

FINAVESTAN white oils

Compliance with laws and regulations

The **FINAVESTAN white oils** can be used in a variety of industries: Pharmaceuticals & Cosmetics, Plastics & Rubber and Food. It is important to note that the application is subject to the applicable laws and regulations **in each country**. Therefore, the FINAVESTAN user must check compliance with applicable regulations of the concerned country.

TOTAL certifies that FINAVESTAN white oils comply with the following regulations:

▪ Pharmaceuticals and Cosmetics industry:

Country	Regulation	Definition
USA	• US Pharmacopoeia (most recent edition)	• Mineral Oil ⁽¹⁾
	• US National Formulary, NF 21	• Light Mineral Oil ⁽¹⁾
	• USA FDA, 21 CFR 178.3620(a)	• White Mineral Oil
European Union	• European Pharmacopoeia (most recent edition) ⁽³⁾ (specification on content of PAH-Polycyclic Aromatic Hydrocarbons measured by UV test)	• Paraffin, light liquid ⁽²⁾
	• COLIPA Recommendation n°14 (Mineral hydrocarbons in oral and lip care, 2014)	• Paraffin, liquid ⁽²⁾ • Paraffinum, Liquidum

⁽¹⁾ Mineral oil: FINAVESTAN A 210 B, A 360 B, and A 520 B

Light Mineral oil: FINAVESTAN A 50 B, A 80 B, A 100 B and A 180 B

⁽²⁾ Paraffin, light liquid: FINAVESTAN A 80 B, A 100 B and A 180 B

Paraffin, liquid: FINAVESTAN A 360 B

⁽³⁾ FINAVESTAN A 50 B, A 210 B and A 520 B are not covered by the European Pharmacopoeia due to their viscosity but they comply with all the purity requirements of this pharmacopoeia, as well as of the various national Pharmacopoeias of the European countries which have adopted it.

▪ Plastics and Rubber industry

Country	Regulation	Definition
USA	• USA FDA, 21 CFR 178.3620(a)	• White Mineral Oil
	• FDA, 21 CFR 170 to 189	• Indirect Food Additives ⁽⁴⁾
European Union	• Commission Regulation (EU) No 10/2011 replacing the directives 2007/19/CE, 2004/19/EC and 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs ⁽⁵⁾	• White Mineral Oil ⁽⁵⁾ • FINAVESTAN A 360 B and A 520 B

⁽⁴⁾ Indirect Food additives: substances that may come into contact with food as part of packaging or processing equipment, but are not intended to be added directly to food

⁽⁵⁾ "White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks" are listed in the Annex 1 of the Commission Regulation (EU) No 10/2011 (Identification No: 95) and are authorized to be used as additive or polymer production aid in compliance with the related restrictions and specifications. Due to their viscosity, only FINAVESTAN A 360 B and FINAVESTAN A 520 B comply with the Regulation EU No 10/2011.

▪ Food industry

Country	Regulation	Definition
USA	• FDA, 21 CFR 178.3570	• Lubricants with incidental food contact
	• Lubricants with incidental food contact (NSF-H1)	
	• USA FDA, 21 CFR 178.3620(a)	• Mineral Oil
	• Lubricants with direct food contact (NSF-3H)	
European Union	• White Mineral Oils are not included in the positive list of the Directive 2006/52/EC (amending 95/2/EC)	• Direct Food Additive
	• Not covered by any European Directive: The national regulations must be applied	• Processing aid

As an example for the Food Industry: in USA, FINAVESTAN A 360 B can be used as a food additive but in Europe it cannot be used this way, it can only be used as processing aid in a few European countries.

Please note that the above lists are not exhaustive. The compliance with other specific regulations can be checked upon request.