



HICCS 2008 – Helsinki Fair Centre – 22nd May 2008

SUBSTANCE IDENTIFICATION PARAMETERS, ANALYTICAL INFORMATION AND PROCEDURE WITHIN THE CONTEXT OF REACH

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WHEN YOU NEED TO BE SURE

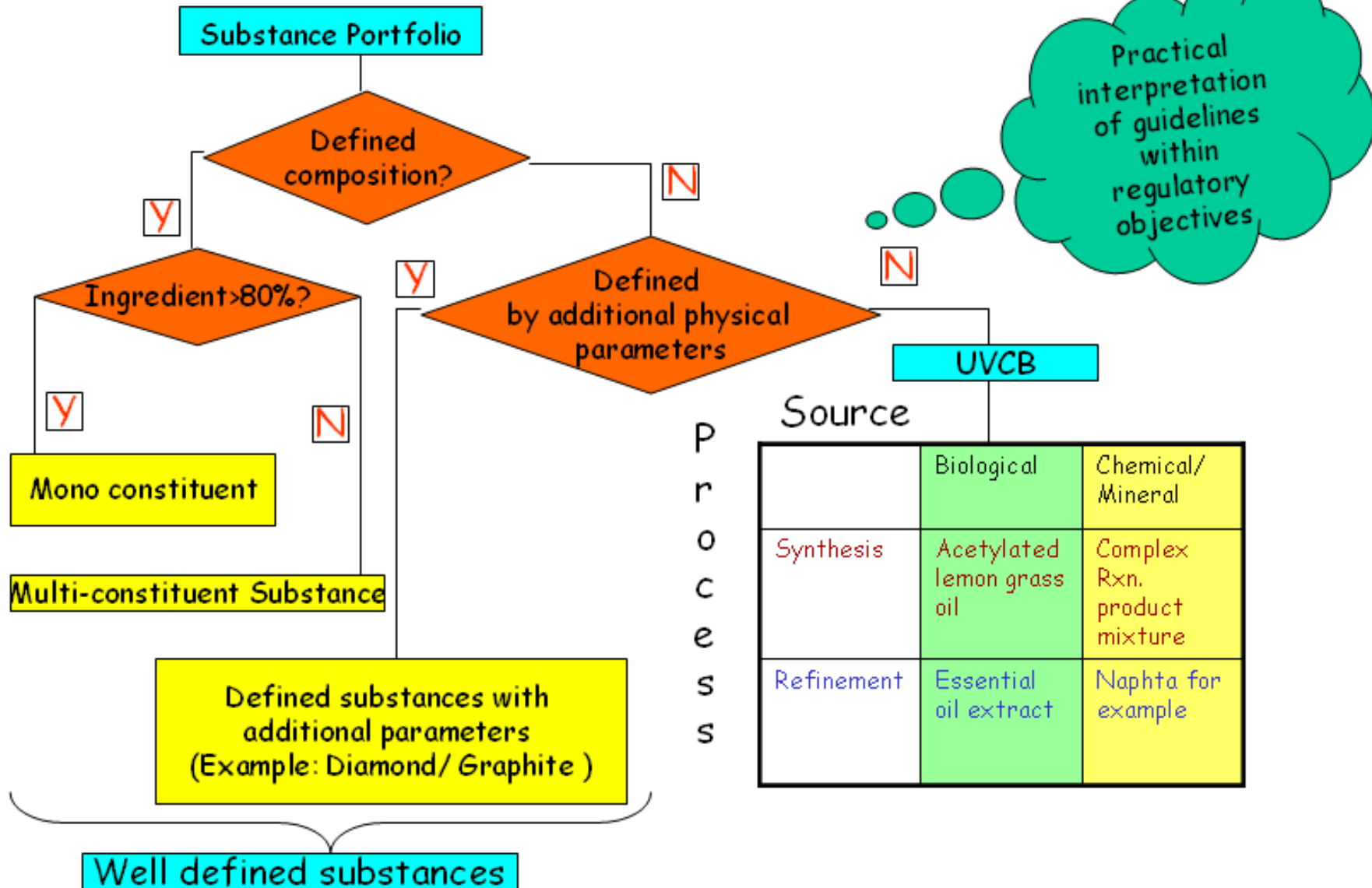


1. Required parameters for substance identification in REACH annex VI item 2 and analytical procedures
2. Classification of substance types under REACH (TGD RIP 3.10)
3. Analytical methods appropriate for the various types of substances
4. Analytical techniques for analytical information
5. Main identifiers for various types of well-defined substances
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10. IUCLID 5: reporting of analytical information
11. Validation of method under GLP studies
12. GLP studies process
13. Analytical laboratory capacity to implement tests required under REACH requirement

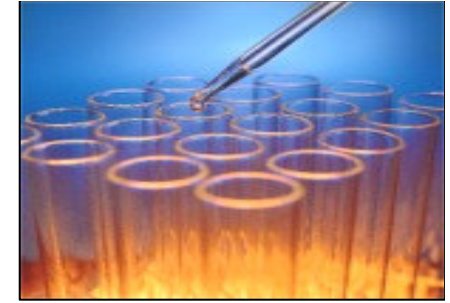
1. Required parameters for substance identification in REACH annex VI item 2 and analytical procedures

2.2	Information related to molecular and structural formula of each substance
2.2.1	<i>Molecular and structural formula (including SMILES notation, if available)</i>
2.2.2	<i>Information on optical activity and typical ratio of (stereo) isomer (if applicable and appropriate)</i>
2.2.3	<i>Molecular weight or molecular weight range</i>
2.3.	Composition of each substance
2.3.1	<i>Degree of purity (%)</i>
2.3.2	<i>Nature of impurities, including isomers and by-products</i>
2.3.3	<i>Percentage of (significant) main impurities</i>
2.3.4	<i>Nature and order of magnitude (.....ppm,%) of any additives (e.g. stabilising agents or inhibitors)</i>
2.3.5	<i>Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)</i>
2.3.6	<i>High performance liquid chromatogram, gas chromatogram</i>
2.3.7	<i>Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.</i>

2. Classification of substance types under REACH (TGD RIP 3.10)



3. Analytical methods appropriate for the various types of substances



- For the identification of the substance
- For the identification of impurities and additives, that need to be given to allow methods to be reproduced
- The laboratory has a GLP acknowledgement, the analytical procedures are validated under GLP procedures which provides a certain reliability in compliance with EOCD guidelines as stated in REACH.

