	4	27	0.0529
4	4.71	29766	822	BB	4	67	4.1957
5	7.10	16052	270	BV	4	77	2.2627
6	8.16	6491	133	VV	12	44	0.9150
7	8.73	156	6	VB	69	17	0.0221
8	9.34	78737	1477	BV	97	67	11.0986
9	10.70	26291	385	VV	122	106	3.7060
10	12.46	171507	2834	VV	12	91	24.1752
11	13.58	5865	139	VV	65	35	0.8267
12	14.18	24571	508	VB	138	76	3.4634
13	20.26	170	6	BV	14	20	0.0239
14	20.75	271	10	BV	20	22	0.0382
15	21.66	159	5	BB	25	23	0.0224
16	22.14	382	15	BV	33	22	0.0538
17	22.47	1018	26	VV	48	45	0.1435
18	23.83	11540	138	VV	26	104	1.6266
19	25.58	248859	5359	BV	31	73	35.0785
20	26.39	16684	374	VV	369	55	2.3518
21	26.98	59	3	VV	88	15	0.0083
22	27.63	9432	198	VV	85	38	1.3295
23	28.07	15101	450	VV	261	40	2.1286
24	28.84	14551	332	VV	110	51	2.0511
25	30.07	12474	205	VV	89	63	1.7583
26	30.68	14138	315	VV	173	60	1.9928
27	31.68	2072	43	VB	58	58	0.2921
28	33.54	1078	18	BB	41	63	0.1520
29	44.94	102	5	BV	40	16	0.0144
30	45.29	80	4	BV	49	15	0.0112
31	46.49	80	1	BB	63	35	0.0113
32	47.93	259	18	BB	32	17	0.0365

SAMPLE ID = TTL-207 PLOT Squeeze = 10.4 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-13-1995 TIME 12:40:26
TEXT:TEA TREE OIL STANDARD TTL-207 1995



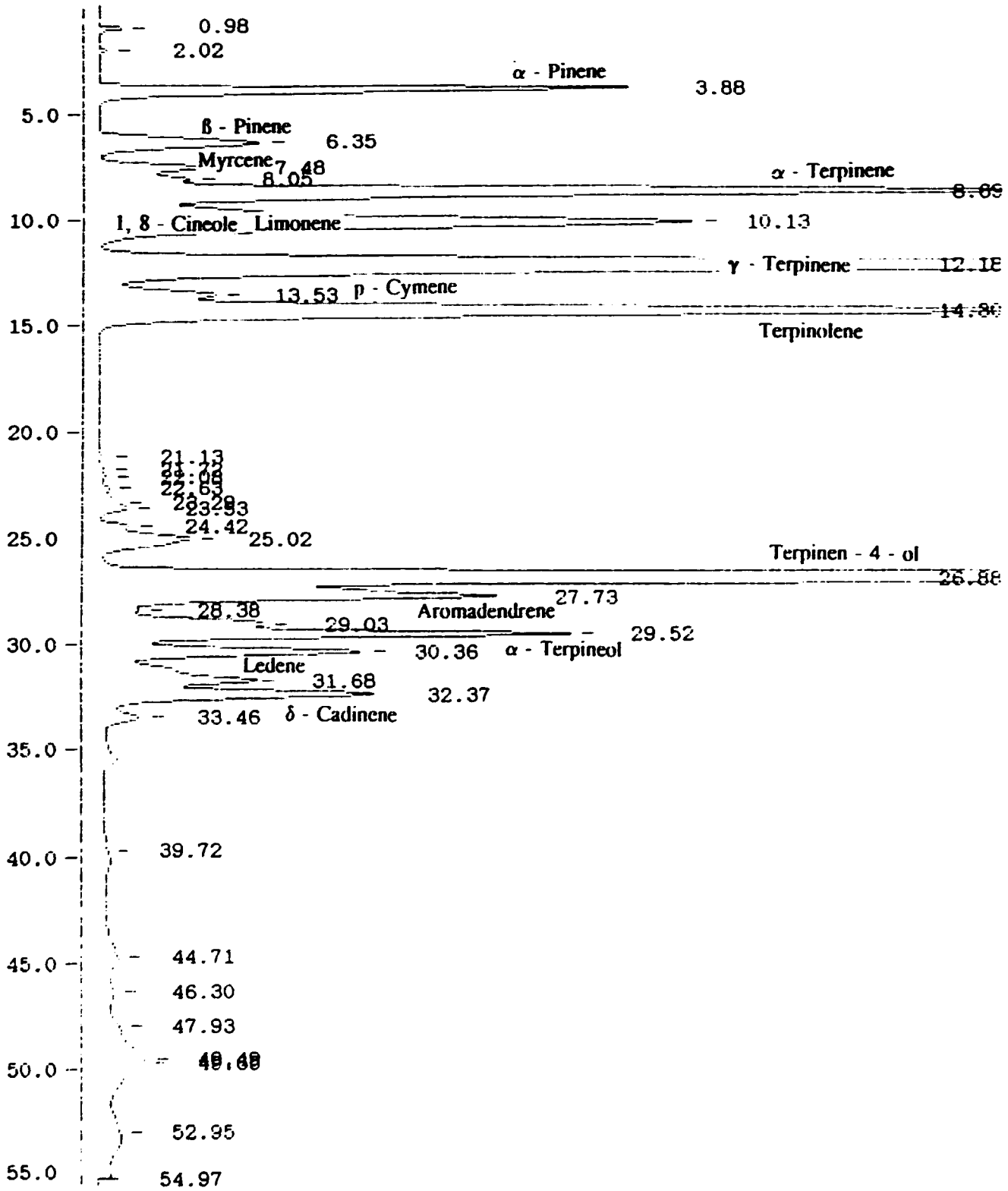
A 3

SAMPLE ID = TTL-207 PLOT Squeeze = 10.4 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-13-1995 TIME 12:40:26
TEXT:TEA TREE OIL STANDARD TTL-207 1995

PLOTTING IS FROM 0.00 to 55.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	1.73	118	7	BB	2	19	0.0182
2	2.59	136	7	BB	1	22	0.0209
3	4.39	17374	457	BB	2	61	2.6787
4	6.77	3353	61	BB	1	67	0.5170
5	8.13	9237	182	BV	4	46	1.4241
6	8.73	7078	163	VV	123	41	1.0912
7	9.38	7242	161	VV	150	47	1.1166
8	10.83	177854	2439	VV	61	120	27.4217
9	12.36	33967	629	VV	32	76	5.2370
10	14.18	289980	5125	VB	20	125	44.7094
11	19.76	1385	34	BV	24	45	0.2135
12	21.57	130	5	BV	35	17	0.0200
13	21.88	369	11	VV	40	34	0.0568
14	22.63	5232	138	VV	30	42	0.8067
15	23.25	1291	32	VB	47	46	0.1990
16	24.85	43840	1102	BV	29	61	6.7594
17	25.68	7215	147	VV	129	60	1.1125
18	27.41	30131	634	BV	63	79	4.6456
19	28.17	4227	100	VV	80	50	0.6517
20	29.08	809	19	VV	54	31	0.1247
21	30.03	6658	129	BV	60	66	1.0265
22	31.00	646	14	VB	49	45	0.0996
23	32.34	318	8	BB	43	32	0.0490

SAMPLE ID = TTA-170 PLOT Squeeze = 10.3 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-13-1995 TIME 14:41:00
TEXT:TEA TREE OIL STANDARD TTA-170 blend



A 4

INTEGRATION REPORT FOR FILE TTA-170

SAMPLE ID = TTA-170 PLOT Squeeze = 10.3 times ATTEN = 2

Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0

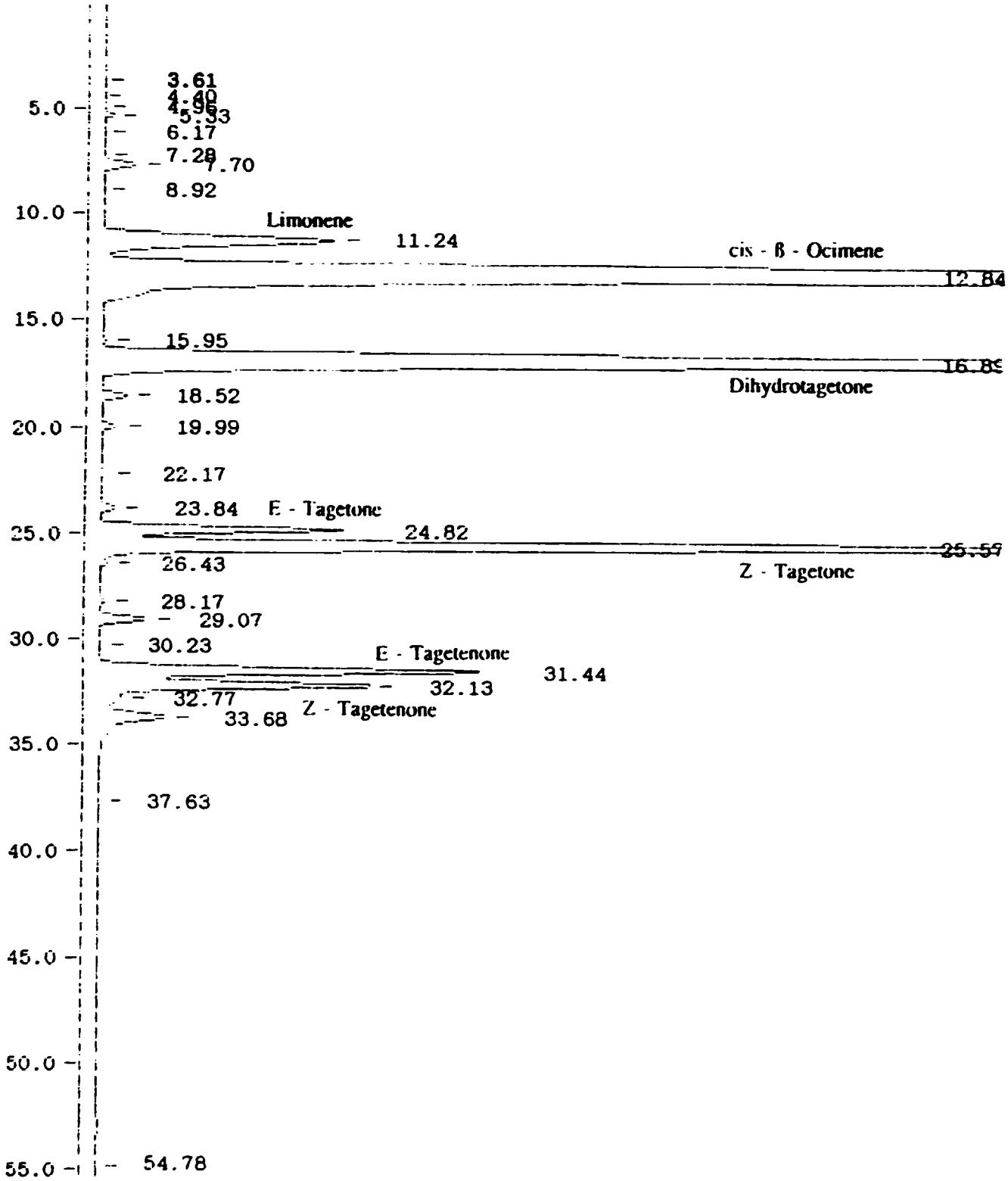
DATE 09-13-1995 TIME 14:41:00

TEXT:TEA TREE OIL STANDARD TTA-170 blend

PLOTTING IS FROM 0.00 to 55.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.98	877	47	BV	2	30	0.1151
2	2.02	278	13	BB	-1	23	0.0365
3	3.88	28854	758	BB	-2	65	3.7894
4	6.35	14596	232	BV	-2	79	1.9169
5	7.48	7436	151	VV	3	45	0.9767
6	8.05	590	25	TAN	83	22	0.0775
7	8.69	65175	1199	TVV	122	90	8.5596
8	10.13	59031	774	VV	116	121	7.7528
9	12.18	150966	2099	VV	5	106	19.8269
10	13.53	6873	134	VV	36	42	0.9027
11	14.30	76135	1289	VB	143	95	9.9991
12	21.13	100	4	BB	-5	25	0.0132
13	21.72	205	7	BV	2	20	0.0269
14	22.08	93	4	BV	10	23	0.0122
15	22.63	146	8	BV	9	14	0.0191
16	23.29	531	15	BV	13	28	0.0697
17	23.53	836	21	VV	31	40	0.1099
18	24.43	1253	37	BV	9	25	0.1646
19	25.03	7733	107	VB	40	78	1.0157
20	26.88	248591	5440	BV	11	72	32.6483
21	27.73	17432	367	VV	310	61	2.2894
22	28.38	75	4	VV	57	16	0.0099
23	29.03	9207	185	VV	55	38	1.2092
24	29.52	18456	510	VV	227	45	2.4239
25	30.36	14647	311	VV	77	55	1.9236
26	31.68	11625	175	VV	56	70	1.5268
27	32.37	14771	304	VV	121	63	1.9399
28	33.46	2173	42	VV	28	60	0.2854
29	39.72	76	3	BV	13	18	0.0100
30	44.71	56	3	BV	27	14	0.0074
31	46.30	89	3	BV	21	21	0.0117
32	47.93	149	6	BV	26	20	0.0196
33	49.49	2221	30	BV	39	62	0.2917
34	49.65	65	1	VB	68	41	0.0085
35	52.95	80	3	BV	30	19	0.0106

SAMPLE ID = TAG-95 PLOT Squeeze = 10.3 times ATTEN = 2
Sampling Frequency (2) Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-13-1995 TIME 15:40:59
TEXT:TAGETES OIL STANDARD TAG-95 22/06/95



INTEGRATION REPORT FOR FILE TAG-95

SAMPLE ID = TAG-95 PLOT Squeeze = 10.3 times ATTEN = 2

Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0

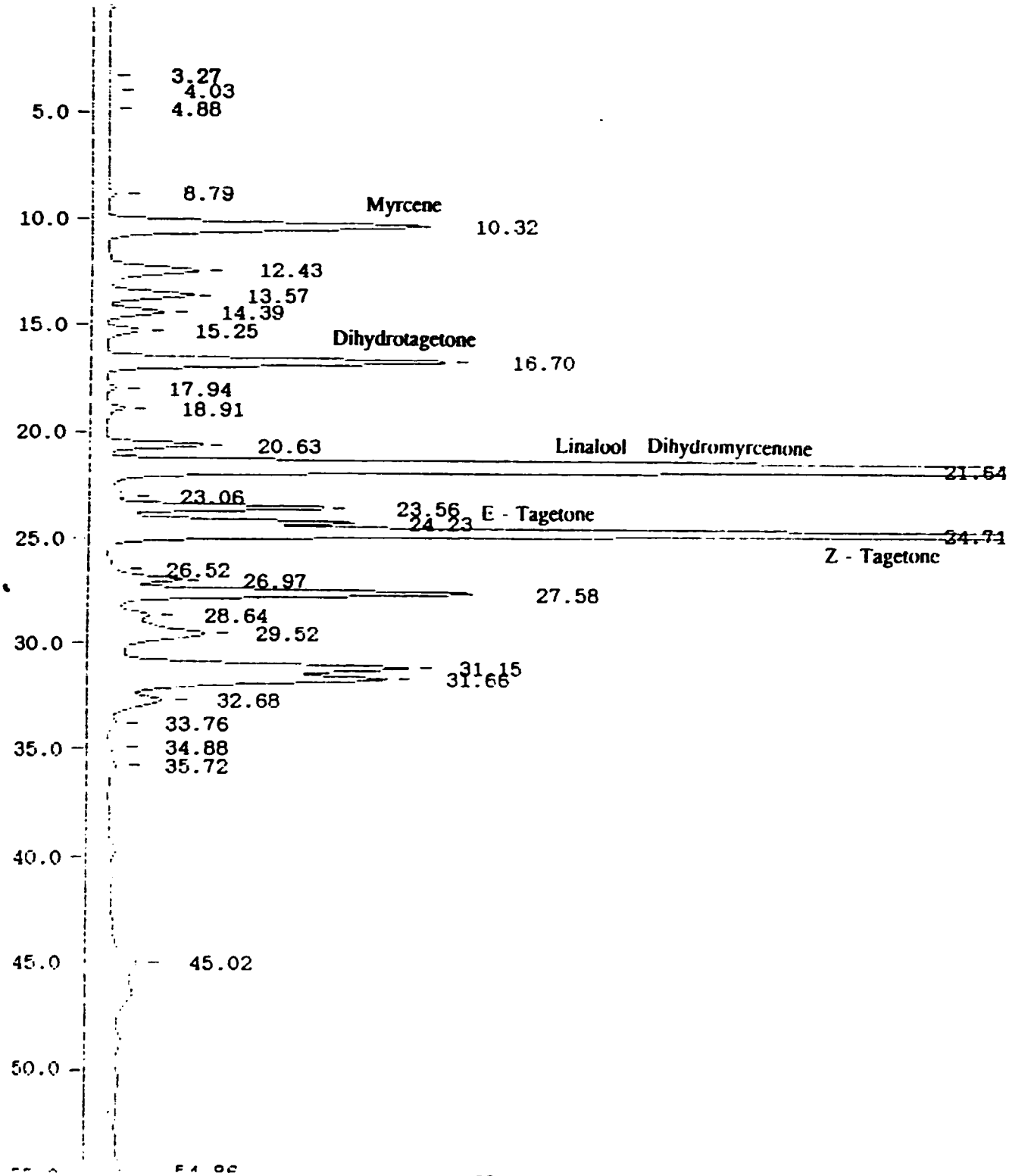
DATE 09-13-1995 TIME 15:40:59

TEXT:TAGETES OIL STANDARD TAG-95 22/06/95

PLOTTING IS FROM 0.00 to 55.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.16	138	6	BB	-7	16	0.0251
2	3.61	177	6	BV	-11	27	0.0323
3	4.40	77	4	BV	-11	14	0.0142
4	4.96	73	4	BB	-10	19	0.0134
5	5.33	699	22	BB	-4	37	0.1278
6	6.17	99	4	BB	-10	24	0.0180
7	7.28	293	12	BV	-12	23	0.0535
8	7.70	2483	51	VB	2	62	0.4540
9	8.92	158	5	BB	-11	28	0.0289
10	11.24	24004	342	BV	-13	85	4.3886
11	12.84	221327	3013	VV	9	145	40.4653
12	15.95	405	11	TAN	-16	38	0.0741
13	16.89	150000	2505	TVV	1	148	27.4246
14	18.52	2218	47	BB	-12	52	0.4055
15	19.99	1414	33	BV	-4	47	0.2585
16	22.17	194	5	BB	-10	23	0.0354
17	23.84	1601	30	BV	-7	49	0.2927
18	24.82	15032	351	BV	-3	47	2.7484
19	25.57	80654	1952	VV	63	105	14.7460
20	26.43	354	22	TAN	7	34	0.0648
21	28.18	331	13	BB	-9	26	0.0605
22	29.07	2814	68	BV	5	45	0.5145
23	30.23	62	3	BB	-1	20	0.0114
24	31.44	24392	544	BV	1	61	4.4595
25	32.13	13253	330	VV	91	51	2.4230
26	32.77	160	5	VB	31	28	0.0292
27	33.68	4491	83	BV	18	62	0.8211
28	37.63	53	4	BV	-1	10	0.0097

SAMPLE ID = LIP-JAV PLOT Squeeze = 10.3 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-14-1995 TIME 10:28:43
TEXT:LIPPIA JAVANICA OIL BATCH Z 203



