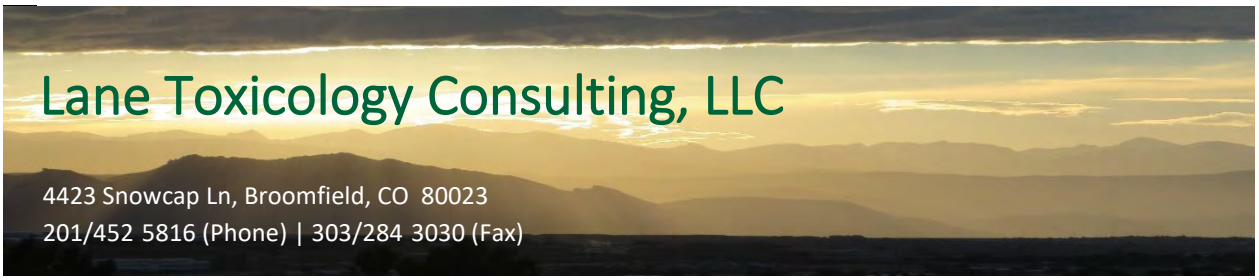


August 16, 2021

Karen Hall
Regulatory Review Scientist
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Dear Ms. Hall,

Re: GRAS Notice 000972

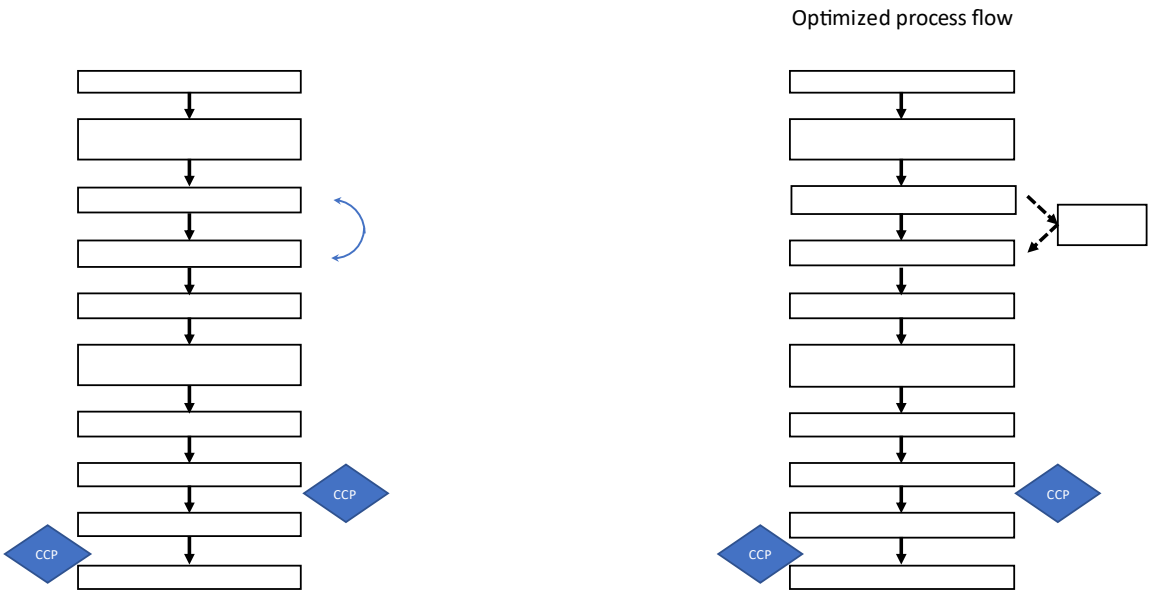
The following information responds to questions sent to me, acting on behalf of NutriLeads, BV, on July 20, 2021. Thank you for granting additional time to provide these answers.

Before answering the questions themselves, NutriLeads would like to inform FDA that it has replaced its previous supplier of carrot pomace, in part because of the very issues raised in the agency's review. The new supplier (Mainfrucht, based in Germany) is considered to be more reliable and will allow NutriLeads to produce cRG-I that addresses the issues raised.

Also, NutriLeads continues to improve its processing methods. These minor modifications were made when moving from the pilot plant production facilities to full commercial scale. The production process has been improved by 1) using a new supplier of carrot pomace with full traceability of carrot origin, 2) the use of fresh (wet) carrot pomace in addition to the use of dry pomace that needs to be rehydrated, 3) enzyme inactivation and sterilization prior to decanting, allowing better control of reaction time and optional storage of the enzymatically hydrolyzed pomace mix prior to decanting, 4) optimization of the diafiltration step resulting in a lower ash content, and 5) increasing the temperature of pasteurization to sterilization. The modifications in the process are minor and improve the quality of the final product, as well as further reducing microbial risk. They do not alter the overall manufacture of cRG-I presented in GRN 972 but allow NutriLeads to produce material more consistently and with more desirable characteristics.

The updated manufacturing process, along with the original process, are shown in Figure 1.

Figure 1. Process optimizations implemented by NutriLeads.



Material produced using pomace from the new supplier and with the modifications described has been analyzed. The data show that the modifications have improved the quality of the material and will allow NutriLeads to adjust it specifications for lead and ash (see below). NutriLeads provides certificates of analyses (CoAs) for four recent batches of cRG-I made using pomace from its new supplier and using the processing modifications. These are appended to the response.

Answers to questions begin on the next page. NutriLeads believes it has addressed the concerns raised by your review. Should you need further clarification of any sort, please feel free to contact me.

Sincerely,

Richard W Lane, PhD
Lane Toxicology Consulting, LLC
richardlanephd@gmail.com

Question 1. NutriLeads presents a specification for maximum level of lead at 1.5 mg/kg based on 5 batch analysis results ranging from 0.34 mg/kg to 1.5 mg/kg of lead in the pectin hydrolysate food ingredient. Given that the source carrot pomace has a lead specification of less than 0.1 mg/kg (Appendix 1), please address this variability in the results as well as the increase in lead levels in the final product compared to the source material. While the specification for lead at 1.5 mg/kg is below the FCC 12 specified level of lead in pectin (< 5 mg/kg), it is above the JECFA 2016 specification of 0.5 mg/kg lead for use in infant formula. Given the intended uses in multiple food categories including baby foods, we request that you reduce the specification limit for lead. Further, the FCC is currently engaging in efforts to reduce specifications for heavy metals, including lead, in a number of its monographs.