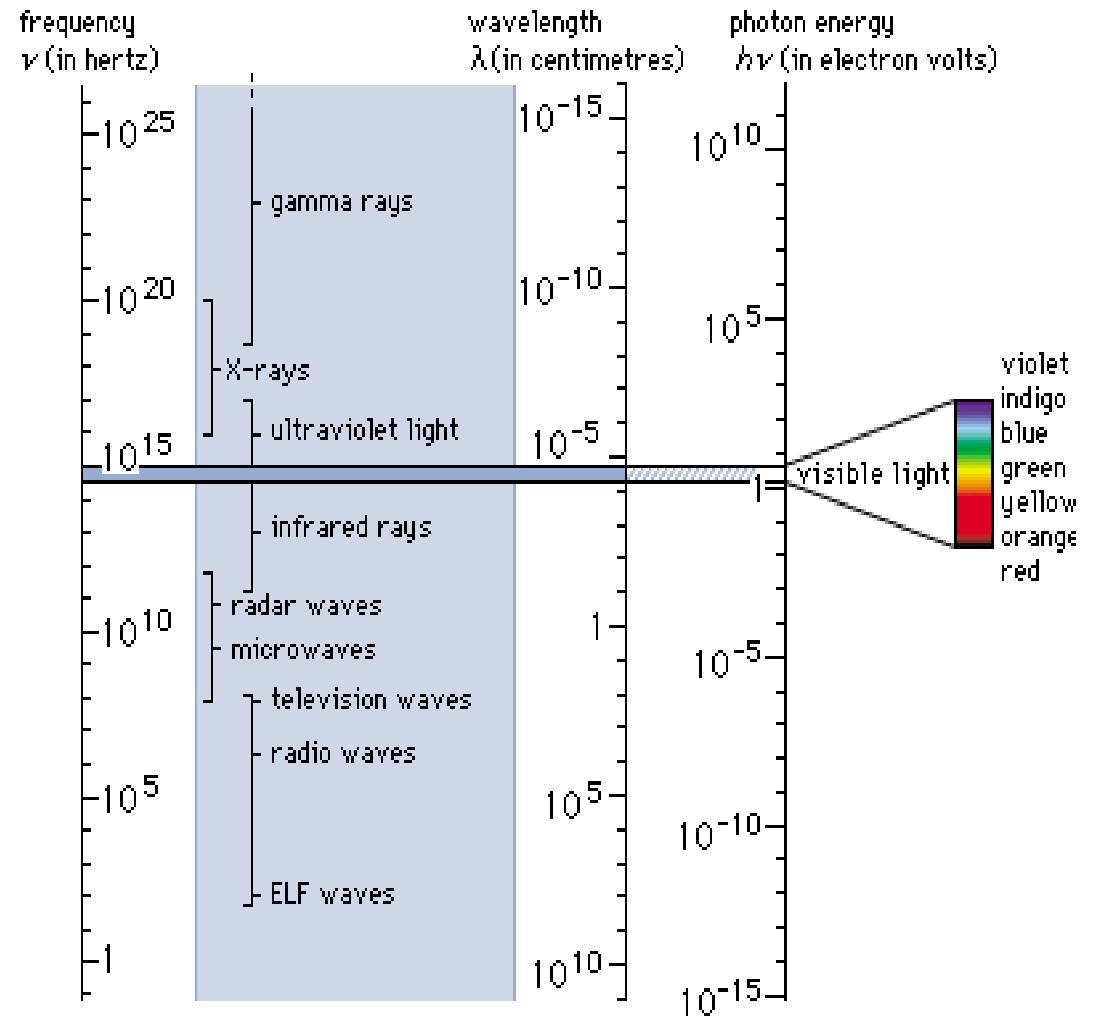
- **What kind of analytical information?**

- 4. a/ Structure:**

- **Spectral data** to confirm structure of mono constituent substances
- **Spectroscopic methods** suitable
 - ✓ **UV/VIS Spectroscopy** (Ultra Violet and Visible absorption Spectroscopy)
 - ✓ **IR Spectroscopy** (Infrared Spectroscopy)
 - ✓ **NMR** (Nuclear Magnetic Resonance Spectroscopy)
 - ✓ **MS** Mass Spectroscopy (molecular & structural formula, molecular weight)
- **Inorganic**
 - ✓ **XRD** (X-Ray Diffraction)
 - ✓ **XRF** (X-Ray Fluorescence)
 - ✓ **AAS**
 - ✓ **AOES**
 - ✓ **ICP/MS**

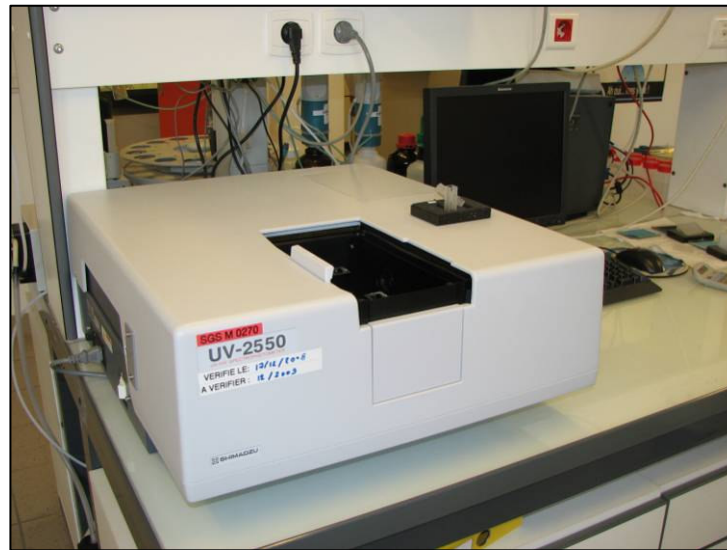
4. a/ Spectroscopy, an analytical method

- Spectroscopy is the study of the interaction between radiation and matter.
- Spectrometry is the measurement of these interactions.
- The machine which performs these measurements is a spectrometer.



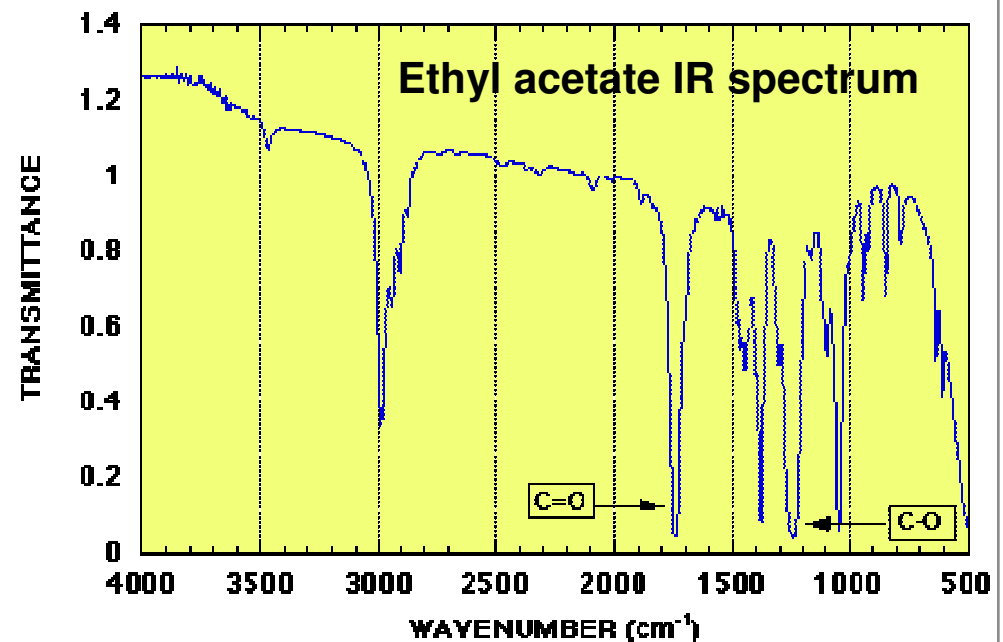
4. a/ UV Visible Spectroscopy

- Spectroscopy of photons in the UV-visible region.
- In this region of the electromagnetic spectrum, molecules undergo **electronic transitions**.
- The UV/visible spectrophotometer measures the intensity of light passing through a sample and the intensity of light before the beam of light passes through the sample.



