

Regulatory Information Sheet



Version 1.2	Revision Date: 09.01.2024	Article-No.: 340007	Date of last issue: 27.03.2023
----------------	------------------------------	------------------------	--------------------------------

Trade name ALBERDINGK® 12-HSA Flakes 81

Article-No. 340007

INCI name

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	On the inventory, or 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

Regulatory Information Sheet



Version 1.2	Revision Date: 09.01.2024	Article-No.: 340007	Date of last issue: 27.03.2023
----------------	------------------------------	------------------------	--------------------------------

IECSC	Substances (PICCS) China. Inventory of Existing Chemical Substances in China (IECSC)
NZIoC	New Zealand. Inventory of Chemical Substances

2. REACH

3. Components/Ingredients Information

Undesirable or Restricted Substances

Heavy Metals / RoHS

Heavy metals	Nickel is used as catalyst for the hydrogenation of Castor Oil. Its residues are below 1 ppm. Apart from that we do not use or add heavy metals (such as lead, mercury, cadmium, chromium, zinc, cobalt, vanadium, zirconium, tin, arsenic, copper, iron, 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

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.: 340007	Date of last issue: 27.03.2023
----------------	------------------------------	------------------------	--------------------------------

5. Miscellaneous

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.
----------------------------	---

Information Concerning Animal Ingredients	This product is free from animal ingredients; it is not made from animal source.
---	--

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.
------------	---