INTEGRATION REPORT FOR FILE LIP-JAV

SAMPLE ID = LIP-JAV PLOT Squeeze = 10.3 times ATTEN = 2

Sampling Frequency (2) Hz Tg/Pk/Sp/Wth= 20 3 .1 0

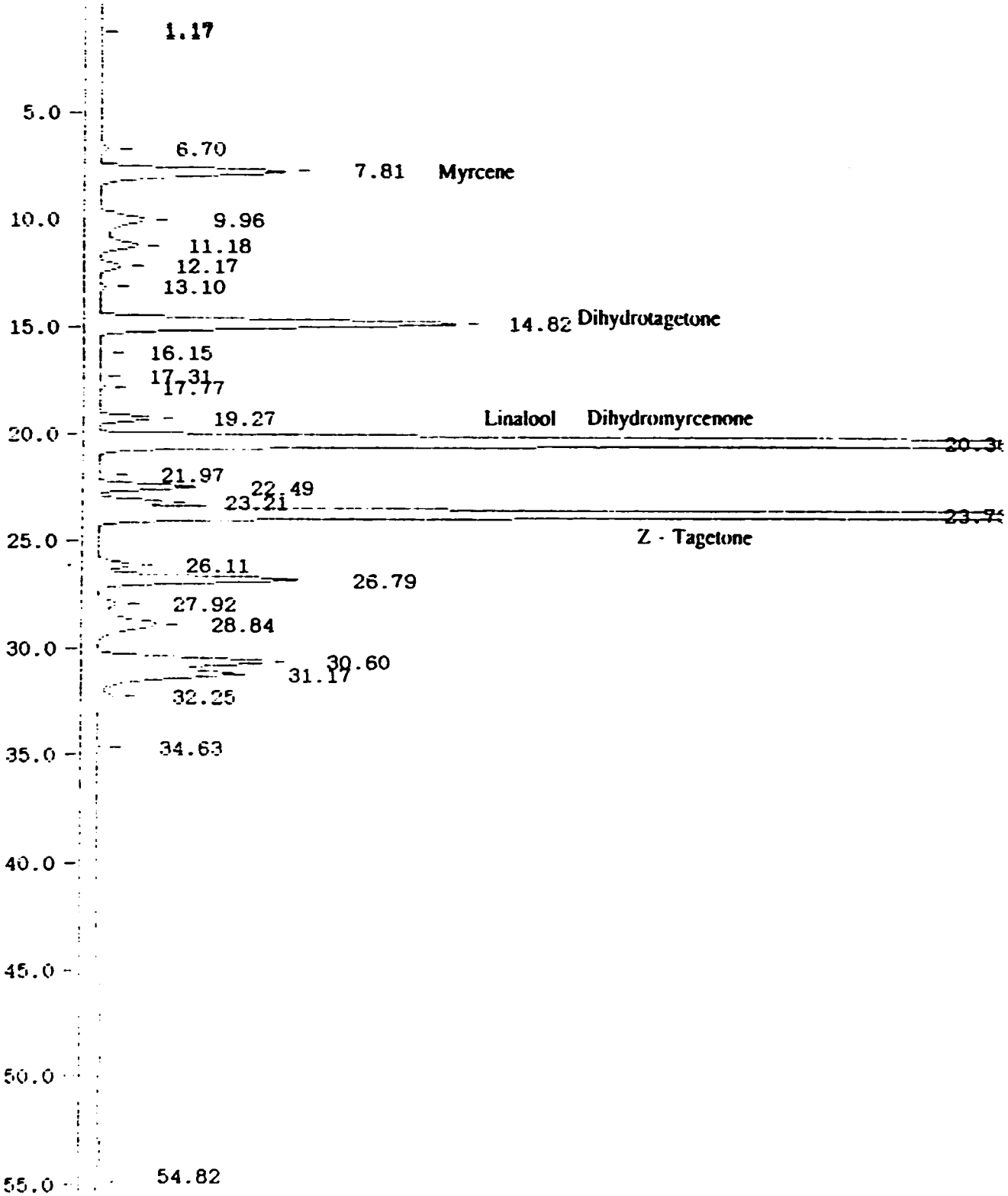
DATE 09-14-1995 TIME 10:28:43

TEXT:LIPPIA JAVANICA OIL BATCH Z 203

PLOTTING IS FROM 0.00 to 55.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.06	177	16	BV	-6	7	0.0416
2	3.27	91	5	BB	-4	19	0.0213
3	4.03	260	9	BB	-6	34	0.0610
4	4.88	58	3	BB	-5	16	0.0137
5	8.79	954	17	BB	-4	56	0.2239
6	10.33	26525	453	BB	-6	90	6.2258
7	12.43	6797	126	BV	6	70	1.5955
8	13.58	5461	118	VV	7	54	1.2817
9	14.39	3544	79	VV	6	52	0.8317
10	15.25	2509	49	VV	-0	58	0.5890
11	16.70	24157	503	BB	-5	77	5.6701
12	17.94	979	23	BB	-5	43	0.2298
13	18.91	1461	35	BV	-7	41	0.3429
14	20.63	5991	144	BV	-2	50	1.4063
15	21.64	191321	4459	VV	8	84	44.9068
16	23.06	246	10	BV	21	23	0.0577
17	23.56	11230	306	VV	23	41	2.6360
18	24.23	10548	311	VV	40	29	2.4757
19	24.71	66568	1838	VB	252	71	15.6249
20	26.52	251	10	BV	9	22	0.0588
21	26.97	3801	92	VV	20	38	0.8921
22	27.58	20720	464	VV	53	62	4.8633
23	28.64	1971	42	VV	26	39	0.4627
24	29.52	7326	101	VB	54	86	1.7196
25	31.15	21388	402	BV	32	53	5.0203
26	31.66	7143	177	VV	285	57	1.6766
27	32.68	2790	48	VB	47	65	0.6550
28	33.76	64	3	BB	16	23	0.0150
29	34.88	198	6	BB	9	32	0.0465
30	35.72	187	6	BV	14	23	0.0438
31	45.02	1324	26	BV	25	43	0.3107

SAMPLE ID = A25 PLOT Squeeze = 10.3 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-14-1995 TIME 13:33:06
TEXT:ZIMBANI OIL - 6/1/95



INTEGRATION REPORT FOR FILE A25

SAMPLE ID = A25 PLOT Squeeze = 10.3 times ATTEN = 2

Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0

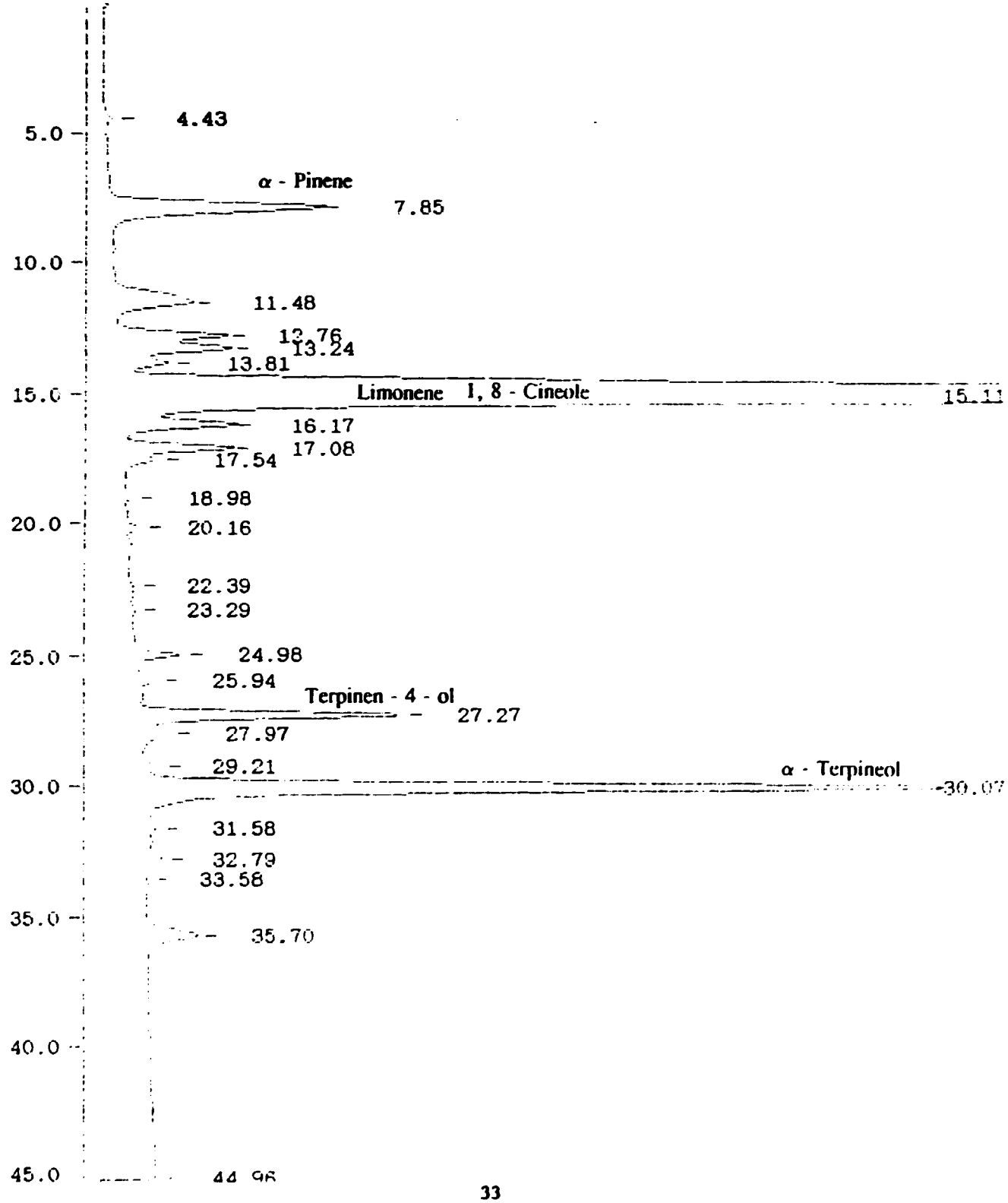
DATE 09-14-1995 TIME 13:33:06

TEXT:ZIMBANI OIL - 6/1/95

PLOTTING IS FROM 0.00 to 55.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.11	205	13	BV	-12	10	0.0707
2	1.17	110	7	BV	-13	17	0.0378
3	6.70	842	18	BB	-3	47	0.2899
4	7.81	15054	269	BV	-5	83	5.1806
5	9.96	3677	61	BB	-3	70	1.2653
6	11.18	2647	49	BB	12	58	0.9110
7	12.17	1885	35	BV	-2	58	0.6486
8	13.10	171	7	BB	-3	22	0.0590
9	14.83	28973	516	BV	-9	84	9.9706
10	16.15	435	15	BV	-13	23	0.1496
11	17.31	321	11	BV	-14	26	0.1106
12	17.78	686	18	BV	-6	39	0.2361
13	19.27	4037	91	BV	-12	52	1.3893
14	20.36	107703	2373	VB	-9	89	37.0643
15	21.97	528	16	BV	-6	30	0.1817
16	22.49	5220	138	VV	-2	43	1.7964
17	23.21	1148	45	TAN	2	25	0.3950
18	23.73	78958	1963	TVB	74	103	27.1722
19	26.11	1934	43	BV	2	39	0.6655
20	26.79	11999	272	VB	19	61	4.1293
21	27.92	1386	28	BV	1	40	0.4768
22	28.84	5354	76	VV	16	87	1.8424
23	30.60	13247	239	BV	2	56	4.5586
24	31.18	3848	94	VV	130	60	1.3241
25	32.25	108	4	BB	12	20	0.0372
26	34.63	109	4	BB	0	23	0.0375

SAMPLE ID = A18 PLOT Squeeze = 8.4 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-14-1995 TIME 08:49:59
TEXT:EUCALYPTUS RADIATA WAI 95564



B 1

INTEGRATION REPORT FOR FILE A18

SAMPLE ID = A18 PLOT Squeeze = 8.4 times ATTEN = 2

Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0

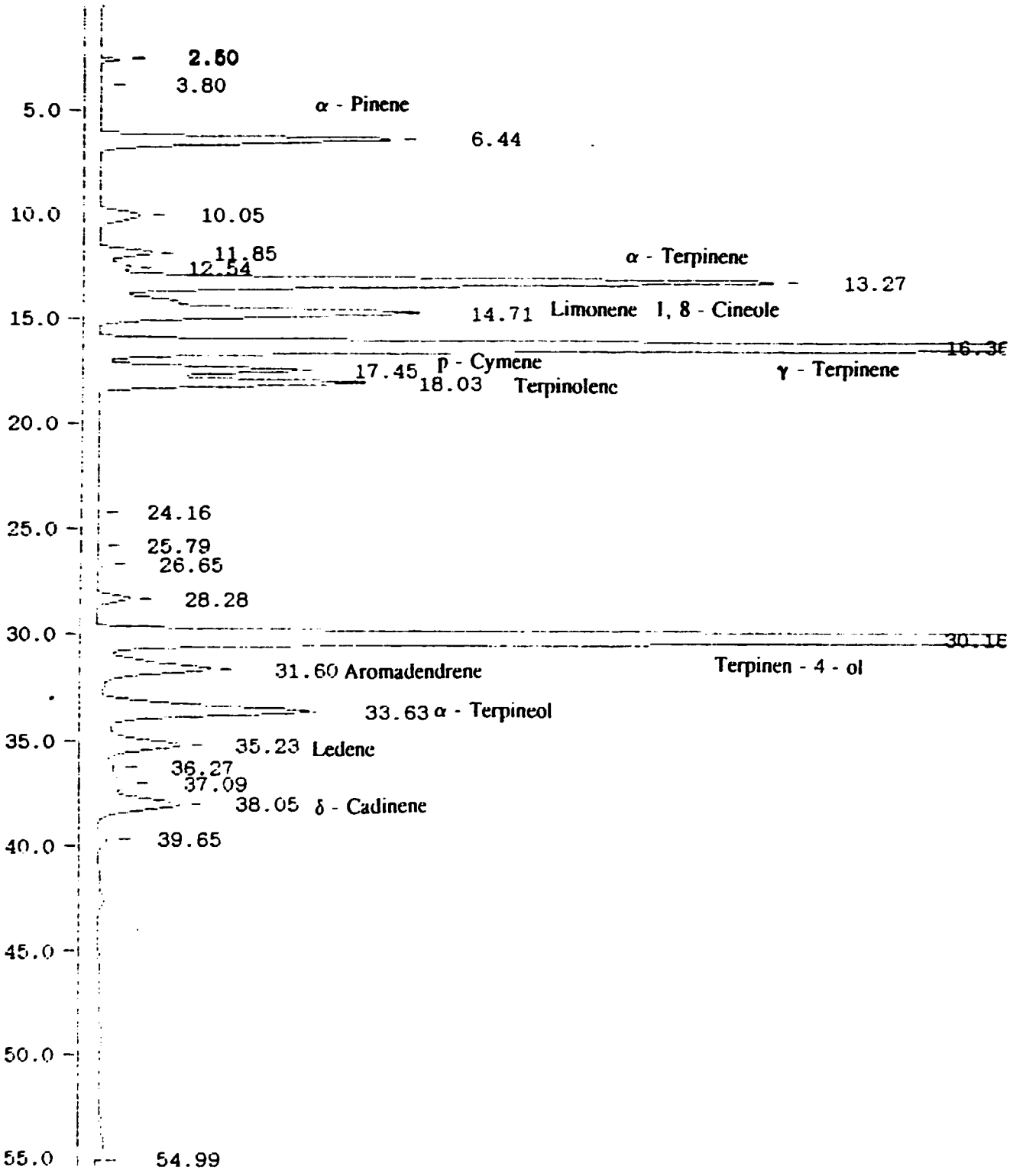
DATE 09-14-1995 TIME 08:49:59

TEXT:EUCALYPTUS RADIATA WAI 95564

PLOTTING IS FROM 0.00 to 45.05 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.13	288	12	BV	-1	27	0.0517
2	4.43	189	7	BB	4	26	0.0340
3	7.85	17042	305	BB	12	86	3.0641
4	11.48	8352	112	BB	19	89	1.5017
5	12.76	6537	157	BV	25	37	1.1754
6	13.24	3234	95	VV	112	35	0.5814
7	13.81	1195	37	VV	71	34	0.2148
8	15.11	427631	7527	VV	45	155	76.8841
9	16.17	4942	160	TAN	84	46	0.8885
10	17.08	6235	154	VV	37	43	1.1210
11	17.54	446	16	VB	70	32	0.0802
12	18.98	147	5	BB	33	28	0.0264
13	20.16	599	16	BV	37	37	0.1077
14	22.39	68	3	BV	44	13	0.0121
15	23.29	75	4	BV	46	15	0.0134
16	24.98	2127	61	BB	52	44	0.3823
17	25.94	621	19	BB	57	34	0.1116
18	27.27	14359	369	BV	60	52	2.5816
19	27.97	842	19	VB	81	49	0.1513
20	29.21	442	13	TAN	63	35	0.0794
21	30.07	54727	1138	TVV	74	132	9.8395
22	31.58	71	3	BB	75	20	0.0128
23	32.79	826	18	BB	75	50	0.1485
24	33.58	58	3	BV	67	17	0.0105
25	35.70	4549	72	BB	68	79	0.8179
26	44.96	602	16	BB	79	8	0.1082

SAMPLE ID = A8 PLOT Squeeze = 10.5 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-13-1995 TIME 09:38:01
TEXT:TEA TREE OIL STANDARD WAI 95735



INTEGRATION REPORT FOR FILE A8 B 2

SAMPLE ID = A8 PLOT Squeeze = 10.5 times ATTEN = 2

Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0

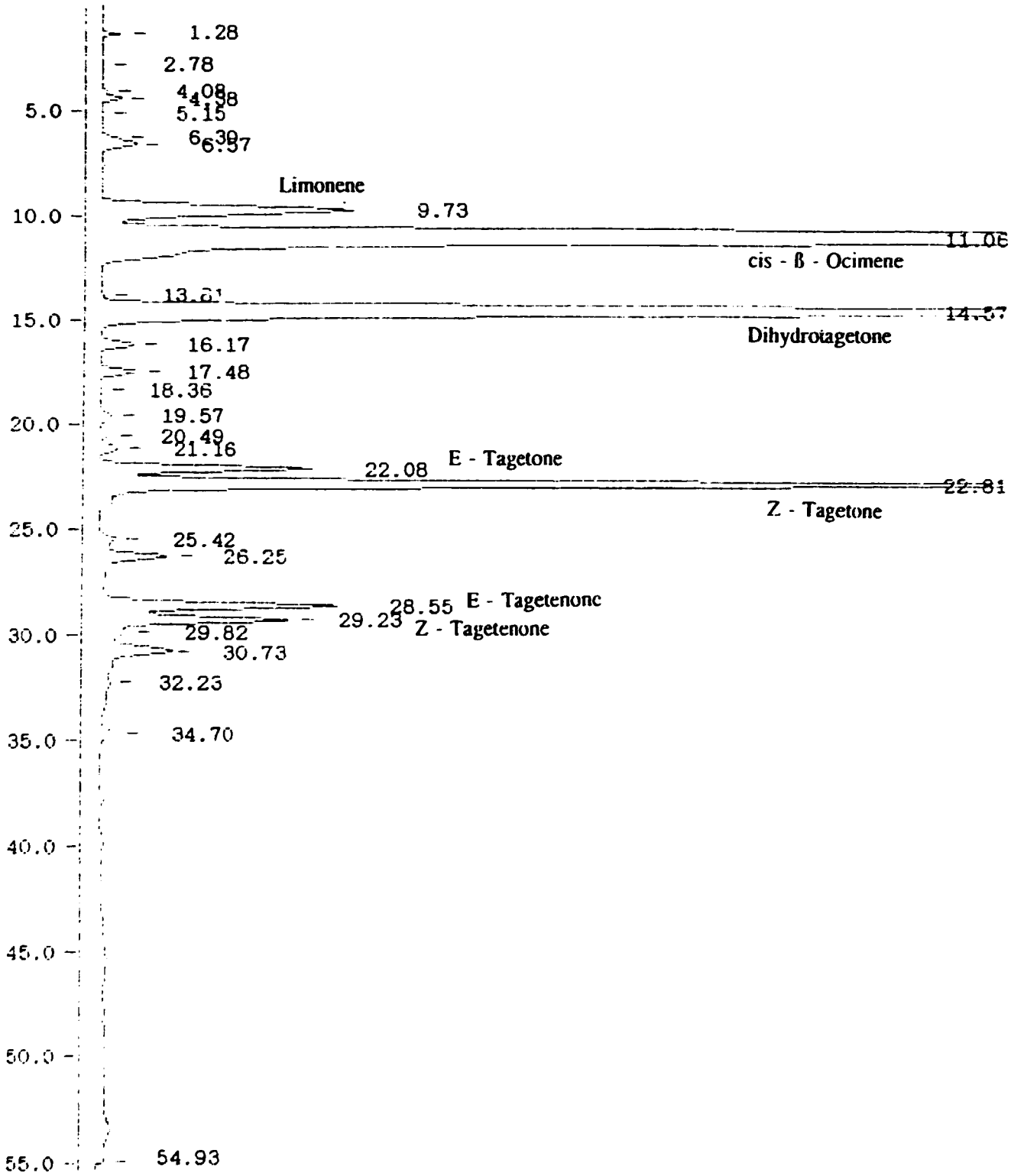
DATE 09-13-1995 TIME 09:38:01

TEXT:TEA TREE OIL STANDARD WAI 95735

PLOTTING IS FROM 0.00 to 55.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.18	344	13	BB	-4	29	0.0674
2	2.50	835	43	BB	-6	31	0.1636
3	3.80	257	11	BV	-5	26	0.0504
4	6.44	21043	426	BB	-8	77	4.1216
5	10.05	4895	68	BB	-9	79	0.9587
6	11.85	4981	87	BV	-10	57	0.9756
7	12.54	1072	28	VV	18	30	0.2100
8	13.27	49480	928	VV	36	68	9.6915
9	14.71	28593	434	VB	41	106	5.6004
10	16.36	115927	2259	BV	-8	82	22.7062
11	17.45	12276	270	VV	17	43	2.4045
12	18.03	12222	297	VB	117	61	2.3938
13	24.16	71	4	BB	-4	17	0.0139
14	25.79	66	3	BB	-6	28	0.0129
15	26.65	151	8	BV	-1	17	0.0296
16	28.28	2264	48	BB	0	52	0.4434
17	30.16	212416	4212	BV	0	173	41.6051
18	31.60	9832	151	TAN	26	87	1.9258
19	33.63	19319	285	BB	10	97	3.7839
20	35.23	6889	102	BV	22	87	1.3494
21	36.27	224	6	VV	19	28	0.0439
22	37.09	118	4	BB	30	28	0.0231
23	38.05	6908	100	BB	33	79	1.3531
24	39.65	312	11	BV	6	28	0.0611
25	54.99	57	9	BB	14	5	0.0111