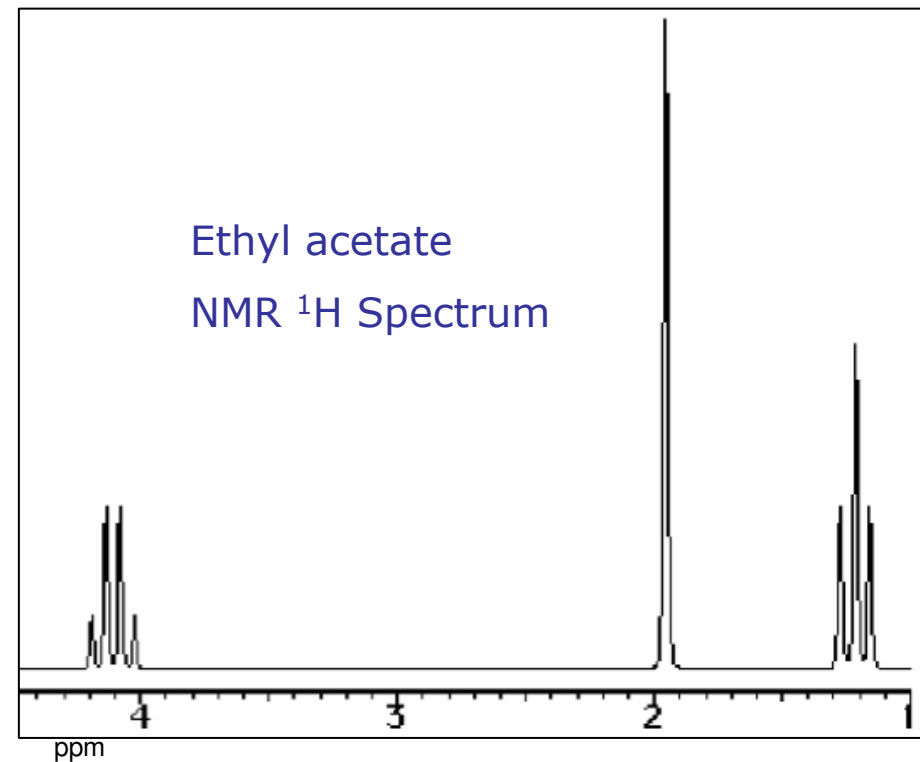
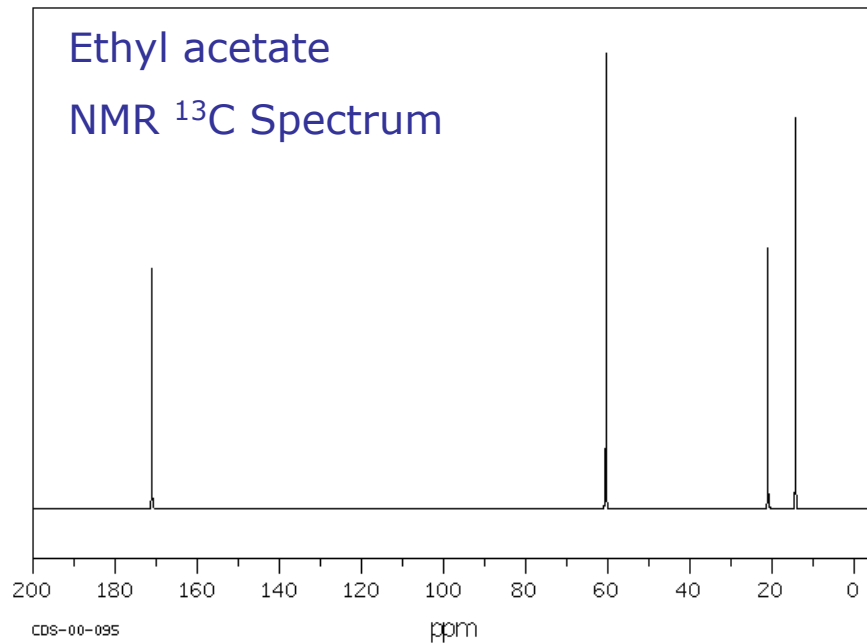
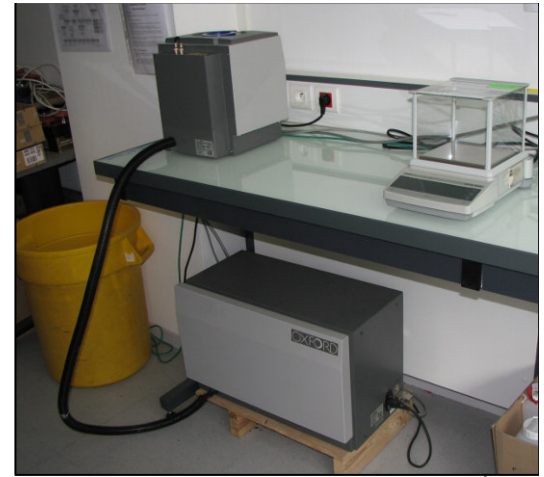


- IR spectroscopy deals with the infrared region of the electromagnetic spectrum
- Molecules have specific frequencies at which they rotate or vibrate corresponding to discrete energy levels.
- Infrared spectroscopy offers the possibility to measure different types of inter atomic bond vibrations at different frequencies.
- 2 areas in an IR spectrum:
 - **Fingerprint**
(wave number <math>< 1500 \text{ cm}^{-1}</math>)
 - Characteristic bands of functional groups
(wave number >math>> 1500 \text{ cm}^{-1}</math>)

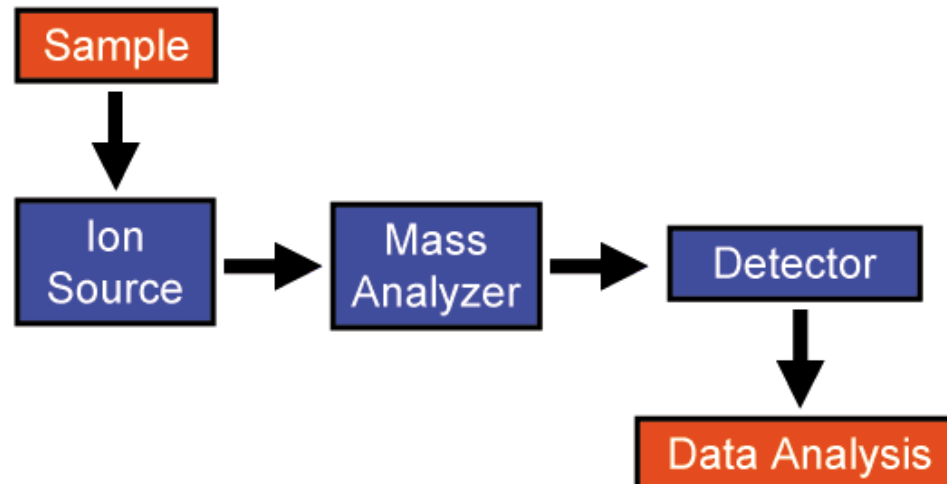


4. a/ NMR Spectroscopy

- Nuclear magnetic resonance spectroscopy
- Technique which exploits the magnetic properties of certain nuclei
- NMR is applicable to nucleus possessing **spin**