There are limited data for heavy metal content in pomace obtained from the previous suppler, Greenfield, as this supplier only monitored lead on an annual basis. The actual level in the monitoring sample did not meet the supplier's lead specification of 0.1 mg/kg, but was 0.34 mg/kg.

As noted, Nutrileads has selected another supplier of carrot pomace. Analyses of recent batches of cRG-I produced using pomace from the new supplier, Mainfrucht, show lead levels in cRG-I range from 0.4 – 1.0 mg/kg, while in batches using pomace from the previous supplier levels were from 0.3 – 1.5 (Table 1). Based on the level of lead in the new cRG-I batches (Appendix 1), NutriLeads has lowered the specification for lead from 1.5 mg/kg to 1.0 mg/kg.

Table 1. Lead levels in cRG-I batches from pomace from the previous and current suppliers.

	Old cRG-I batches					New cRG-I batches			
Batch number	**NL91**	**NL100**	**NL176**	**NL189**	**NL204**	**NL256C**	**NL272**	**NL284**	**NL283**
Lead (mg/kg)	0.34	0.38	1.5	0.76	0.91	0.40	0.96	0.47	0.84

Literature references show that the lead content in carrots varies from peeled carrot from orchard soil (0.885 mg/kg), and peeled roots from organic soil (0.147 mg/kg) (Zandstra and Kryger 2007)[1]. In another publication, it is described that lead in peeled carrots ranged from 2.67 to 7.3 mg/kg dry weight (Codling *et al.* 2014)[2]. In a recent publication (Rusin *et al.* 2021)[3], the lead level found in dried carrot was 0.206 mg/kg, and in fresh carrot samples 0.027 mg/kg. Levels from FDA's Total Diet Study show lower lead levels in carrots but this may reflect different sampling, carrots from different regions or a difference between whole carrots and pomace. Assessment of the published literature and publicly available data and the results from analyses of cRG-I indicates that it is not possible to produce cRG-I with less than 0.1 mg/kg lead.

NutriLeads' intention is not to use cRG-I in infant formula. On page 34 of the GRAS notice NutriLeads notes that, "The target population is the general population, excluding infants younger

than six months of age, who do not consume products intended for addition of cRG-I". Thus, the JECFA specification for lead in infant formula does not apply.

NutriLeads acknowledges the concern about lead in foods for children. While foods consumed by young children may contain cRG-I the amount that will be used is unlikely to reach the maximum levels indicated in the Notice. The major factor is the cost of cRG-I. Also, the intake estimates for the large categories of baby food tends to exaggerate intake. Thus, intake of lead from ingesting cRG-I will be lower than might be expected. Additionally, as just noted, NutriLeads has reduced the specification for lead. Taken together NutriLeads believes that particular concern for young children is not warranted. Nonetheless, given the widespread concern about heavy metals in baby foods, NutriLeads believes it is everyone's best interest to withdraw its request for that use. As no other uses are being withdrawn the exposure estimates in the GRAS document are considered to be robust.

NutriLeads notes that one batch of cRG-I (NL272) has a cadmium level just above the specification set in the GRAS notice. This batch is being retested; the data are not available at this time.

Question 2. We request that you provide additional information to characterize the extent of hydrolysis of the carrot pectin:

a. What is a typical use level (TOS/kg carrot pectin) for the pectinase enzymes?

b. How does NutriLeads determine completion of the enzymatic reaction and that the reaction produces reproducible pectin hydrolysate molecules? Is it rheological behavior only? What is the distribution of molecular weight of the hydrolyzed pectins? What is the degree of methylation (DM) or degree of esterification (DE) within the galacturonan chains?

a. The content of Total Organic Solids (TOS) for Pectinex Ultra Mash is 6%. In the production of cRG-I, 1.7 g of Pectinex Ultra Mash is used in 100 g of dry carrot pomace, equal to 0.1 g TOS per 100 g of dry carrot pomace (1 g/kg).

b. NutriLeads has established that reaction for 1.5-2 h at 44-46°C is the optimal time and temperature for sufficient hydrolysis of the linear portion of pectin.

The desired degree of hydrolysis is confirmed by analysis of the molecular size distribution using the molecular weight by High Performance Size Exclusion Chromatography (HPSEC) as described in the GRAS notice on page 26. As an example, chromatograms for batch NL91 are shown in Figures 5 (page 27) and 8 (page 29). The monosaccharide profile is on page 13, Table 3.

cRG-I does not gel and has no impact on rheology. The degree of methylation (DM) and degree of acetylation (DA) are not part of the specification. The values shown below (Table 2), from

Wageningen University, Food Chemistry Department, are provided as indication. These values are from batches from the previous pomace supplier but are still relevant to the current supplier.

Table 2. Degree of methylation and acetylation (%) of cRG-I.

Batch number	NL91	NL100	NL176	NL189	NL204
DM (% methylated)	11	17	10	9	9
DA (% acetylated)	38	40	40	44	50

Question 3. We request that you provide additional information regarding the ash component of your ingredient:

a. Sodium content varies from 1400 mg/kg to 10000 mg/kg. What is the cause of this large variation?

b. Please provide a description of the typical composition of the minerals contributing to the 10% ash level in the ingredient.

a. The variability in sodium levels comes from the differences in the extent of diafiltration (separation of components of a solution based on their molecular size using a micro-molecule permeable filter). Since the diafiltration step has been optimized (as described in Figure 1), resulting in a more controlled process, most of the minerals are removed. In the new cRG-I batches the level of sodium ranges from 480 – 890 mg/kg while in the old batches the range was from 2100 – 10000 mg/kg (Table 3).