SAMPLE ID = TAG-WAI PLOT Squeeze = 10.5 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-14-1995 TIME 11:30:59
TEXT:TAGETES OIL WAI 93404



INTEGRATION REPORT FOR FILE TAG-WAI

SAMPLE ID = TAG-WAI PLOT Squeeze = 10.5 times ATTEN = 2

Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0

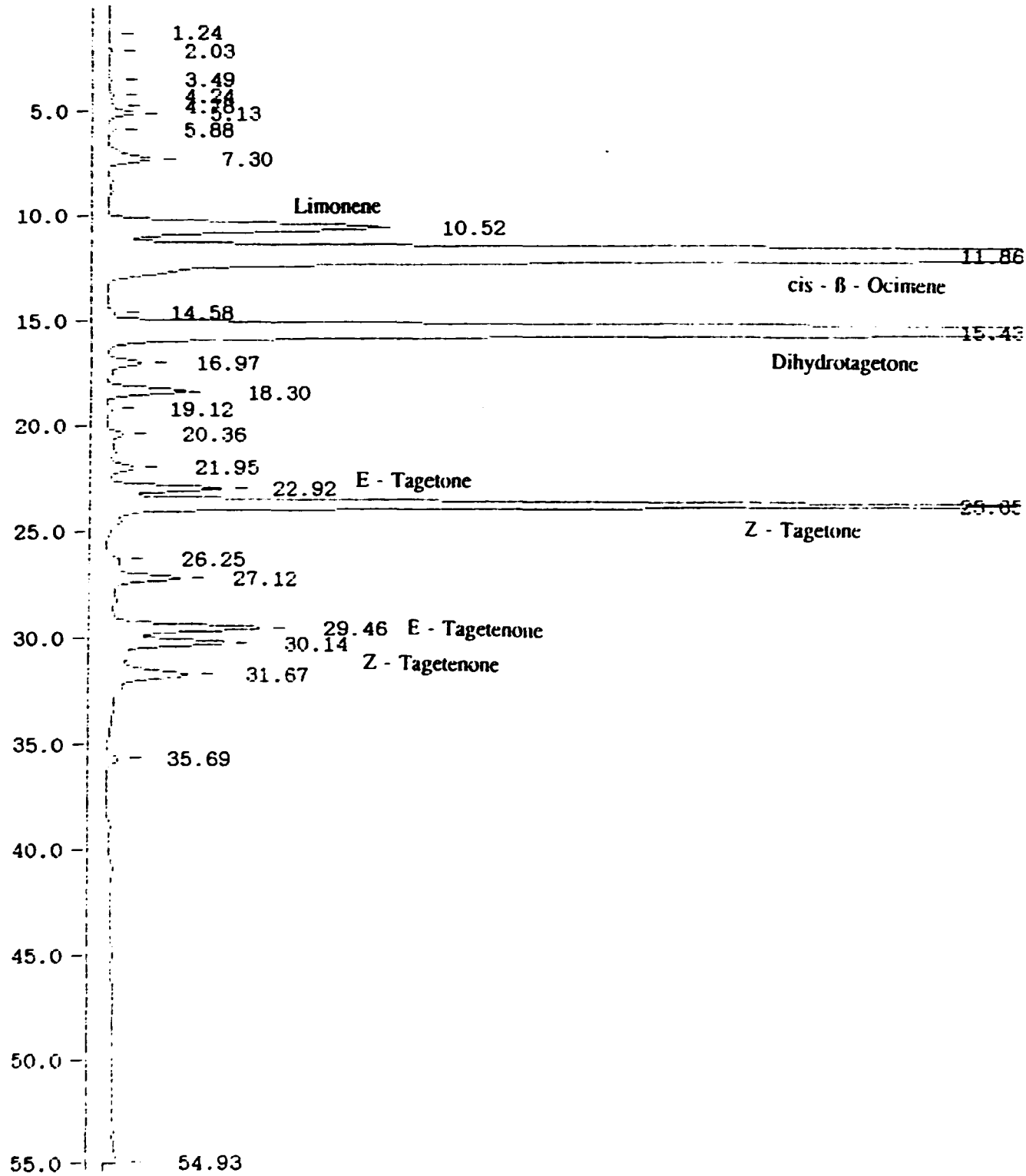
DATE 09-14-1995 TIME 11:30:59

TEXT:TAGETES OIL WAI 93404

PLOTTING IS FROM 0.00 to 55.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	1.28	735	39	BV	-3	29	0.1496
2	2.78	82	4	BB	-3	19	0.0167
3	4.08	60	3	BB	-0	18	0.0123
4	4.38	843	28	BV	7	37	0.1718
5	5.15	50	3	BB	-2	19	0.0102
6	6.30	638	30	BV	-3	26	0.1299
7	6.57	1440	37	VB	24	46	0.2932
8	9.73	22375	351	BV	-4	78	4.5566
9	11.06	241100	3742	VB	32	134	49.1001
10	13.81	138	5	TAN	-5	28	0.0281
11	14.58	115470	2079	TVB	4	133	23.5156
12	16.17	2759	55	BV	-4	53	0.5618
13	17.48	2684	59	BB	-3	52	0.5466
14	18.36	104	6	BV	-3	15	0.0211
15	19.57	515	13	BB	-5	35	0.1049
16	20.49	256	9	BV	5	26	0.0522
17	21.16	879	22	BB	12	40	0.1791
18	22.08	12308	295	BV	1	46	2.5066
19	22.81	55946	1374	VV	56	66	11.3934
20	25.42	1015	25	BV	3	31	0.2066
21	26.25	3673	87	BB	14	53	0.7479
22	28.55	14457	328	BV	10	52	2.9441
23	29.23	8237	216	VV	71	46	1.6775
24	29.82	255	8	VV	37	32	0.0519
25	30.73	4246	83	BV	29	60	0.8647
26	32.23	99	4	BV	16	23	0.0202
27	34.70	674	15	BB	8	41	0.1373

SAMPLE ID = TAG-CAV PLOT Squeeze = 10.5 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-14-1995 TIME 12:30:43
TEXT:TAGETE OIL-CAVALLIER FRERES - QUATITY TARGET SAMPLE : 24/2/94

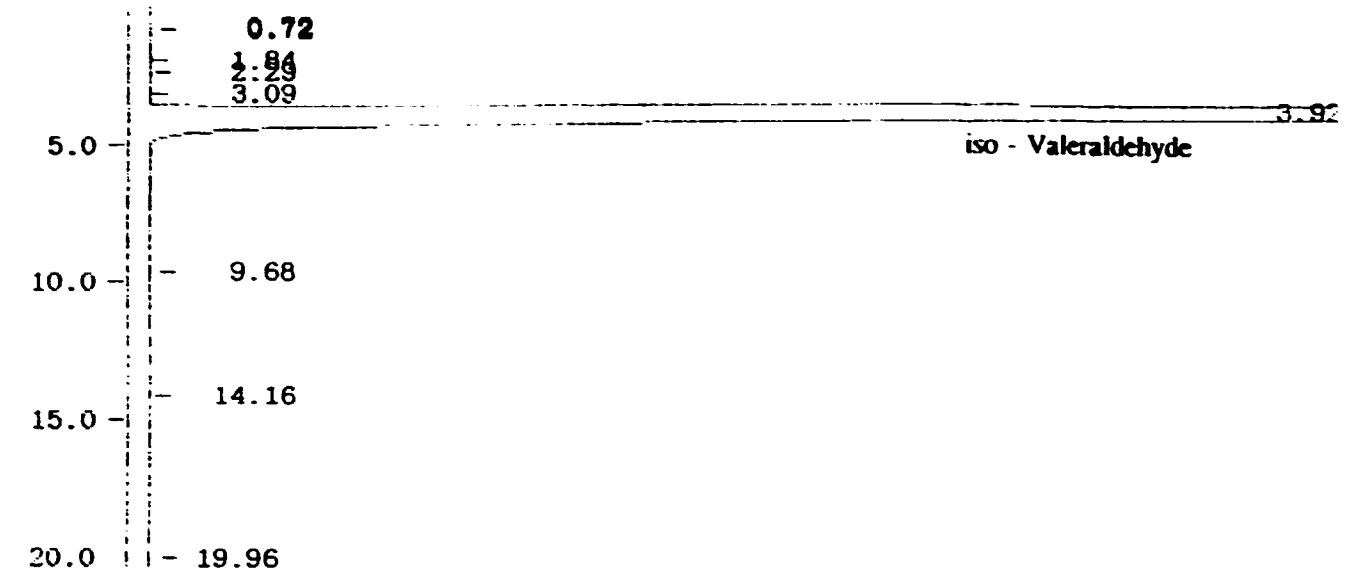


SAMPLE ID = TAG-CAV PLOT Squeeze = 10.5 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-14-1995 TIME 12:30:43
TEXT:TAGETE OIL-CAVALLIER FRERES - QUATITY TARGET SAMPLE ; 24/2/94

PLOTTING IS FROM 0.00 to 55.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	1.24	187	8	BV	-6	13	0.0347
2	2.03	100	5	BB	2	20	0.0185
3	3.49	170	6	BV	1	27	0.0315
4	4.24	61	4	BB	1	16	0.0112
5	4.78	180	8	BV	4	18	0.0335
6	5.13	1036	34	VB	11	36	0.1923
7	5.88	162	6	BB	2	25	0.0301
8	7.30	3776	65	BB	-0	77	0.7006
9	10.53	24321	383	BV	1	71	4.5122
10	11.86	257660	4028	VB	36	130	47.8030
11	14.58	166	6	TAN	-1	26	0.0309
12	15.43	158857	2853	TVV	10	134	29.4724
13	16.97	2485	50	VV	-0	54	0.4610
14	18.30	5244	113	BV	1	62	0.9729
15	19.12	68	5	BV	2	11	0.0126
16	20.36	891	21	BB	-1	44	0.1652
17	21.95	218	8	BB	6	31	0.0404
18	22.93	6471	157	BV	7	47	1.2005
19	23.65	53603	1304	VV	42	67	9.9448
20	26.25	144	6	BB	8	23	0.0267
21	27.12	3576	86	BB	24	52	0.6635
22	29.46	9579	211	BV	14	49	1.7771
23	30.14	4954	128	VV	56	46	0.9190
24	31.68	5016	93	BV	28	62	0.9305
25	35.69	80	3	BB	11	22	0.0148

```
SAMPLE ID = A33                PLOT Squeeze =  10.5  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-15-1995                TIME 10:25:23
 TEXT:ISO-VALERALDEHYDE STANDARD
```

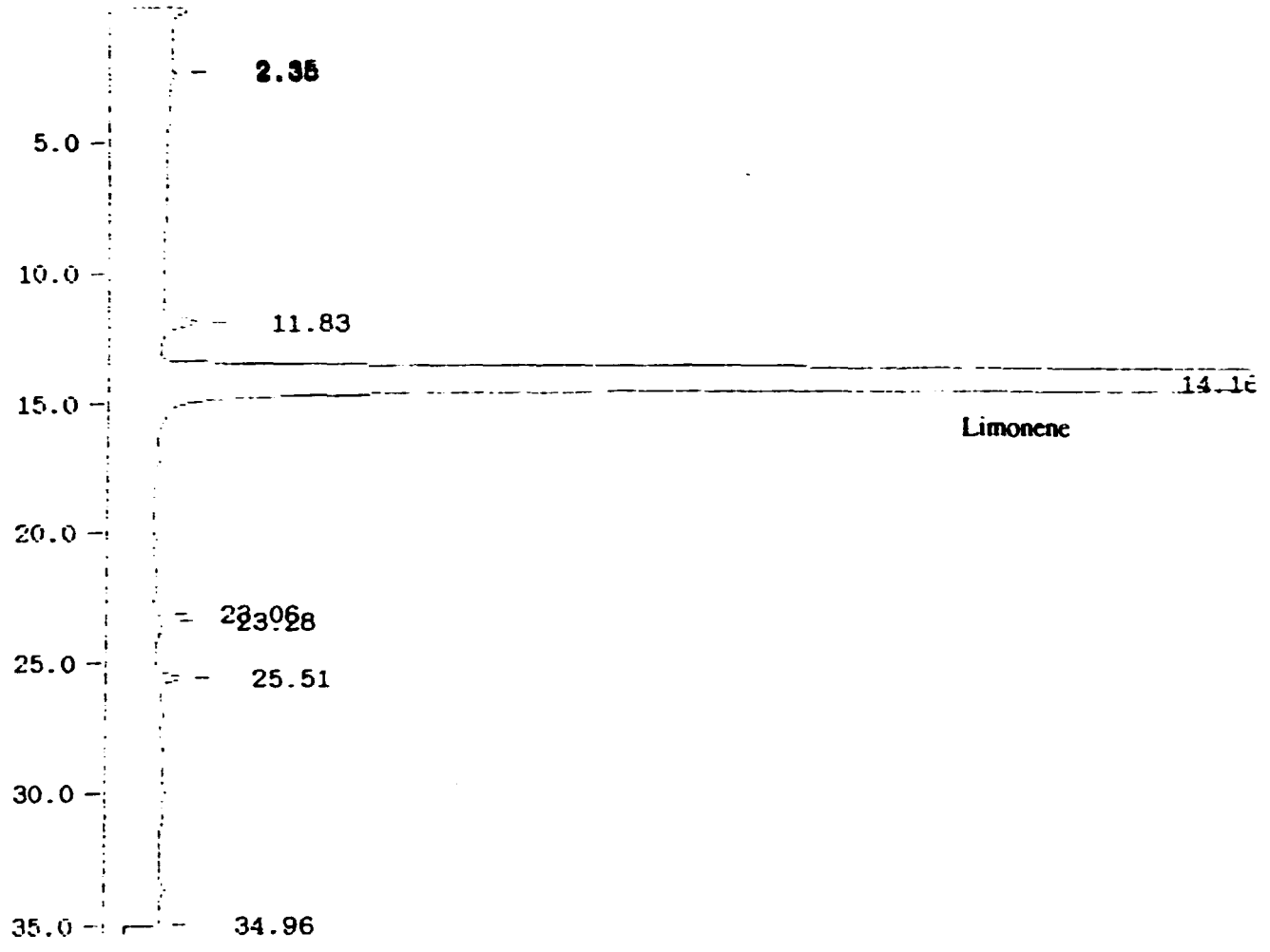



```
          INTEGRATION REPORT FOR FILE A33
SAMPLE ID = A33                PLOT Squeeze =  10.5  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-15-1995                TIME 10:25:23
 TEXT:ISO-VALERALDEHYDE STANDARD
```

PLOTTING IS FROM 0.00 to 20.03 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.16	91	4	BV	1	23	0.0239
2	0.72	173	25	BB	-13	13	0.0454
3	1.84	71	4	BB	-15	17	0.0186
4	2.29	63	3	BV	-12	17	0.0167
5	3.09	55	3	BV	-15	14	0.0143
6	3.92	380402	9109	BB	-14	101	99.8135
7	9.68	137	5	BB	-12	23	0.0359
8	14.16	121	4	BB	-19	29	0.0317

SAMPLE ID = LIMONENE PLOT Squeeze = 10.5 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-15-1995 TIME 12:32:46
TEXT:LIMONENE STANDARD

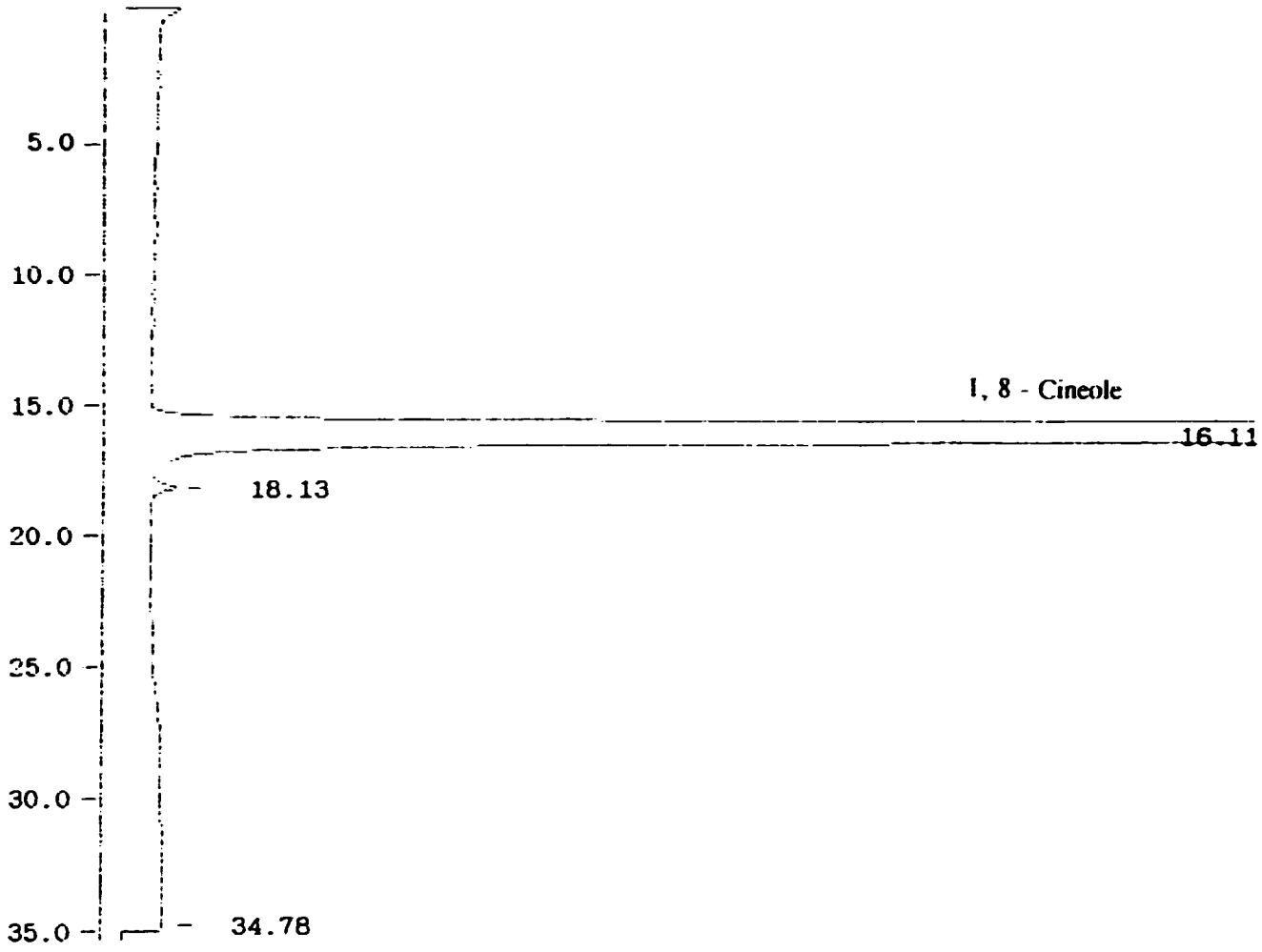


INTEGRATION REPORT FOR FILE LIMONENE
SAMPLE ID = LIMONENE PLOT Squeeze = 10.5 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-15-1995 TIME 12:32:46
TEXT:LIMONENE STANDARD