- MS measures the mass-to-charge (m/z) ratio of charged particles
- Mass spectrometers consist of 3 basic parts: an ion source, a mass analyzer, and a detector system.
- The stages within the mass spectrometer are:
 - Production of ions from the sample
 - Separation of ions with different masses
 - Detection of the number of ions of each mass produced
 - Collection of data to generate the mass spectrum



GC-MS

- **What kind of analytical information?**

4. b/ **Composition:**

In order to determine nature & percentage of impurities and additives, there are different techniques:

- Gas chromatography **GC** (mobile phase = gas)
- Liquid chromatography **HPLC** (mobile phase = liquid)

4. b/ Chromatography, an analytical method

- Technical separation
- Chromatography is a physical method of separation in which the components to be separated are distributed between two phases, one of which is stationary while the other moves in a definite direction. The stationary phase permits the separation of the analytes and their isolation.




GC



HPLC

5. Main identifiers for various types of well-defined substances

<p>Mono-constituent substances</p> <ul style="list-style-type: none"> - ethyl acetate 99% - nickel 	<p>Main identifiers</p> <ul style="list-style-type: none"> - chemical composition : one main constituent - chemical identity CAS - spectrum, concentration
<p>Multi-constituent substances Identity: reaction of mass of m-xylene, o-xylene</p>	<ul style="list-style-type: none"> - quantitative analysis of the constituents - impurity - chemical identity, molecular and structural formula of the constituent -> proven by analytical information
<p>Substance defined by more than the chemical composition</p> <p> - minerals</p>	<p>Chemical composition as mono or multi constituent and other physical or characterization parameters</p> <ul style="list-style-type: none"> - crystallography - X-Ray - Infrared, swelling index

6. Example of Ethyl acetate (a mono constituent substance)

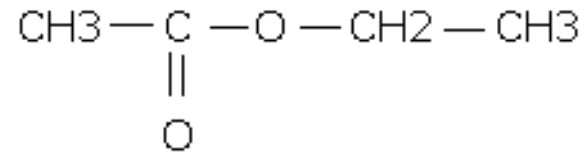
- Name and identity of the substance: C₄H₈O₂
 - Data bank **ESIS**: 26 substances have the same molecular formula (isomers)

ESIS: European Substances Information System

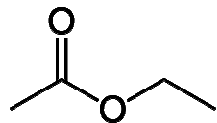
Result for Molecular Formula: C4H8O2				
26 substances have been found. Results 1 to 26 of 26				
ID	Molecular Formula	Substance Name	EC#	CAS#
0001	> C4H8O2	Isobutyric acid	201-195-7	79-31-2
0002	> C4H8O2	3-hydroxybutyraldehyde	203-530-2	107-89-1
0003	> C4H8O2	Butyric acid	203-532-3	107-92-6
0004	> C4H8O2	But-2-ene-1,4-diol	203-787-0	110-64-5
0005	> C4H8O2	Propyl formate	203-798-0	110-74-7
0006	> C4H8O2	1,4-dioxane	204-661-8	123-91-1
0007	> C4H8O2	Ethyl acetate	205-500-4	141-78-6
0008	> C4H8O2	Tetrahydrofuran-3-ol	207-219-2	453-20-3
0009	> C4H8O2	3-butene-1,2-diol	207-835-1	497-06-3
0010	> C4H8O2	2-methyl-1,3-dioxolane	207-841-4	497-26-7
0011	> C4H8O2	1,3-dioxane	208-005-1	505-22-6
0012	> C4H8O2	Acetoin	208-174-1	513-86-0
0013	> C4H8O2	Methyl propionate	209-060-4	554-12-1
0014	> C4H8O2	4-hydroxybutan-2-one	209-693-6	590-90-9
0015	> C4H8O2	Isopropyl formate	210-901-2	625-55-8
0016	> C4H8O2	2-(vinylloxy)ethanol	212-124-4	764-48-7
0017	> C4H8O2	(methoxymethyl)oxirane	213-216-7	930-37-0
0018	> C4H8O2	4-methyl-1,3-dioxolane	214-008-9	1072-47-5
0019	> C4H8O2	2-methylenepropane-1,3-diol	222-516-7	3513-81-3
0020	> C4H8O2	1-hydroxybutan-2-one	225-790-6	5077-67-8
0021	> C4H8O2	Methoxyacetone	227-549-0	5878-19-3
0022	> C4H8O2	(Z)-2-butene-1,4-diol	228-085-1	6117-80-2
0023	> C4H8O2	1,2-dimethoxyethylene	233-737-3	10340-88-2
0024	> C4H8O2	2-hydroxy-2-methylpropionaldehyde	244-059-2	20818-81-9
0025	> C4H8O2	4-hydroxybutyraldehyde	247-205-3	25714-71-0
0026	> C4H8O2	Butene-1,4-diol	249-819-7	29733-86-6

6. Example of Ethyl acetate (a mono constituent substance)

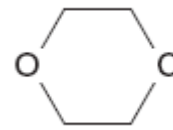
- From molecular formula $C_4H_8O_2$ to structural formula:



- Spectral data: Mass spectrometry
 - Ethyl acetate and 1,4-Dioxane:
 - ✓ The same molecular formula $C_4H_8O_2$
 - ✓ A different structural formula

