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ENVIRONMENTAL SCIENCE FOR THE EUROPEAN REFINING INDUSTRY

Mocrinis II Workshop

Manufacture of Mineral Oil and Wax Composition and Specifications

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Agenda

- Manufacture of Mineral Oil and Wax
- Impact on Substance Composition
- Definitions, Uses, Specifications, Regulations

Part 1

Manufacture of Mineral Oil and Wax

Impact on Substance Composition

Complex Flow Diagram of typical integrated Refinery

Lubricant Base Oils, White Oils, Wax: < 10% of total refinery production

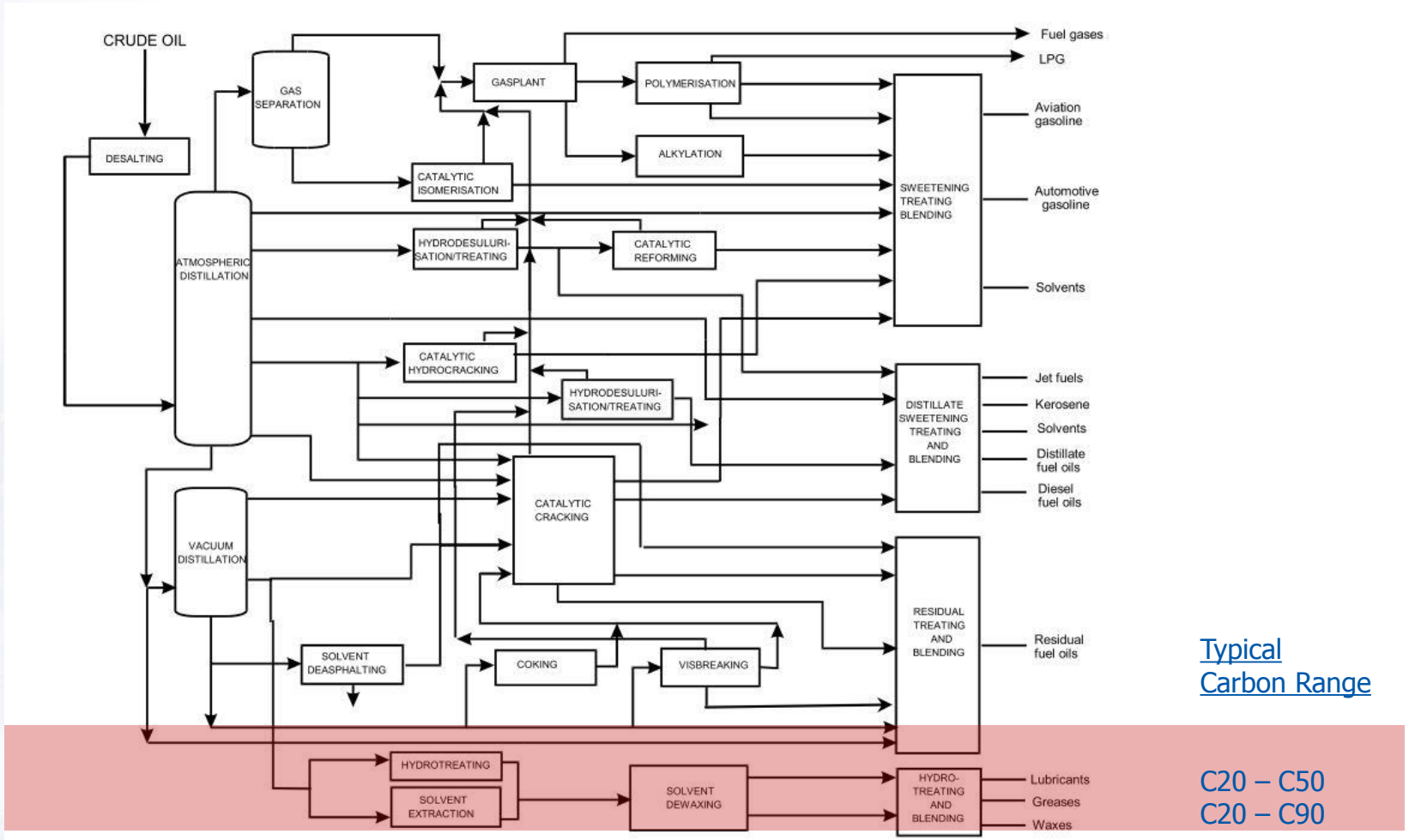


Figure 4: Schematic flow diagram of a typical integrated oil refinery.

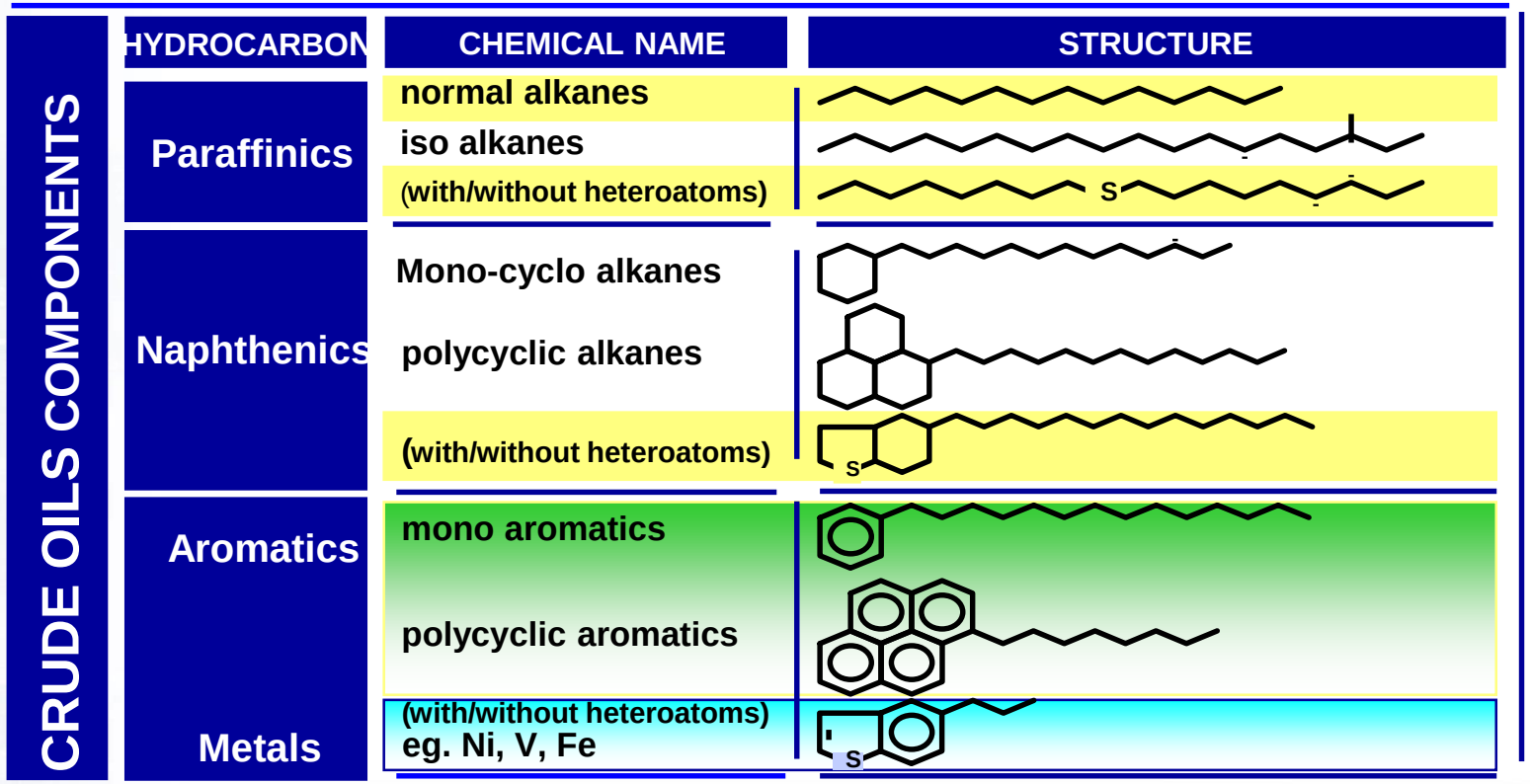
Typical Carbon Range

C20 – C50
C20 – C90

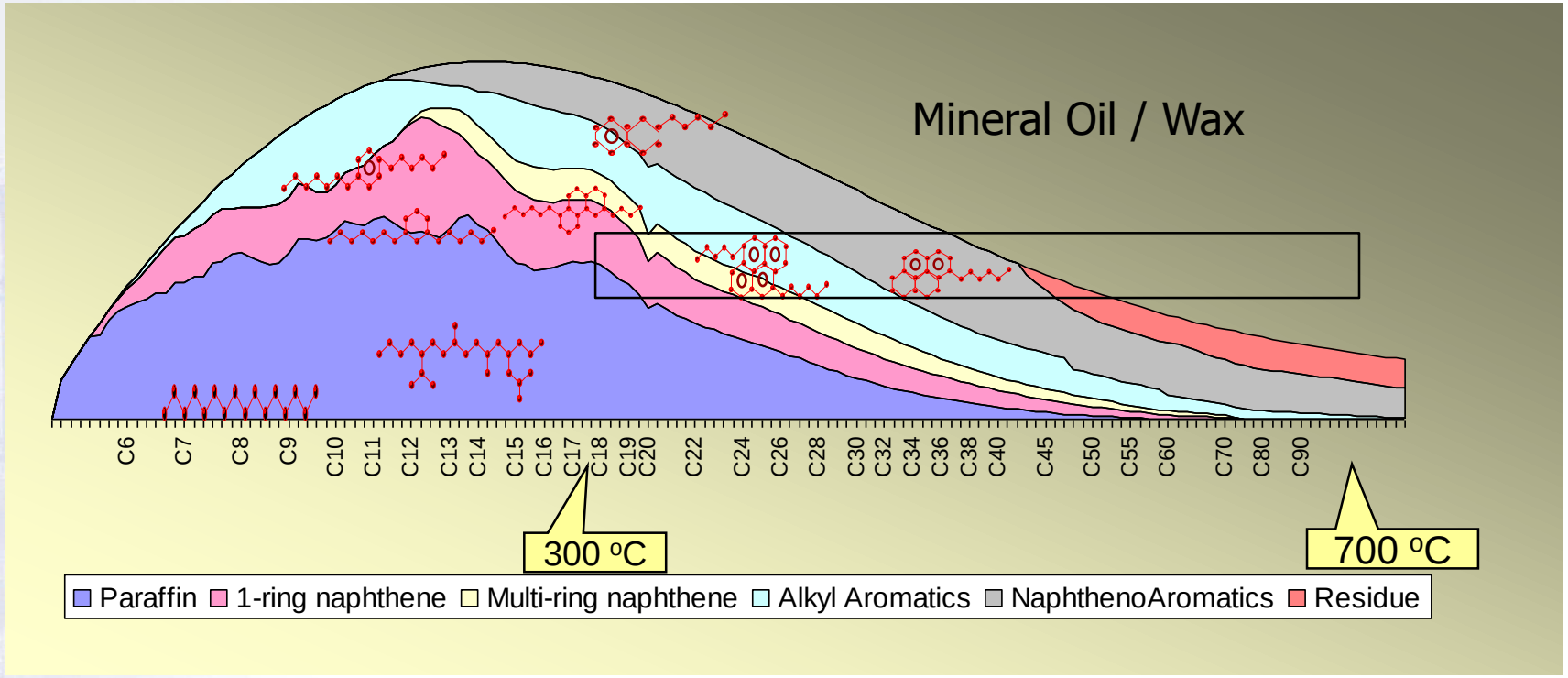
Source: EFSA Opinion 2012

Hydrocarbon type molecules from crude are selected during Refining

- **Crude Oil: "complex" matrix of** naturally occurring **hydrocarbons** ("UVCBs"- Substances of Unknown or Variable composition, Complex reaction products or Biological materials) which can be orderly classified
  - by molecular weight and by molecular structure
  - in limited number of chemical families because of natural origin of crude
- **Refining will select the desired molecules** for the targeted applications

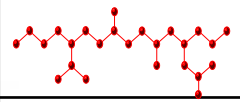
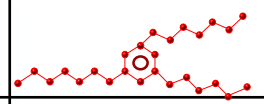
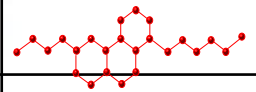
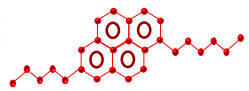


Content in various Hydrocarbon types vary with crude type and carbon number/boiling range



- Above example: typical hydrocarbon distribution of a lube crude (e.g. Arab Light)
  - Broad lumping of molecule types in the whole crude
  - Lubricant Base Oils / Wax / White Oils typically fall in 300°C to 700°C distillation range
- Petroleum **refining primarily controlled by Boiling range/temperature**
  - Carbon number of distillation cuts estimated from corresponding n-paraffin molecules
- Refining is needed to isolate the desired Lubricant Base Oils/Wax/White Oils components
- **Hydrocarbon solvents** (Carbon number below C20) **out of scope of mineral oils**

Mineral Base Oils Constituents vs Performance

		Lubricant Base Oils Characteristics				Wax
Molecule	**Structure**	**Viscosity Index**	**Pour point**	**Oxidation Stability**	**Solubility**	
n-paraffins		Excellent	Poor	Excellent	Poor	Main component
Iso-paraffins		Good/ Excellent	Good	Excellent	Good	
Highly alkylated aromatics		Poor	Good	Good	Good	
Naphthenics		Poor	Excellent	Good	Excellent	
Polynuclear aromatics		Poor	Poor	Very Poor	Good	

