Regulatory Information Sheet

Version	Revision Date:	Article-No.:	Date of last issue: 28.05.2024
1.5	20.03.2025	310500	

Trade name	ALBERDINGK® Pharm. Castor Oil Virgin Ph.Eur.
Article-No.	310500
INCI name	RICINUS COMMUNIS OIL
CAS-no.	8001-79-4
REACh-reg.no.	
Company	Alberdingk Boley GmbH Düsseldorfer Str. 53 47829 Krefeld, Germany Telephone +4921515280
E-mail address	trm@alberdingk-boley.de

1. Notification status

The components of the product are listed in the following countries

TCSI	On the inventory, or in compliance with the inventory
TSCA	All substances listed as active on the TSCA inventory
AIIC	On the inventory, or in compliance with the inventory
DSL	All components of this product are on the Canadian DSL
ENCS	On the inventory, or in compliance with the inventory
ISHL	Not in compliance with the inventory
KECI	On the inventory, or in compliance with the inventory
PICCS	On the inventory, or in compliance with the inventory
NZIoC	On the inventory, or in compliance with the inventory
IECSC	On the inventory, or in compliance with the inventory

Abbreviations

TCSI	Taiwan Chemical Substance Inventory (TCSI)
TSCA	United States TSCA Inventory
AIIC	Australian Inventory of Industrial Chemicals
DSL	Canadian Domestic Substances List (DSL)
ENCS	Japan. ENCS - Existing and New Chemical Substances Inventory

ISHL	Japan. ISHL - Inventory of Chemical Substances
KECI	Korea. Korean Existing Chemicals Inventory (KECI)
PICCS	Philippines Inventory of Chemicals and Chemical Substances (PICCS)
IECSC	China. Inventory of Existing Chemical Substances in China (IECSC)
NZIoC	New Zealand. Inventory of Chemical Substances

2. REACH

Chemical Legislation	REACH EU
	The product is exempt from registration according to Annex V (9) of the REACH Regulation.
SVHCs (Substances of Very High Concern)	The product doesn't contain any SVHCs in concentrations >= 0.1% (w/w).
	In case any of the substances used in our products will be categorized in future as SVHC under REACH or added to the substance list of Annex XIV, this component will be mentioned in section 3 of the EU Safety Data Sheet if the concentration is >= 0.1% (w/w). Any change concerning this matter will be communicated immediately to our customers via the updated Safety Data Sheet.
Restrictions acc. to Annex XVII	No restrictions exist for the use of the product and/or its components according to Annex XVII of the REACH regulation.
Chemical Legislation	UK REACH
	Our product is exempt under the regulation from the obligation to register as it fulfils the conditions mentioned in Annex 5.

3. Components/Ingredients Information

Undesirable or Restricted Substances

Dioxines	This product complies with the EU Regulations 1881/2006/EC, 2006/13/EC, 183/2005/EC and 225/2012/EC in respect of contents of PCDDs, PCDFs and

	Dioxin-like PCBs.
Aflatoxines	ALBERDINGK®Pharmaceutical Castor Oils have been analysed for the content of Aflatoxin B1, B2, G1 and G2 since 2006 on a regular basis. These analyses have been and will be performed also in future once a year by accredited institutes. In all cases the contents of these Aflatoxins have been below the quantification limit (<0.1 µg/kg) with two exceptions: 2009: Aflatoxin B1 0.38 µg/kg; 2014: Aflatoxin B1 0.2 µg/kg. This is well below the accepted limit according to REGULATION (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (max. 2.0 µg/kg Aflatoxin B1 for oilseeds). As a bulk producer of Castor Oil for being used as excipient and active pharmaceutical ingredient (API), it is not feasible for us to determine the Aflatoxin content of every batch.
APEO	Not contained in the product.
CMR Substances	Not contained in the product.
Formaldehyde	Not contained in the product.
Ozone depleting substances	Not contained in the product.
Phthalates	Not contained in the product.
PFAS (Per- and polyfluorinated Substances) incl. PFOS and PFOA	Not contained in the product.
Melamine	Not contained in the product.
Bisphenol A	Not contained in the product.
Pesticides	The content of residues of pesticides in this product is below the limits given in the EU directive 396/2005/EC and its amendments.
Latex	This product does not contain, nor was manufactured with, natural rubber latex or synthetic latex.
Allergenes	None of the listed ingredients from Annex II of Regulation (EU) No 1169/2011 are used or added.
VOC	Not contained in the product.