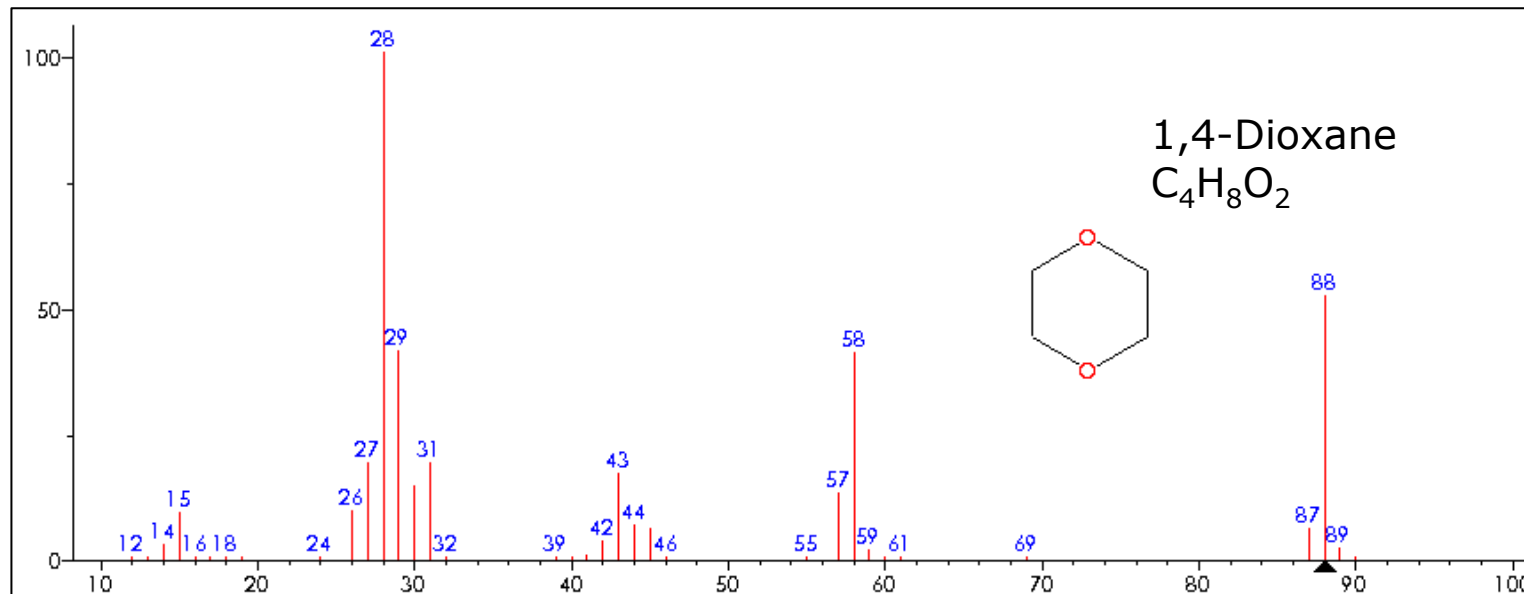
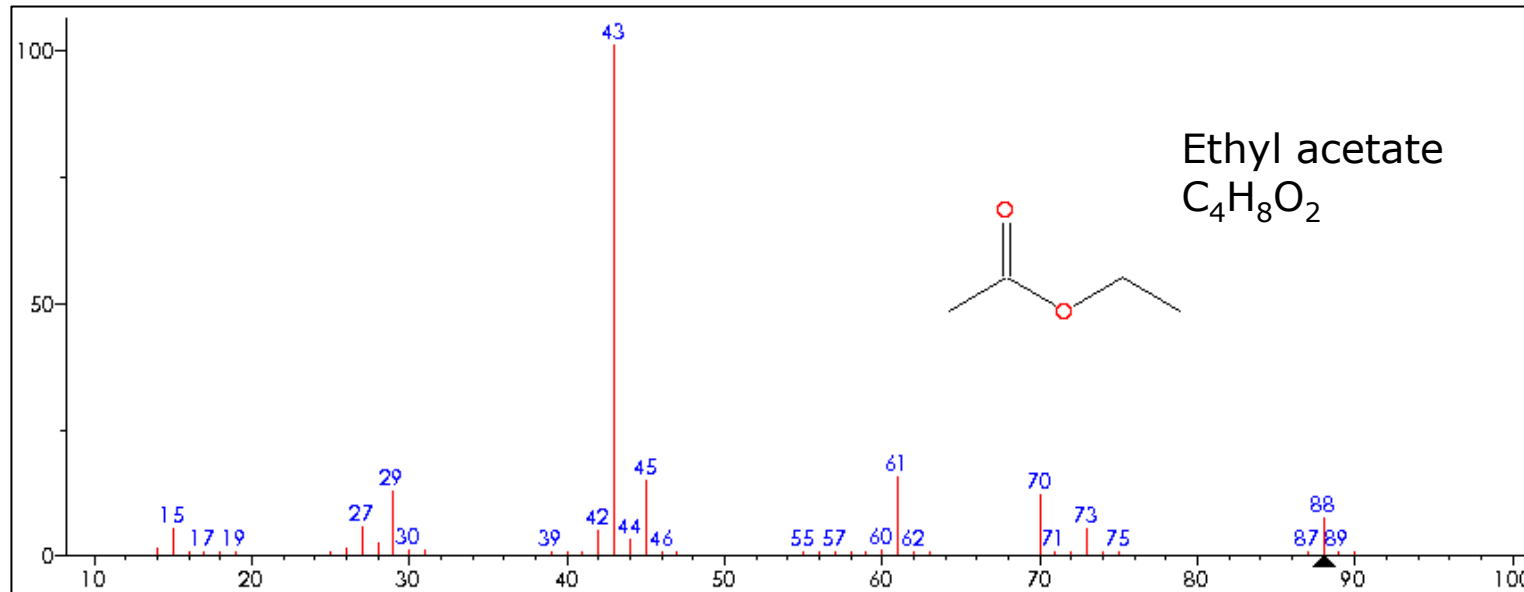


Ethyl acetate



1,4-Dioxane

6. Example of Ethyl acetate (a mono constituent substance)



7. Well-defined substances: Substances defined with other main identifiers (minerals)

- Substances (minerals) that can be identified by chemical composition need to be further specified by additional identification, in order to record the substance's identity unequivocally.

- Identifications and related analysis

The other specific main identifying parameters to be added depend on the substance

Element composition

- ✓ Spectral data to identify mineralogical and crystalline structure

- ✓ Confirmed by physico-chemical properties

- Shape

- Hardness

- Swelling capacity

- Density

- Surface area

Very low hardness for talc

Swelling capacity for bentonite

Very high density for barite

8. UVCB substances Identification and analytical fingerprint

- **UVCB substance:** substance of Unknown or Variable composition, Complex reaction product or Biological material
 - The number of constituents is relatively large
 - The composition is to a significant point unknown
 - The variability of composition is relatively large or poorly predictable
- Main identifiers for the various types of UVCB substances are related to:
 - Source of the substance
 - Process used
 - Other identification
 - ✓ Chromatographic or other fingerprint

What is a **chromatographic fingerprint**?

It is the representation of the substance composition from the characteristic distribution of constituents in an analytical chromatogram.

Table 4.2 Grouping of main identifiers for examples that represent various types of UVCB substances

Common features		Examples or representatives	Main identifiers		
			Source	Process	Other Identifiers
UVCB substances (Substances of Unknown or Variable composition, Complex reaction products or Biological materials) <i>[Chapter 4.3]</i>	Biological materials (B)	Extracts of biological materials e.g. natural fragrances, natural oils, natural dyes and pigments	<ul style="list-style-type: none"> Plant or animal species and family Part of plant/animal 	<ul style="list-style-type: none"> Extraction Fractioning, concentrating, isolation, purification, etc. <u>Derivation*</u> 	<ul style="list-style-type: none"> Known or generic composition Chromatographic and other fingerprints Reference to standards Colour index
		Complex biological macromolecules e.g. enzymes, proteins, DNA or RNA-fragments, hormones, antibiotics			<ul style="list-style-type: none"> Standard enzyme index Genetic code Stereo configuration Physical properties Function/activity Structure Amino acid sequence
		Fermentation products antibiotics, biopolymers, enzyme mixtures, vinasses (products of sugar fermentation) etc.	<ul style="list-style-type: none"> Culture medium Micro-organism applied 	<ul style="list-style-type: none"> Fermentation Isolation of products Purification steps 	<ul style="list-style-type: none"> Type of products: e.g. antibiotics, biopolymers, proteins etc Known composition
	Chemical and mineral substances with poorly defined, complex or variable composition (UVC)	Reaction mixtures with poorly predictable and/or variable composition	<ul style="list-style-type: none"> Starting materials 	<ul style="list-style-type: none"> <u>Chemical reaction type</u>, e.g. esterification, alkylation, hydrogenation 	<ul style="list-style-type: none"> Known composition Chromatographic and other fingerprints Reference to standards
		<ul style="list-style-type: none"> Fractions or distillates, e.g. petroleum substances Clay e.g. bentonite Tars 	<ul style="list-style-type: none"> Crude oils Coal/peat Mineral gases Minerals 	<ul style="list-style-type: none"> Fractionation, distillation <u>Conversion of fractions</u> Physical processing Residues 	<ul style="list-style-type: none"> Cut off ranges Range of chain length Ratio aromatic/ aliphatic Known composition Standard index
		Concentrates or melts, e.g. metallic minerals, or residues of various melting or metallurgic processes, e.g. slags	<ul style="list-style-type: none"> Ores 	<ul style="list-style-type: none"> Smelting Heat treatment Various metallurgic processes 	<ul style="list-style-type: none"> Known or generic composition Concentration of metals