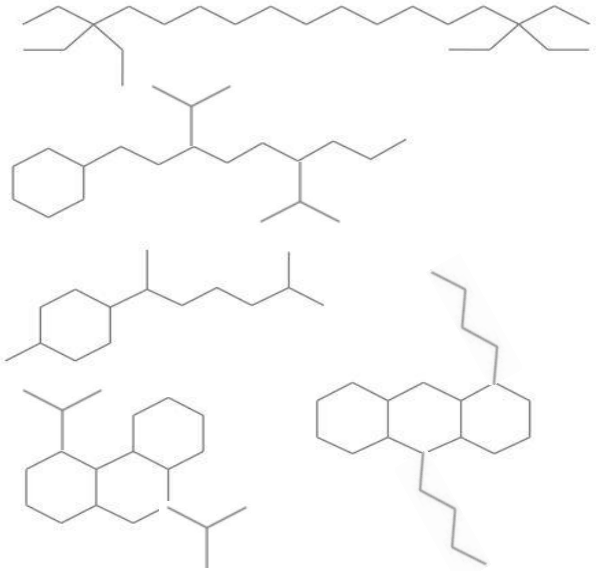
- "Good" vs "Poor" performance **depends on final application**
  - eg "good" for wax is different from "good" for oil

- **Sulfur and nitrogen** in crudes significantly **reduced through refinery processing**
  - Sulfur can contribute to oxidation stability in conventionally refined base oil
  - Nitrogen can contribute to product color and is generally eliminated in processing

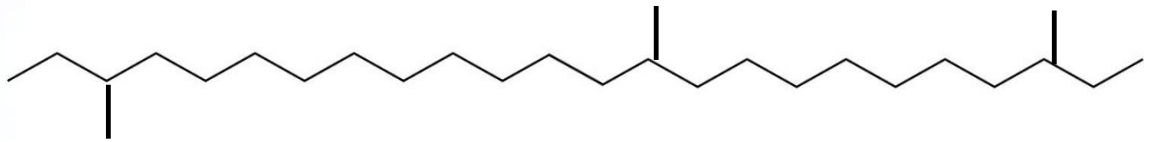
Molecular Structures Waxes and Oils

Waxes

Oils



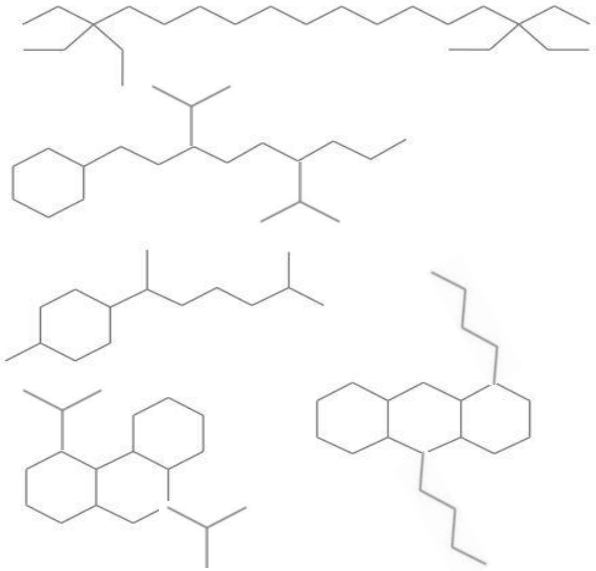
Wax Fraction or Oil Fraction ?



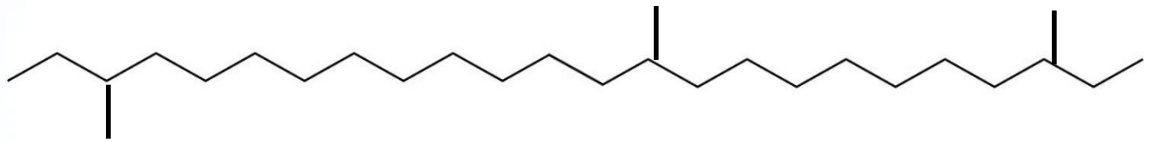
Molecular Structures Waxes and Oils: Iso-paraffins

Waxes

Oils



~~Wax Fraction~~ or Oil Fraction



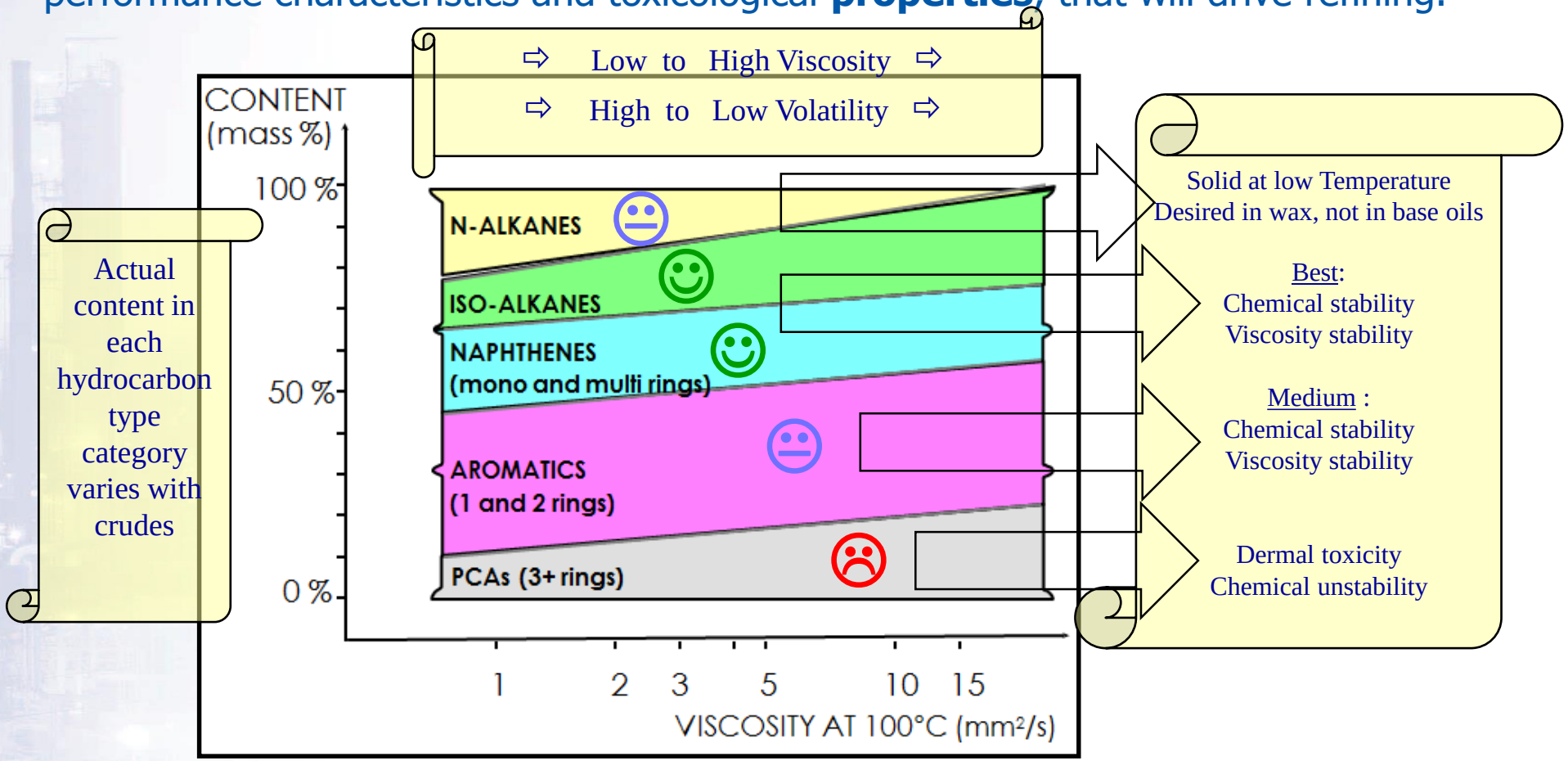
What Mineral Oil- and Wax is / is not

- The **terms "mineral oil" or "wax" are generic** and do not mean the same thing for everyone. Definitions and **context is needed** to understand the issue.
- Refined "mineral oils" and "waxes" are **refinery products** manufactured to meet specific standards.
- While Mineral oil can be chromatographically described as MOSH and MOAH fractions, these fractions do not always represent the products on the market.
- **MOSH and MOAH** does **not** necessarily **mean "mineral oil".**
  - An isolated MOSH fraction does not imply that ALL saturated hydrocarbons are from mineral oil origin. It can contain natural n-alkanes.
- An isolated **MOAH** fraction **does not imply PAC** presence neither refinement level.
- The **MOSH term applied to** the saturated fraction of a **wax is misleading** because **MO refers to an "oil"**. At 25^0C an oil is liquid, a wax is solid.

Remember: MOSH and MOAH terms are highly **contextual**.

Crude Oil Initial Chemical Composition

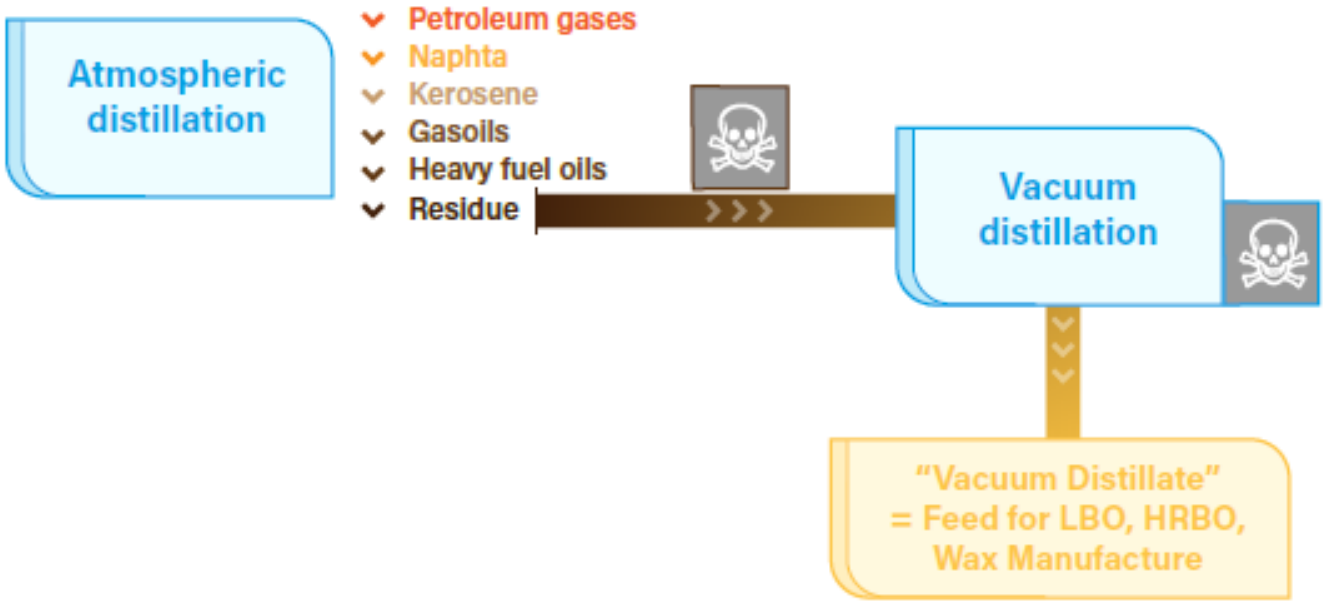
The individual **hydrocarbon components have** diverse and **well known** performance characteristics and toxicological **properties**, that will drive refining.