Heavy Metals / RoHS

Heavy metals	Heavy metals are not intentionally added during production (lead, mercury, cadmium, chromium, zinc, manganese, cobalt, vanadium, zirconium, tin, arsenic,

	copper, iron, nickel, rhodium, platinum, palladium, molybdenum, iridium, ruthenium, osmium).
RoHS	No prohibited substances are used or intentionally added that fall within the scope of Regulation 2011/65 EC and subsequent amendments.
Conflict Minerals	The conflict minerals Tantalum, Tin, Tungsten and Gold are not intentionally added during production.

4. Food Contact Regulations

Regulation (10/2011/EU)	The composition of the product complies with the currently valid regulation.
FDA Regulation 21 CFR 175.105	The composition of the product complies with the currently valid regulation.
FDA Regulation 21 CFR 175.300	The composition of the product complies with the currently valid regulation.
FDA Regulation 21 CFR 178.3570	The composition of the product complies with the currently valid regulation.
Swiss Ordinance 817.023.021 Annex X	The composition of the product complies with the currently valid regulation.
Remarks Food Contact	A positive assessment of the binder does not release the user from the duty to test his readymade formulation concerning e.g. migration in order to confirm suitability for the desired application. If the product is not on the positive list of the respective Food Contact Regulation you might be able to approve your final product by conducting migration tests via a respective institute. You will receive further information upon request.
GMP (Good Manufacturing Practice)	Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food sets out general principles to ensure the suitability of the material or article for the intended end use. Article 2 states that this Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances. Regulation (EC) No 2023/2006 deals mainly with the principles of quality assurance covering the manufacturing process, starting materials, operation processes, premises, equipment and quality control. Alberdingk Boley GmbH has already established and implemented Quality Management

Systems such as ISO 9001.

5. Miscellaneous

Nanoparticles	The product doesn't contain any nano-particles.
Synthetic polymer microparticles	The product doesn't contain any synthetic polymer microparticles.
Synthetic polymer microparticles	The product doesn't contain any synthetic polymer microparticles.
Information concerning BSE	This product is free from BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy). No materials of human or animal origin are used during the manufacturing process. The material used for primary packaging is not of animal derived material and no animal or human origin materials come into contact with the equipment.
BASTA	We confirm compliance with all BASTA criteria.
Halal	This product is manufactured according to all Halal regulations/restrictions. We do not use any animal products in the process of making our oil products and no animal products in the same process lines that we produce oils in.
Kosher	This product is manufactured according to all Kosher regulations/restrictions.
Renewable Raw Materials	The product only consists of Castor Oil obtained from the seeds of Ricinus Communis L. (100 % renewable resources/Bio based). The seeds are pressed without addition of heat and are not solvent extracted. They contain no other ingredients.
Animal Testing	This product has not been subject to animal testing for more than 25 years.
Information Concerning Animal Ingredients	This product is free from animal ingredients; it is not made from animal source.
GMO Information	This product has not been tested for GMO. But we hereby confirm that the DNA of crude Castor Oil, which is the raw material for ALBERDINGK® Castor Oils and its derivatives, has been analysed with

regards to GMO since 2000 on a regular basis. In the samples no DNA components have been detected. These DNA components form the basis in a standard analysis to confirm the presence of GMOs or GMO derived materials.

6. Further Information

Disclaimer	The raw materials used for the manufacture of pharmaceutical Alberdingk® castor oil and derivatives are raw materials suitable for the production of edible oils and fats. Analyses of possible contaminations with substances listed in section 3 are performed once a year. All information is presented in good faith and to the best of our knowledge and belief as of today. Alberdingk Boley GmbH assumes no obligation or liability for use of or updating this information and gives no warranty. The customer is solely responsible for compliance with any applicable federal, state or provincial law.