PLOTTING IS FROM 0.00 to 35.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.12	172	8	BB	61	23	0.0277
2	2.35	93	6	BB	48	17	0.0150
3	11.83	1929	38	BB	41	59	0.3115
4	14.16	615824	9943	BB	39	121	99.4647
5	23.06	77	5	BV	34	14	0.0125
6	23.28	192	7	VV	40	22	0.0310
7	25.51	852	26	BB	37	41	0.1376

```
SAMPLE ID = CINEOLE          PLOT Squeeze =  10.5  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-15-1995              TIME 11:47:05
 TEXT:CINEOLE STANDARD
```

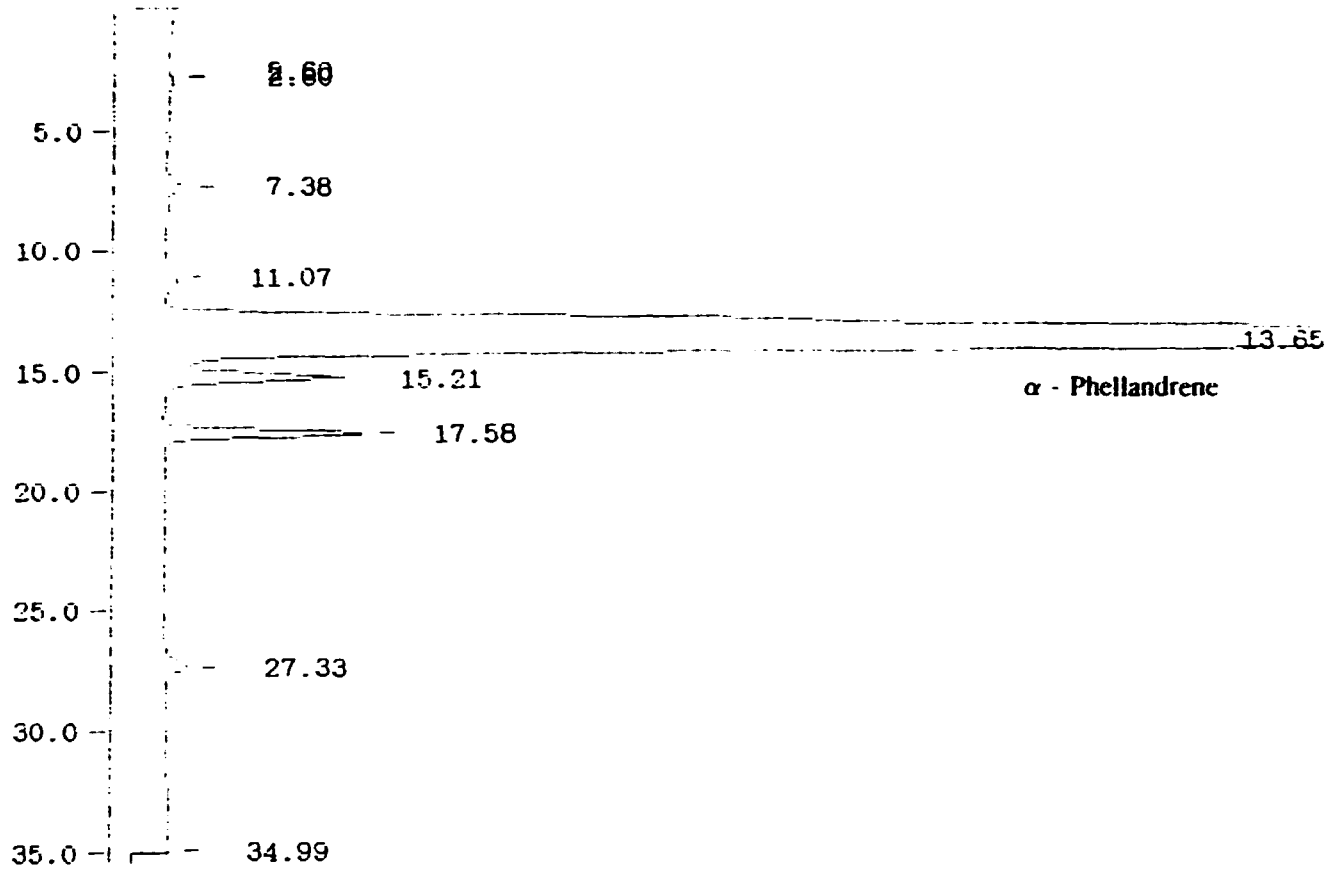



```
          INTEGRATION REPORT FOR FILE CINEOLE
SAMPLE ID = CINEOLE          PLOT Squeeze =  10.5  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-15-1995              TIME 11:47:05
 TEXT:CINEOLE STANDARD

:     PLOTTING IS FROM    0.00  to   35.00   MINUTES
```

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.11	148	6	BB	60	31	0.0288
2	16.11	512273	9023	BB	31	148	99.8119
3	18.13	817	23	BB	39	37	0.1593

```
SAMPLE ID = PHELLAND          PLOT Squeeze =  12  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-15-1995               TIME 14:05:34
 TEXT:PHELLANDRENE STANDARD
```

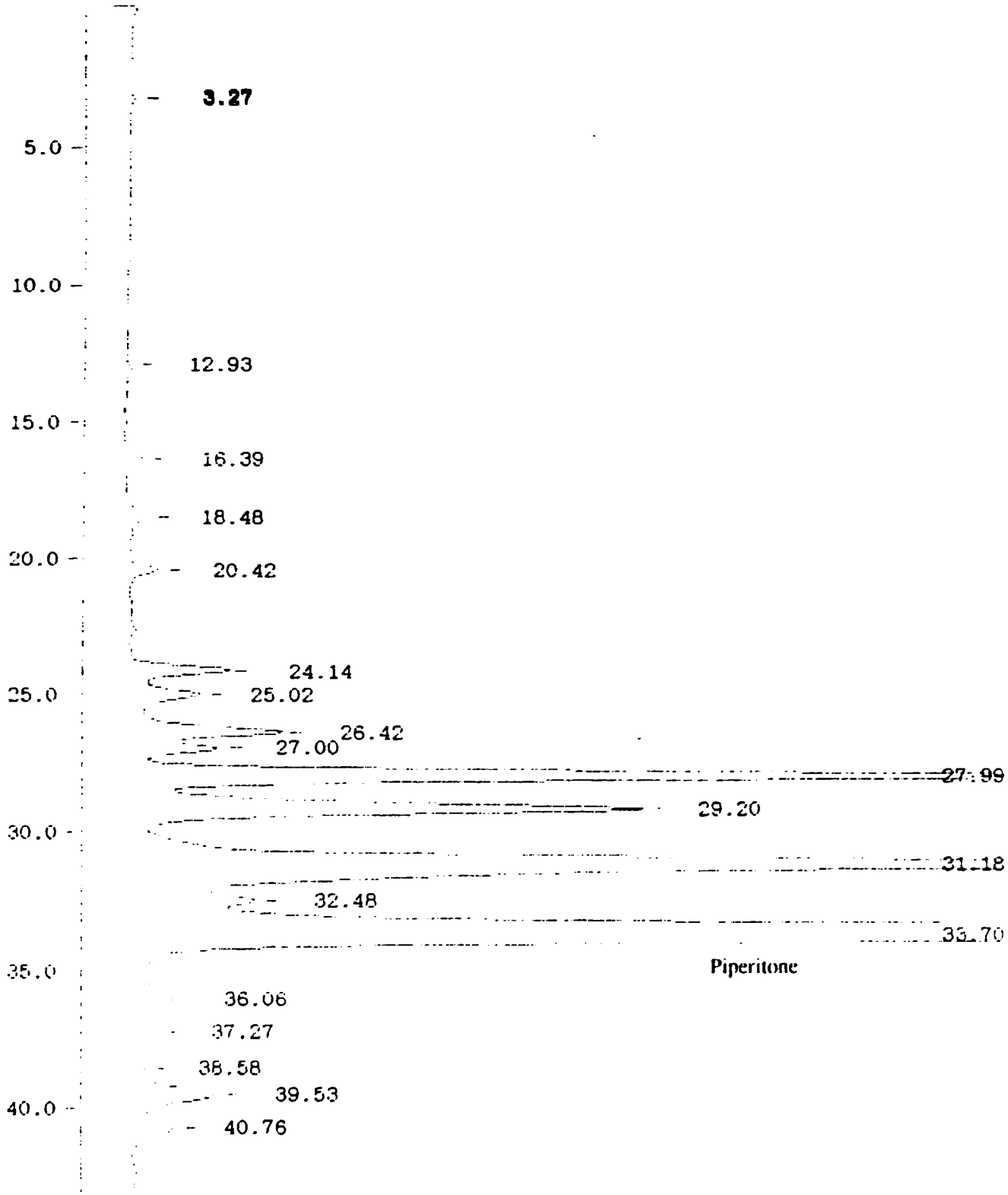



```
          INTEGRATION REPORT FOR FILE PHELLAND
SAMPLE ID = PHELLAND          PLOT Squeeze =  12  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-15-1995               TIME 14:05:34
 TEXT:PHELLANDRENE STANDARD
```

PLOTTING IS FROM 0.00 to 35.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.13	108	6	BB	50	23	0.0166
2	2.60	84	4	BB	38	20	0.0128
3	7.38	889	17	BV	37	52	0.1358
4	11.08	61	4	BV	42	13	0.0093
5	13.65	635047	9594	BV	38	146	97.0299
6	15.21	7582	159	BB	66	65	1.1585
7	17.58	9473	216	BB	34	62	1.4473
8	27.33	1145	21	BB	40	53	0.1749
9	34.99	98	18	BB	42	4	0.0149

SAMPLE ID = PIP'TONE PLOT Squeeze = 8 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-15-1995 TIME 14:46:18
TEXT:PIPERITONE STANDARD



INTEGRATION REPORT FOR FILE PIP'TONE

SAMPLE ID = PIP'TONE PLOT Squeeze = 8 times ATTEN = 2

Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0

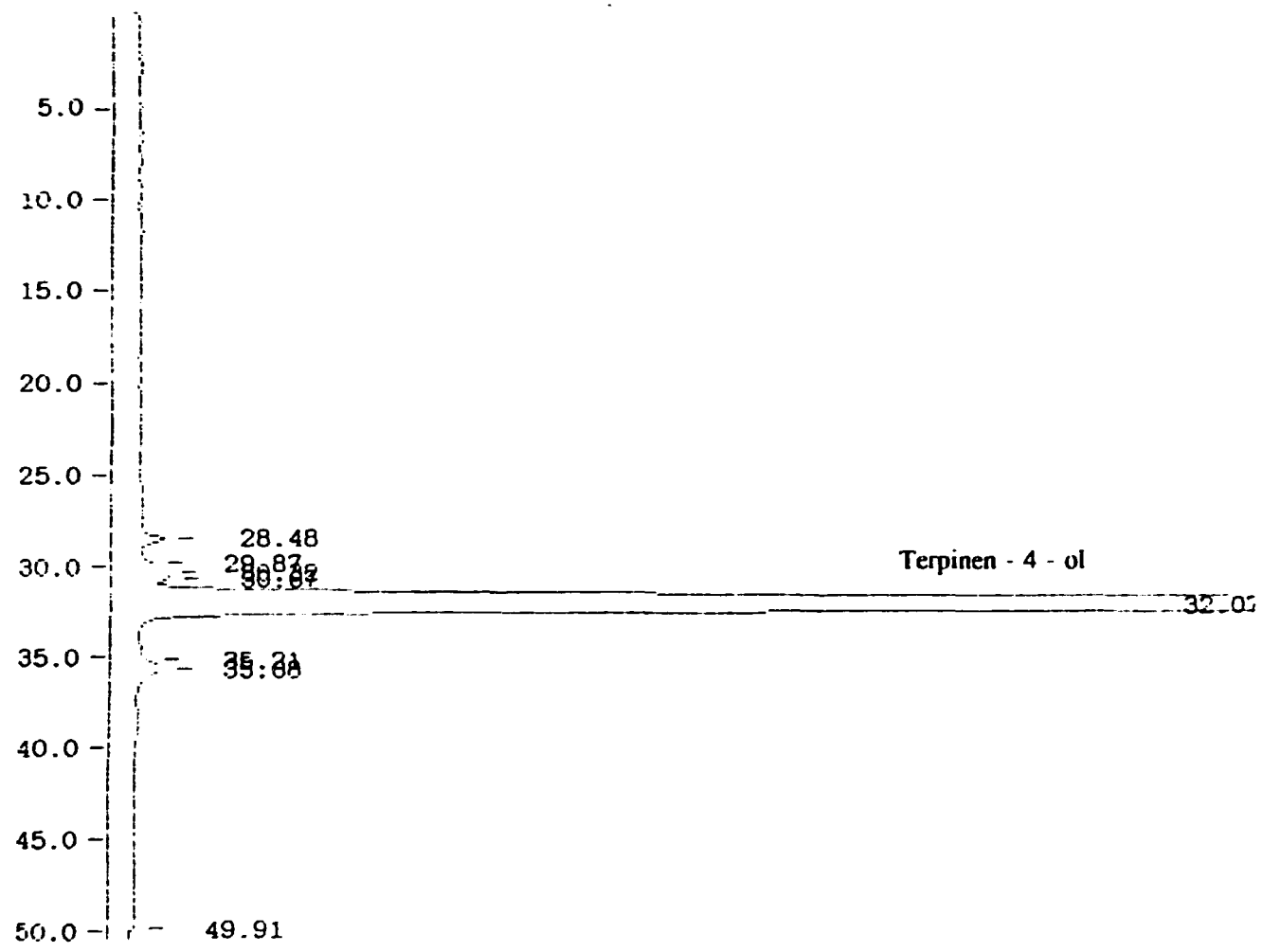
DATE 09-15-1995 TIME 14:46:18

TEXT:PIPERITONE STANDARD

PLOTTING IS FROM 0.00 to 45.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.12	52	4	BB	46	11	0.0105
2	3.27	150	6	BB	43	26	0.0301
3	12.93	75	3	BV	37	13	0.0150
4	16.39	277	6	BB	44	29	0.0557
5	18.48	174	6	BB	41	41	0.0349
6	20.42	1369	37	BB	49	38	0.2750
7	24.14	6906	141	BV	47	53	1.3872
8	25.02	3913	79	VV	69	65	0.7859
9	26.43	10282	199	VV	64	66	2.0652
10	27.00	2651	72	VV	114	40	0.5325
11	27.99	62864	1288	VV	71	69	12.6267
12	29.20	38527	678	VV	110	84	7.7386
13	31.18	117407	1636	VV	71	131	23.5822
14	32.48	1964	54	TAN	154	35	0.3945
15	33.70	240625	3912	TVV	183	165	48.3318
16	36.06	2671	41	BV	75	70	0.5366
17	37.27	193	6	VB	61	44	0.0388
18	38.58	127	6	BV	63	18	0.0254
19	39.53	6615	98	BV	70	77	1.3286
20	40.76	340	9	BB	73	32	0.0684
21	43.68	462	12	BV	55	34	0.0929
22	44.98	217	29	BB	58	5	0.0435

```
SAMPLE ID = T-4-OL              PLOT Squeeze =  15  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz      Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995                 TIME 12:44:18
 TEXT:TERPINEN-4-OL STANDARD
```

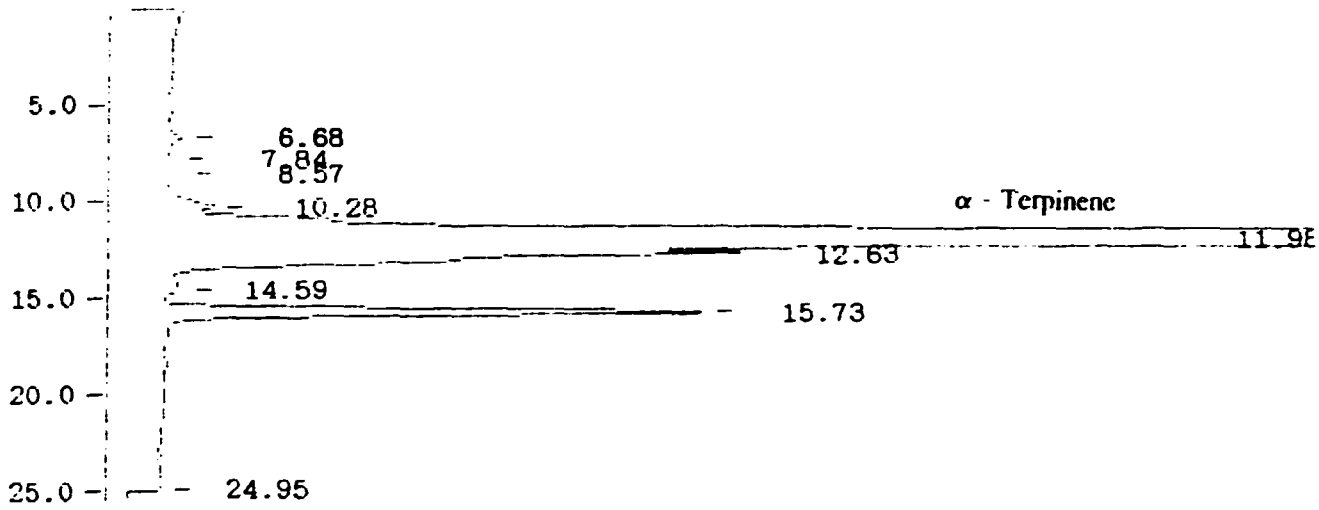



```
            INTEGRATION REPOF   FOR FILE T-4-OL
SAMPLE ID = T-4-OL              PLOT Squeeze =  15  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz      Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995                 TIME 12:44:18
 TEXT:TERPINEN-4-OL STANDARD
```

PLOTTING IS FROM 0.00 to 50.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	28.48	162	6	BB	18	28	0.0505
2	29.87	246	11	BV	17	22	0.0770
3	30.32	409	11	VV	30	29	0.1276
4	30.68	48	2	TAN	45	22	0.0149
5	32.07	318915	4099	TVB	33	159	99.6533
6	35.21	77	5	BV	17	13	0.0239
7	35.68	169	4	VB	24	32	0.0527

SAMPLE ID = TERPINEN PLOT Squeeze = 15 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-15-1995 TIME 16:26:49
TEXT:TERPINENE STANDARD