Table 3. Mineral content of cRG-I

		Old cRG-I batches					New cRG-I batches			
Batch number	**Units**	**NL91**	**NL100**	**NL176**	**NL189**	**NL204**	**NL256C**	**NL272**	**NL284**	**NL283**
Ash	% (w/w)	5.31	6.11	5.53	7.13	5.05	3.37	2.74	2.89	3.34
Sodium	mg/kg	1400	1700	4000	10000	2100	890	480	790	750
Magnesium	mg/kg	1300	1400	1100	1700	n.a.	1200	1300	1000	1100
Potassium	mg/kg	15000	20000	14000	14000	n.a.	4500	3000	5700	5600
Calcium	mg/kg	9900	8400	7600	9700	7400	7400	7100	5900	7400
Phosphorus	mg/kg	690	930	180	140	n.a.	240	92	190	270

b. The old batch with the highest level of ash is NL189 with 7.13%. The 7.13% consists of approximately 1% sodium, 1.4% potassium, 0.97% calcium and 0.17% magnesium. Thus, half of the ash content comes from these four cations. The remainder comes from counter ions, mainly chloride and some phosphate. In the batches made with pomace from the

current supplier and using improved processing, the ash content has been reduced (Table 4) and now contains predominantly calcium and potassium.

Table 4. The contribution of minerals (converted to %) to the total ash content

	Old cRG-I batches					New cRG-I batches			
Batch number	**NL91**	**NL100**	**NL176**	**NL189**	**NL204**	**NL256C**	**NL272**	**NL284**	**NL283**
Ash	5.31%	6.11%	5.53%	7.13%	5.05%	3.37%	2.74%	2.89%	3.34%
Sodium	0.14%	0.17%	0.40%	1.00%	0.21%	0.09%	0.05%	0.08%	0.08%
Magnesium	0.13%	0.14%	0.11%	0.17%	na	0.12%	0.13%	0.10%	0.11%
Potassium	1.50%	2.00%	1.40%	1.40%	na	0.45%	0.30%	0.57%	0.56%
Calcium	0.99%	0.84%	0.76%	0.97%	0.74%	0.74%	0.71%	0.59%	0.74%
Phosphorus	0.069%	0.093%	0.018%	0.014%	na	0.02%	0.01%	0.02%	0.03%
Total of measured ions	**2.83%**	**3.24%**	**2.69%**	**3.55%**		**1.42%**	**1.20%**	**1.36%**	**1.51%**

Based on the level of ash in the new batches of cRG-I, NutriLeads has lowered the specification to 5%.

Analyses of the ash and mineral levels of the four new batches of cRG-I are in Appendix 2.

Question 4. The notifier refers to pectinase from *Aspergillus aculeatus*, citing GRAS petition 5G0297 (filed April 12, 1985). Please provide a statement that the enzyme is GRAS for its intended use.

The Novozymes statement from 22 July 2020 (Appendix 3) states that:

> *"This is to inform you of the current US regulatory status of Novozymes' Pectinex® Ultra Mash. Pectinex® Ultra Mash is a blended pectin lyase enzyme preparation produced by submerged fermentation of selected strains of Aspergillus aculeatus and Aspergillus niger.*
> *"Pectinex® Ultra Mash is a GRAS substance as defined by 21 CFR §170.30 (a) for the intended use as a processing aid in juice processing.*
> *"Pectinex® Ultra Mash is a food grade product and complies with the Food Chemicals Codex (FCC) and FAO/WHO JECFA recommended purity specifications for food grade enzymes*"

NutriLeads believes that the process it uses to manufacture cRG-I is essentially the same as that used in juice processing. The main difference is that juice processing starts with the whole fruit and the manufacture of cRG-I starts with pomace. The action of the enzyme preparation is exactly the same as with juice processing, a similar amount of enzyme is used, and the action is on the same

constituents. Thus, NutriLeads concludes that the use of the enzyme preparation used to make cRG-I falls within the intended use described by the supplier and is therefore GRAS.

Question 5. In Appendix 1, you note that the remains of pesticides are "in accordance with the present rules in Poland and EU regarding remains of plant protection agents." Please provide a statement that the starting material is food-grade and produced in accordance with good agricultural practices and that levels of residual pesticides reported in the notice are within with US regulations for pesticide residues in carrots (40 CFR Part 180).

The starting material is food grade and produced in accordance with good agricultural practices, as confirmed by Mainfrucht (current supplier), and is in Appendix 4. Mainfrucht is certified to ISO 22000 and 14001 standards. Mainfrucht has provided the following certifications (Appendix 4):

1. Food Safety System Certification 22000 FSSC 22000, version 5 for Production and Processing of Fruit Juices, Fruit Juice Concentrates, Fruit Purees, Fruit Preparations, Natural Fruit Juice Aromas, frozen Fruits and Vegetable Products
2. Certification scheme for HACCP Management Systems
3. ISO 14001:2015 and ISO 50001:2018

Compliance with U.S. pesticide residue regulations requires specific attention by European companies because the positive lists for the EU and U.S. differ and farmers there focus on the EU list. The supplier of the pomace, Mainfrucht, already sells carrot juice in U.S. and for that purpose it selects carrots that do not contain residues of pesticides that are not authorized for use on carrots in the U.S. NutriLeads will have Mainfrucht do the same for the pomace it will use to make cRG-I. Further, Mainfrucht has guaranteed that cRG-I made from its pomace will meet U.S. regulations for pesticide residues in carrots (Appendix 4; data are in the CoAs, the pesticides evaluated are in the explanation sheets following them). Finally, analyses of new batches cRG-I indicates no pesticide residues above the limit of detection (Appendix 1). Based on all this information, NutriLeads states that residual pesticides in the carrot pomace and cRG-I will be within with EPA's regulations for pesticide residues in carrots (as found in 40 CFR Part 180).

References

1. Zandstra BH and De Kryger TA. Arsenic and lead residues in carrots from foliar applications of monosodium methanearsonate (MSMA): A comparison between mineral and organic soils, or from soil residues. *Food Addit Contam*. 2007; 24:34-42. doi:10.1080/02652030600930568.