Refining will select the molecules from the crude oil in controlled manner **to set the final chemical composition** (and properties) of the mineral oil

Base Oil, Wax, White Oil Manufacture

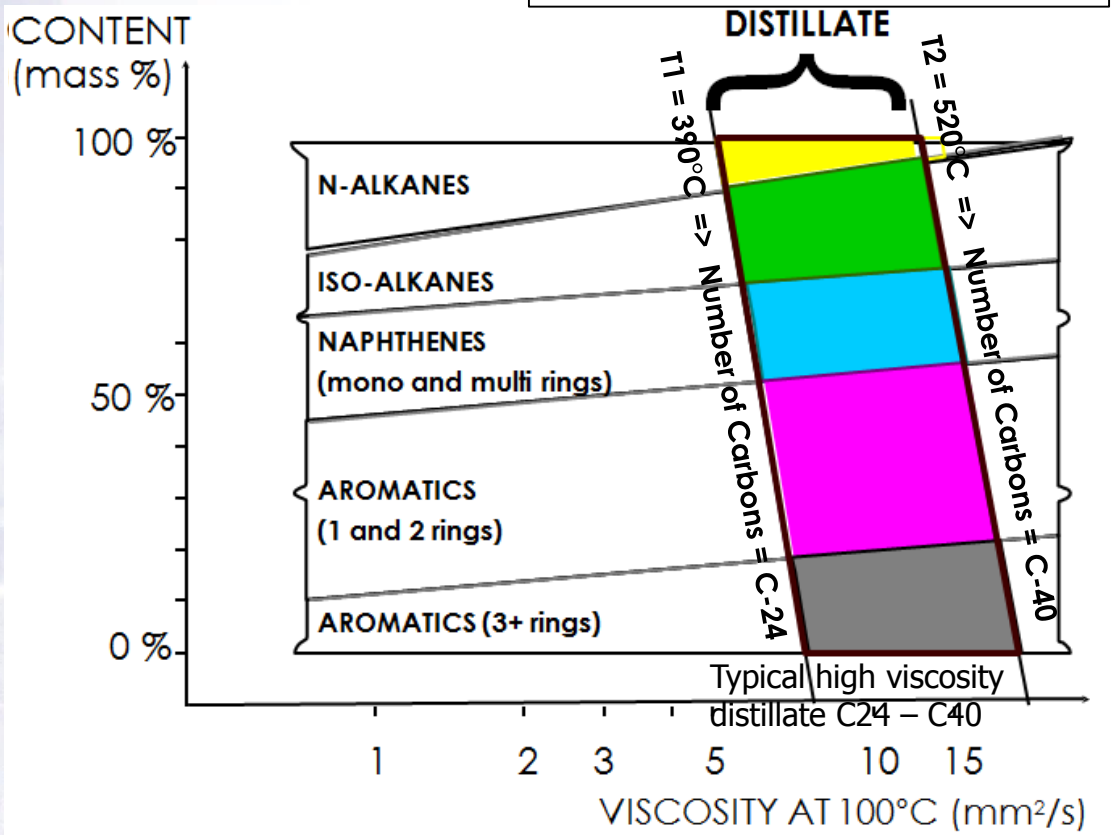
Step 1 : Distillation



Atmospheric and Vacuum Distillation Impact

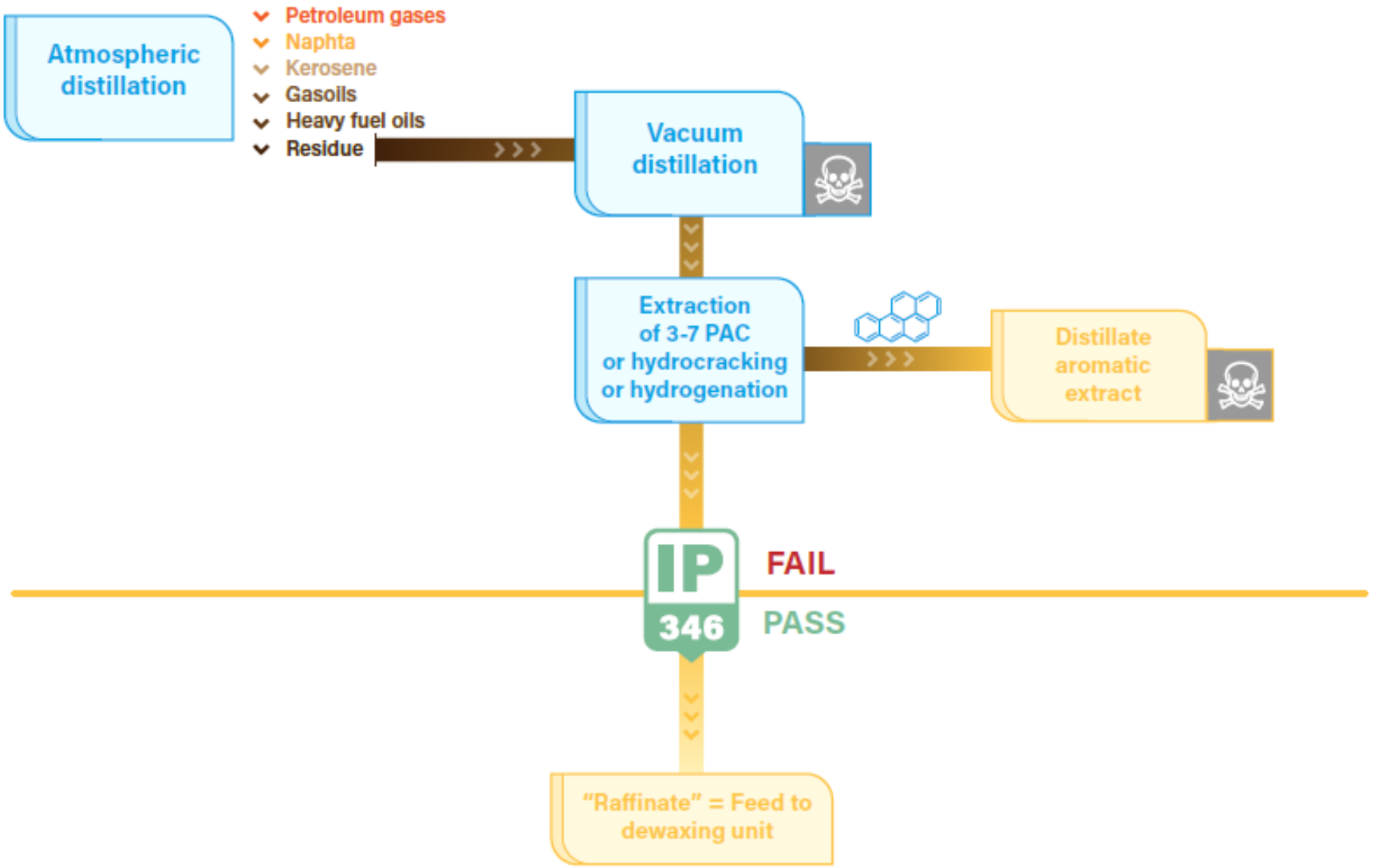
Distillation determines the Boiling/Carbon/molecular weight range of the final oil

Boiling range / Carbon # range, Viscosity, Volatility are set by **Distillation** Units



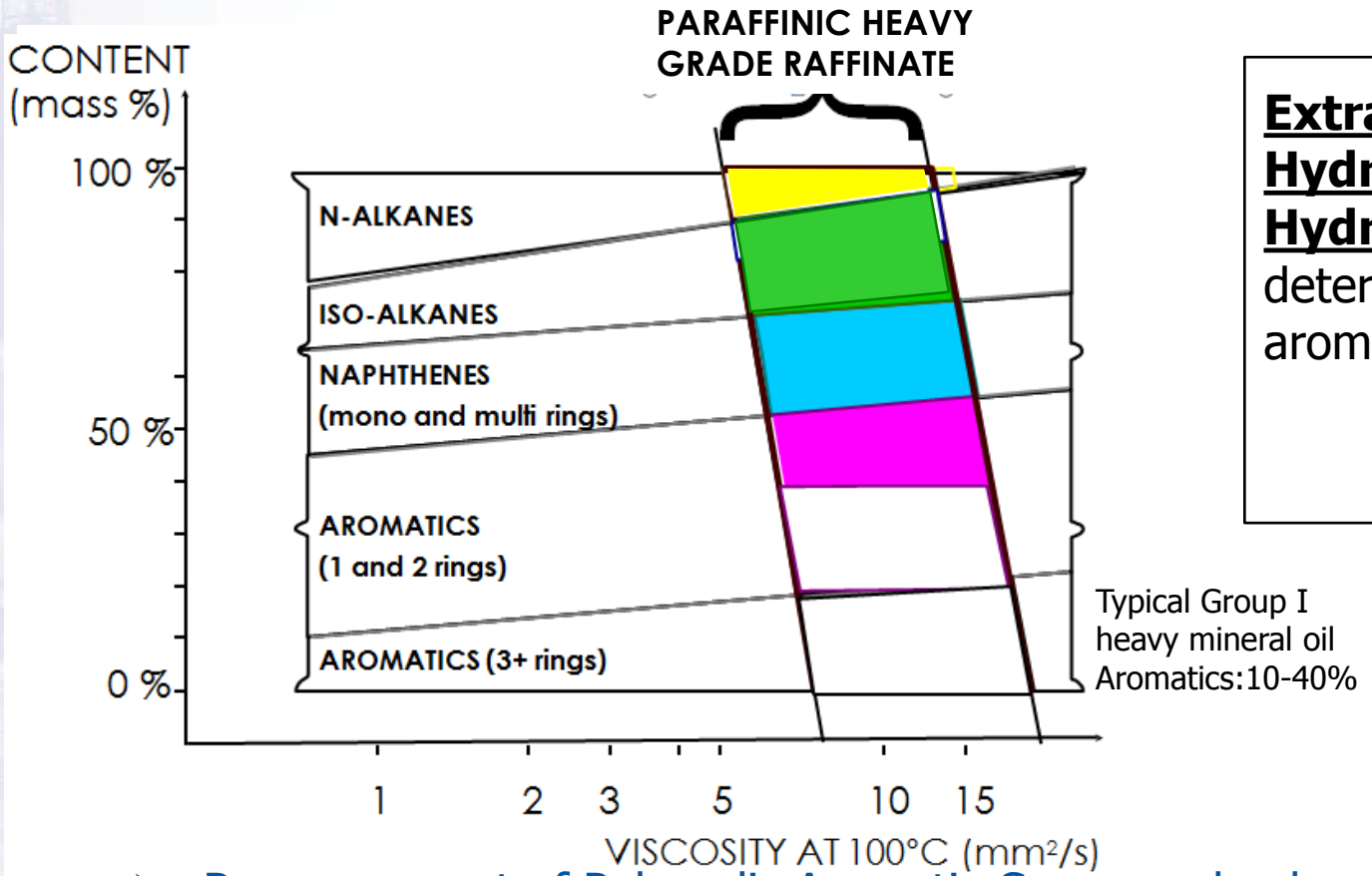
Base Oil, Wax, White Oil Manufacture

Step 2: Aromatic Removal



Aromatic Removal Impact (Extraction or Hydrocracking)

Extraction or Hydrocracking or Hydrogenation determines the total aromatics content and removes most of Polycyclic Aromatic Compounds



Typical Group I heavy mineral oil Aromatics:10-40%

Extraction or Hydrocracking or Hydrogenation determines the total aromatics content

- Removes most of Polycyclic Aromatic Compounds, down to IP346<3%
- **Critical step to ensure** mineral oils and wax are **non-carcinogenic**