* Underlined processes indicate synthesis of new molecule

8. UVCB substances

Analytical substance identification parameters

- Main constituents and impurities are not relevant for UVCB chemical composition given in a general way (linear fatty acid C-C16)
 - Generic description of chemical composition
 - Chromatographic fingerprint or other type of fingerprint show characteristic peak distribution
 - Reference material (e.g. ISO)
 - Physico-chemical parameters (e.g. boiling point)
 - Colour index number
 - AISE number

9. Example of UVCB substance : Essential oil of Lavandin grosso

■ Substance name:

- Substance type: UVCB, biological refinement
- ESIS: lavender, *lavandula hybrida grosso*
- Other: ISO standard (ISO 8902-1999)

Source

Species	<i>Lavendula hybrida grosso</i> (Lamiaceae)
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Process

<p>Description of (bio)chemical reaction processes used for the manufacture of the substance:</p> <p>Water steam distillation of the flowering tops of <i>Lavendula hybrida grosso</i> (Lamiaceae) and subsequent separation of the water from the Essential Oil;</p> <p>The subsequent separation is a spontaneous, physical process, which normally takes place in a separator (a so-called "florentine flask") enabling an easy isolation of the separated oil. The temperature at this stage of the distillation process is about 40 °C.</p>

Name

IUPAC name or other international chemical name	Essential oil of <i>Lavendula hybrida grosso</i> (Lamiaceae)
EC number	297-385-2
EC name	Lavender, <i>Lavandula hybrida grosso</i> , ext.
EC description	Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from <i>Lavandula hybrida grosso</i> , Labiatae ¹⁸ .
CAS number	93455-97-1
CAS name	Lavender, <i>Lavandula hybrida grosso</i> , ext.

9. Example of UVCB substance: Essential oil of Lavandin grosso

- **Substance identification**

- Analysis of essential oil carried out by gas chromatography, known constituents of the composition

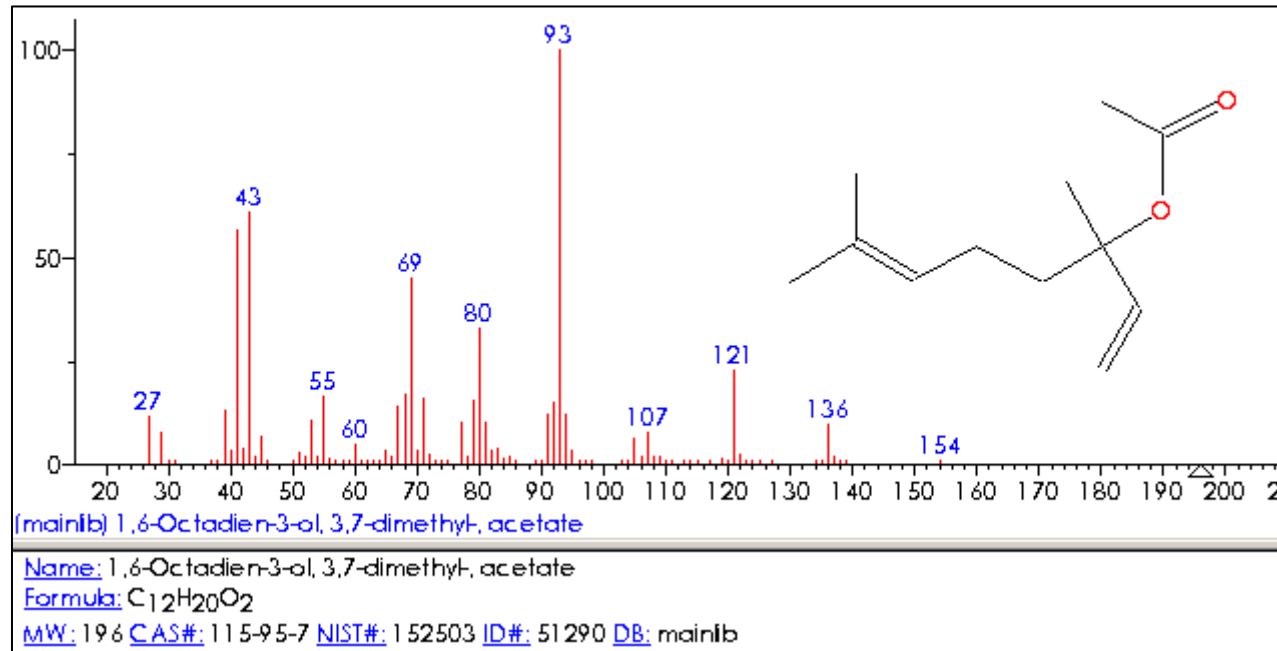
Table 1 - Chromatographic profile

Component	Minimum %	Maximum %
1,8-Cineole	4	7
Limonene	0,5	1,5
cis-β-Ocimene	0,5	1,5
trans-β-Ocimene	traces	1
Camphor	6	8
Linalool	24	35
Linalyl acetate	28	38
Terpinen-4-ol	1,5	5
Borneol	1,5	3
Lavandulol	0,2	0,8
Lavandulyl acetate	1,5	3