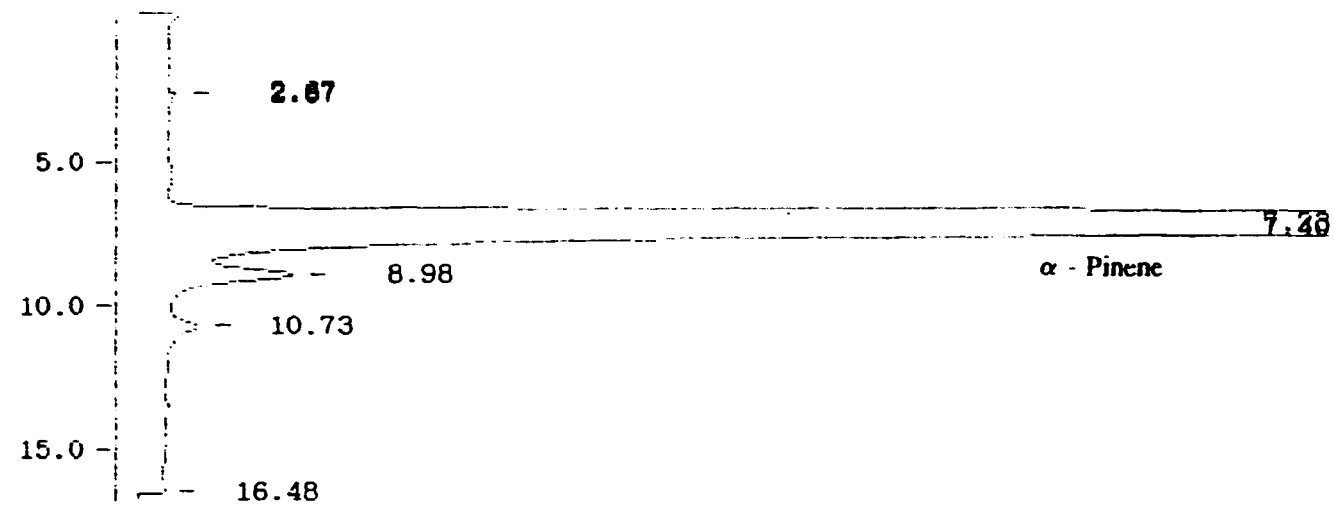


INTEGRATION REPORT FOR FILE TERPINEN
SAMPLE ID = TERPINEN PLOT Squeeze = 15 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-15-1995 TIME 16:26:49
TEXT:TERPINENE STANDARD

PLOTTING IS FROM 0.00 to 25.02 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.13	95	5	BB	56	17	0.0153
2	6.68	93	4	BB	45	26	0.0150
3	7.84	55	3	BV	45	12	0.0089
4	8.57	424	10	BB	49	43	0.0681
5	10.28	2209	39	BV	55	45	0.3554
6	11.98	585804	8971	VV	78	115	94.2284
7	12.63	4468	150	VB	568	35	0.7187
8	14.59	51	1	BB	56	23	0.0081
9	15.73	28486	579	BB	42	73	4.5821

SAMPLE ID = A-PIN PLOT Squeeze = 10 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-15-1995 TIME 16:56:05
TEXT:ALPHA-PINENE STANDARD

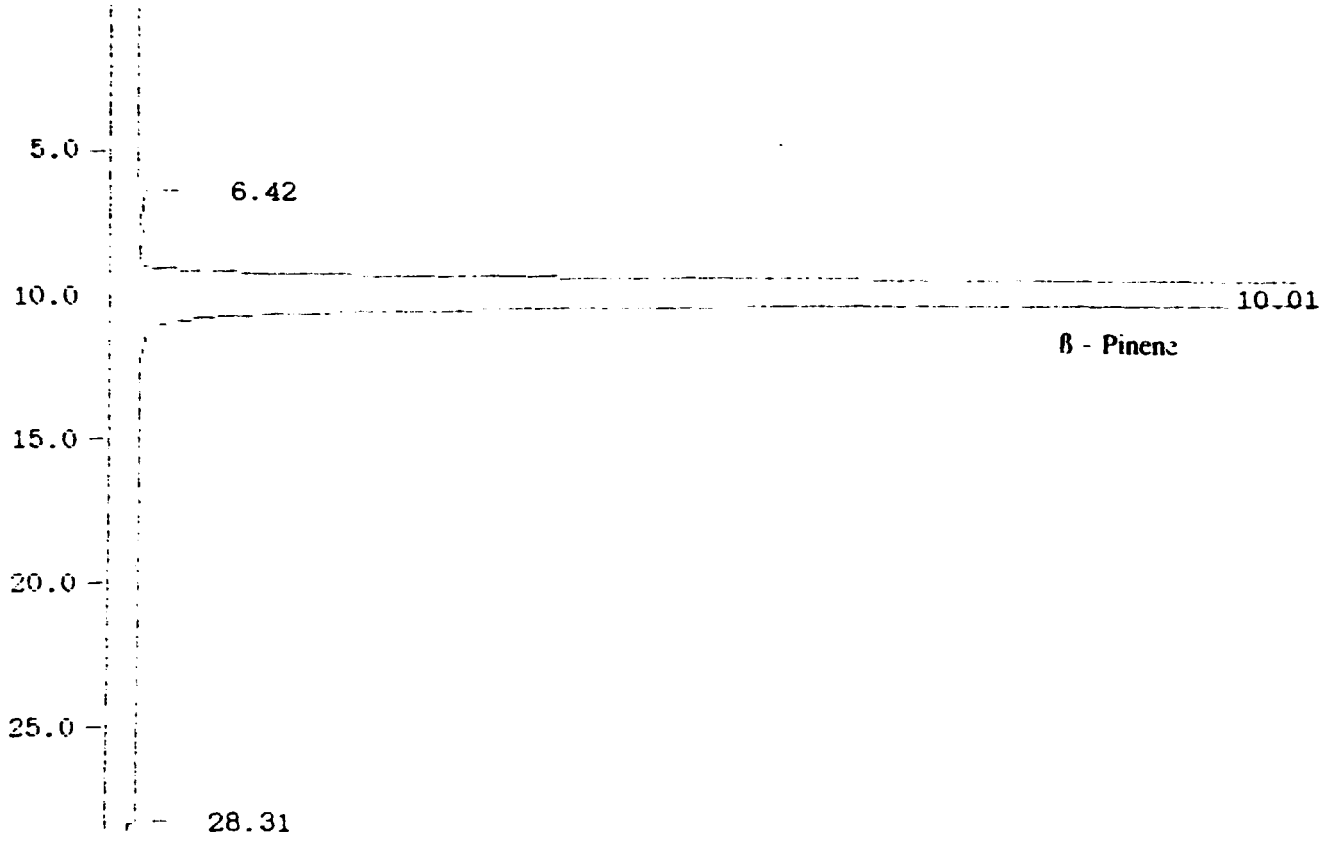


INTEGRATION REPORT FOR FILE A-PIN
SAMPLE ID = A-PIN PLOT Squeeze = 10 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-15-1995 TIME 16:56:05
TEXT:ALPHA-PINENE STANDARD

PLOTTING IS FROM 0.00 to 16.57 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.14	163	8	BV	41	25	0.0487
2	2.67	158	8	BV	35	18	0.0474
3	7.23	322414	10229	BV	34	64	96.4862
4	7.40	4274	174	VB	7258	13	1.2789
5	8.98	5786	103	BV	83	72	1.7316
6	10.73	1361	28	BB	41	50	0.4072

```
SAMPLE ID = B-PINENE          PLOT Squeeze =  10  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995               TIME 11:34:57
 TEXT:B-PINENE STANDARD
```

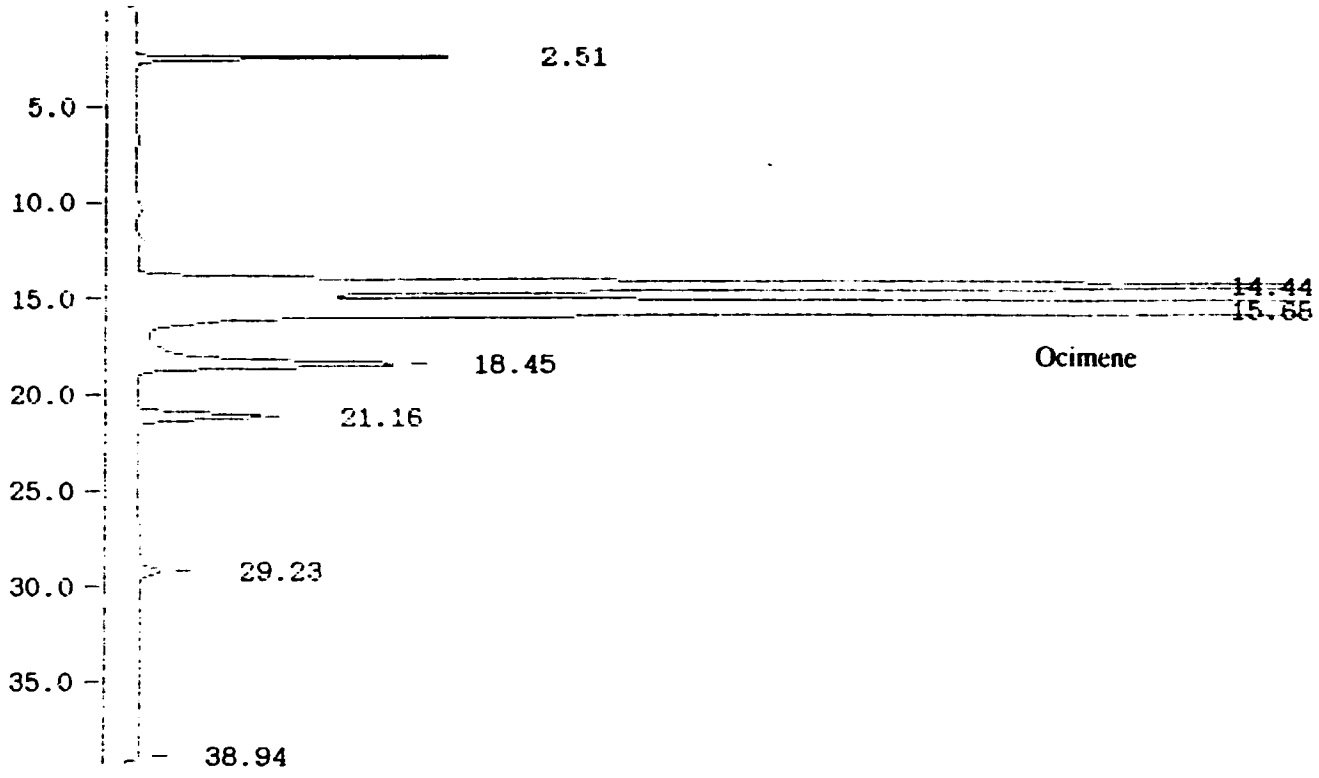



```
          INTEGRATION REPORT FOR FILE B-PINENE
SAMPLE ID = B-PINENE          PLOT Squeeze =  10  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995               TIME 11:34:57
 TEXT:B-PINENE STANDARD
```

PLOTTING IS FROM 0.00 to 28.33 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	6.42	100	4	BB	14	19	0.0327
2	10.01	306101	4183	BB	11	139	99.9417
3	28.31	78	8	BB	11	8	0.0256

```
SAMPLE ID = OCIMENE          PLOT Squeeze =  15  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995              TIME 13:55:43
 TEXT:OCIMENE STANDARD
```

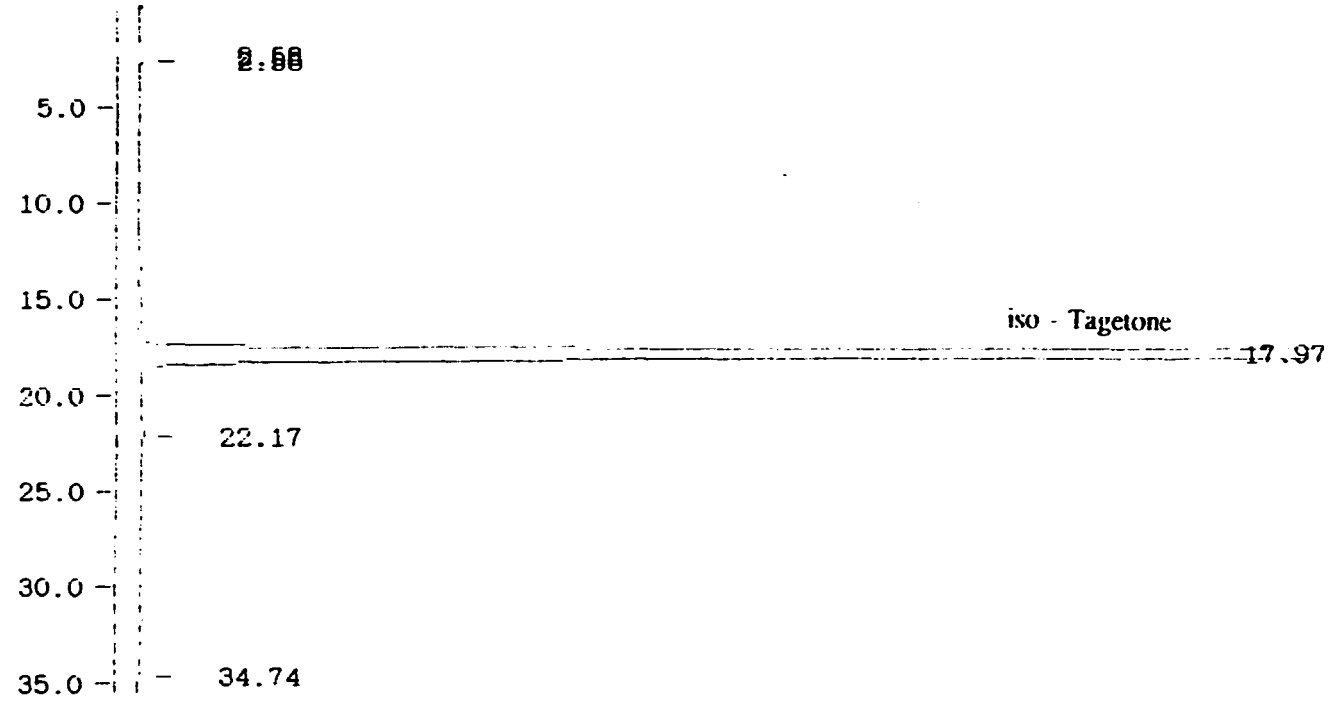



```
          INTEGRATION REPORT FOR FILE OCIMENE
SAMPLE ID = OCIMENE          PLOT Squeeze =  15  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995              TIME 13:55:43
 TEXT:OCIMENE STANDARD
```

PLOTTING IS FROM 0.00 to 39.20 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	2.51	7166	342	BB	10	37	1.4859
2	14.44	96832	1558	BV	16	76	20.0800
3	15.68	353731	6550	VB	201	111	73.3529
4	18.45	16895	283	BB	29	107	3.5035
5	21.16	6354	136	BB	20	61	1.3176
6	29.23	1254	23	BV	18	59	0.2601

```
SAMPLE ID = I-TAGETO          PLOT Squeeze =  15  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995               TIME 14:39:22
 TEXT:ISO-TAGETONE STANDARD
```

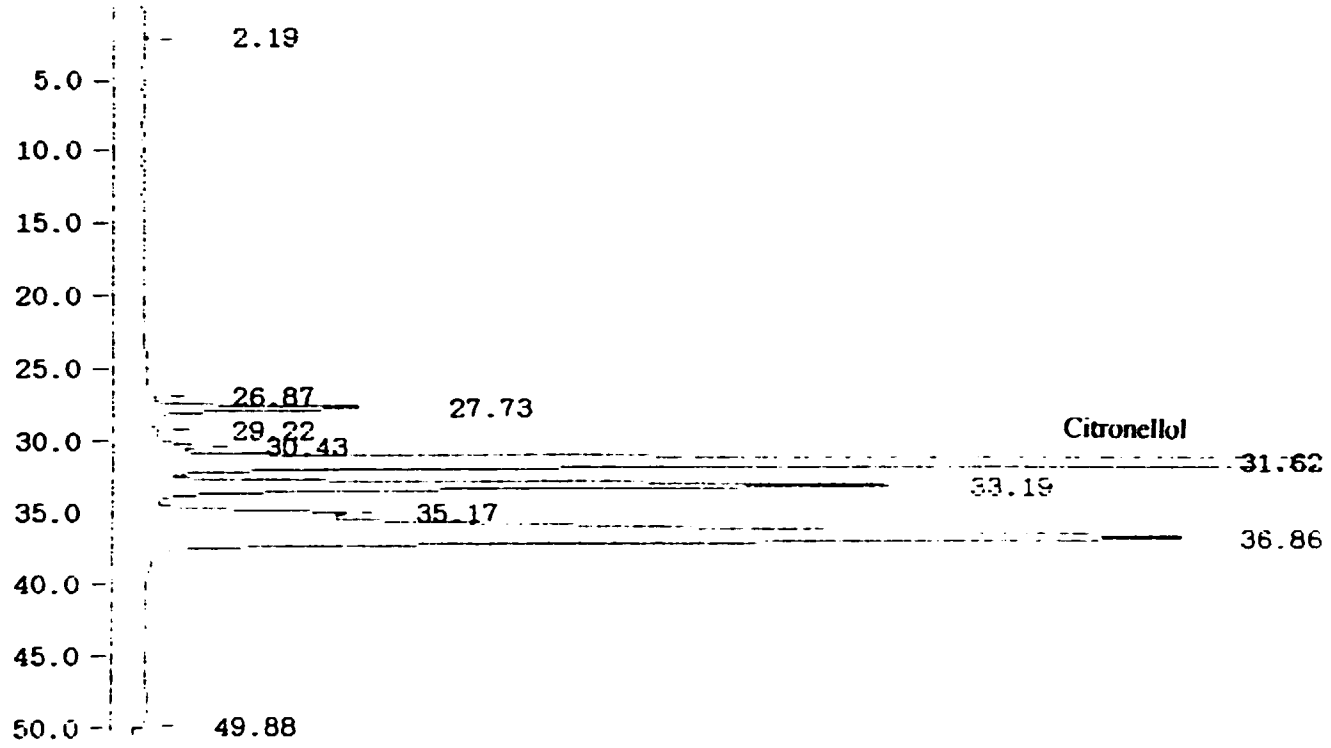



```
          INTEGRATION REPORT FOR FILE I-TAGETO
SAMPLE ID = I-TAGETO          PLOT Squeeze =  15  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995               TIME 14:39:22
 TEXT:ISO-TAGETONE STANDARD
```

: PLOTTING IS FROM 0.00 to 34.82 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.05	2984	725	BV	-88	8	2.0914
2	2.58	200	8	BV	0	24	0.1404
3	17.97	139434	2850	BB	5	100	97.7236
4	22.18	64	6	BV	1	7	0.0446

```
SAMPLE ID = CITRNLOL          PLOT Squeeze =  20  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995               TIME 15:18:17
 TEXT:CITRONELLOL STANDARD
```

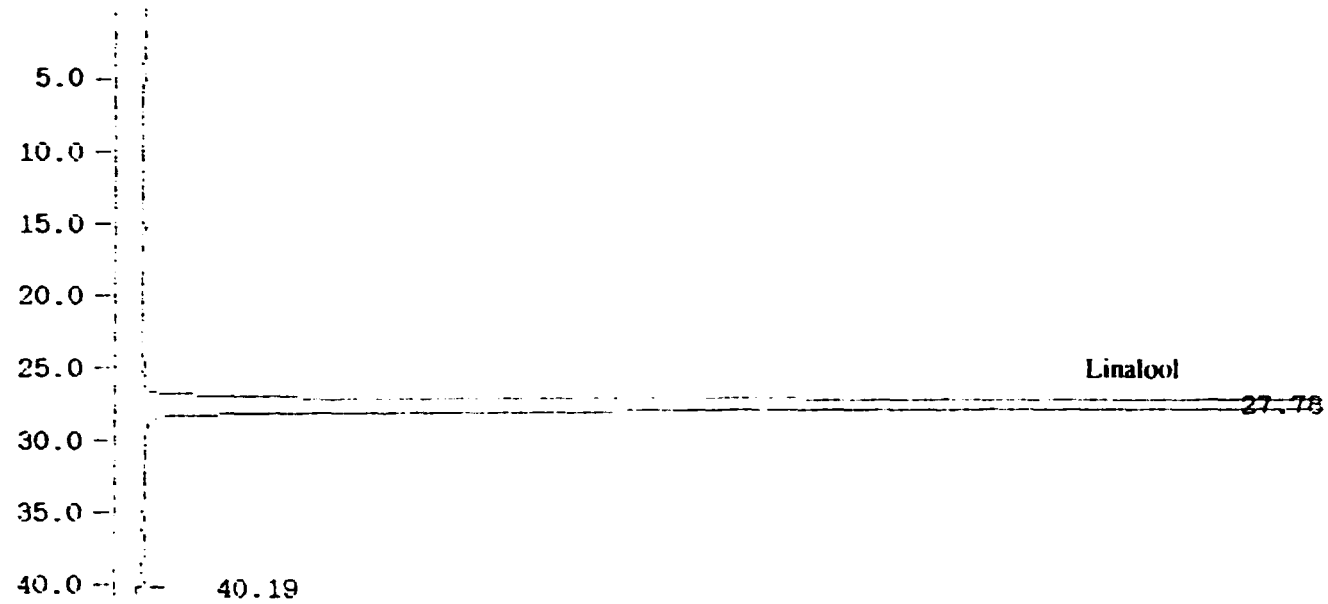



```
          INTEGRATION REPORT FOR FILE CITRNLOL
SAMPLE ID = CITRNLOL          PLOT Squeeze =  20  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995               TIME 15:18:17
 TEXT:CITRONELLOL STANDARD
```