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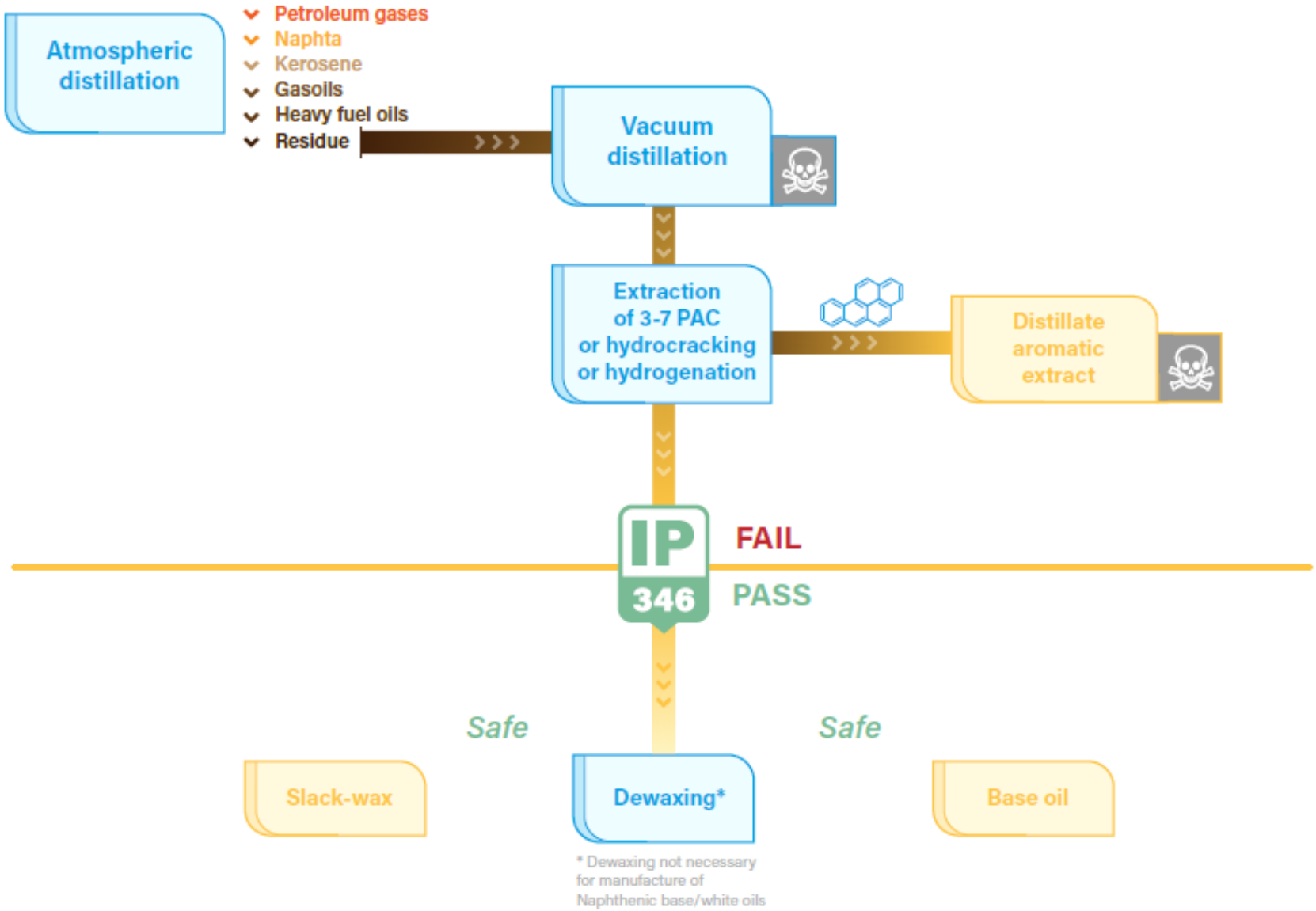
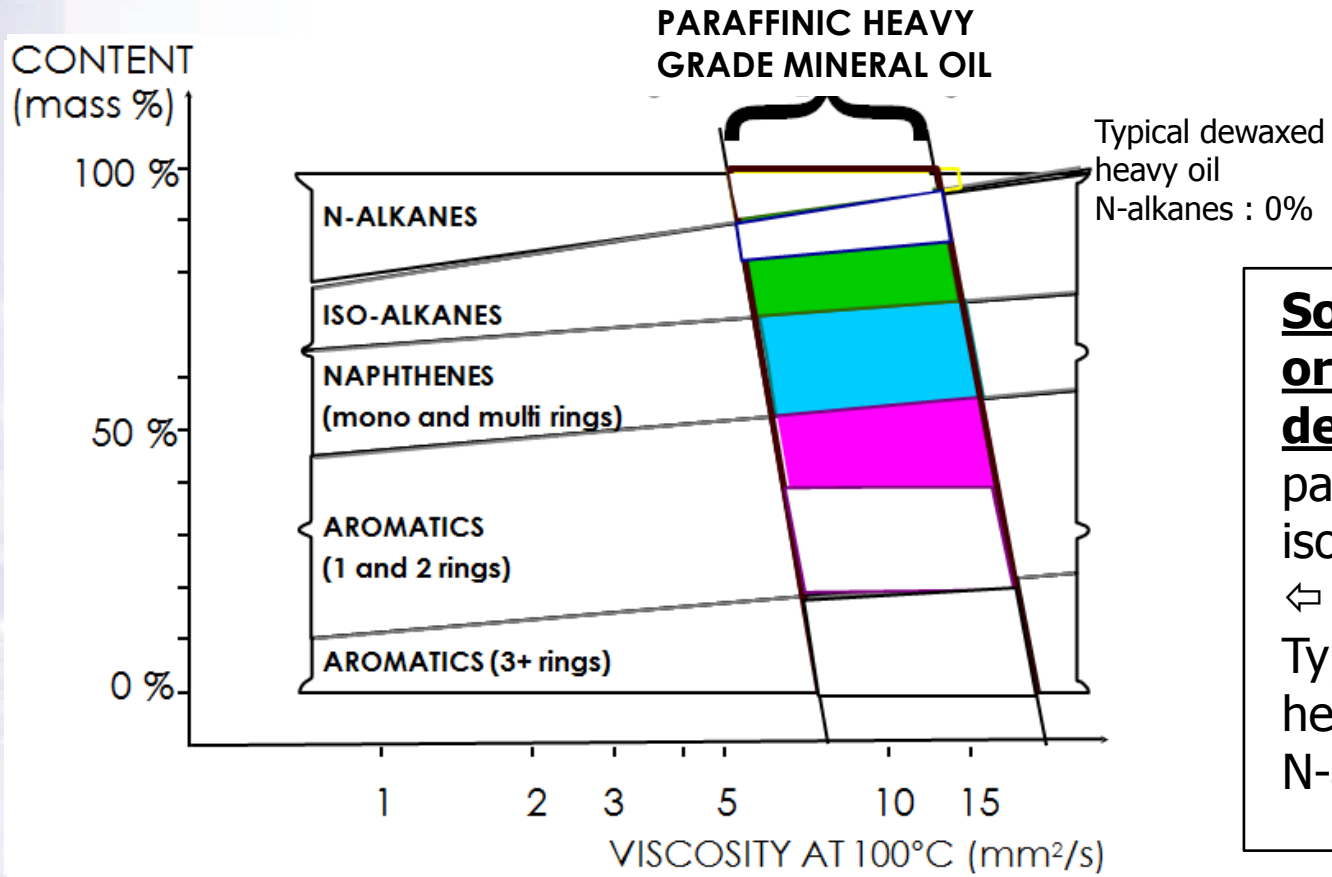
Base Oil, Wax, White Oil Manufacture

Step 3: wax separation



Paraffin separation through Dewaxing

Solvent Dewaxing or Iso-Catalytic dewaxing **removes solid waxy hydrocarbons** (n-paraffins and some isoparaffins) from mineral oil. **Creates Wax** as a co-product.



Solvent Dewaxing or Catalytic dewaxing removes paraffins and some isoparaffins

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Typical dewaxed heavy oil
N-alkanes : 0%

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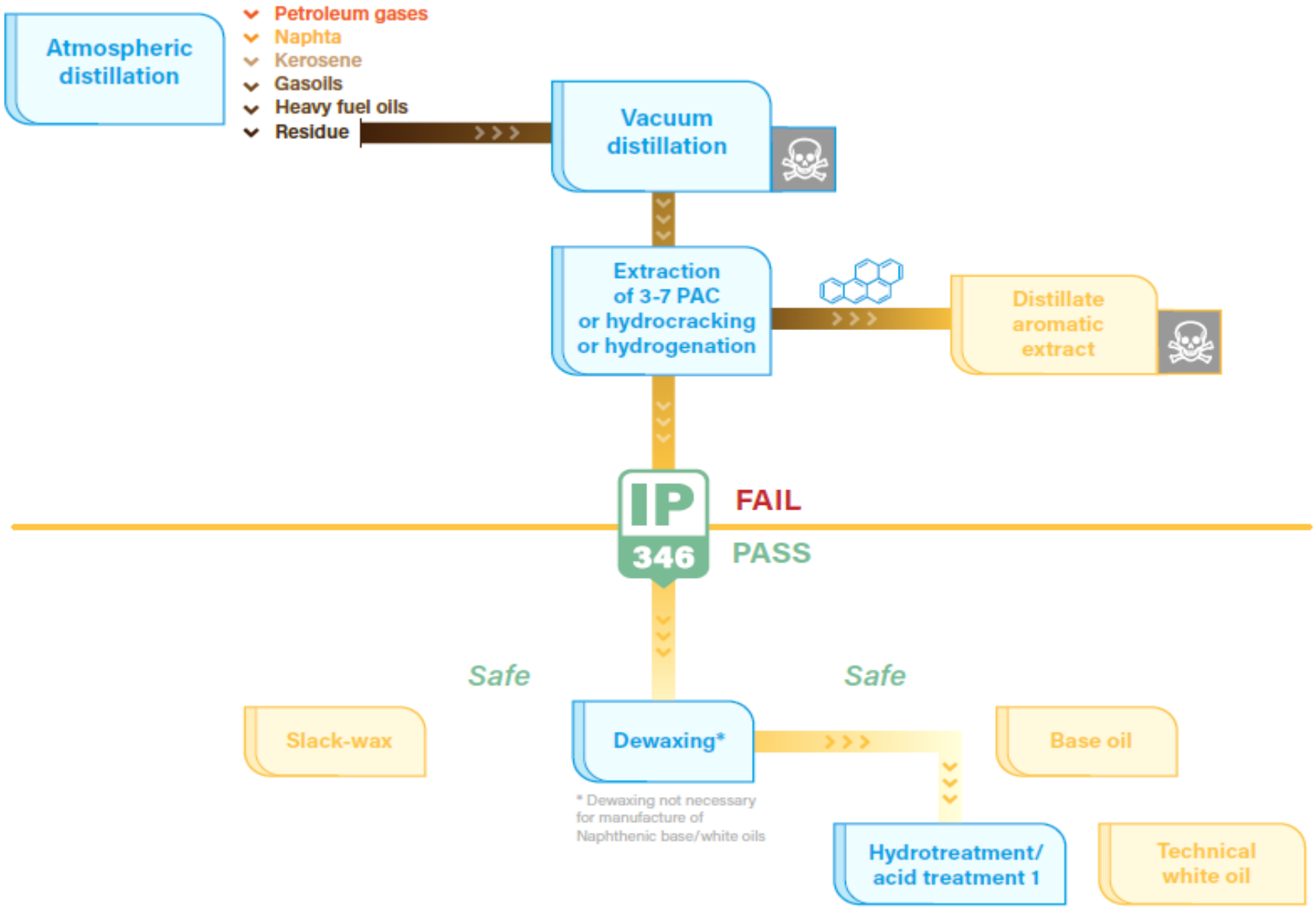
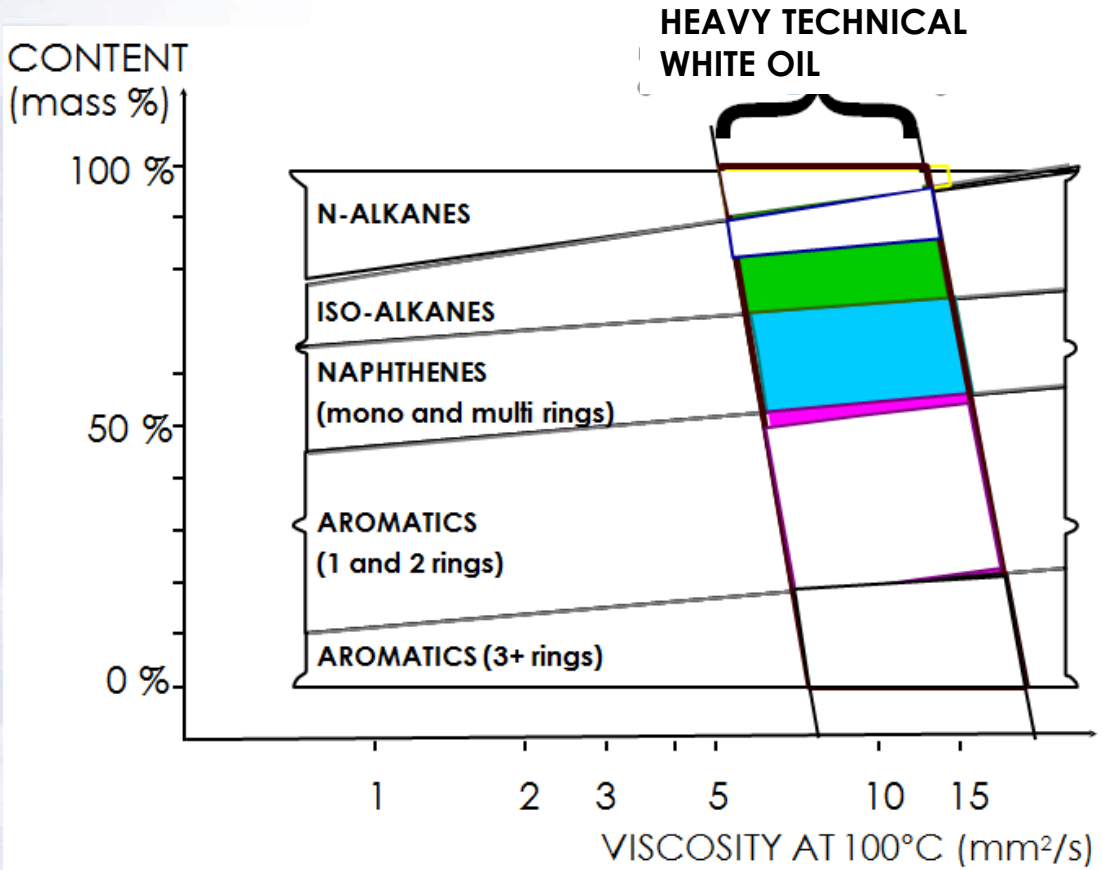
Technical White Oil Manufacture



Aromatic saturation through High pressure Hydrotreatment or Hydrocracking (1st step)

Hydrocracking or Moderate Hydrotreatment or Acid Treatment remove most of aromatics (to a few %), and Polyaromatics below ppm level=>**Technical White Oils**



Hydrocracking or Moderate Hydrotreatment or Acid Treatment removes most of aromatics (to a few%)

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Typical Heavy Technical White Oil:
Aromatics%: 0.5-5%

- Total Aromatics% typically 0.5-5% level in technical white oils
- PAC% below ppm level in technical white oils