2. Codling EE, Chaney RL and Green CE. Accumulation of lead and arsenic by carrots grown on lead-arsenate contaminated orchard soils. *J Plant Nutr*. 2014; 38:509-525. doi:10.1080/01904167.2014.934477.

3. Rusin M, Domagalska J, Rogala D, Razzaghi M and Szymala I. Concentration of cadmium and lead in vegetables and fruits. *Sci Rep*. 2021; 11:11913. doi:10.1038/s41598-021-91554-z.

From: Richard Lane
To: Hall, Karen
Cc: Ruud Albers | Nutrileads; Marcela Aparicio | Nutrileads
Subject: [EXTERNAL] Re: Regarding GRN 000972
Date: Tuesday, September 14, 2021 1:12:09 PM
Attachments: Reply to FDA.pdf

Dear Ms. Hall,

NutriLeads' response to questions raised earlier this month and to comments made during the Zoom meeting yesterday are attached. We trust that this information addresses the concerns raised.

Regards,
Richard
Richard W Lane, PhD
Lane Toxicology Consulting, LLC
Tel: 201/452-5816
richardlanephd@gmail.com

On Fri, Sep 3, 2021 at 12:45 PM Hall, Karen <Karen.Hall@fda.hhs.gov> wrote:

> Good Afternoon,
>
> After reviewing NutriLeads' August 15, 2021 Amendment for GRAS Notice 000972, we noted some concerns listed below that need to be addressed. Responses may be sent in an email or in a separate document. Please do not send a revised copy of the notice. We respectively request a response within 10 business days. If you are unable to complete the response within that time frame or have questions, please contact me to discuss further options at 240-402-9195 or via email.
>
> Toxicology
>
> 1. In your response to Question 1, you provided levels of lead detected in four samples from your batch analyses using a new supplier of carrot pomace. We note that two of the four batches (NL272 and NL283) showed lead levels that would exceed FDA's interim safe exposure level for the general population. According to our estimation based on lead levels from NL272 & 283, exposure from your intended use would result in approximately 18.0 and 15.8 ug Pb/day, respectively, which would exceed

levels considered safe (12.5 ug/day; Flannery et al., 2020). Please provide an explanation as to how you would rectify this safety concern. If you are unable to address this safety concern, you may request that we cease to evaluate this notice.

Reference:

Flannery BM, Dolan LC, Hoffman-Pennesi D, Gavelek A, Jones OE, Kanwal R, Wolpert B, Gensheimer K, Dennis S, Fitzpatrick S. U.S. Food and Drug Administration's interim reference levels for dietary lead exposure in children and women of childbearing age. Regul Toxicol Pharmacol. 2020 Feb;110:104516. doi: 10.1016/j.yrtph.2019.104516. Epub 2019 Nov 7. PMID: 31707132.

Chemistry

2. Please provide a specification and analytical method for lead in the starting carrot pomace material. In order to determine whether lead is introduced in the manufacturing process, FDA requests that Nutrileads provide results from batches of the starting material and batches of the pectin hydrolysate produced with that starting material. If there is a change in the lead level from the starting material to the final pectin hydrolysate, please discuss the reasons for the change.
3. In the reply to FDA questions dated August 15, 2021, Nutrileads provided lead levels of 0.40, 0.96, 0.47, and 0.84 mg/kg from the analyses of four batches of pectin hydrolysate. As noted above, the results from two of these batches lead to concerns regarding dietary exposure to lead. In order to determine if these are typical levels of lead in the final product, FDA requests that the notifier provide lead analyses from additional batches, if available. This will be helpful to ascertain whether Nutrileads can lower the specification for lead in the pectin hydrolysate food ingredient to a level that would not raise a safety concern with the resulting dietary exposure to lead.

Kind Regards,

Karen

Karen Hall

Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety

Center for Food Safety and Applied Nutrition
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Karen.Hall@fda.hhs.gov

Lane Toxicology Consulting, LLC

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September 14, 2021

Karen Hall
Regulatory Review Scientist
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5001 Campus Drive
College Park, MD 20740

Dear Ms. Hall,

Re: GRAS Notice 000972

This letter responds to questions sent to me, acting on behalf of NutriLeads, BV, on September 3, 2021, regarding issues raised after the review of our August 15, 2021, amendment.

Toxicology

Thank you for providing the Flannery *et al.* (2020) reference about lead exposure. We were unaware of the article, as was the panel of outside experts we used.

For the amendment sent last month, NutriLeads was pleased to have data from recent batches of cRG-I. NutriLeads was also pleased to inform you that its new supplier is able to produce carrot pomace that allowed it to lower the lead specification to 1 mg/kg. As you know, this level is 20% of the amount permitted for pectins per *Food Chemicals Codex* (FCC) (NMT 5 mg/kg, FCC 9; most other polysaccharides in FCC 9 have maximum lead levels of 2-5 mg/kg). Based on this, NutriLeads considered the new level to be protective of public health. Given the recent assessment by Flannery *et al.*, the Food and Drug Administration (FDA) considers even 1 mg/kg could cause some people to exceed an interim safe exposure level at the use levels proposed.

NutriLeads has obtained more data about the lead content of newer batches of its product (see Table 3, below). Based on these data and those already submitted, NutriLeads will not be able to further reduce its specification for lead at this time (discussed in more detail below). Instead,

NutriLeads will reduce exposure to lead by reducing the levels of cRG-I in all the food categories it has proposed for use.

FDA calculated that lead exposure from batches of cRG-I with the highest levels would be approximately 18.0 μg Pb/day. This is above the maximum safe level for women of childbearing age described in Flannery *et al.* In order to reduce lead intake into the safe range, below 12.5 μg/day, a reduction of approximately 30% is required. To achieve this, NutriLeads will reduce the proposed maximum amount of cRG-I used in foods from 2.8 g/serving to 1.5 g/serving, a 47% reduction. This will provide intakes of lead within the interim safe exposure level for the vulnerable population, to approximately 9.6 μg/day.

A revised version of Table 14 presented in the original GRAS Notice is provided here (Table 1). This table includes both the changes noted in NutriLeads' amendment of August 15 (i.e., removal of the proposed uses in baby foods) and the maximum amount per serving mentioned here.