: PLOTTING IS FROM 0.00 to 50.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	2.19	138	9	BV	10	20	0.0317
2	26.87	61	2	BV	20	13	0.0140
3	27.73	11165	242	BB	21	82	2.5632
4	29.22	143	5	BV	21	19	0.0328
5	30.43	1165	28	TAN	35	38	0.2674
6	31.62	235521	4012	TVB	51	146	54.0706
7	33.19	51276	783	BB	43	107	11.7718
8	35.17	14074	206	BV	27	61	3.2311
9	36.86	122039	1016	VB	213	161	28.0176

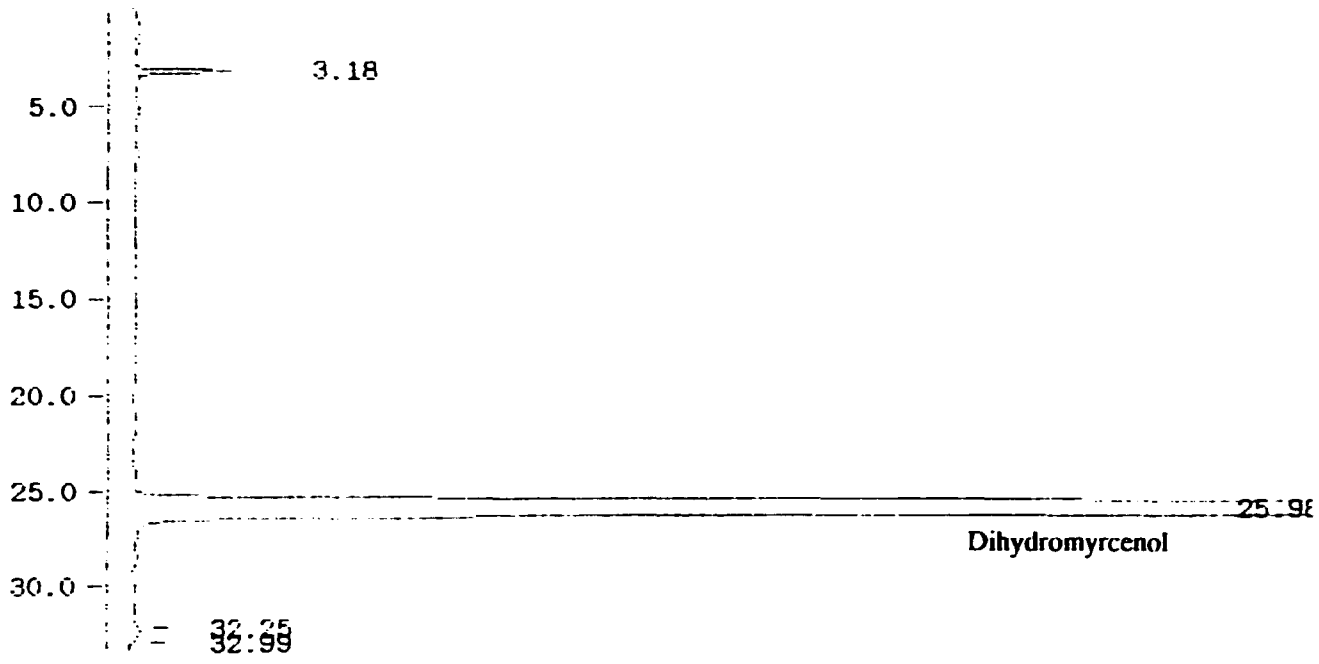
```
SAMPLE ID = LINALOOL          PLOT Squeeze =  20  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995               TIME 16:17:55
 TEXT:LINALOOL STANDARD
```




```
          INTEGRATION REPORT FOR FILE LINALOOL
SAMPLE ID = LINALOOL          PLOT Squeeze =  20  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-18-1995               TIME 16:17:55
 TEXT:LINALOOL STANDARD
```

PLOTTING IS FROM 0.00 to 40.23 MINUTES							
PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	27.78	387664	6789	BB	13	125	100.0000

SAMPLE ID = H2MYRCOL PLOT Squeeze = 15 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-18-1995 TIME 17:02:51
TEXT:DIHYDROMYRCENOL STANDARD

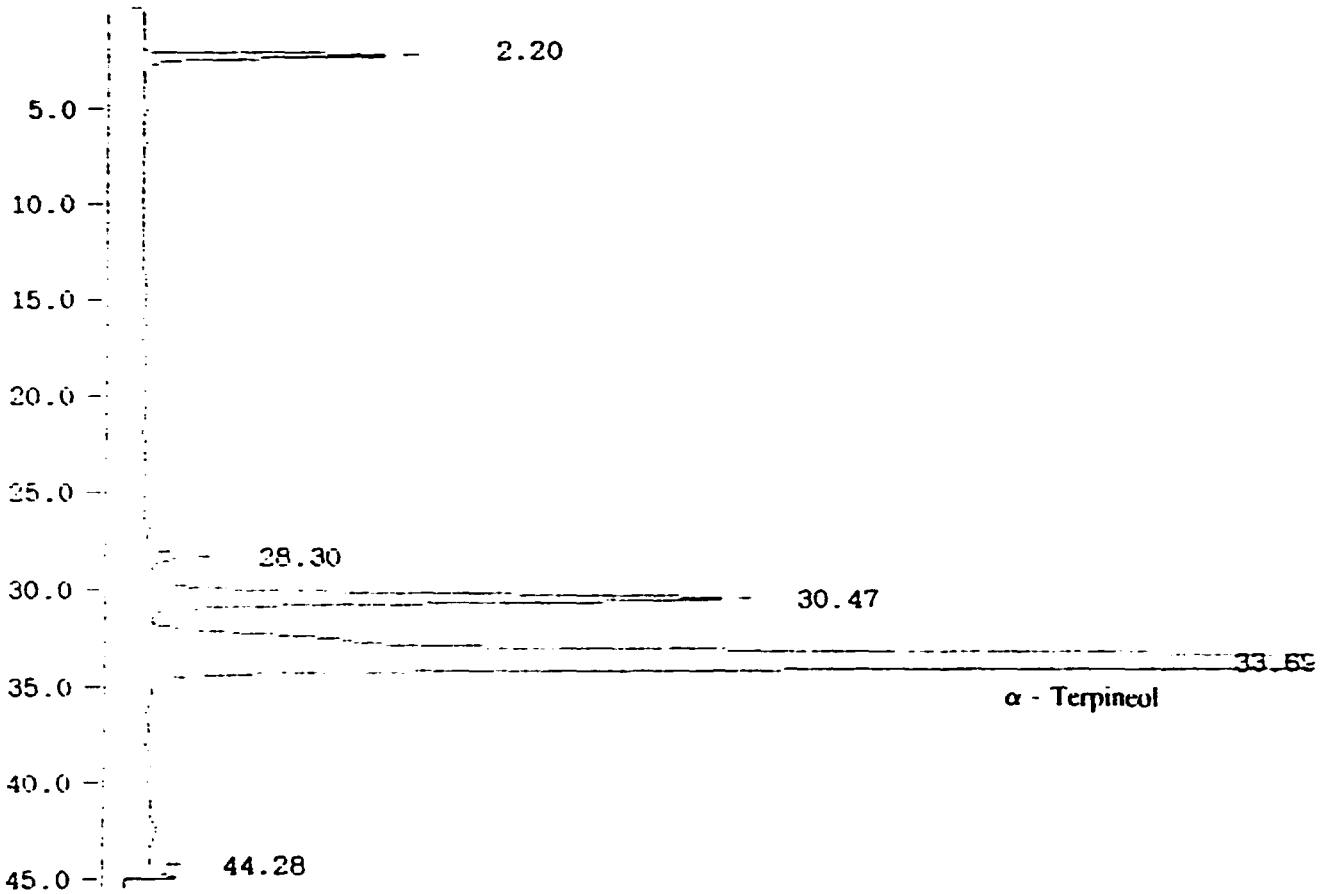


INTEGRATION REPORT FOR FILE H2MYRCOL
SAMPLE ID = H2MYRCOL PLOT Squeeze = 15 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-18-1995 TIME 17:02:51
TEXT:DIHYDROMYRCENOL STANDARD

PLOTTING IS FROM 0.00 to 33.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	3.18	2441	97	BB	10	32	0.5306
2	25.98	457589	7764	BB	10	113	99.4584
3	32.25	51	3	BV	10	15	0.0110

```
SAMPLE ID = TERP-EOL          PLOT Squeeze =  15  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-23-1995               TIME 12:15:45
 TEXT:TERPINEOL STANDARD
```

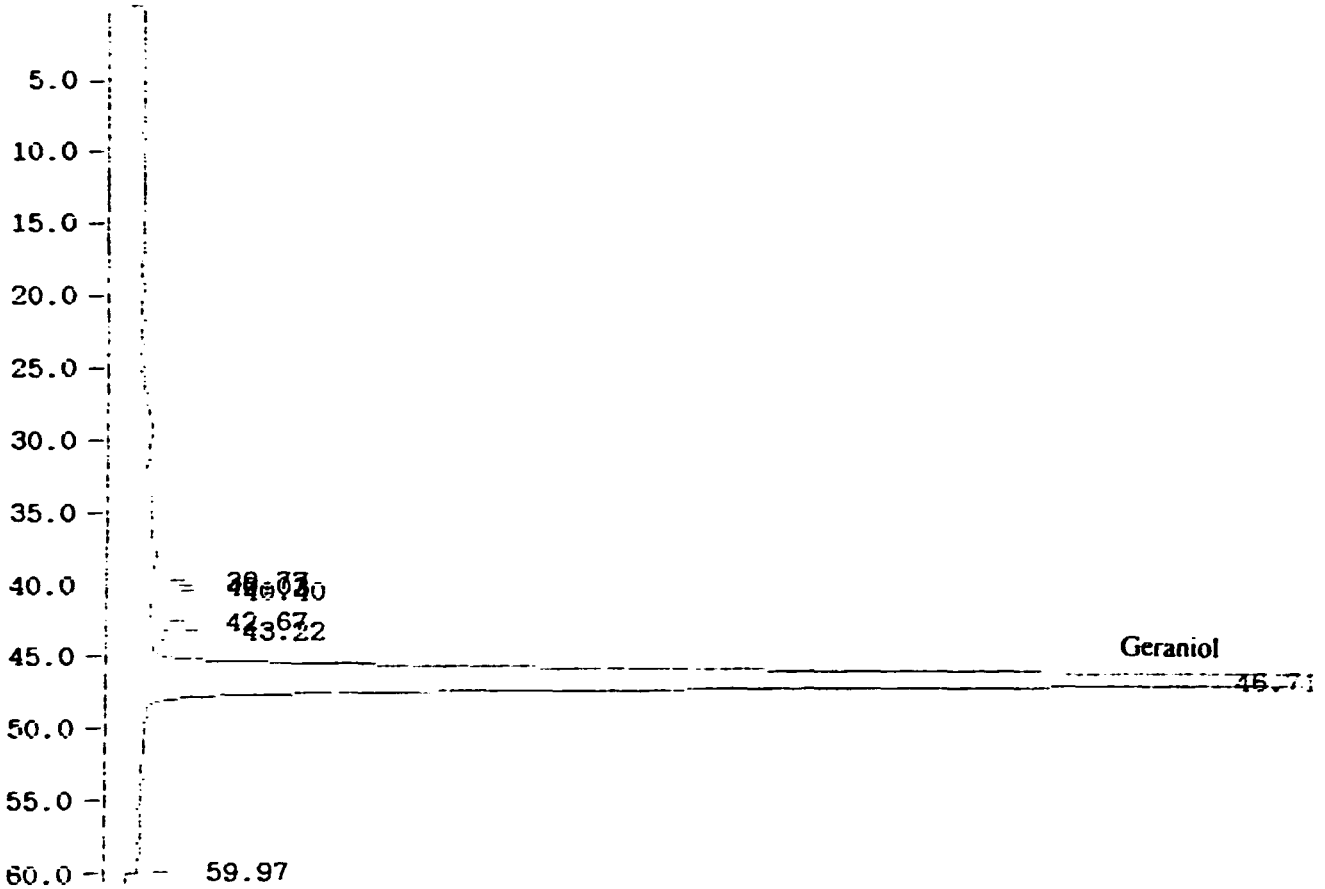



```
          INTEGRATION REPORT FOR FILE TERP-EOL
SAMPLE ID = TERP-EOL          PLOT Squeeze =  15  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz    Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-23-1995               TIME 12:15:45
 TEXT:TERPINEOL STANDARD

      PLOTTING IS FROM    0.00  to   45.00   MINUTES

 PK#:  RT   :   AREA  :   HT   : PK TYPE :B/Line:  WTH  :  AREA% :
   1 :  2.20:     9634:     282:     BB   :   15 :    56 :  2.9203:
   2 : 28.30:     1918:      34:     BB   :   26 :    58 :  0.5815:
   3 : 30.47:    43819:     615:     BB   :   33 :   125 : 13.2824:
   4 : 33.69:   274532:    3061:     BB   :   28 :   197 : 83.2159:
```

SAMPLE ID = GERANIOL PLOT Squeeze = 20 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-23-1995 TIME 14:06:02
TEXT:GERANIOL STANDARD

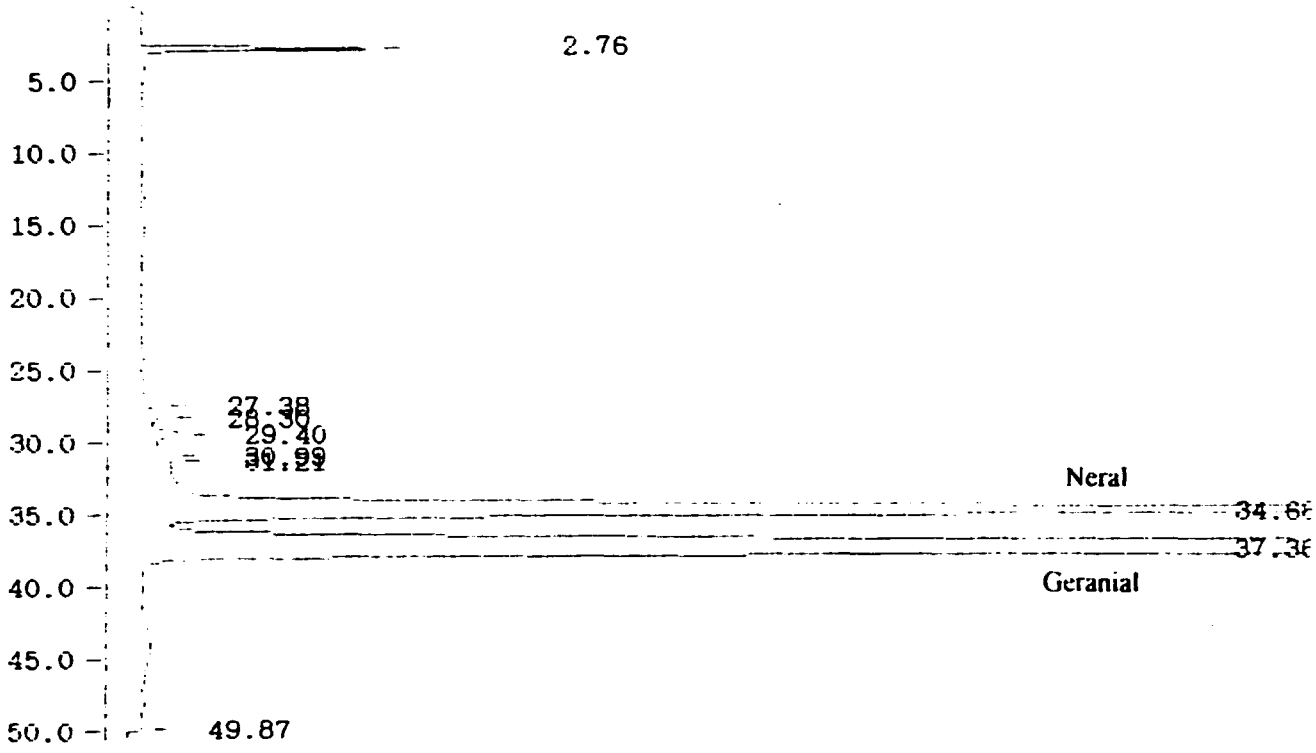


INTEGRATION REPORT FOR FILE GERANIOL
SAMPLE ID = GERANIOL PLOT Squeeze = 20 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-23-1995 TIME 14:06:02
TEXT:GERANIOL STANDARD

: PLOTTING IS FROM 0.00 to 60.02 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	39.77	63	3	BV	27	17	0.0256
2	40.03	78	5	VV	30	13	0.0317
3	40.40	230	7	VV	36	28	0.0934
4	42.67	50	3	BV	26	12	0.0205
5	43.22	474	14	VV	29	32	0.1926
6	46.71	245507	1754	BB	31	215	99.6362

SAMPLE ID = CITRAL PLOT Squeeze = 20 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-23-1995 TIME 15:12:33
TEXT:CITRAL STANDARD

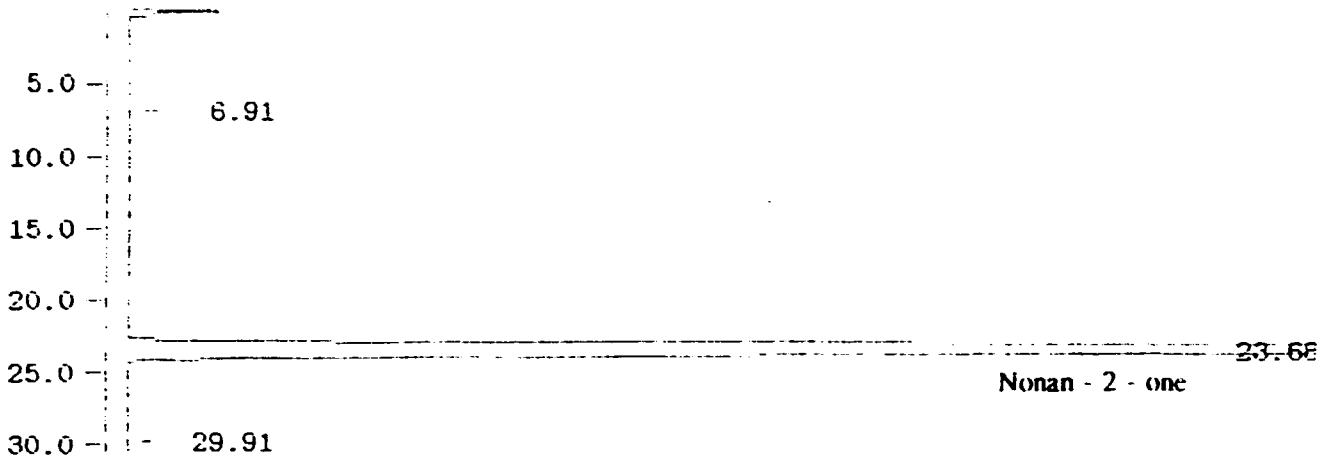


INTEGRATION REPORT FOR FILE CITRAL
SAMPLE ID = CITRAL PLOT Squeeze = 20 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-23-1995 TIME 15:12:33
TEXT:CITRAL STANDARD

PLOTTING IS FROM 0.00 to 50.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	2.76	8265	354	BB	14	41	1.7525
2	27.38	82	3	BB	18	29	0.0174
3	28.30	186	5	BB	22	28	0.0394
4	29.40	2015	29	BV	26	61	0.4272
5	30.99	72	4	BV	39	16	0.0152
6	31.21	57	3	VV	44	15	0.0121
7	34.68	151983	1728	BV	56	156	32.2252
8	37.36	308968	3134	VB	47	164	65.5111

```
SAMPLE ID = NONANONE          PLOT Squeeze =  20  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-23-1995               TIME 16:06:48
 TEXT:NONAN-2-ONE STANDARD
```