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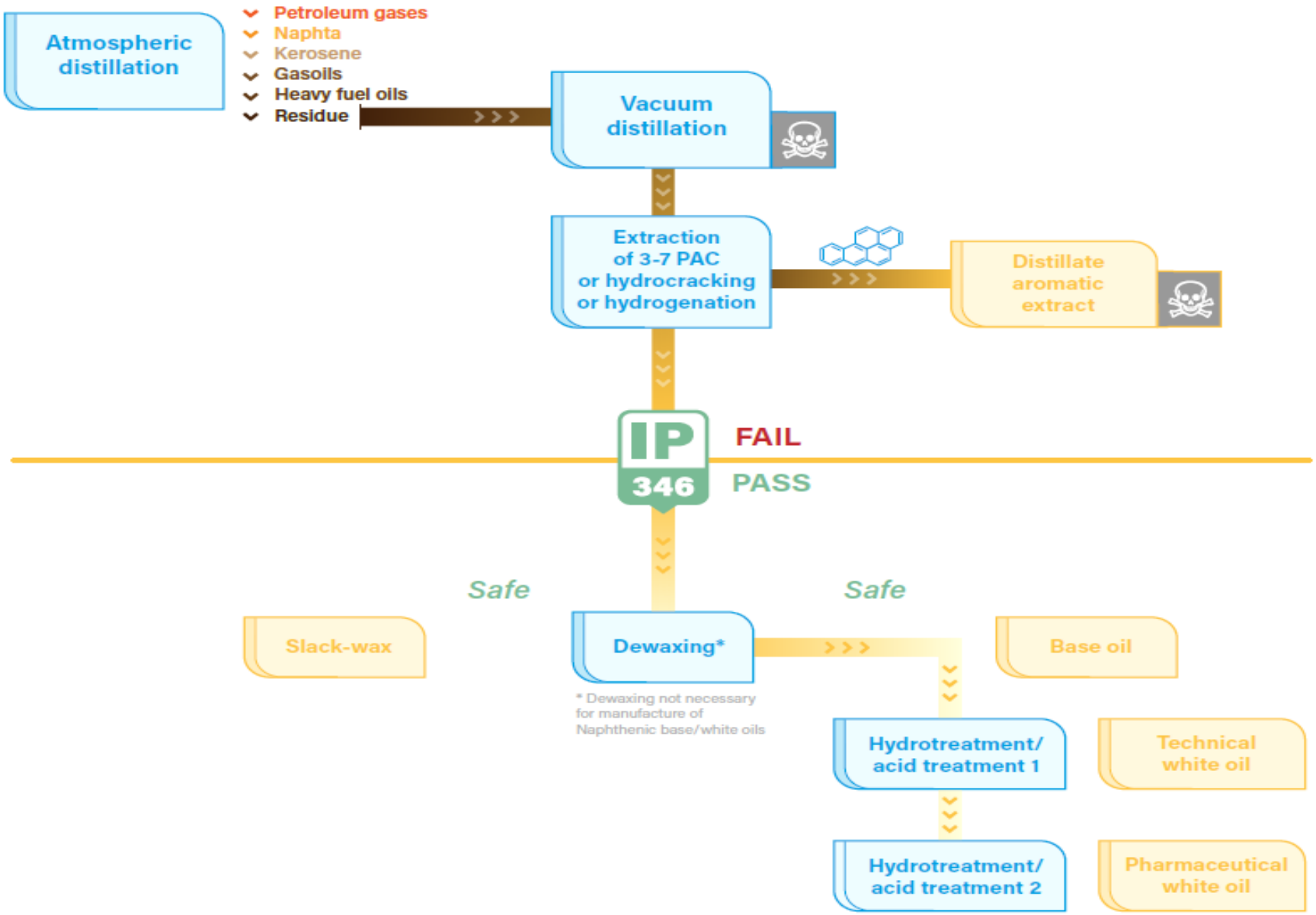
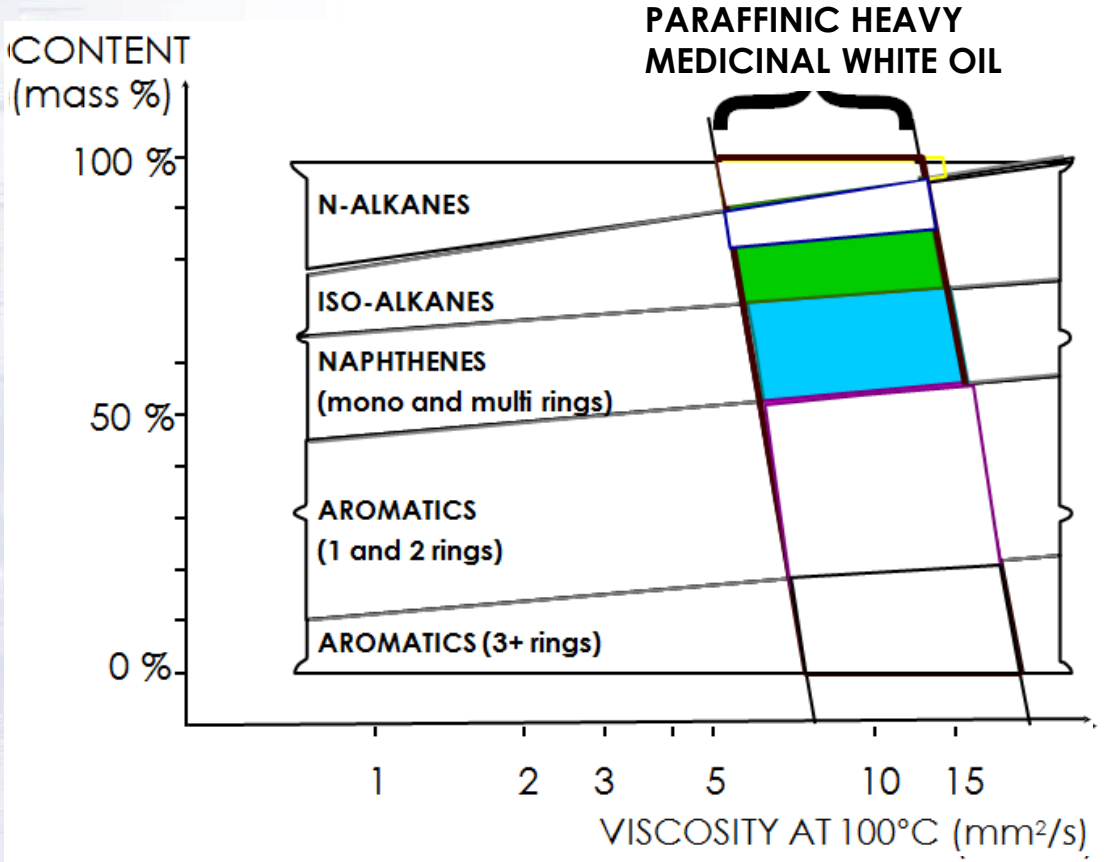
Pharmaceutical White Oil Manufacture



Full Aromatic saturation through High pressure Hydrogenation (2nd step)

Severe Hydrogenation or Acid Treatment remove nearly all remaining aromatics (to ~0.1%), and bring Polyaromatics to ppb level => **Medicinal White Oils**



Hydrogenation or Severe Acid Treatment = ultimate severity for removal of aromatics

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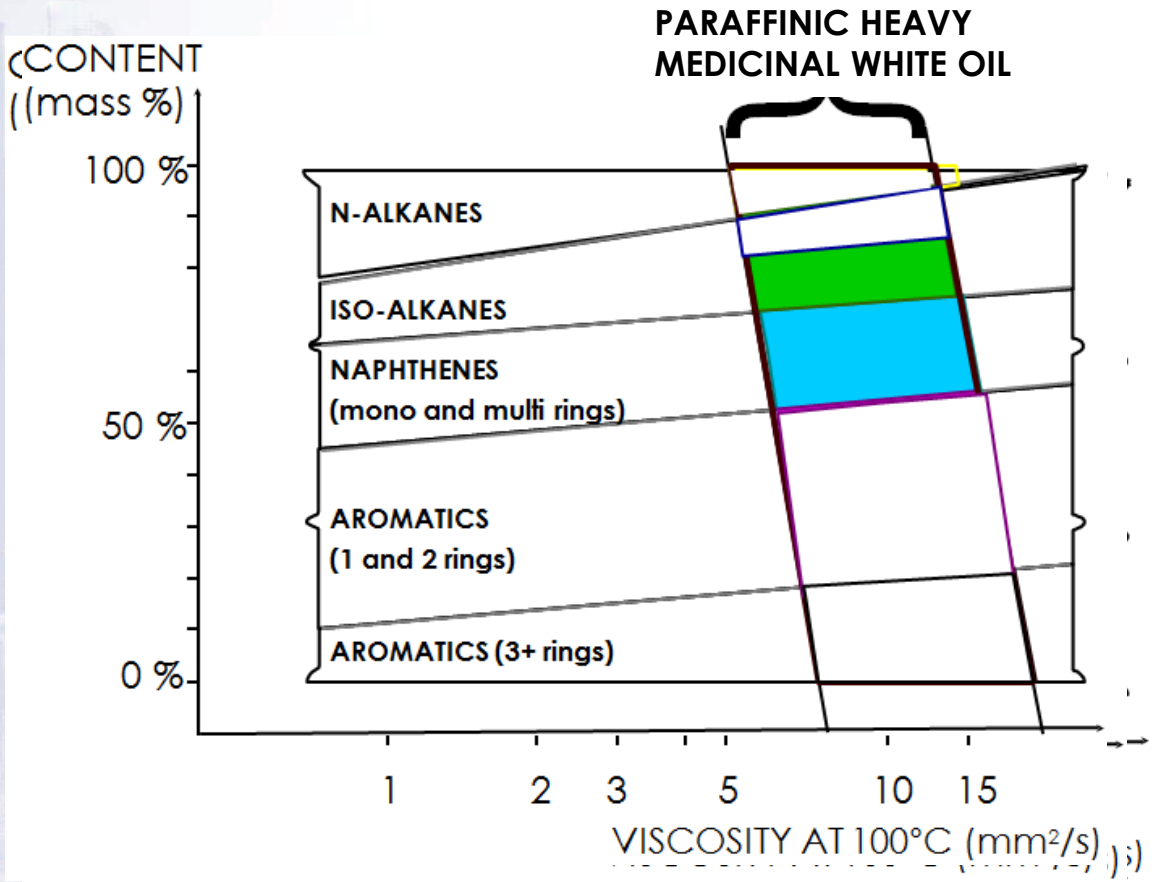
Typical heavy viscosity white oil Aromatics %<=0.1%

- Total Aromatics typically around 0.1% level in pharmaceutical white oils
- PAC% at ppb level or below in pharmaceutical white oils

Refining Summary: from crude to pharmaceutical white oil

Refining selects the molecules from the crude oil in a controlled manner to **set the** final chemical **composition** (and properties) of the mineral oil



<u>Severe Hydrogenation / Acid Treatment</u> removes nearly all aromatics/PCAs

Severe Hydrogenation / Acid Treatment = ultimate severity

⇦

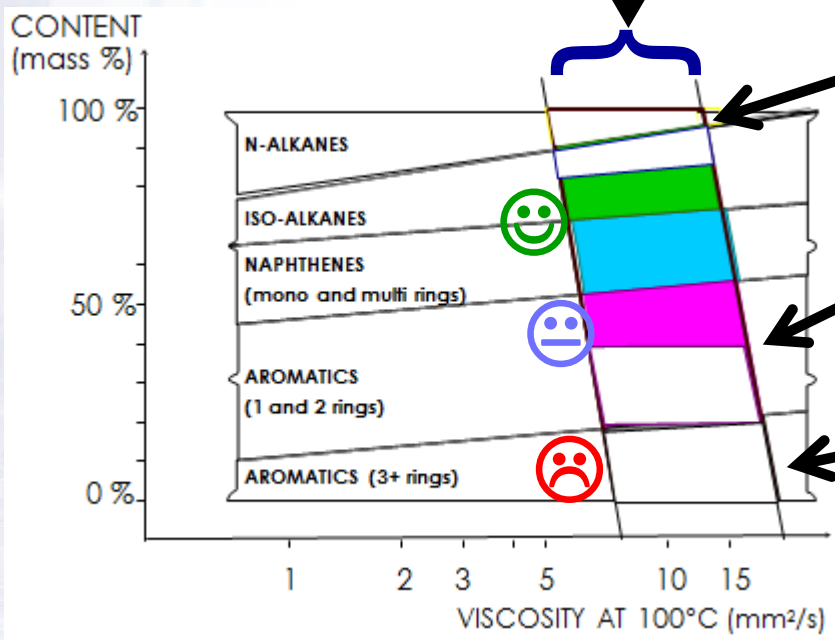
Typical heavy viscosity white oil Aromatics%<=0.1%

- Mineral Oils: Total aromatics range 0-50%, with PAC%<< Aromatic%
- Pharma white oils: Total aromatics around 0.1%, PAC below ppb level

Chemical composition is adjusted through refining

Removal or conversion of undesirable molecules + Selection of desired molecules is obtained through the various refining units
Final **chemical composition adapted to targeted properties and performance**