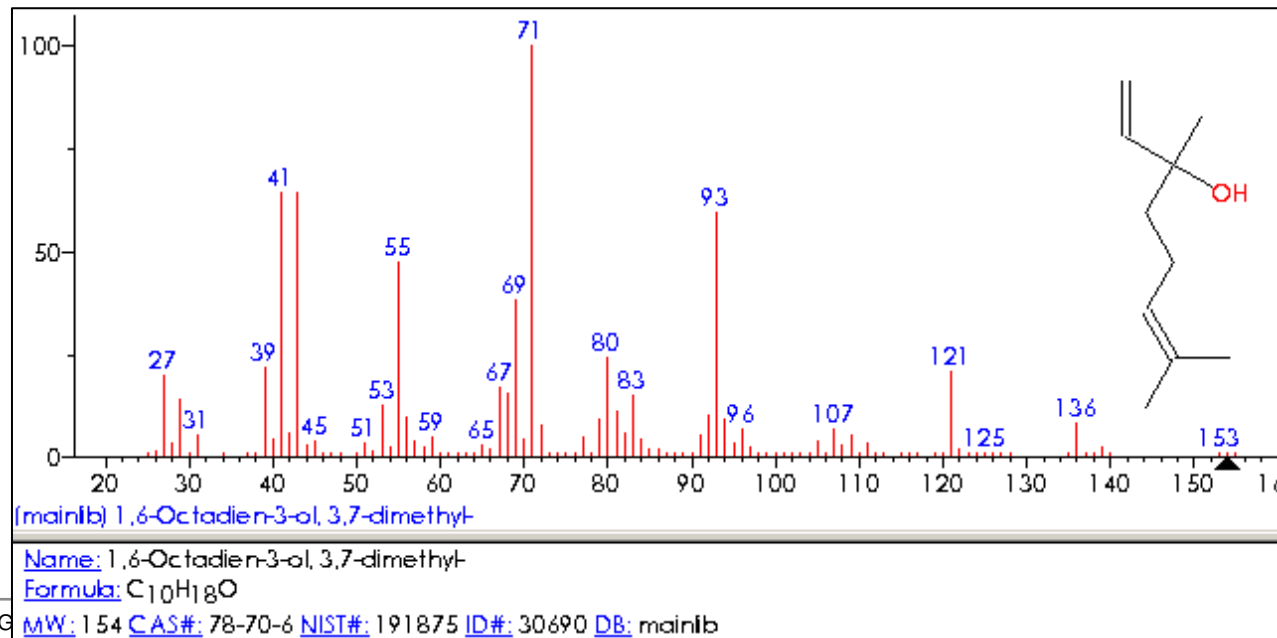
Chromatographic profile composition

- The analysis of essential oils are carried out by gas chromatography (characteristic of components identified)
- UVCB: the proportions of these components with lower and upper levels
 - Identification with CAS number by GC/MS
 - Known constituents $\geq 10\%$
 - Molecular formula, molecular weight, structural formula
 - Linalyl acetate $C_{12}H_{20}O_2$
 - Linalool $C_{10}H_{18}O$

Molecular formula and structural formula: linalyl acetate by Mass Spectrometry



Molecular formula and structural formula: linalol by Mass Spectrometry



Composition and other analytical identification

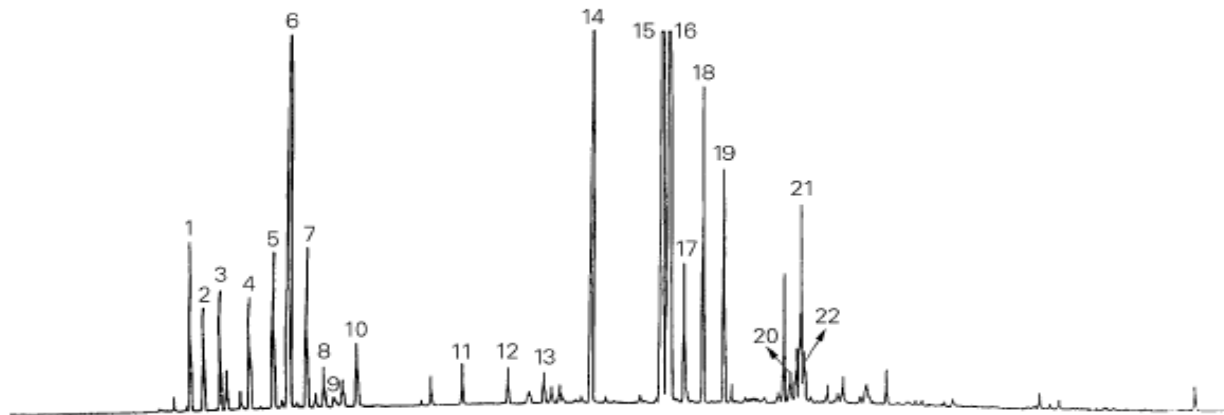
- Content (see table)
 - Linalool acetate 28% to 38%
 - Linalool 24% to 35%
- Other key identifiers (requirement under ISO 8902: 1999)
 - Clear mobile liquid
 - Colour is a light yellow
 - Odour is characteristic, slightly camphoraceous lavender like
 - Relative density at 20 °C
 - ✓ Minimum 0,891
 - ✓ Maximum 0,899
 - Refractive index at 20 °C
 - ✓ Minimum 1,458
 - ✓ Maximum 1,462
 - Optical rotation at 20 °C
 - ✓ Between -7 °C and -3,5 °C
 - Chromatographic profile (fingerprint)

Composition and other analytical identification

- Test methods
 - Relative density ISO 279
 - Refractive index ISO 280
 - Optical rotation ISO 592
 - Chromatographic profile ISO 11024-1 and ISO 11024-2

9. Example of UVCB substance : Essential oil of Lavandin grosso

Fingerprint chromatographic profile of UVCB substance



Peak identification

- 1 α -Pinene
- 2 Camphene
- 3 β -Pinene
- 4 Myrcene
- 5 Limonene
- 6 1,8-Cineole
- 7 *cis*- β -Ocimene
- 8 *trans*- β -Ocimene
- 9 3-Octanone
- 10 Hexyl acetate + terpinolene
- 11 1-Octen-3-yl acetate
- 12 Hexyl butyrate
- 13 1-Octen-3-ol
- 14 Camphor
- 15 Linalool
- 16 Linalyl acetate
- 17 β -Caryophyllene
- 18 Terpinen-4-ol
- 19 Lavandulyl acetate
- 20 Lavandulol
- 21 Borneol
- 22 α -Terpineol

Operating conditions

Column: capillary; length 50 m; internal diameter 0,32 mm
 Thickness of film: 0,25 μ m
 Stationary phase: polyethylene glycol (Carbowax 20 M)
 Oven temperature: isothermal at 70 °C for 15 min, then programmed from 70 °C to 180 °C at a rate of 2 °C/min
 Injector temperature: 200 °C
 Detector temperature: 220 °C
 Detector: flame ionization type
 Carrier gas: hydrogen
 Volume injected: 0,2 μ l
 Split ratio: 100:1

Chromatographic profile
of *lavendula hybrida grosso*

- Analytical information
- Result of analysis
- This sub-division is directly related to requirements of REACH (Annex VI):

Analytical information:

- Analytical methods: in this field the description of analytical methods should be given (REACH, annex VI, 2.3.7). For long texts the possibility to attach documents is included
- Optical activity: in this field information on the optical activity and typical ratio of (stereo) isomers should be given if applicable and appropriate (REACH, annex VI, 2.2.2)

Results of analysis:

The result of analysis block is intended to give the user the possibility to provide information on identification related results of analysis and attach items like chromatograms. It can be used to provide spectral data (REACH, annex VI, 2.3.5) or to provide chromatographical data (REACH, annex VI, 2.3.6).

Substance identification: UV-Visible spectrometry

■ Principle:

- This method uses a double-beam spectrophotometer which records only the absorption differences between the blank and test solutions to give the spectrum of the chemical being tested.
- The spectra were obtained with a recording double-beam spectrophotometer. The instruments have a photometric accuracy of ± 0.02 units over the absorbance range of 0 to 2 units. It was capable of recording absorbances at wavelengths of 200 to 750 nanometers with a wavelength accuracy of ± 0.5 nm. The cells employed with the instrument were made in quartz (transparent over this wavelength range).
- A solution of 0.1g/L of UVCB was made in methanol

Substance identification: Infrared spectrometry

■ Principle:

- This method uses a FT-IR spectrophotometer. FT-IR instruments use a polychromatic light source and have a data processing system to convert the interferogram produced to an absorption/transmission spectrum by a mathematical function known as Fourier transformation. The resolution and the wave-number scale are checked using a reference polystyrene film.
- The sample was sandwiched between two plates of a high purity salt (potassium bromide). The plates are transparent to the infrared light and introduce all lines onto the spectra.