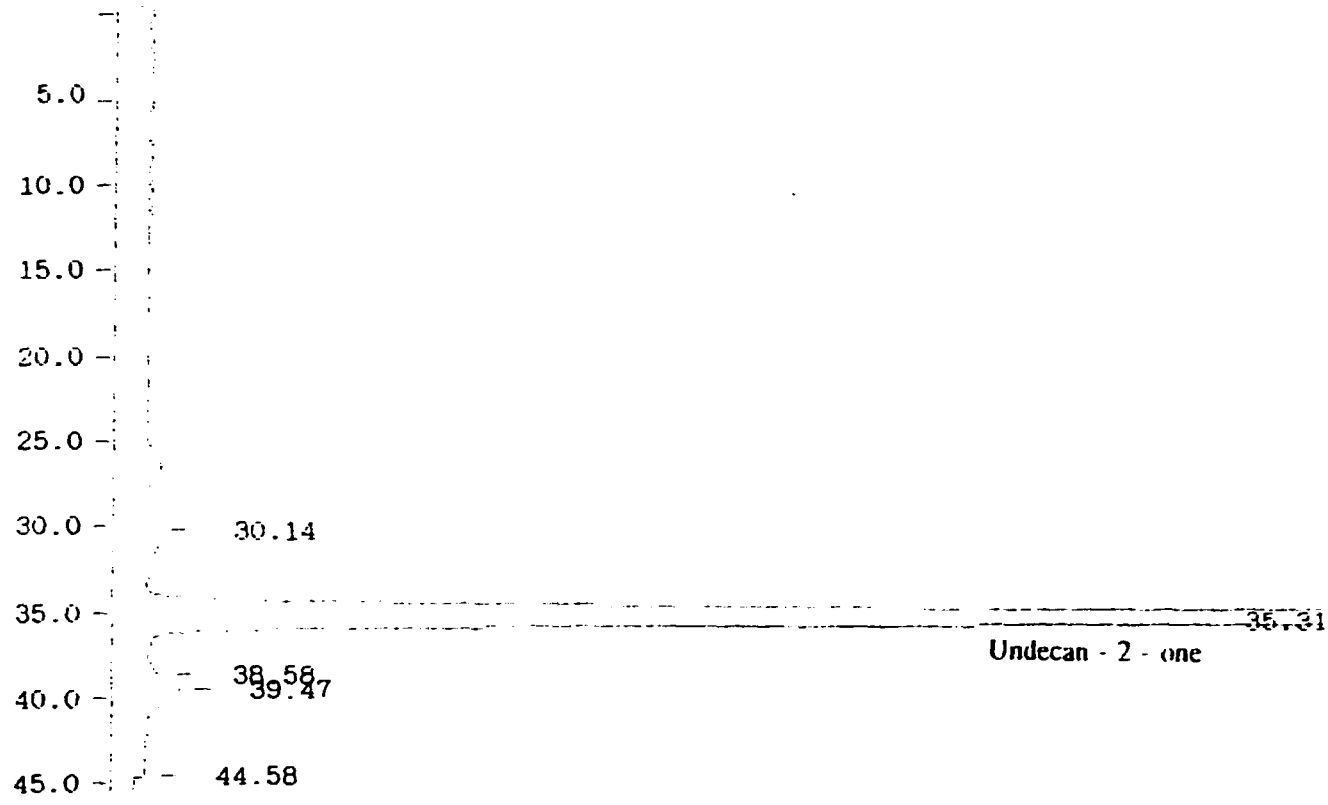



```
          INTEGRATION REPORT FOR FILE NONANONE
SAMPLE ID = NONANONE          PLOT Squeeze =  20  times  ATTEN =  2
Sampling Frequency [ 2 ] Hz     Tg/Pk/Sp/Wth=  20  3  .1  0
DATE 09-23-1995               TIME 16:06:48
 TEXT:NONAN-2-ONE STANDARD
```

: PLOTTING IS FROM 0.00 to 29.98 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	6.91	65	3	BV	-3	16	0.0187
2	23.68	346964	5537	BB	-4	112	99.9813

SAMPLE ID = UNDECONE PLOT Squeeze = 17 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-23-1995 TIME 16:41:29
TEXT:UNDECAN-2-ONE STANDARD

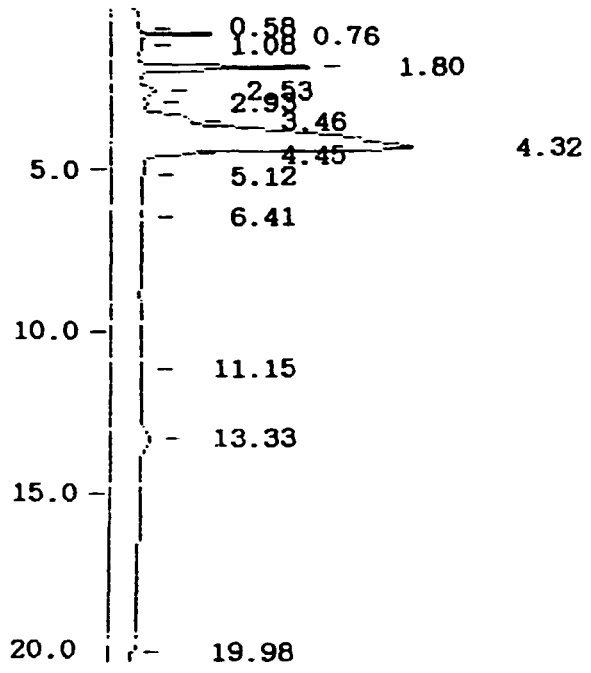


INTEGRATION REPORT FOR FILE UNDECONE
SAMPLE ID = UNDECONE PLOT Squeeze = 17 times ATTEN = 2
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 09-23-1995 TIME 16:41:29
TEXT:UNDECAN-2-ONE STANDARD

PLOTTING IS FROM 0.00 to 44.65 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	30.14	63	4	BV	21	13	0.0237
2	35.31	262835	2632	BV	17	164	99.4689
3	38.58	61	4	BV	24	14	0.0230
4	39.47	1280	22	VV	28	54	0.4844

SAMPLE ID = ES172345 PLOT Squeeze = 9 times ATTEN = 15
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 05-08-1994 TIME 11:42:32
TEXT:ESSEN OIL CO. LAB REPORT EUCALYPTUS (smithii) 70-75% BATCH No:ES172/3/4/5

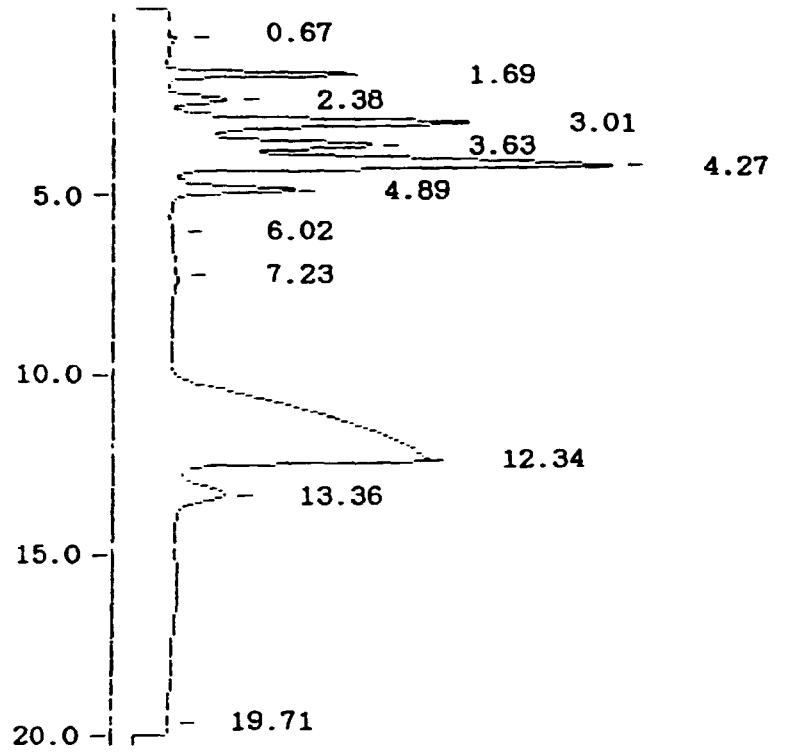


INTEGRATION REPORT FOR FILE ES172345
SAMPLE ID = ES172345 PLOT Squeeze = 9 times ATTEN = 15
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 05-08-1994 TIME 11:42:32
TEXT:ESSEN OIL CO. LAB REPORT EUCALYPTUS (smithii) 70-75% BATCH No:ES172/3/4/5

PLOTTING IS FROM 0.00 to 20.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.58	514	22	BV	66	13	0.2955
2	0.76	6284	687	VV	25	19	3.6156
3	1.08	215	17	VB	69	22	0.1235
4	1.80	24462	1383	BV	67	41	14.0744
5	2.53	4310	136	VV	72	31	2.4799
6	2.93	967	38	VV	98	21	0.5565
7	3.46	12934	369	VV	110	26	7.4419
8	4.32	108390	1874	VV	483	54	62.3638
9	4.45	7843	34	VV	520	33	4.5129
10	5.12	307	13	VB	92	32	0.1769
11	6.41	314	9	BB	72	35	0.1806
12	11.15	758	14	BB	69	55	0.4358
13	13.33	6505	83	BB	70	91	3.7427

SAMPLE ID = AUSBODCR PLOT Squeeze = 8 times ATTEN = 5
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 03-30-1995 TIME 17:19:36
TEXT:ESSEN OILS CO. LAB. REPORT TTO AUS. BODYCARE SAMPLE 30/03/95

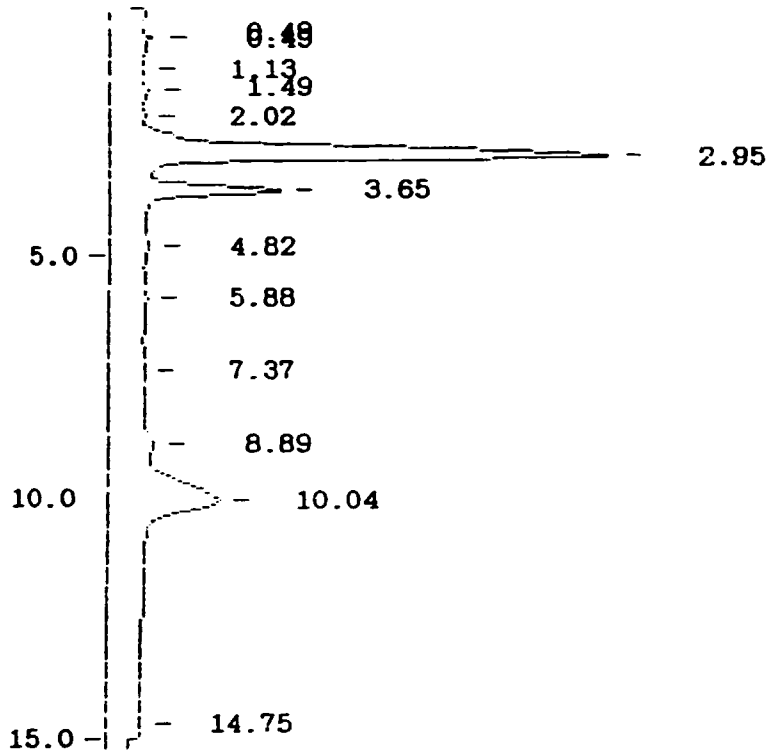


INTEGRATION REPORT FOR FILE AUSBODCR
SAMPLE ID = AUSBODCR PLOT Squeeze = 8 times ATTEN = 5
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 03-30-1995 TIME 17:19:36
TEXT:ESSEN OILS CO. LAB. REPORT TTO AUS. BODYCARE SAMPLE 30/03/95

PLOTTING IS FROM 0.00 to 20.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.67	142	15	BB	101	10	0.0622
2	1.69	10174	549	BV	89	26	4.4567
3	2.38	4666	161	BV	95	29	2.0442
4	3.01	27633	806	VV	105	44	12.1046
5	3.63	13421	441	VV	213	28	5.8791
6	4.27	38512	1082	VV	326	46	16.8703
7	4.89	9151	338	VB	114	43	4.0087
8	6.02	78	4	BB	97	19	0.0341
9	7.23	191	7	BV	107	22	0.0835
10	12.34	117047	689	BV	108	172	51.2726
11	13.36	7269	122	VV	133	67	3.1842

SAMPLE ID = TAG145 PLOT Squeeze = 6 times ATTEN = 10
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 03-05-1994 TIME 06:58:55
TEXT:ESSEN OILS CO.LAB.GC REPORT OIL OF TAGETES BATCH TG145

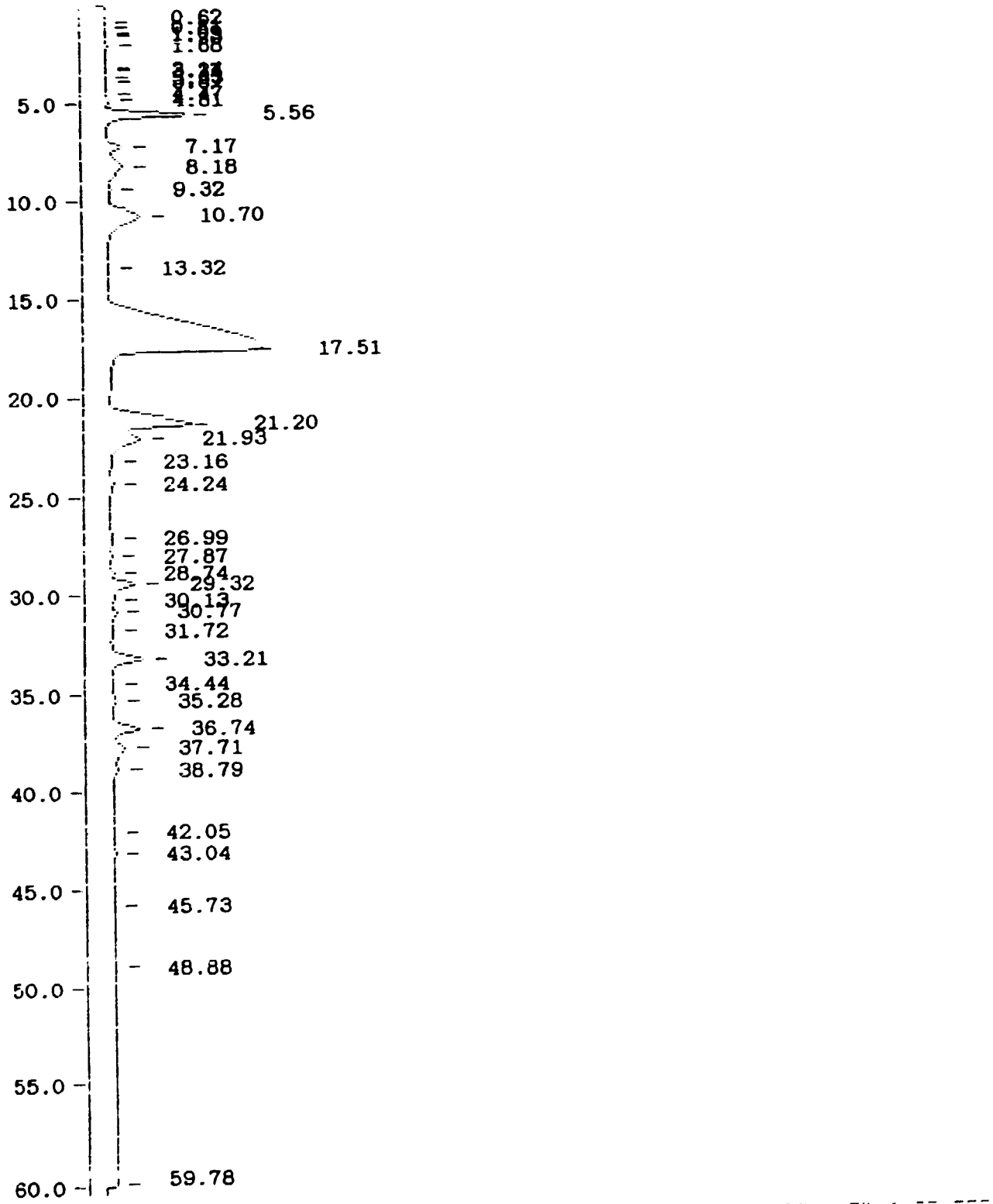


INTEGRATION REPORT FOR FILE TAG145
SAMPLE ID = TAG145 PLOT Squeeze = 6 times ATTEN = 10
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 03-05-1994 TIME 06:58:55
TEXT:ESSEN OILS CO.LAB.GC REPORT OIL OF TAGETES BATCH TG145

PLOTTING IS FROM 0.00 to 15.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.07	82	11	BB	79	10	0.0550
2	0.49	769	66	BV	71	15	0.5144
3	1.13	59	5	BV	75	16	0.0396
4	1.49	928	40	VV	70	32	0.6208
5	2.02	275	13	VV	70	20	0.1836
6	2.95	94544	2505	VV	72	72	63.2163
7	3.65	19268	714	VB	111	59	12.8838
8	4.82	961	26	BB	77	44	0.6426
9	5.88	753	17	BV	75	43	0.5035
10	7.37	50	2	BV	77	14	0.0335
11	8.89	2829	50	BV	81	46	1.8918
12	10.04	29036	389	VB	106	100	19.4150

SAMPLE ID = ZIMARCH PLOT Squeeze = 11.4 times ATTEN = 30
Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0
DATE 03-31-1995 TIME 15:58:33
TEXT:ESSEN OILS CO. LAB. REPORT LIPPIA JAVANICA MARCH 95 HARVEST 31/03/95



D 4

INTEGRATION REPORT FOR FILE ZIMARCH

SAMPLE ID = ZIMARCH PLOT Squeeze = 11.4 times ATTEN = 30

Sampling Frequency [2] Hz Tg/Pk/Sp/Wth= 20 3 .1 0

DATE 03-31-1995 TIME 15:58:33

TEXT:ESSEN OILS CO. LAB. REPORT LIPPIA JAVANICA MARCH 95 HARVEST 31/03/95

PLOTTING IS FROM 0.00 to 60.00 MINUTES

PK#	RT	AREA	HT	PK TYPE	B/Line	WTH	AREA%
1	0.62	275	36	BV	190	12	0.0259
2	0.81	54	6	VB	193	10	0.0051
3	1.09	228	25	BV	197	7	0.0214
4	1.23	103	12	VB	209	13	0.0097
5	1.68	1868	99	BB	200	37	0.1758
6	3.14	57	4	TAN	197	12	0.0053
7	3.27	199	5	TVV	206	31	0.0187
8	3.63	23	2	TAN	195	11	0.0022
9	3.87	390	13	TVV	197	41	0.0367
10	4.47	465	21	VV	195	22	0.0438
11	4.81	2394	77	TAN	215	35	0.2252
12	5.56	70633	1763	TVV	217	115	6.6449
13	7.17	15633	327	BV	215	49	1.4707
14	8.18	23548	267	VV	299	95	2.2153
15	9.33	1560	30	TAN	248	49	0.1467
16	10.70	68346	666	TVB	226	192	6.4297
17	13.33	68	3	BV	204	18	0.0064
18	17.51	598156	3238	BV	204	236	56.2721
19	21.20	126760	1727	BV	220	81	11.9251
20	21.93	21654	357	VV	596	88	2.0371
21	23.16	534	12	VB	250	49	0.0502
22	24.24	3978	72	BB	215	65	0.3742
23	26.99	2183	38	BB	217	61	0.2054
24	27.87	66	4	BB	223	20	0.0062
25	28.74	2908	77	BV	212	26	0.2736
26	29.32	22853	469	VV	266	63	2.1499
27	30.13	338	11	VV	280	33	0.0318
28	30.77	4454	83	VB	238	53	0.4190
29	31.72	733	15	BB	248	46	0.0689
30	33.21	36698	666	BB	229	101	3.4524
31	34.44	664	17	BV	241	35	0.0624
32	35.28	5561	84	VV	244	71	0.5232
33	36.74	30750	577	BV	243	69	2.8928
34	37.71	12508	185	VV	306	76	1.1767
35	38.79	2096	50	VB	309	67	0.1972
36	42.05	317	9	BB	241	34	0.0298
37	43.04	3461	50	BV	240	78	0.3256
38	45.73	57	3	BV	233	16	0.0054
39	48.88	401	6	BB	233	40	0.0377

ANNEX 5

Representative specimen sheet for the promotion of an essential oil.