Boiling/Carbon # range, Viscosity, Volatility set by **Distillation** Units



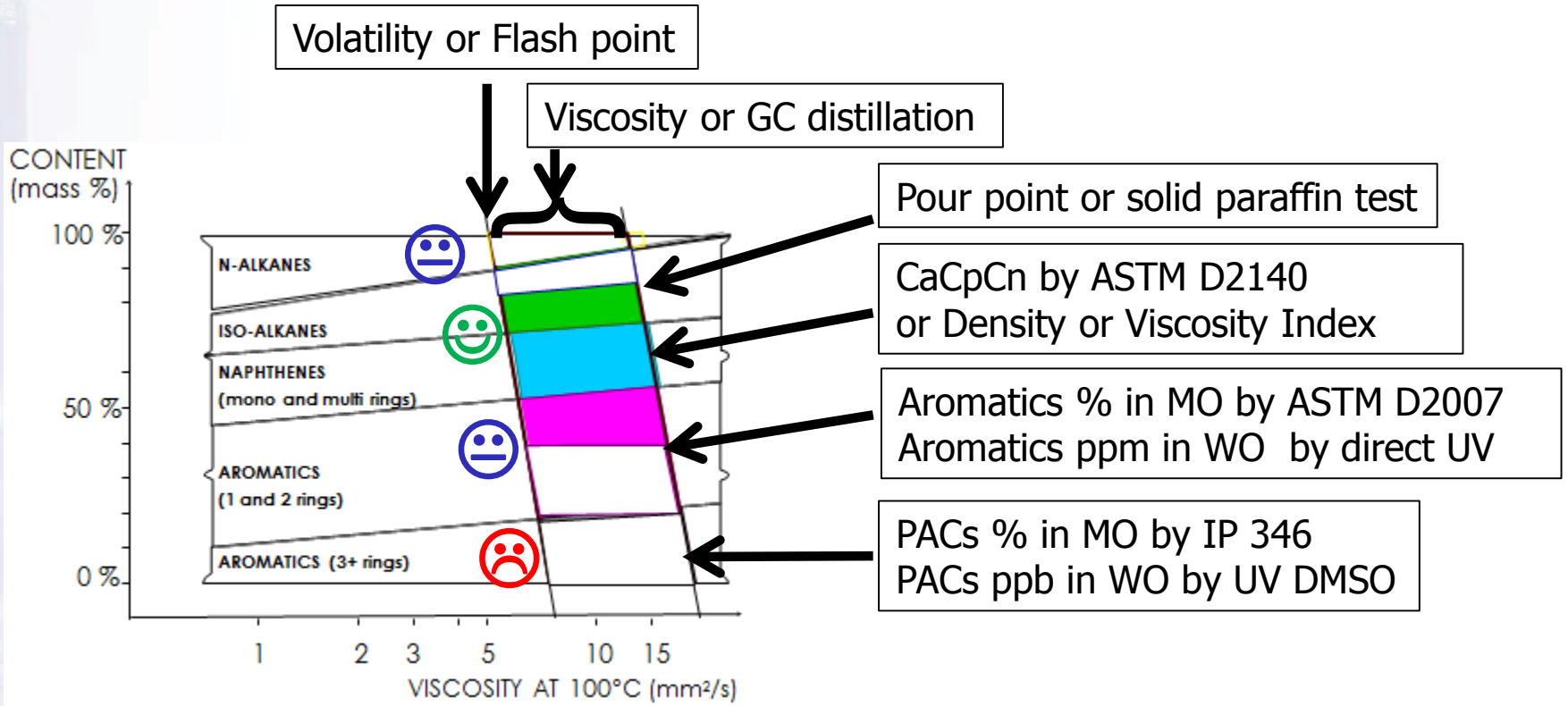
n-Paraffins removal / Wax production in **Dewaxing** Unit

Full aromatic saturation from **severe Hydrotreatment or Acid Treatment** (eg White Oil Units)

Poly-Aromatics (+some mono-/di-aromatics) removal in **Extraction or Hydrocracking** Units

Chemical composition is controlled by specifications

A set of **specifications** has been **developed to** efficiently and tightly **control** mineral oil **composition** according to its intended application



- Specifications defined to ensure Performance in application and absence of Health and Safety concern for end consumers
- Specification **tests shall be simple and quick** to be run on each production batch

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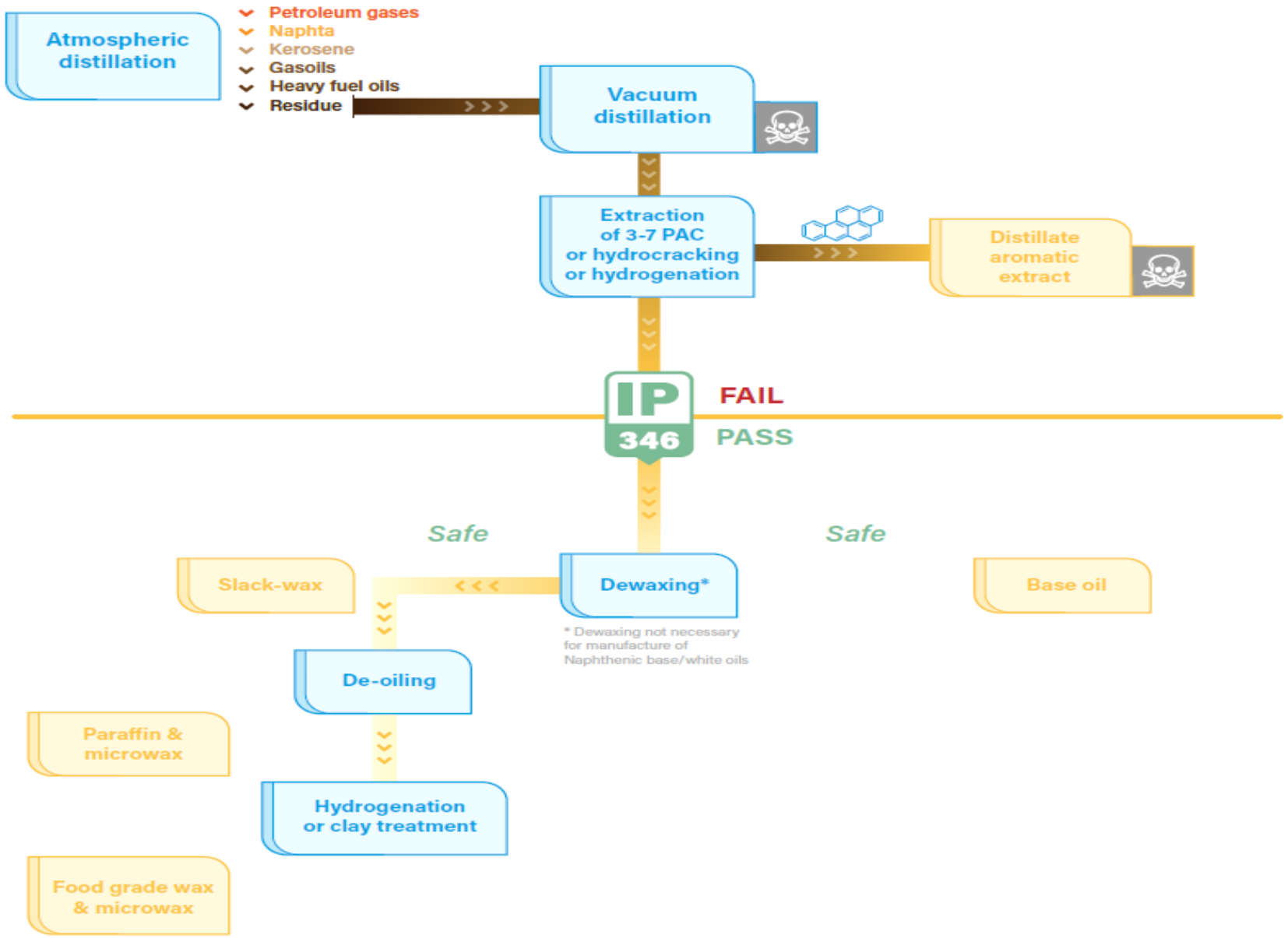
Paraffin and MicroWax Manufacture



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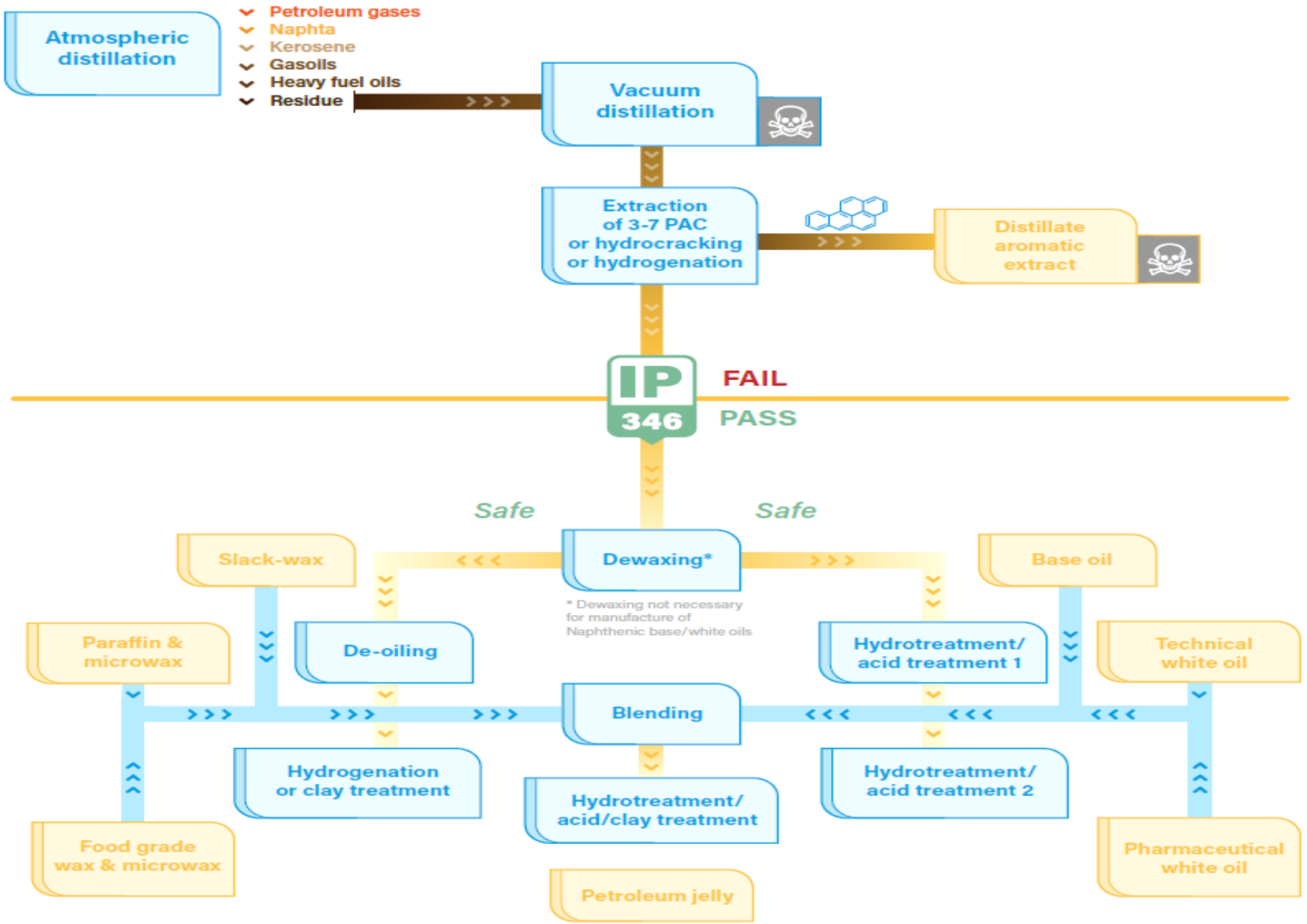
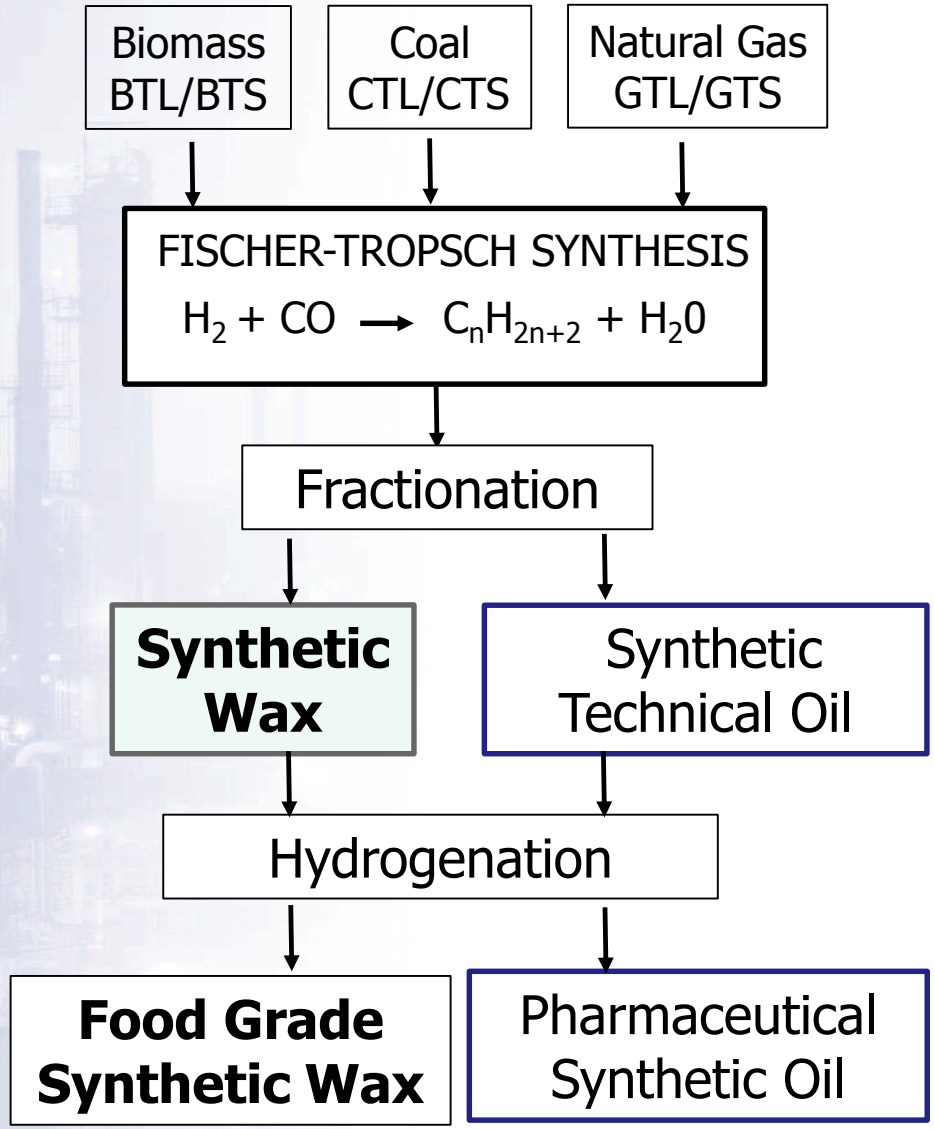
Petroleum Jelly Manufacture



Synthetic Wax and Oil Manufacturing (Fischer Tropsch)



- Process invented in 1925 by Franz Fischer and Hans Tropsch
- Uses several carbon sources
  - Biomass to Liquids/Solids
  - Coal to Liquids/Solids
  - Gas to Liquid/Solid
- Manufactures a variety of products
  - Diesel, Naphta, Jet Fuel, Base Oils, Waxes, etc
- Commercial product range **includes oils** of different viscosities **and low and high melting waxes**

Questions?