Substance identification: UV-Visible spectrometry

- **Result: UV-Visible Spectrum**

Substance identification: Infrared spectrometry

- **Result: IR Spectrum**

Identification of the compounds and quantification: Gas Chromatography

■ Principle:

- All the peaks having a chromatographic surface higher than 0.1% of the sum of the peaks were presented.
- The identifications were made in gas chromatography coupled with the mass spectrometry (GC/MS).
- The compounds in bold characters were identified by research in library (NIST) and confirmed by injection under the same conditions. The compounds in normal character were identified by research in library (NIST). The compounds in italic character were determined by interpretation of the spectra.
- The estimates of the contents were made by standardization of areas in gas chromatography detection with flame ionization

Identification of the compounds and quantification: Gas Chromatography

■ Gas chromatography conditions:

- Gas Chromatography with mass spectrometer detector (GC/MS)
 - ✓ GC/FID AGILENT 7890A & 5975C.
 - ✓ Column Rtx-Wax (reference : 12424, length : 30m, internal diameter : 320µm, : film thickness: 0.25µm, (No GC07-40).
 - ✓ Carrier gas : helium,
 - ✓ Flow : 1mL/min during 10min, then 2mL/min at 1mL/min/min.
 - ✓ Injector temperature: 250 °C.
 - ✓ Oven temperature : 50 °C during 3min, then 240 °C at 20 °C/min, and 240 °C during 11 min.
 - ✓ Interface temperature : 250 °C
 - ✓ Source temperature : 230 °C
 - ✓ Quadripole temperature : 150 °C
 - ✓ Ionisation : Electronic Impact at 70eV.
 - ✓ Acquisition : 50 to 500 Daltons.
 - ✓ Injection of 1µL in splitless mode.

11. Validation of method under GLP STUDIES

N° OF STUDY..... GLP SPONSOR
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NB: Performance tests aim to demonstrate the laboratory's capability to apply a standard method without any modification, but these tests are not part of the conception/validation process

Assessment of the need and context of the project: <i>check off and complete</i>	
Origin of the need	
<input type="checkbox"/> EXTENSION OF THE EXISTING DA (MATRIX/ANALYTE /CONTENT): <input type="checkbox"/> VALIDATION COMPLEMENT (SAME DA): <input type="checkbox"/> TRANSPOSITION ON AN IDENTICAL EQUIPMENT <input type="checkbox"/> OTHER MINOR DEVIATION FROM A REFERENCE METHOD: <input type="checkbox"/> GLP STUDY	<input type="checkbox"/> INTEGRAL DEVELOPMENT <input type="checkbox"/> CHANGE OF EQUIPMENT TYPE: <input type="checkbox"/> OTHER MAJOR DEVIATION FROM A REFERENCE METHOD: <input type="checkbox"/> REQUIREMENTS LINKED TO A SPECIFIC REFERENTIAL: <input type="checkbox"/> REQUIREMENTS LINKED TO A SPECIFIC DEMAND (INCLUDING CUSTOMERS'):
Range of validation	
<input type="checkbox"/> SIMPLIFIED VALIDATION (JUSTIFICATION OF THE SIMPLIFIED VALIDATION (SEE FORM Nr 0048))	<input type="checkbox"/> COMPLETE VALIDATION ACCORDING TO PG-0042 <input type="checkbox"/> VALIDATION ACCORDING TO SPECIFIC REFERENTIAL (INCLUDING CUSTOMERS') :
Needs	
SPECIFIC PURCHASE NEED (INCLUDING MRC)? <input type="checkbox"/> Yes <input type="checkbox"/> No IF YES, WHAT ITEM AND ESTIMATED COST :	BIBLIOGRAPHY RESEARCH NECESSARY?: <input type="checkbox"/> Yes <input type="checkbox"/> No
PRELIMINARY TESTS OF FEASIBILITY REALIZED ON : CONCLUSION: <input type="checkbox"/> C <input type="checkbox"/> NC	REGULATION RESEARCH NECESSARY?: <input type="checkbox"/> Yes <input type="checkbox"/> No
TRAINING NECESSARY ? : <input type="checkbox"/> Yes <input type="checkbox"/> No	EXPLANATION OF CUSTOMERS' REQUIREMENTS NECESSARY?: <input type="checkbox"/> Yes <input type="checkbox"/> No
Destination of the method	
METHOD CANDIDATE FOR ACCREDITATION? : <input type="checkbox"/> Yes <input type="checkbox"/> No	METHOD TRANSMITTED TO CUSTOMER? : <input type="checkbox"/> Yes <input type="checkbox"/> No

12. GLP Studies process

N° OF STUDY..... GLP SPONSOR	
Staff :	
UP/ UA: STUDY DIRECTOR: SUBSTITUTE:	PERSON IN CHARGE OF CHECKS (GLP) TECHNICAL STAFF:
Test item	
Field of application (matrix and range of content)	
Test system	
Reference documents	
<input checked="" type="checkbox"/> PAQ/GLP EDITION (PRECISE N° AND DATE OF EDITION):	<input type="checkbox"/> METHOD OR NORM (PRECISE N° AND REVISION INDEX):
<input checked="" type="checkbox"/> QUALITY MANUAL (PRECISE N° AND DATE OF EDITION):	<input type="checkbox"/> OTHER
Planning	
PROVISIONAL DATE OF BEGINNING:	PROVISIONAL DATE OF ENDING:
<input checked="" type="checkbox"/> Planning of GLP checks: according to the check list for study verification	
<input type="checkbox"/> Validation for GLP study : <input type="checkbox"/> no <input type="checkbox"/> yes : <input type="checkbox"/> under GLP <input type="checkbox"/> outside GLP	
Validation plan	
<p>(to complete if the validation is under GLP : This validation will also be detailed in the study plan without the initial form IM-0048) NB : If the validation is not under GLP, then form IM-0048 is completed after the validation meeting (and not the chart below), as specified in the general process of validation plan</p>	

13. Analytical laboratory capacity to implement tests required under REACH requirement

REACH : GENERAL QUESTIONS REGARDING LABORATORY AS COMPETENCE CENTER

LABS TEST CENTER

- ① Is the laboratory recognized as GLP Laboratory ?
- ② What proportion of the total lab capacity can be used to test chemicals according to REACH?
- ③ What kind of tests can be conducted under REACH requirement?
- ④ Is the lab able to develop analytical method to conduct tests (GLP, EOCD guideline)?

13. Analytical laboratory capacity to implement tests required under REACH requirement

Substance identification and analytical laboratory offer and delivery service

- ① Substances identification : analytical information
- ② Physicochemicals tests : water solubility, partition coefficient...
- ③ Toxicological test : aims test, acute toxicity test
- ④ Ecotoxicological test : short term toxicity on daphnias, growth inhibition study on algae, activated sludge respiration inhibition...



WHEN YOU NEED TO BE SURE

SGS

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