Table 1. Revised proposed food uses and use levels of cRG-I in the U.S. and corresponding fiber levels.

Food Category (21 CFR §170.3 – FDA, 2019a)	**Food Uses[a]**	**Revised Maximum Added Fiber Level**	**RACC[b]**	**Revised Maximum Added Fiber Level**	**Revised Maximum cRG-I Use Level**
		(g/serving)	**(g or mL)**	**(g/100 g)**	**(g/100 g)**
Beverages and Beverage Bases, Nonalcoholic	Energy Drinks	1.5	360	0.42	0.52
	Enhanced, Flavored, Carbonated, or Fortified Water Beverages	1.5	360	0.42	0.52
	Non-Milk-Based Meal Replacement, Protein, and Nutritional Beverages	1.5	240	0.63	0.78
	Soft Drinks (including Regular and Diet)	1.5	360	0.42	0.52
	Sport or Electrolyte Drinks, Fluid Replacement Drinks	1.5	360	0.42	0.52
Breakfast Cereals	Hot Breakfast Cereals (e.g., Oatmeal, Grits), including Instant and Regular	1.5	240 (or 1 cup prepared)[c]	0.63 (prepared)	0.78 (prepared)
	Ready-to-Eat Breakfast Cereals				
	Puffed Cereals	1.5	15	10.00	12.52
	High-Fiber Cereals	1.5	40	3.75	4.70
	Biscuit-Type Cereals	1.5	60	2.50	3.13
Dairy Product Analogs	Non-Dairy Milk	1.5	240	0.63	0.78
	Non-Dairy Cream	1.5	15	10.00	12.52
	Non-Dairy Yogurts	1.5	170	0.88	1.10
	Non-dairy Ice Creams	1.5	160 (or ⅔ cup)[c]	0.94	1.18
	Cereal and Granola Bars	1.5	40	3.75	4.70

Grain Products and Pastas	Energy Bars, Protein Bars, and Meal Replacement Bars	1.5	40	3.75	4.70
Milk Products	Dry Milks	1.5	240 (prepared)	0.62 (prepared)	0.78 (prepared)
	Evaporated or Condensed Milk	1.5	30	5.00	6.26
	Fermented Milks, Plain or Flavored	1.5	240	0.63	0.78
	Flavored Milk, Milk Drinks, and Mixes, Milk Shakes	1.5	240	0.63	0.78
	Milk-Based Meal Replacement and Nutritional Beverages	1.5	240	0.63	0.78
	Plain or Flavored Yogurt	1.5	170	0.88	1.10
	Yogurt Drinks	1.5	93 to 207[d]	1.6	2.00
Processed Fruits and Fruit Juices	Fruit Drinks and Ades including Smoothies	1.5	240	0.63	0.78
	Fruit Juices and Nectars	1.5	240	0.63	0.78
Processed Vegetables and Vegetable Juices	Vegetable Juices, Nectars and Blends	1.5	240	0.63	0.78
Snack Foods	Snack Foods (Potato Chips, Popcorn, Pretzels and Corn-based Savory Snacks)	1.5	30	5.00	6.26
Soups and Soup Mixes	Soups (Prepared and Canned)[e]	1.5	245 (prepared)	0.61	0.76

CFR = Code of Federal Regulations; RACC = Reference Amounts Customarily Consumed per Eating Occasion; U.S. = United States.

[a] cRG-I is intended for use in unstandardized products and not in foods where standards of identity exist and do not permit its addition.

[b] RACC based on values established in 21 CFR §101.12 (U.S. FDA, 2019b). RACCs are included for reference, however the assessment was conducted based on use levels expressed per liter. When a range of values is reported for a proposed food use, particular foods within that food use may differ with respect to their RACC.

[c] Calculated based on food item density using unit converter (https://www.aqua-calc.com/calculate/food-volume-to-weight).

[d] RACC has not been established for yogurt drinks; however, an approximate serving size was established based on products currently on the U.S. market.

[e] Food codes with meat products were included in the intake estimate; however, cRG-I is not intended for use in meat products. Inclusion of meat products in these food-use categories is not expected to appreciably affect the intake calculations.

Since this reduction is for all proposed food uses, it results in estimated intakes that are 47% below those given in the Notice. The revised EDI of cRG-I among users in the total U.S. population from all proposed uses, assuming the maximum proposed use level for each food category, is now approximately 5.9 g/day at the mean and 11.2 g/day at the 90th percentile of intake (equivalent to 99 and 198 mg/kg/day, respectively).

NutriLeads recognizes that revised maximum level of cRG-I will not allow food manufacturers to make a fiber claim without other fiber already being present in or added to the food. However, the presence of other fiber was most likely what would have been the case and the use of cRG-I would therefore simply augment the total amount in order to permit a claim.

Chemistry

The supplier of carrot pomace does not have a specification for lead at this time. NutriLeads is in discussions with them; since the issue just arose nothing has been finalized yet. However, the supplier has provided three recent certificates of analysis, which are performed on a yearly basis. These are attached. Levels of lead are:

Table 2. Lead levels in carrot pomace.

Year	Measured result	Unit	Converted to	Unit
2020	0.068	mg/kg (88% solids)	0.077	mg/kg (dry solids)
2019	0.130	mg/kg (88% solids)	0.148	mg/kg (dry solids)
2018	0.110	mg/kg (88% solids)	0.125	mg/kg (dry solids)
		Average	*0.117*	mg/kg (dry solids)

The method of measuring lead is cited in the attached certificates as "DIN EN ISO 17294-2: 2017-01."

FDA requested that Nutrileads provide results from batches of the starting material and batches of the pectin hydrolysate produced with that starting material. NutriLeads does not have data for lead levels from the pomace used to produce the recent batches of cRG-I. Therefore, there is no direct comparison of starting levels in pomace and the final level in cRG-I in those batches.

All equipment used is food grade and the manufacturer follows current good manufacturing practices. It is therefore considered unlikely that lead is coming from the manufacturing process. That means, to the best of NutriLeads ability to determine, there are only three possible sources of lead: the pomace, the enzyme preparation, and water.