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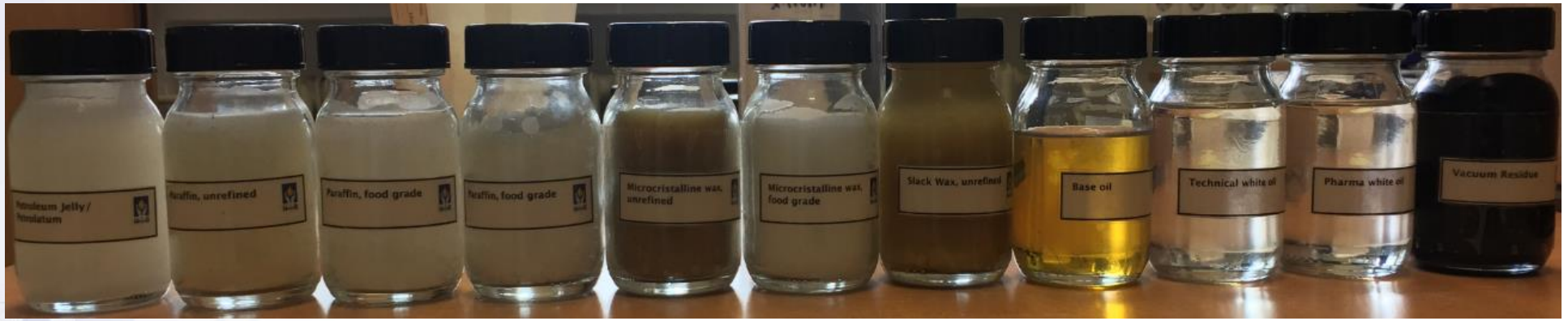
COFFEE BREAK !

Part 2



Mineral Oil and Wax:

Definitions, Uses, Specifications,

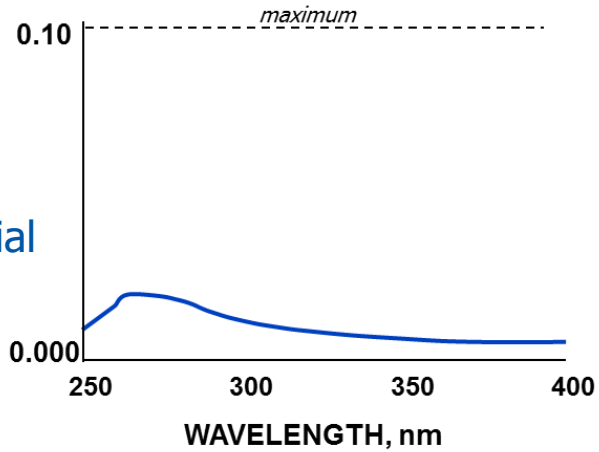
Regulations

Technical vs Medicinal White Oils Definitions, Specifications

- Definition: "white oils" also defined as Highly Refined Base Oils (**HRBO**):
  - Colorless, highly refined mineral oils derived from non-carcinogenic LBO (excludes synthetic oils)
  - Hydrotreatment or Acid treatment to achieve **extremely low levels of aromatics**
- Technical white oils:
  - HRBOs not complying with pharmacopeia monograph purity
  - Meet requirements of US **FDA 21 CFR-178.3620(b) – color and UV-DMSO limits**
  - **Very low Aromatics,** mainly 1-2 ring highly alkylated structures (**typically 0.5 to 5%**)
  - **Uses**: Food Grade Lubricants, rubber extender oils, textile oils, Petroleum Jellies,…
- Pharmaceutical/Medicinal/Food Grade white oils (paraffinum liquidum)
  - Derived from technical white oils, refined in a second step (Hydrotreatment or Acid treatment)
  - Comply with **purity of pharmacopeia monographs** (Eur or US) or FDA (US)
  - **Extremely low** levels of **aromatics** (1-2 ring highly alkylated structures) - **typically ~0.1%**
  - **Purity tests** :
    - **UV-DMSO**: tracks PACs, used in Pharmacopeias (EU/US) and FDA (US, food-contact)
      - Direct UV test was used in former DAB (German Pharmacopeia), indicator of «Total aromatics»
    - **Readily Carbonisable Substances**: tracks aromatics and impurities
  - Several categories based on **viscosity range** in pharmacopeias
  - Kin viscosity, Mol Weight and Carbon Nber used by JECFA to define mineral oils categories
    - Also used in EU Plastic Regulation

White Oils main purity test: UV-DMSO

- Based on **UV absorption of DMSO extract** of a white oil
  - WO first diluted with n-hexane
  - PAHs selectively extracted with DMSO
  - Absorbance of the extract (260-350 nm range) compared to a reference
  - described in ASTM D 2269 method
- **Pharmacopeias Pass limits**
  - max extract absorbance (10 mm cell) **~ 0.10**
  - Estimated equivalent to ~0.3 ppm max of PAHs
  - Typical PAHs contents in ppb range for most of commercial WOs
- required **in Pharmacopoeias and FDA** specifications
  - Max absorbance Limit 4.0 for Tech White oils (FDA (b))
  - Another UV-DMSO test procedure used for FDA(c) oils
- **simple method**, well **suited to routine** PAH content **control** of production batches in refinery labs



White Oils for Food Applications Regulations and Specifications

Application	Example	EU Regulation	US Regulation
Food Additive	Glazing agent, anti-foaming, carriers, preservative for eggs or dried fruits	EU 1333/2008/EC (Directive 95/2/EEC): **White Oils not on positive list**[1]	21 CFR 172.878
Processing Aid	Release agent/lubricant, dedusting agent in grain, pan oil, demoulding oil	**No EU Directive** **Some** specific **local regulations**[2]	21 CFR 172.878 (not differentiated from food additives)
Food Contact Materials	Extender oil in plastics, elastomers, paper, glass, metal, wood, cork, textiles, adhesives, pigments …	Framework (EC) 1935/2004 **Plastics: EU 10/2011** Others: to be developed Some local regulations[3]	Various FDA chapters Require mineral oils that meet 21CFR178.3620 (a),(b) or (c) purity
Lubricant for incidental food contact	Formulation of lubricants for food machinery	**No EU regulation**	21 CFR 178.3570 (requires 178.3620(b) oils) NSF H-1 registration

- Most existing purity requirements are based on PACs using UV-DMSO methods

(1) Microcrystalline waxes are listed as E 905
(2) Eg French Arrêté for "Auxiliaires technologiques" (Food Processing Aids) – 21 Oct 2006 – demoulding uses (biscuits)
(3) Germany: BfR recommendation XXV Purity requirements for mineral oil (155 BGA Mitteilung), microcristalline wax and paraffin

EU Plastics Regulation 10/2011 – Food Contact

General requirements outlined in Art. 3 of EU framework Regulation (EC) N° 1935/2004 for materials and articles intended to come into contact with foodstuff.

Products permitted for the use in plastics for food contact applications

White mineral oils	FCM 95	Viscosity not less than 8,5 mm²/s at 100°C Carbon number amount <C25, max 5 % Average molecular weight not less than 480
Microcrystalline wax	FCM 94	Viscosity not less than 11 mm²/s at 100°C Carbon number amount <C25, max. 5% Average molecular weight not less than 500
Paraffin wax*	FCM 93	Viscosity not less than 2.5,mm²/s at 100°C Carbon number amount <C25, max 40% Average molecular weight not less than 350

* Restriction: 0.05 mg/kg food
Not to be used for articles in contact with fatty foods

EU Plastics Regulation vs JECFA/EFSA ADI

- EFSA and JECFA have set ADIs to various oil categories (food additive use)
- EU Plastic regulation specifies oils and waxes that meet EFSA/JECFA categories
  - No direct regulatory link between EFSA/JECFA ADIs and the Plastic regulation

JECFA/EFSA Categories Specifications and ADIs	ADI JECFA	ADI EFSA	Kinematic viscosity at 100°C (cSt)	Average molecular weight	Carbon number at 5% boiling point	EU 10/2011 Plastic Regulation
Microcrystalline wax	0-20 mg/kg	0-20 mg/kg	≥ 11	≥ 500	≥ 25	X
Paraffin wax	-	-	≥ 2.5	≥ 350	Max 40% C<25	X
Mineral oil (high viscosity)	0-20 mg/kg	0-12 mg/kg	> 11	≥ 500	≥ 28	X
Mineral oil (medium and low viscosity) Class I	0-10 mg/kg	0-12 mg/kg	8.5-11	480-500	≥ 25	X
Class II	- (removed)	- (removed)	7.0 – 8.5	400-480	≥ 22	
Class III	- (removed)	- (removed)	3.0 – 7.0	300-400	≥ 17	

ADI : Admissible Daily Intake

- Some local regulations have set same oil requirements as EU Plastics Regulation, even if for different materials than plastics
  - e.g. German Draft Ordinance on Printing Inks, Elastomerleitlinie (Leitlinie zur hygienischen Beurteilung von Elastomeren im Kontakt mit Trinkwasser), Swiss Ordinance 817.023.21 April 2010 for food contact

Legislative framework – Paraffins and Microwax

	Food Contact Legislation		Food Additive		Pharmacopeia	Cosmetic	Pharmacopoeia and Cosmetic
Product	Regulation	Purity test	Regulation	Purity test	Regulation		Purity Criteria
Hard Paraffin/ Microcrystalline	FDA.178.3710	FDA 172.886	US Petroleum Wax Monograph FDA 172.886	FDA 172.886 (PCA -UV Absorption)			
	EC-1935/2004	Framework regulation					
	EC-42/2007 (Regenerated Cellulose film)	< 2 mg/dm2					
	Bfr - Recomendations for Paraffin: XXI, XXXV, XXXVI, XLIV, XLVIII, LII.	Bfr - Recomendation XXV					
Hard Paraffin	EU 10/2011 (PLASTIC), German Elastomer Guidance, Swiss Ordinance 817.023.21	95858 LVP			Eur /Ph- 9.0 USP -40	EC/1223-2009 and Cosmetic Europe recommendation	PAH Level (< 1/3 of absorbance of a solution containing 7 ppm naphtalene in DMSO at 278 nm)
Microcrystalline		95859 HVP	JECFA (CODEX: INS-905); EU 95/2 (E-905)	EC-231/2012	Eur /Ph- 9.0 USP -40 (*)	EC/1223-2009 and Cosmetic Europe recommendation	PAH (FDA 172.886)
	Bfr - Recomendations: XXI, XXV,XXXV, XXXVI, XLIV, XLVIII, LII					Colipa Recommendation nº 14	PAH Level (EC-1223/209) and (KV ≥ 11, MW≥ 500, Carbon number at 5% boiling point ≥25)

(*)- Microcrystalline Monograph in progress for European Regulation

Hydrocarbon Waxes as Food Contact Materials - Regulations

Hydrocarbon Waxes as Additive or Formulation Ingredient		Waxes as FCM Group (EC 1935/2004) Framework Regulation
Harmonized FCM	**Non-Harmonized FCM (Member State Legislation)**	**Non-Harmonized FCM (Member State Legislation)**
Plastics Regulation 10/2011	Adhesives Coatings and Varnishes Printing Inks Rubber Paper and Board Textiles	Germany: Recommendation XXV Holland: Warenwet Chapter X

The **principle of mutual recognition** allows for the legal importation and sale into one Member State of products that are legally marketed in another Member State, even if the products do not comply with the specific regulatory requirements of the country of import.

