

2022-11-15

To whom it may concern

FAQ statement – Regulatory aspects for AAK Cosmetic ingredients.

This statement comprises the products according to Table 1.

Akoline GC™	LIPEX® Collect™
Akoline LC™	LIPEX® Shea WM™
Akoline MCM™	LIPEX® Shea-U™
Akoline PG7™	LIPEX® Shea W™
Akoline PGPR™	LIPEX® SheaLight™
Akoline SL™	LIPEX® SheaTris™
LIPEX® 102 E75 100%™	LIPEX® SheaSolve™
LIPEX® 102 E75 50%™	

Table 1

EU 1223/2009, Annex II.

With respect to substances listed Annex II EU 1223/2009:

AAK has identified the substances of concern, which are part of the contaminant standard, see contaminant standard with respect to dioxin, mineral oil, heavy metals including Nickel (added as process aid during hydrogenation and removed) and polyaromatic hydrocarbons such as benz(a)pyrene.

For substances listed in Annex II, EU 1223/2009 outside the contaminant standard. AAK do neither add any of the listed substances, nor are any of the substances created during the processing. AAK conclude, the products listed in Table 1 do not contain the substances listed.

EU 1223/2009, Annex III.

With respect to substances listed Annex III EU 1223/2009:

AAK do neither add any of the listed substances, nor are any of the substances created during the processing. AAK conclude, the products listed in Table 1 do not contain the substances listed.

SVHC:

None of the products sold by AAK Personal Care contain any of the listed substances on ECHA Candidate List of Substances of Very High Concern for Authorization published in accordance with Article 59(10) of the REACH Regulation (last update: June 10, 2022).

Animal testing:

AAK has not tested or allowed on behalf of AAK any of the products in Table 1 to be tested on animal in breach of the European directive on cosmetic regulation EC 1223/2009, and prior to that the 76/776/EEC and the commission's recommendation 2006/406/EC. The statement also confirms that no products have been tested on animals by or on behalf of AAK breaching the principles of standards of NGO's such as Humane Cosmetic Standards. AAK confirms that the products fulfil the requirements claiming that the products are conformative with the non-animal testing ban.

Nano particles:

To the best of our knowledge do not any of these products in Table 1 contain nano particles according to EC 1223/2009 article 2.1.k

CMR:

The products produced by AAK Sweden AB and listed in the Table 1 have all been subjected to a thorough safety assessment found in the product documentation for each product respectively. None of the products found in the Table require special labelling. Based on the reasoning found for each product, AAK to the best of our knowledge do not any of these products to be considered CMR, thus the current documentation complies with the EU Regulation EC 1272/2008.

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It is up for each user of these product to read through the product documentation and take an active decision that the conclusion hereby is correct.

Proposition 65:

Lipex and other products from AAK produced in Karlshamn listed in Table 1, have long history of usage in food, personal care, pharmaceutical and technical application.

Read Across from other vegetable oils with similar fatty acid profile show no sign to be carcinogenic. They are not listed among the substances with respect to proposition 65. AAK conclude that the products found in Table 1 are non-carcinogenic thus not substances restricted according to proposition 65.

Biodiversity and Access, Benefit and Sharing legislation, including Nagoya protocol:

The EU ABS directive (EU 511/2014) is based on the Nagoya protocol. The Nagoya protocol relates to products where AAK in access of genetic sources performed R&D. Based on the best knowledge currently, none of the products in the Table 1 are found to live up to the conditions to be considered as within the scope of EU ABS legislation or the Nagoya protocol. AAK thus conclude that the products are out of scope.

Brazil biodiversity laws (law 13,123/2015 and decree 8,776/2016) govern the biodiversity legislation in Brazil. The legislation does not comprise commodity crops such as soybeans and its derivatives. AAK thus conclude that the products are out of scope.

Indian Biodiversity Act, 2002 governs the biodiversity in India. The legislation exempt commodity crops such as Mango. AAK thus conclude that the products are out of scope.

CITES:

The products in Table 1 are not considered as endangered species. The cites convention therefore is not applicable to these products, thus no CITES certification to trade with these products are required.



Christer Lindström
Technical Product Manager