> Pomace: The average amount of lead in the pomace is 0.117 mg/kg (see Table 2). Production yield of cRG-I from pomace is about 5% (solids/solids), requiring 20 kg of pomace solids to produce 1 kg of cRG-I. A hypothetical starting batch of 20 kg of pomace solids thus contains, on average, (20 kg * 0.12 mg Pb/kg =) 2.4 mg Pb (using two significant figures).
>
> Enzyme preparation: The pectinolytic enzyme preparation used to make cRG-I, Pectinex® Ultra Mash, is GRAS and commonly used in juice production. The specifications are provided in the GRAS Notice and also supplied here. According to the specifications, the preparation may contain up to 5 mg Pb/kg, which conforms with limits in FCC 9. NutriLeads does not have certificate of analysis for this material (one has been requested), so it does not know how much might be in the batches it has used. The enzyme preparation is dosed at 2.3% of pomace solids (i.e., 23 g/kg) and thus could conceivably contribute up to (23 g/kg * 20 kg * 5 mg Pb/kg =) 2.3 mg Pb/kg of cRG-I produced.

> Water: For each kg of cRG-I, approximately 430 L of water is used to dilute the pomace and remove small molecules during ultra- and diafiltration. The water is demineralized from city water, which has a legal limit of 0.002 mg/kg. NutriLeads does not have a certificate of analysis of the demineralized water (one has been requested), but levels are likely to be below the legal limit. Nonetheless, water could conceivably contribute up to (430 kg * 0.002 mg/kg =) 0.86 mg Pb/kg of cRG-I.

Combining these three sources of lead yields a maximum of 5.6 mg Pb from the starting materials. If it all went to the cRG-I, the measured level of lead would be 5.6 mg/kg cRG-I. Instead, on average, only 0.59 mg Pb is in 1 kg of cRG-I produced (see the MF average in Table 3). Thus, 90% of the theoretical amount in the starting materials has been removed.

If the enzyme preparation contains 1 mg Pb/kg, the total amount of lead from pomace, enzyme preparation and water would be 3.7 mg, meaning that 84% of what was in the starting materials was removed.

And if the enzyme preparation contains no lead at all, the total lead from pomace and water would be 3.3 mg, which means that cRG-I contains only 18% of what was in the starting materials.

Finally, if both the enzyme preparation and water contain no lead at all, then 75% of the 2.4 mg of lead in the pomace is removed during manufacture.

As can be seen, lead is being removed during production, even considering the possible introduction from the enzyme preparation and water. It just *seems* that it is being added because the reduction in the solids is greater (95%, 20 kg to 1 kg). The reason for the difference between solids removal and lead removal is unknown.

In order to determine whether the levels of lead provided previously are typical, you requested any new data from additional batches that might be available. NutriLeads is pleased to have done more testing of lead from additional batches. A table with lead analyses from all batches made from both the previous ("GF") and current ("MF") suppliers is provided:

Table 3. Lead levels in cRG-I

Supplier	Batch	NutriLeads' Code	Pb (mg/kg)
GF	--	NL91	0.34
GF	--	NL100	0.38
GF	--	NL176	1.5
GF	--	NL189	0.76
GF	--	NL204	0.91
		Average	*0.78*
MF	002	NL256C	0.40
MF	003	NL272	0.96
MF	004	NL284	0.47
MF	005	NL283	0.84
MF	006	NL285	0.42
MF	007	NL286	0.42
MF	008	NL287	0.62
		Average	*0.59*

As can be seen, the lead levels in the newer batches of cRG-I produced at MF will meet the new, lower specification of 1 mg/kg. As can also be seen, the lead levels in the newer batches made by the new manufacturer are 25% lower than those produced by the previous one. NutriLeads continues to examine its production methods and ingredients to determine whether the specification can be reduced further. However, a sufficiently large change seems impractical at this time and Nutrileads concludes it cannot lower the specification for lead in cRG-I. Therefore, as discussed above, NutriLeads has reduced the maximum amount to be used in each proposed food category. This will result in dietary exposures to lead that are within the interim safe exposure level for women of childbearing age, as derived by Flannery *et al.*

NutriLeads recognizes that reducing lead exposure is a public health priority for the Food and Drug Administration and agencies around the world. NutriLeads likewise shares the concern and has taken numerous steps to reduce lead in its product. However, NutriLeads also recognizes that lead is ubiquitous, present in the environment from natural and anthropogenic sources. It enters the food supply through uptake by plants from soil and water, by animals in their foraging, feed and water consumption, and through manufacturing processes. The presence of lead throughout the environment explains why it is detectable in many foods and why it is not possible to prevent it from entering the food supply. As a consequence, minimizing dietary exposure to lead takes on greater importance.

NutriLeads recognizes that it is not possible to remove all lead from its product due to leads' presence in the overall environment. However, lead exposure can be minimized through monitoring

lead concentrations in its product and adjusting its manufacturing processes. NutriLeads has tried to address both of these issues by changing to a new supplier of carrot pomace that has data on lead and by revising its manufacturing processes.

Because no safe level of lead exposure has yet been identified for the health of vulnerable populations, NutriLeads agrees with FDA that reducing intake to conform to prudent guidance on safe exposure levels is in society's best interest. Thus, NutriLeads has reduced the specification for lead from 1.5 to 1 mg/kg and reduced the maximum use level of cRG-I from 2.8 to 1.5 mg/serving. Together, these reduce the intake of lead to one that will prevent exposure to levels above those considered to be safe in Flannery *et al.*

In summary, NutriLeads shares the concerns raised by FDA and believes the steps it has taken, as described herein and as part of the answers provided last month, address the lead issue. The work has resulted in a lower lead specification that meets or exceeds those for other polysaccharides in *Food Chemicals Codex* and a lower maximum use level of cRG-I in the intended food categories. NutriLeads believes lead intake from its product will be within levels considered to be safe, even for vulnerable populations.

As always, please contact me if there is anything more you need.