ATEOL®

AUSTRALIAN TEA TREE OIL

(Oil of *Melaleuca alternifolia*)

Tea Tree Oil is the natural oil obtained by steam distillation of the foliage and branches of *Melaleuca alternifolia*, a tree indigenous to only one area in the world, New South Wales, Australia.

Tea Tree Oil has been used as a natural antiseptic and fungicide for over 60 years in Australia and has been shown to possess antimicrobial activity against a wide range of Gram positive and Gram negative bacteria and fungi. The intrinsic antimicrobial activity in combination with the penetrating power of the oil are believed to be responsible for the efficacy of this natural product.

Tea Tree Oil has been widely used in a range of products throughout the pharmaceutical, cosmetic, veterinary and household products industries including

Therapeutic topical products (e.g. antiseptics)

Veterinary products (topical antiseptics, shampoos etc.)

Cosmetic and toiletry products (e.g. shampoos, soaps, creams, deodorants etc.)

Household Products (disinfectants, cleaners etc.)

THE ADVANTAGES OF TEA TREE OIL INCLUDE:

Completely natural oil

Broad spectrum antimicrobial activity

Bactericidal mode of action

Antifungal activity

Excellent skin penetration properties

Non-irritating (may be applied to open wounds without stinging)

Low incidence of skin sensitivity

A reliable supply of high quality Ateol brand Tea Tree Oil derived solely from *Melaleuca alternifolia* may be obtained from Bronson & Jacobs

BRONSON & JACOBS PTY LTD

China ◆ Hong Kong ◆ Malaysia
Singapore ◆ Indonesia ◆ Australia
◆ New Zealand

Please direct initial enquiry to Bronson & Jacobs Head Office

請即聯絡總公司垂詢

Untuk kontak selanjutnya, hubungi Kantor Pusat

Sydney Australia Telephone 61 2 394 3288
Facsimile 61 2 394 3222
Telex AA 26322 BJ Aust

ATEOL®
TEA TREE OIL

(Oil of *Melaleuca alternifolia*)

GENERAL INFORMATION

PRODUCT DESCRIPTION

A volatile oil obtained from the foliage and terminal branchlets of *Melaleuca alternifolia*, a plant indigenous to Northern New South Wales, Australia. The oil is a clear colourless to pale yellow liquid with myristic odour.

EXTRACTION

By steam distillation of freshly harvested plant material

PRODUCTION AREAS

Tea Tree Oil has until recently been produced from trees harvested from bush stands of *Melaleuca alternifolia*. Bronson & Jacobs has transformed the industry by establishing large scale commercial plantations on its own properties outside Lismore, Northern New South Wales. Commercial quantities of high quality oil are being produced with further intensive plantation development in progress and increased production capacity scheduled

AVAILABILITY

Supply of Tea Tree Oil was previously limited, however, using large scale advanced mechanical harvesting and modern distillation techniques, production efficiencies have been maximised to ensure continuity of supply.

CHEMICAL COMPOSITION

Over 50 components have been identified by gas chromatography/mass spectrometry. The major components are terpinen 4-ol and 1,8-cineole

STORAGE

Recommended storage is a cool dry area in tightly closed, light proof containers.

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ATEOL®

ANTIMICROBIAL ACTIVITY

(Oil of *Melaleuca alternifolia*)

Independent microbiological testing of ATEOL has shown the minimum inhibitory concentration (MIC) of the oil against a variety of micro-organisms (i.e. the lowest concentration which will inhibit the growth of a specified microorganism).

Several hundred *in vitro* tests have been conducted. In summary, it may be concluded that ATEOL is active against a wide range of microorganisms including the following:

A. ORGANISM MIC (% ATEOL BRAND TEA TREE OIL)

GRAM POSITIVE BACTERIA	
Staphylococcus aureus	0.5 - 1.0
Staphylococcus epidermidis	0.5 - 1.0
Streptococcus pneumoniae	0.25
Streptococcus faecalis	1.0
Streptococcus pyogenes	1.0
Streptococcus agalactiae	1.25
Propionibacterium acnes	0.75
Beta haemolytic streptococcus	0.5
GRAM NEGATIVE BACTERIA	
Escherichia coli	0.5
Klebsiella pneumoniae	1.20
Citrobacter spp	0.5 - 1.0
Shigella sonnei	0.5
Proteus mirabilis	0.5 - 1.0
Legionella spp	0.75 - 1.0
Pseudomonas aeruginosa	2.0
FUNGI	
Trichophyton mentagrophytes	0.75
Trichophyton rubrum	0.5
Aspergillus niger	1.0
Aspergillus flavus	0.25
Candida albicans	0.5
Microsporum canis	1.0
Microsporum gypseum	1.0
Thermoactinomycetes vulgarus	1.25

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B. PRESERVATIVE CHALLENGE TEST

1. United States Pharmacopoeia (XXI)
Challenge against:

Staphylococcus aureus
Escherichia coli
Pseudomonas aeruginosa USP strain
Candida albicans
Aspergillus niger

Tea Tree Oil, 0.8% V/V - Pass

2. British Pharmacopoeia (1980) Preservative Challenge against:

Staphylococcus aureus
Escherichia coli
Pseudomonas aeruginosa BP strain
Candida albicans
Aspergillus niger

Tea Tree Oil, 0.8% V/V - Pass

C. NSW HEALTH DEPARTMENT THERAPEUTIC GOODS ACT (TGA) TEST

1. TGA Hospital Grade Disinfectant Option A

Tea Tree Oil, NEAT - Pass

2. TGA Antiseptic Grade Option D

Tea Tree Oil, CREAM 5% - Pass

3. TGA Hospital Grade Dirty Disinfectant Option B

Tea Tree Oil, NEAT - Pass

All tests were performed on Ateol Brand Tea Tree Oil.
(Oil of *Melaleuca alternifolia*).

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ATEOL®

PRODUCT SPECIFICATION

(Oil of Melaleuca alternifolia)

The Bronson & Jacobs Standard for ATEOL brand Tea Tree Oil is provided below and includes various physical and chemical limits. The rigid Bronson & Jacobs Standard exceeds the Australian Standard AS2782 and complies with the British Pharmaceutical Codex 1949

DEFINITION

ATEOL Tea Tree Oil is obtained solely by steam distillation of the foliage and terminal branchlets of *Melaleuca alternifolia*.

PHYSICAL CHARACTERISTICS

Appearance: A clear colourless to pale yellow liquid

Odour: Myristic

Relative Density 20°C/20°C 0.890 to 0.900 Method (ISO 279)

Refractive Index at 20°C 1.476 to 1.481 Method (ISO 280)

Optical Rotation [α]2D. +6 to +10 Method (ISO 592)

Solubility in 85% v/v ethanol at 20° The miscibility in ethanol shall be such that one volume of the oil shall not require more than two volumes of 85% ethanol to give a clear solution - Method (ISO 875)

CHEMICAL COMPOSITION

Chromatographic Determination Method (AS2782)
1,8-Cineole: 4± 2%
Terpinen-4-ol: Greater than 35%

ANTIMICROBIAL ACTIVITY

MIC (minimum inhibitory concentrations) against most commonly encountered pathogenic Gram negative and Gram positive bacteria and fungi are typically in the range 0.5 - 1.0% v/v.

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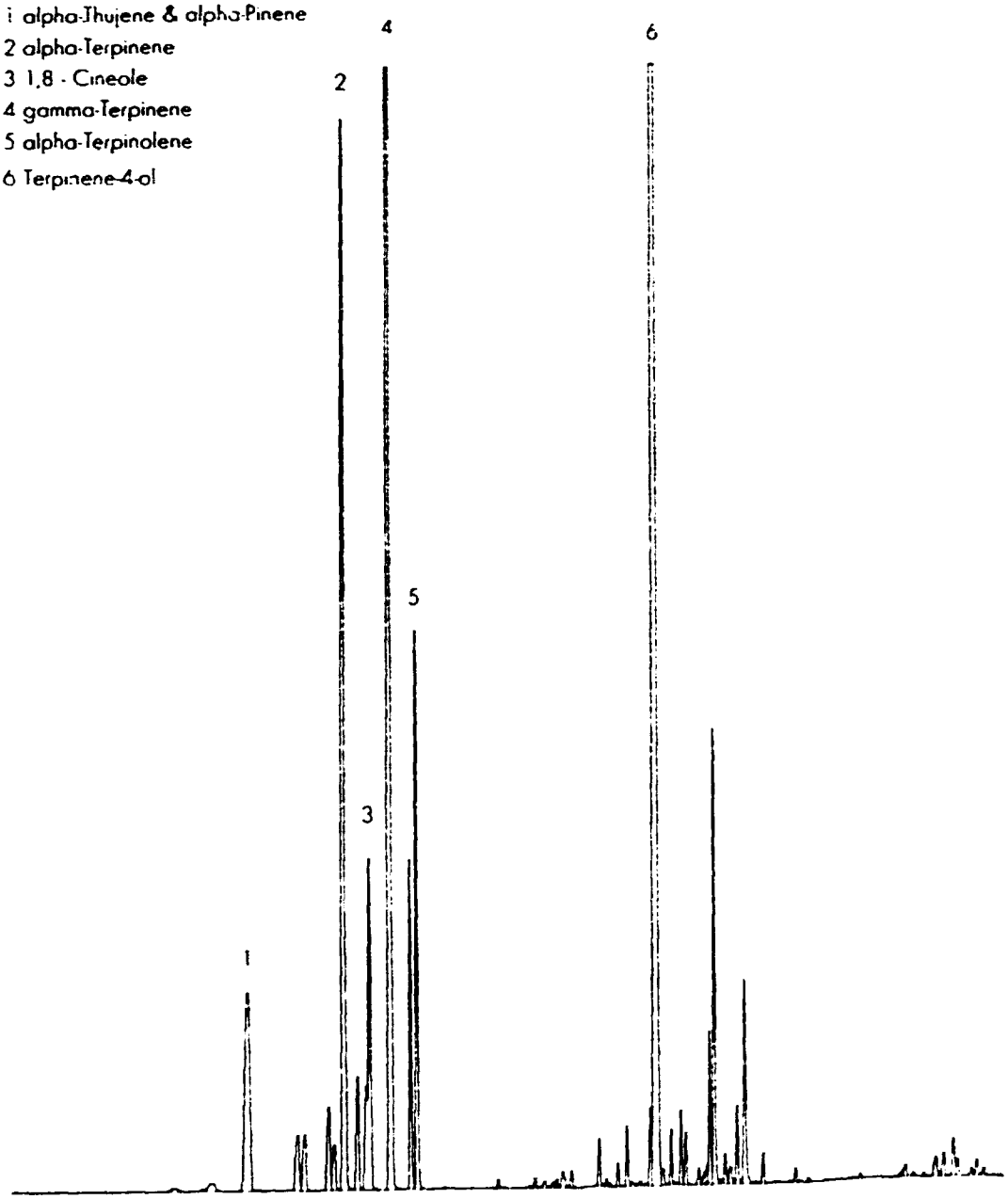
ATEOL - TYPICAL GAS CHROMATOGRAM

1 alpha-Thujene & alpha-Pinene
2 alpha-Terpinene
3 1,8 - Cineole
4 gamma-Terpinene
5 alpha-Terpinolene
6 Terpinene-4-ol



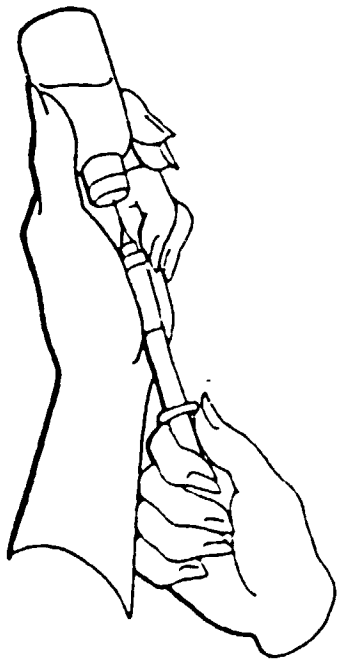
ANNEX 6

The Australian Therapeutic Goods Administration's requirements for tea tree oil product preparation under CGMP.

Department of Health, Housing and Community Services

TGA Therapeutic Goods Administration

Licensing of Australian Manufacturers of Therapeutic Goods



GMP Audit & Licensing Section

LICENSING OF AUSTRALIAN MANUFACTURERS OF THERAPEUTIC GOODS

With certain exceptions, the Therapeutic Goods Act 1989 requires Australian manufacturers of therapeutic goods for human use to hold a licence. It is an offence, carrying heavy penalties, to manufacture therapeutic goods without such a licence unless the goods are exempted from this requirement.

Manufacturer is defined in the Act, as follows:

"manufacture", in relation to therapeutic goods, means:

(a) to produce the goods; or

(b) to engage in any part of the process of producing the goods or of bringing the goods to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for sale of the goods or of any component or ingredient of the goods as part of that process.

This broad definition means that contractors such as contract sterilising or analytical or microbiological laboratory services and contract packers are also subject to licensing if they handle or test therapeutic goods. A sponsor who has goods made by others but who engages in any step of manufacture is also licenceable.

The licence relates to specific manufacturing premises, so that separate licences are required for each building, group of buildings or site except where buildings, groups or sites are used to make only one kind of goods and are under common production and quality control. These provisions cover warehousing or storage of goods as part of manufacture. However, they do not include wholesaling from the manufacturing or other premises, which comes under State or Territory controls.

The requirement for licensing applies to manufacturers who are trading corporations generally and to persons or corporations who are involved in export, import, interstate trade, supply of pharmaceutical or repatriation benefits or supply to the Commonwealth. However, certain classes of person are exempt, namely

- medical practitioners, dentists and other health care workers registered under State or Territory legislation making goods for their own patients;
- pharmacists, biomedical engineers and radiochemists within public hospital systems manufacturing goods for use within the hospitals in the same State or Territory;
- pharmacists in their own retail shops Friendly Society dispensories and private hospitals, provided the goods are not sold by wholesale, but supplied from there premises;
- alternative therapy practitioners making goods for private supply to their own clients; and
- persons who are adding a supplementary label to show their name and address or a product registration or listing number.

The manufacture of certain classes of goods is exempt from licensing unless supplied as Pharmaceutical Benefits, namely:

- inactive starting materials (except water),
- herbs, or oils extracted from herbs, the sole therapeutic use of which is for supply as starting materials to licenced manufacturers;
- unmedicated anti-acne cleansing preparations;
- anti-perspirants based only on salts Al, Zn or Zr;
- disinfectants;
- medicated insect repellents;
- medicated solid and semi-solid soaps;
- medicated throat lozenges containing only volatile oils, with or without vitamin C;
- non-sterile homeopathic preparations more dilute than a thousand fold dilution of a mother tincture;
- dentifrices containing no therapeutically active substance other than not more than 1000 mg/kg fluoride;
- sunscreen products for dermal use (this is a transitional exemption);

- unscheduled dandruff prevention or treatment preparations;
- goods prepared for initial experimental studies in human volunteers;
- non-sterile "in vitro" diagnostics, unless they are for home use or contain human tissue or are for diagnosis of AIDS or are antimicrobial susceptibility discs;
- containers, except certain plastic containers which are intended to contain or transmit goods for parenteral use, e.g. blood bags;
- non-sterile devices except:
  - contraceptives;
  - devices for preventing transmission of disease between persons such as condoms and surgical examination gloves;
  - dental and other restoratives and replacements;
  - implantable devices;
  - lubricant gels;
  - bandages, dressings, gauzes & undercast padding;
  - soft contact lenses;
  - any other device that must be a "registered" good under Part 3 of the Act, as distinct from a "listed" good.

Note that the above classes of person and classes of goods are abbreviated entries: for the precise classification the Regulations must be consulted. In addition, it should be noted that certain goods are exempted by Declaration from the Act as a whole.

Although drugs exempt from licensing are in general exempt from registration or listing, therapeutic devices exempt from licensing may nevertheless be required to be registered or listed on the Australian Register of Therapeutic Goods.

Application for licensing must be made on an official application form available from the Therapeutic Goods Administration. At the commencement of the legislation on 15 February 1991, existing manufacturers had four months to apply for a licence. These manufacturers who have submitted applications within this period can continue to manufacture without a licence until the application is decided upon.

Other manufacturers, or an existing manufacturer who wishes to extend to another type of manufacture after 15 June 1991, must hold a licence prior to manufacturing such goods for use in humans.

Applications must be accompanied by the prescribed application fee of $300, and should be sent to the Business Management Unit, Therapeutic Goods Administration, PO Box 100, Woden, ACT, 2606. The applicant may be required, in some cases, to provide further data.

An audit of the premises will usually be required unless there has been a reasonably recent audit or a satisfactory audit history that demonstrates that a licence can be issued. An annual licence charge is payable, depending on the class of licence applicable. A fee will also be charged for each audit.

The Act provides criteria for refusing a manufacturer's licence application, including an inability to comply with the "manufacturing principles" determined by the Minister, which include Codes of Good Manufacturing Practice. Copies of these codes may be purchased from the GMP Audit and Licensing Section.

Licences are issued subject to conditions. The licence itself will usually restrict manufacturers to one or more major categories of activity. Further conditions are issued separately but form part of the licence to manufacture, and further define the sub-categories of goods or activities which the manufacturer wishes to and is competent to engage in. Applications to the GMP Audit and Licensing Section for variation of conditions other than major categories may be made at any time without payment of an additional fee.

Applicants will be notified of the approval or refusal of a licence application and of any proposed suspension or revocation of their licence or of any modification of the conditions of their licence. Unless there is an immediate and serious health risk, a reasonable time to make submissions in relation to changes that would adversely affect the applicant or licencee will be given and the Act provides for an appeal mechanism.

The licence and the separate list of conditions that may apply must be publicly displayed by the licence holder at the premises specified in the licence.

A licence will remain in force unless suspended or revoked, but may be modified, suspended or revoked at any time subject to notice and appeal as above. Periodic audits will monitor compliance with the requirements of the Act and Regulations including conformity to the "manufacturing principles". Each audit will be followed by the issue of a report, advising the manufacturer of the assessment of the observed level of compliance with the "manufacturing principles" and listing any deficiencies. A response, indicating any necessary corrective measures taken or proposed, is expected from the manufacturer. The opportunity may also be taken to correct any misunderstandings, present data not available at the audit or debate interpretations.

Failure to pay the annual licence charge or any payable audit fee is a reason to revoke a licence, without notice, though it is intended to issue a warning. Serious and/or chronic inability to comply with GMP will also be grounds to suspend or revoke licences.

Suspended licences may be restored at any time where the Therapeutic Goods Administration is satisfied that corrective action has been taken and will continue.

Certain other conditions are applied by the Act and Regulations to all licences, the most important of which is that the persons who are to have control of the production and quality control measures must be nominated and must exert that control.

Where they are to be replaced, the GMP Audit and Licensing Section must be notified at once and the licence will be amended if the replacements are judged suitable.

The Regulations permit the publication of a list of licencees together with the categories of goods or the kinds of manufacture which their licence authorises them to manufacture. It is intended to issue such a list at least annually.

Where products are manufactured overseas the Australian sponsor is required to provide evidence that the standard of manufacture at the overseas site is equivalent to that expected of Australian manufacturers. A guideline document providing information on what is considered to be acceptable forms of evidence is available from the GMP Audit & Licensing Section.

This summary is issued for the guidance of manufacturers. It does not modify legal obligations. In case of doubt the Act, Regulations and relevant Declarations should be consulted.

To obtain more information, write to:

GMP Audit and Licensing Section
Therapeutic Goods Administration
Department of Health, Housing & Community Services

PO Box 100
Woden ACT 2606
Australia

☎ 06 286 0212 Fax: 06 2861386

1 October 1991

TABLE OF CONTENTS

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NOTE: Each test calibration and procedure is followed by supplementary notes. Where practicable, the clause numbers of these notes is linked to the corresponding main text numbers.