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Food supplements with whole-leaf Aloe preparations containing anthranoids are associated with health risks

BfR Opinion No. 032/2017 of 2 November 2017

The Aloe genus comprises approximately 250 species of succulent dry climate plants (xerophytes). The best known species is *Aloe barbadensis* (syn. *Aloe vera*), the inner leaf pulp of which has many uses in the food and cosmetics sector as Aloe vera gel.

In addition to *Aloe barbadensis*, however, other Aloe species are used for many different purposes. Inter alia, the sap of the pressed, whole, unpeeled leaves of *Aloe arborescens* (krantz aloe, candelabra aloe) is marketed in the form of food supplements. The German Federal Institute for Risk Assessment (BfR) has assessed the possible health risks of such food supplements. The outer layers of the leaves of *Aloe arborescens* are of toxicological relevance. As with all Aloe species, these layers contain plant-based anthranoids which have long been suspected of having a genotoxic and carcinogenic effect. In addition to data on the pure substances, tests have also been conducted in the meantime on anthranoid-containing preparations made from Aloe leaves. The results of these long-term studies also confirm the suspicion of carcinogenicity, but there are data gaps which should be closed with regard to the details and mechanisms of cancer development.

The BfR comes to the following conclusion on the basis of the available data: according to the latest guidelines issued by the European Food Safety Authority (EFSA) for the assessment of botanical preparations, products which contain preparations of the unpeeled leaves of *Aloe arborescens*, and thereby anthranoids, do not belong to the category of botanical food supplements which can be designated as being of “no safety concern” based on current knowledge. Due to the suspicion that plant-based anthranoids have a carcinogenic effect in humans, the BfR does not consider preparations containing anthranoids to be suitable for use in foods, including food supplements. This assessment does not apply to preparations made from anthranoid-free gel or inner pulp from the leaves of Aloe species (mostly *Aloe barbadensis* or *Aloe vera*), which are commonly used in foods and cosmetics in the EU. Anthranoids should generally not be present in foods in the view of the BfR. When producing foods with leaves of plants of the Aloe genus, the anthranoid-containing outer leaf layers should be carefully removed in order to keep contamination with anthranoids, which are suspected carcinogens, as low as possible.

		BfR Risk Profile: Whole-leaf preparations of <i>Aloe arborescens</i> (Opinion No. 032/2017)			
A Affected groups	General population 				
B Likelihood of a health impairment with regular intake of dietary supplements made from whole-leaf preparations of the plant <i>Aloe arborescens</i>	Practically excluded	Unlikely	Possible	Probable	Certain
C Severity of the health impairment with regular intake of dietary supplements made from whole-leaf preparations of the plant <i>Aloe arborescens</i>	No impairment	Slight impairment [reversible/irreversible]	Moderate impairment [reversible/irreversible]	Severe impairment [irreversible]	
D Reliability of available data	High: The most important data are available and free of contradiction	Medium: Some data are missing or contradictory		Low: Numerous important data are missing or contradictory	
E Controllability by the consumer	Control not necessary	Controllable through precautionary measures	Controllable through avoidance	Not controllable	

Boxes highlighted in dark blue indicate the properties of the risk assessed in this opinion (more detailed information on this is available in the text of BfR Opinion No. 032/2017 of 2 November 2017).

Explanations

The risk profile is intended to visualise the risk outlined in the BfR opinion. It is not intended to make risk comparisons. The risk profile should only be read in conjunction with the opinion.

BUNDESINSTITUT FÜR RISIKOBEWERTUNG (BfR)

Line E – Controllability by the consumer

[1] – The details given in the line “Controllability by the consumer” should not be seen as a recommendation from the BfR, they have a purely descriptive character.

This text version is a translation of the original German text which is the only legally binding version.

The full version of this BfR opinion is available in German on:
<http://www.bfr.bund.de/cm/343/nahrungsergaenzungsmittel-mit-anthranoidhaltigen-aloe-ganzblattzubereitungen-bergen-gesundheitliche-risiken.pdf>

About the BfR

The German Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

The BfR is celebrating its 15th anniversary this year. To mark the occasion, the institute has published a jubilee brochure (in German) which can be downloaded or ordered free of charge at: <http://www.bfr.bund.de/en/publication/brochures-61045.html>