Sincerely,

Richard W Lane, PhD
Lane Toxicology Consulting, LLC
richardlanephd@gmail.com

Valid from 2015-09-21

Pectinex® Ultra Mash

In this product the key enzyme activity is provided by

pectin lyase catalyzing eliminative cleavage of (1,4)-alpha-D-galacturonan methyl ester giving oligosaccharides with 4-deoxy-6-O-methyl-alpha-D-galact-4-enuronosyl groups at their non-reducing ends

PRODUCT CHARACTERISTICS/PROPERTIES

Component name	Pectin lyase
Activity	9500 PECTU/g
Other activities	Polygalacturonase
Color	Brown
Physical form	Liquid
Approximate density (g/ml)	1.15
Odor	Slight fermentation odor
Solubility	Active component is readily soluble in water at all concentrations that occur in normal usage. Standardisation components can cause turbidity in solution.

Color can vary from batch to batch. Color intensity is not an indication of enzyme activity.

PRODUCT SPECIFICATION

	Lower Limit	Upper Limit	Unit
Pectinase unit PECTU	9500		/g
Total viable count	-	50000	/g
Coliform bacteria	-	30	/g
E.coli	Not Detected		/25 g
Salmonella	Not Detected		/25 g
Heavy metals		Max 30	mg/kg
Lead		Max 5	mg/kg
Arsenic		Max 3	mg/kg
Cadmium		Max 0.5	mg/kg
Mercury		Max 0.5	mg/kg

The enzyme analytical method is available from the Customer Center or sales representative.

COMPOSITION

Ingredients	Appr. % (w/w)
Glycerol, CAS no. 56-81-5	49,50
Water, CAS no. 7732-18-5	44
Pectin lyase, CAS no. 9033-35-6*	3
Polygalacturonase, CAS no. 9032-75-1*	3
Potassium chloride, CAS no. 7447-40-7	0,50

*Defined as enzyme conc. (dry matter basis)

No preservatives added

ALLERGEN

Allergen	Substance contained[1]	Allergen	Substance contained[1]
Celery	no	Molluscs	no
Cereals containing gluten[2/4]	no	Mustard	no
Crustaceans	no	Nuts[3]	no
Egg	no	Peanuts	no
Fish	no	Sesame	no
Lupin	no	Soy	no
Milk (including lactose)	no	Sulphur dioxide/sulphites, more than 10 mg per kg or l	no

[1]Definition of substances according to EU Regulation 1169/2011, as amended. List covers allergens mentioned in 21 USC 301 (US) and GB 7718-2011 (China).

[2]i.e.wheat, rye, barley, oats, spelt, kamut

[3]i.e. almond, hazelnut, walnut, cashew, pecan nut, Brazil nut, pistacchio nut, macadamia nut and Queensland nut

[4] If No: Glutenfree i,e. < 20ppm (EU Regulation 41/2009)

NUTRITIONAL VALUES

The product has a typical nutritional value of approximately 602 kJ/100 g enzyme product.

• Protein	6 g/100 g
• Polyols	49 g/100 g
• Ash	1 g/100 g
• Moisture	44 g/100 g

GM STATUS

This product is not a GMO.

Production organism	Aspergillus aculeatus Aspergillus niger

The enzyme product is manufactured by fermentation of microorganisms that are not present in the final product. The production organisms are not modified using modern biotechnology.

Pectinex® Ultra Mash

STORAGE CONDITION

Recommended storage: 0-10 °C (32-50 °F)

Packaging must be kept intact, dry, and away from sunlight. Please follow the recommendations and use the product before the best before date to avoid the need for a higher dosage.

Best before: You will find the best before date in the certificate of analysis or on the product label.

The product gives optimal performance when stored as recommended and used prior to the best-before date.

The product can be transported at ambient temperature. Following delivery, the product should be stored as recommended.

SAFETY AND HANDLING PRECAUTIONS

Enzymes are proteins. Inhalation of dust or aerosols may induce sensitization and may cause allergic reactions in sensitized individuals. Some enzymes may irritate the skin, eyes, and mucous membranes upon prolonged contact. See the MSDS or Safety Manual for further information regarding safe handling of the product and spills.

COMPLIANCE

The product complies with the recommended purity specifications for food-grade enzymes given by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Food Chemical Codex (FCC), and with relevant Chinese food safety and product standards for food-grade enzymes.

Kosher and Halal certificates are available from the Customer Center or sales representative.

If used as processing aid in the production of food the final product may be classified as "organic" by relevant authorised associations.

CERTIFICATIONS

Novozymes is a signatory to United Nations Global Compact, United Nations Convention on Biological Diversity and report on our sustainability performance through Global Reporting Initiative (GRI). See all our commitments under sustainability on www.novozymes.com.

FOOD SAFETY

Novozymes has carried out a hazard analysis and prepared an HACCP plan describing the critical control points (CCPs). The HACCP plan is supported by a comprehensive prerequisite program implemented in Novozymes' GMP practices.
The product is produced according to Novozymes' HACCP plan, GMP practices, and additional requirements controlled by Novozymes' Quality Management System.

The product complies with FAO/WHO JECFA- and FCC-recommended purity requirements regarding mycotoxins.

The product is available in different types of packaging. Please contact the sales representative for more information.

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Fax +45 4446 9999

For more information, or for more office addresses, visit www.novozymes.com

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stellv. Arbeitsgruppenleiter
Arbeitsgruppe Futtermittel

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Prüfbericht zum Auftrag Nr. F 18801 - 18

Dokumenten-Nr. F2018-018801-1

Auftraggeber:	Mainfrucht GmbH & Co. KG Julius-Hofmann-Straße 2, 97469 Gochsheim
Pr benumfang:	1 Probe
Pr benart:	Futtermittelausgangserzeugnisse (1x)
Pr benahme:	Auftraggeber, 10.09.2018
Pr beneingang:	12.09.2018
Prüfzeitraum:	12.09.2018 bis 28.09.2018

Bemerkung: Prüfergebnisse beziehen sich ausschließlich auf untersuchte Proben. Die zitierten Normen beziehen sich jeweils auf die aktuell gültige Version, sofern nicht anders erwähnt. Die auszugsweise Vervielfältigung des Prüfberichts bedarf der schriftlichen Genehmigung durch die SYNLA Analytics & Services Germany GmbH. Dieser Prüfbericht wurde durch unten stehende Person validiert und freigegeben.

