

Regulatory Information Sheet



Version 1.2 Revision Date: 09.01.2024 Article-No.: 210200 Date of last issue: 27.03.2023

Trade name ALBERDINGK® Double Boiled Linseed Oil
Article-No. 210200
INCI name
Company Alberdingk Boley GmbH
 Düsseldorf 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	Not 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	Not 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	Not in compliance with the inventory
TECI	Not 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

Regulatory Information Sheet



Version 1.2 Revision Date: 09.01.2024 Article-No.: 210200 Date of last issue: 27.03.2023

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
TECI	Thailand Existing Chemicals Inventory (TECI)

2. REACH

Chemical Legislation

REACH EU

The product is registered according to the REACH regulation. Registration number: Please see above.

SVHCs (Substances of Very High Concern)

The product doesn't contain any SVHCs in concentrations $\geq 0.1\%$ (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 $\geq 0.1\%$ (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

All substances which are restricted for certain uses according to Annex XVII of the REACH regulation are listed in section 15 of the Safety Data Sheet.

Chemical Legislation

UK REACH

We and/or our suppliers have submitted DUINS (Downstream User Import Notifications) for all relevant components of our product via an OR (Only Representative). We would like to point out that the DUIN submitted by our OR may not cover your import. Therefore, as our customer, please check whether you are allowed to import this product to GB. If you have any questions, please contact our Team Regulatory Management: trm@alberdingk-boley.de

Version
1.2

Revision Date:
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Article-No.:
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Date of last issue: 27.03.2023

3. Components/Ingredients Information

Undesirable or Restricted Substances

Mangan Neodecanoat (CAS: 27253-32-3, EC: 248-374-6)	0,4 %(m)
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.
VOC	0,1 %(m)
Allergenes	None of the listed ingredients from Annex II of Regulation (EU) No 1169/2011 are used or added.

Heavy Metals / RoHS

Heavy metals	Annual analyses of the product show that the contents of the mentioned heavy metals are below the limits given in the directives 2002/32/EC and 2005/87/EC. There are no residues of metal catalysts or metal reagents in the product in accordance with the EMA 'Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents' (EMA/CHMP/SWP/4446/2000), the ICH Q3D "Guideline for Elemental Impurities" and other
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Regulatory Information Sheet



Version 1.2 Revision Date: 09.01.2024 Article-No.: 210200 Date of last issue: 27.03.2023

	applicable regulations.
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 doesn't comply with the currently valid regulation.
FDA Regulation 21 CFR 175.105	The composition of the product doesn't comply with the currently valid regulation.
FDA Regulation 21 CFR 175.300	The composition of the product doesn't comply with the currently valid regulation.
Swiss Ordinance 817.023.021 Annex X	The composition of the product doesn't comply 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.

Regulatory Information Sheet



Version 1.2 Revision Date: 09.01.2024 Article-No.: 210200 Date of last issue: 27.03.2023

5. Miscellaneous

Nanoparticles	The product doesn't contain any nano-particles.
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.
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.
Information Concerning Animal Ingredients	This product is free from animal ingredients; it is not made from animal source.
GMO Information	According to the information from our suppliers, there is no genetically modified linseed oil commercially available. The EU currently has a zero tolerance policy regarding unapproved GMOs. Therefore no linseed is imported to Europe containing GMOs.

6. Further Information

Disclaimer	The raw materials used for the manufacture of Alberdingk® oil products and derivatives are technical raw materials and therefore contain process-related additives and impurities caused during transport. We don't check the content of these substances as part of our quality system. All information is presented in good faith and to the best of our knowledge and belief as of today which is based on information from our raw material suppliers. 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.
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