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White mineral oils (HRBOs) are colorless, highly refined mineral oils derived from non-carcinogenic Lubricating Base Oils (LBOs).

- Technical white oils are HRBOs that meet requirements of US FDA 21 CFR-1780.3620(b) for color an UV-DMSO limits by to not comply with pharmacopeia monograph purity. They are mainly used to formulate food grade lubricants, textile oils, petroleum jellies, or as rubber extender oils.

- Pharmaceutical/medicinal/food grade white oils (paraffinum liquidum) are derived from technical white oils and by a second refining step, either hydrotreatment or acid treatment They comply with purity requirements of pharmacopeia monographs (EU or US) or FDA (US), thanks to their extremely low levels of aromatics (1-2 ring highly alkylated structures, typically ~0.1%). They are mainly used in pharmaceutical, cosmetic and food contact (e.g. as extender oils in plastics or elastomers) applications. The main purity tests used are:

    1. UV-DMSO: used in Pharmacopeias (EU/US) and FDA (US, food-contact) to track remaining Polyaromatic compounds.
    2. Readily Carbonisable Substances: tracks aromatics and impurities.

UV-DMSO test is also the key purity test used on food-grade wax and petroleum jellies, in order to control suitability to use these products in food contact, pharmaceutical and cosmetic applications.

As far as regulations are concerned, while pharmaceutical and cosmetic applications are well covered by the Pharmacopeia monographs that are consistent between Europe and the US (with the exception of microcrystalline wax for which no specific monograph currently exists in EU), the European regulations for food contact applications need further harmonization.

Food related applications need to distinguish between:

- Uses as food additives (non-food substances intentionally added to modify a property of the food): EU food directive does not allow any mineral oil, but does list microcrystalline wax in its acceptable list (under E905 additive).

- Uses as processing aid (non-food substances intentionally used during the processing, resulting in the presence of non-intentional residues in the foodstuff):

Mineral Oil and Wax Definitions, Uses, Regulations

Processing aids are not covered in a EU Directive, so national legislations apply.

- In the US, FDA 21 CFR 172.878 (white mineral oils) and 21 CFR 172.886 (paraffins) defines and regulates both food additives and processing aids.

- Food contact materials (materials, like plastic, glass, cardboard, that can come into contact with food): the EU Plastics directive (EU 10/2011) is the main harmonized directive in this category that defines suitable quality level for wax and for mineral oils that can be used as raw materials. In this plastics Directive, a further improvement should be the clarification of the level of purity actually required. For other food contact materials that may incorporate some wax or mineral oil, harmonized directives still need to be developed.

  - In the US, uses in Food contact materials and applications are defined and regulated by FDA 21CFR178.3620 (mineral oils) and 21CFR178.3710 (wax).

- Lubricants with incidental food contact: no existing regulation in EU, so that US regulation (21 CFR 178.3570) and registration ("H1") are often referred to.

In addition to the specifications and regulations, that set the definitions, characteristics and limits to control the chemical composition of mineral oils and wax, strong Quality Assurance processes and procedures, defined at industry or company levels, control the absence of contamination during refinery transfers, loading and packaging. This ensures the product delivered to customers is similar to the one produced by suppliers in their plants.

In conclusion:

- Industry regulations and product specifications tightly control mineral oil and wax composition.

  - To ensure performance in application and no safety concern for consumers.

- Purity of these products used in pharmaceutical, cosmetics and food contact applications are controlled mainly by UV-DMSO Tests (that are used to track remaining Polycyclic Aromatic Compounds (PAC)) and adequate Quality Assurance procedures.

  - Total aromatics content (that could be measured by a so called "MOAH" test) is not a correct safety indicator.

- Development of harmonized EU regulations needs to be pursued, if possible with consistent EU vs US regulations.