

<p>FINAVESTAN white oils Compliance with laws and regulations</p>
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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) US National Formulary, NF 21	Mineral Oil ⁽¹⁾ Light Mineral Oil ⁽¹⁾
	USA FDA, 21 CFR 172.878 and 21 CFR 178.3620(a)	White Mineral Oil
	Japanese Pharmacopoeia, JP XIV	White Oil and Light White Oil
European Union	European Pharmacopoeia (most recent edition) ⁽³⁾	Paraffin, light liquid ⁽²⁾ Paraffin, liquid ⁽²⁾
UK	British Pharmacopoeia, BP 2001 ⁽³⁾	Liquid Paraffin
Germany	Deutsches Arzneibuch DAB10 ⁽³⁾	Dickflüssiges Paraffin
France	Pharmacopée Française, 10ème edition ⁽³⁾	Paraffine Liquide

⁽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.



TOTAL

▪ Plastics and Rubber industry


Country	Regulation	Definition
USA	USA FDA, 21 CFR 172.878 and 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
Germany	BGVV 155 Mitteilung : BgesundhIBL25,192	Füssiges Paraffin

⁽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 authorised to be used as additive or polymer production aid in compliance with the related restrictions and specifications.

Thus, 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 172.878 White Mineral Oil FDA, 21 CFR 173.340 Defoaming Agent	Direct Food Additive
	FDA, 21 CFR 178.3570 Lubricants with incidental food contact (NSF-H1)	Incidental Food Contact Oils
	FDA, 21 CFR 170 to 189 (uses complying with any limitations of 21 CFR parts 170 to 189)	Indirect Food Additives ⁽⁴⁾
	 FINAVESTAN white oils are NSF 3H registered. Registration letters available on http://www.nsf.org/usda/psnclistings.asp	Lubricants acceptable for use as a release agent in contact with food
European Union	White Mineral Oils are <u>not included</u> 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.

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TOTAL LUBRIFIANTS
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