Hydrocarbon Waxes in the (Food Contact) Plastics Regulation EU 10/2011 : specifications and purity

EU 10/2011	FCM 93			FCM 94	
Description	**Waxes,** paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, **low viscosity**			**Waxes**, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, **high viscosity**	
Specification	**Average Mol weight > 350 Dalton. Viscosity 100 °C > 2,5 cSt. Hydrocarbons with Carbon number less than 25, < 40 %.**			**Average Mol weight > 500 Dalton Viscosity 100 °C > 11 cSt Hydrocarbons with Carbon numb less than 25,<5 %**	
Typical Products covered	Mineral paraffin wax and synthetic (low viscosity) paraffin wax (both **foodgrade)**			**Mineral microcrystalline wax and synthetic** (high viscosity) paraffin wax (both **foodgrade)**	
Source	Vacuum distillate **mineral** oil		**FT process**	Residu vacuum distillate **mineral** oil	**FT process**
Abbreviation	**LMPW**	**IMPW**	LMSP	**Micro**	HMSP
Carbon distribution	**C20 - C35**	**C25 - C45**	**C20 - C50**	**C35[(3)] - C80**	**C30 - C90**
N-alkane content (%)	85-90	50 - 70	> 90	10 - 60	> 90
Melting point (°C)	52 - 60	60-68	50 - 100	50 - 100	110
Viscosity 100 °C (cSt)	3	7	3 - 8	11 - 30	8 (120 °C)
Average Mol weight	350	475	360 - 550	600 - 700	600 - 700
SML	0.05 mg/kg	0.05 mg/kg	0.05 mg/kg	None	None
Purity requirments	Based on absence PAH	Based on absence PAH	Based on absence PAH	Based on absence PAH	Based on absence PAH
MOAH by GC (%)	Virtually absent	Virtually absent	Virtually absent	0 - 7	Virtually absent
MOAH by NMR (%)	Virtually absent	Virtually absent	Virtually absent	0 - 0,5	Virtually absent

Legislative framework - Food and Pharma uses White oils and Petroleum Jellies

	Food Contact Legislation		Food Additive		Pharmacopeia	Cosmetic	Pharmacopoeia and Cosmetic
Product	Regulation	Purity test	Regulation	Purity test	Regulation		Purity Criteria
White Mineral Oil	EU 10/2011 (PLASTIC)	95833	FDA 172.878 Food Additive or Process Aid (e.g. Release Agent)	PAH (< 1/3 of absorbance of a solution containing 7 ppm naphtalene in trimethylpentane at 275 nm)	Eur /Ph- 9.0 USP -40	EC/1223-2009 and Cosmetic Europe recommendation	PAH (< 1/3 of absorbance of a solution containing 7 ppm naphtalene in trimethylpentane at 275 nm)
	21 CFR 178.3620 (a), (b) or ©- Food contact Plastics	PCA -UV Absorption					
	21CFR178.3570 (incidental food contact)	PCA -UV Absorption (178.3620(b) level)					
	Bfr-Recomendations V, VI, IX, XXI, XXXVI, XLIV	Bfr - 155 BGA Mitteilung=DAB 8				Colipa Recommendation nº 14	PAH Level (EC-1223/2009) and for **High viscosity**: KV 11 , MW≥ 500 , Carbon number at 5% boiling point ≥ 28
							PAH Level (EC-1223/2009) and for **medium and low viscosity :** KV 8,5 , MW 480-500 , Carbon number at 5% boiling point ≥ 25
	Lubricants: EN ISO 21469 "Security of machine lubricants with no foreseeable product contact - hygiene requirements (ISO 21459:2006)"	JECFA Monographs and 21CFR178.3570					
White Petrolatum					Eur /Ph- 9.0 USP -40 (*)	EC/1223-2009 and Cosmetic Europe recommendation	PAH Level (< 1/3 of absorbance of a solution containing 6 ppm naphtalene in DMSO at 278 nm)
Yellow Petrolatum						EC/1223-2009 and Cosmetic Europe recommendation	PAH Level (< 1/3 of absorbance of a solution containing 9 ppm naphtalene in DMSO at 278 nm)
White and Yellow Petrolatum	FDA.178.3700 and 178.3710 indirect food contact	FDA 172.886(b)	FDA.178.880 direct food contact	FDA 172.886(b)		Colipa Recommendation nº 14	PAH Level (EC-1223/2009) and KV 8,5 , MW 480-500 , Carbon number at 5% boiling point ≥ 25
						Colipa Recommendation nº 15	Nota N (CLP, old Directive 67/548/EEC)

(*)- Microcrystalline Monograph in progress for European Regulation

White Oils Definitions/Specifications Medicinal and Pharmaceutical Applications

- Requirements for Medicinal/Pharmaceutical uses based on Pharmacopeia Monographs
- Purity requirements are very similar to those of FDA and JECFA

TEST	JECFA Definition		US Nat. Formulary 35th edition	US Pharm. 40th ed.	European Pharm. 9th edition	
	Medium Vis MO (2013 edition)	High Vis MO (2006 edition)	Light Mineral Oil	Mineral Oil	Light Liquid Paraffin	Liquid Paraffin
Initial Boiling Point	>= 200°C	>=350°C				
Average Molecular Weight	480 - 500	500 min				
Carbon number at 5% dist point	25 min (BP>391°C)	28 min (BP>422°C)				
Rel. Density 20/20°C					0.810-0.875	0.827-0.890
SpecGravity 25/25°C			0.818-0.880	0.845-0.905		
Viscosity	8.5 - 11 cSt	>= 11 cSt	3.0 - 34.4 cSt	34.5 - 150 cSt	25-80 cPo	110-230 cPo
	at 100°C	at 100°C	at 40°C	at 40°C	at 20°C	at 20°C
IDENTIFICATION						
Infra-red spectrum					Identical to reference spectrum	
Reaction with NaOH					Neutral	
TESTS						
Acidity/Alcalinity	Pass		Pass		Pass	
Heavy Metal Content	Lead : 1ppm max		-		-	
Sulfur Compounds	-		Pass		-	
Solid Paraffin (4h/0°C)	Pass		Pass		Pass	
Polycyclic Arom. Hydrocarbons UV Absorp. of DMSO extract	Pass (≤ 0.1)		Pass (≤ 0.1)		Pass (≤ 0.1)	
Readily Carbonizable Substances	Pass (USP)		Pass		Pass	

Purity Criteria for pharmaceutical and cosmetic uses Mineral Oil and Wax

Substance	European Pharmacopeia Designations	European Pharmacopeia Test	Limit	INCI Term
White Mineral Oil	Paraffin, Light Liquid Paraffin, Liquid	Polycyclic aromatic hydrocarbons	Not more than 1/3 of the absorbance of a solution containing 7 ppm naphthalene in trimethylpentane at 275 nm	Paraffinum Liquidum (EU) Mineral Oil (USA)
Microcrystalline Wax	--- (no Ph. Eur.) USP/NF listed	Polycyclic aromatic hydrocarbons from FDA 21 CFR 172.886 b	Max 0,15 at 280 – 289 nm Max 0,12 at 290 – 299 nm Max 0,08 at 300 – 359 nm Max 0,02 at 360 – 400 nm	Cera Microcrystallina (EU) Microcrystalline Wax (USA)
Paraffin Hard	Hardparaffin	Polycyclic aromatic hydrocarbons	Not more than 1/3 of the absorbance of a solution containing 7 ppm naphthalene in DMSO at 278 nm	Paraffin
White Petrolatum	Paraffin, White Soft	Polycyclic aromatic hydrocarbons	Not more than 1/3 of the absorbance of a solution containing 6 ppm naphthalene in DMSO at 278 nm	Petrolatum
Yellow Petrolatum	Paraffin, Yellow Soft	Polycyclic aromatic hydrocarbons	Not more than 1/3 of the absorbance of a solution containing 9 ppm naphthalene in DMSO at 278 nm	Petrolatum

INCI: International Nomenclature of Cosmetic Ingredients

- No European Pharmacopeia exists for Microcrystalline wax
  - However PACs are strictly controlled

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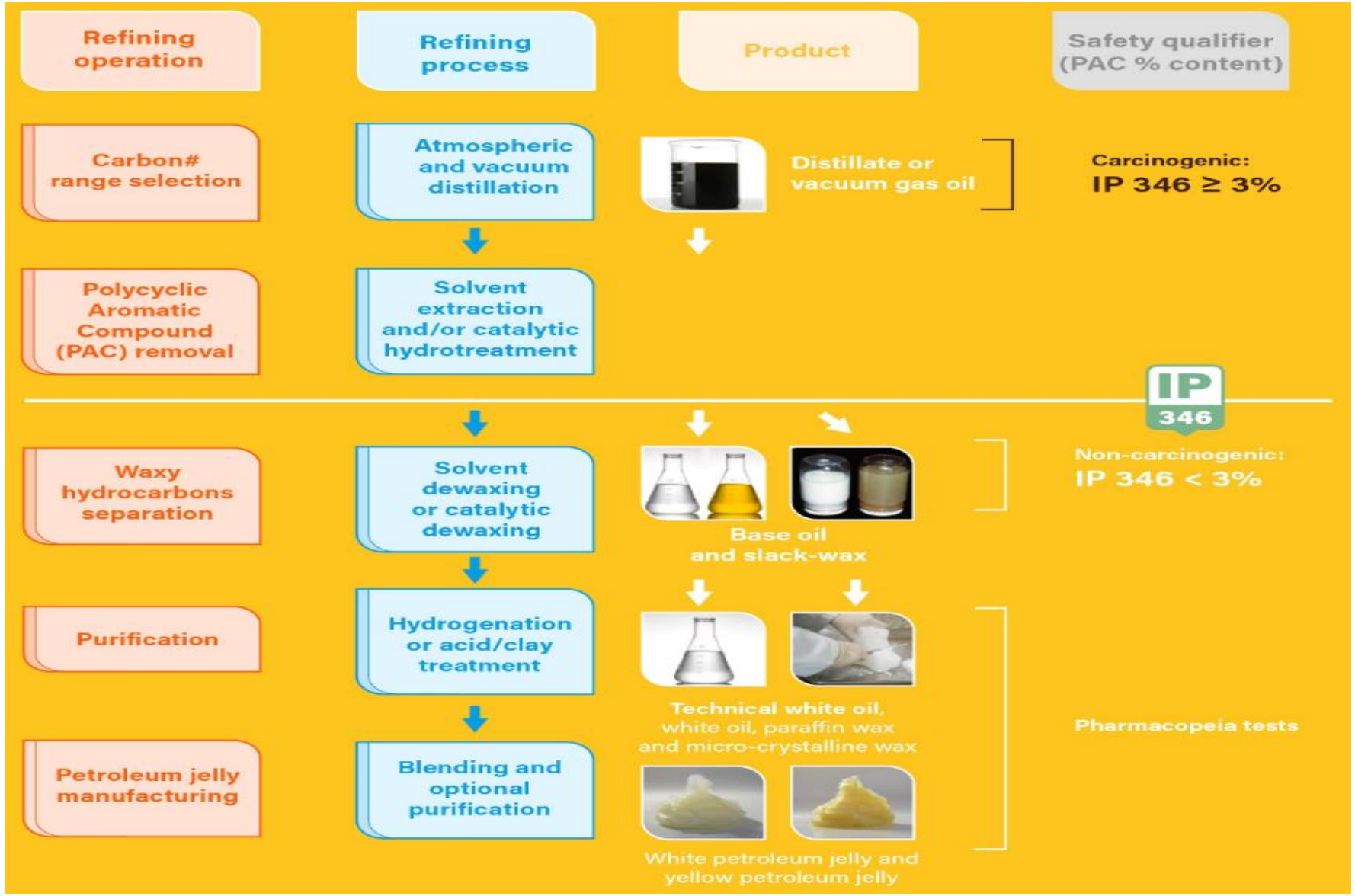
Mineral Oil and Wax - Manufacturing and Quality Assurance Testing

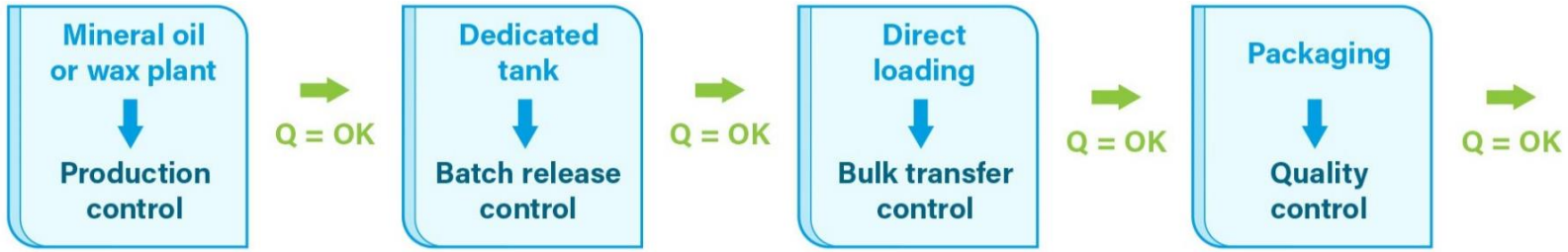


Quality Assurance / Protection from Contamination

- Products are controlled vs **manufacturing and sales specifications**
  - defined at industry or company level
  - carefully designed to **control their chemical composition**
- **Absence of contamination** during refinery transfers, loading and packaging **controlled by Quality Assurance** procedures
  - Eg ISO 9001, ISO 14001, Good Manufacturing Practices (GMP)

Mineral oil / wax handling

Quality control from manufacture to shipment



There are dedicated pipes and tanks for each step in the process.

Procedures are in place for manufacturing, storing, handling, packaging as part of the Quality Assurance process.

Q = Quality

Conclusion – Manufacture and composition of Mineral Oil and Wax

- **Refining** selects the molecules from the crude oil in a controlled manner to **set the final chemical composition** (and properties) of the mineral oil and wax
  - Removal/conversion of undesirable molecules obtained through various refining units
- **Product Specifications** tightly **control** mineral oil and wax **composition**
  - to ensure performance in application and no safety concern for consumer
  - tests shall be simple and quick to be run on each production batch
- **PACs in mineral oil/wax have been removed at desired level**
  - Absence of carcinogenicity controlled by IP346 <3.0% and known refining history
  - Mineral base oils: Total aromatics can be 0-50%, but PAC% << Aromatic%
  - Purity of products used in pharmaceutic/cosmetic/Food contact applications ensured by Pharmacopeia UV Tests and adequate Quality Assurance/Quality Control
    - Medicinal white oils: Total aromatics ~hundreds of ppms, PACs at ppb level
- **Total aromatics content is not a correct safety indicator**
- Development of **harmonized EU regulations needs** to be pursued
  - compatible EU and US regulations are preferred (e.g. pharmacopeias)

Questions?

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