Abkürzungen, Symbole: --: nicht bestimmt / nicht anwendbar, (F): Fremdvergabe in akkreditierte Laboratorien, (S): Durchführung an anderem SYNLA Standort; (N): nicht-akkreditiertes Prüfverfahren, G: estimmungsgrenze, FG: Frischgewicht, n.best.: nicht bestimmt, n.a.: nicht anwendbar, n.n.: nicht nachgewiesen, n.v.: nicht verfügbar, OF: Oberfläche, OS: Originalsubstanz, TM: Trockenmasse, TS: Trockensubstanz; ↑↓: Grenzwert-/Warnwert über-/unterschritten, ↗↘: Richtwert über-/unterschritten

Jena, den 28.09.2018

Frank Tischendorf
stellv. Arbeitsgruppenleiter
Arbeitsgruppe Futtermittel

QS. Ihr Prüfsystem für Lebensmittel.

DAkkS Deutsche Akkreditierungsstelle D-PL-14004-10-00

Lab r-Nr.:	L1	
Pr benart:	Futtermittelausgangserzeugnisse	
Kennzeichnung:	Probenbezeichnung:	Karottentrester, 4.02.02
	QS-Proben-ID:	KE00000766-0000000003
	Artikel-Nr.:	610480300313
	Ursprung:	Deutschland
	etriebsinterne ezeichnung:	Karottentrester orange frisch KW 37 2018
Pr benahme:	Auftraggeber, 10.09.2018	
Pr bentransp rt:	Kurier	
Pr beneingang:	12.09.2018	
Pr benzustand:	einwandfrei	
Prüfzeitraum:	12.09.2018 - 28.09.2018	

Mikr bi l gische Untersuchungen

Parameter	Meth de	Ergebnis	Einheit	Warnwert
Salmonellen	ASU L 00.00-20/20a, DIN EN ISO 6579	n.n.	in 25 g	n.n.

Chemisch-physikalische Untersuchung

Parameter	Meth de	Ergebnis	Einheit
Trockensubstanz	VDLUFA Methodenbuch d. III; 3.1	15,6	% OS

Ergebnisse der Elementmessungen

Parameter	Meth de	Ergebnis	Einheit	Höchstgehalt
Probenvorbereitung HNO3-Druckaufschluss	ASU § 64 LFG L00.00-19/1 und DIN EN 13805:2014-12	--		--
Arsen	DIN EN ISO 17294-2 (2005)	<0,01	mg/kg 88% TS	2 (RL 2002/32/EG)
lei	DIN EN ISO 17294-2 (2005)	0,11	mg/kg 88% TS	10 (RL 2002/32/EG)
Cadmium	DIN EN ISO 17294-2 (2005)	0,20	mg/kg 88% TS	1 (RL 2002/32/EG)
Quecksilber	DIN EN 15763	0,0057	mg/kg 88% TS	0,1 (RL 2002/32/EG)

Untersuchung auf Myc t xine

Parameter	Meth de	Ergebnis	Einheit	Höchstgehalt
Aflatoxin 1	DIN EN ISO 17375	<0,1	µg/kg 88% TS	20 (RL 2002/32/EG)

Untersuchung auf nicht-di xinähnliche P lychl rierte Biphenyle (ndl-PCB)

Parameter	Meth de	Ergebnis	Einheit	Höchstgehalt
PC 28	VDLUFA Methode, d. VII, Methode 3.3.2.2 (2003)	<0,1	µg/kg 88% TS	--
PC 52	VDLUFA Methode, d. VII, Methode 3.3.2.2 (2003)	<0,1	µg/kg 88% TS	--
PC 101	VDLUFA Methode, d. VII, Methode 3.3.2.2 (2003)	<0,1	µg/kg 88% TS	--
PC 153	VDLUFA Methode, d. VII, Methode 3.3.2.2 (2003)	<0,1	µg/kg 88% TS	--
PC 138	VDLUFA Methode, d. VII, Methode 3.3.2.2 (2003)	<0,1	µg/kg 88% TS	--
PC 180	VDLUFA Methode, d. VII, Methode 3.3.2.2 (2003)	<0,1	µg/kg 88% TS	--
Summe Indikat r PCB	VDLUFA Methode, d. VII, Methode 3.3.2.2 (2003)	0,60	µg/kg 88% TS	10 (RL 2002/32/EG)

Bewertungsgrundlagen:

RL 2002/32/EG Richtlinie 2002/32/EG über unerwünschte Stoffe in der Tierernährung in der aktuellen Fassung

Untersuchung auf Pflanzenschutzmittel: Multimeth de

Die Untersuchung auf Pflanzenschutzmittel umfasste die in angehängter Wirkstoffliste zum Pflanzenschutzmittel-Screening aufgeführten Substanzen mit den dort angegebenen estimmungsgrenzen (G).

Parameter	Meth de	Ergebnis	Einheit	Höchstgehalt
Pflanzenschutzmittel	QuEChERS DIN EN 15662, estimmung mit GC-MS/MS und LC-MS/MS	nachgewiesen		--
oscalid	QuEChERS DIN EN 15662, estimmung mit GC-MS/MS und LC-MS/MS	0,048	mg/kg	2 (VO (EG) 396/2005)
Difenoconazol	QuEChERS DIN EN 15662, estimmung mit GC-MS/MS und LC-MS/MS	0,036	mg/kg	0,4 (VO (EG) 396/2005)
Isopyrazam	QuEChERS DIN EN 15662, estimmung mit GC-MS/MS und LC-MS/MS	0,013	mg/kg	0,2 (VO (EG) 396/2005)

Bewertungsgrundlagen:

VO (EG) 396/2005 Verordnung (EG) 396/2005 über Höchstgehalte an Pestizidrückständen in oder auf Lebens- und Futtermitteln pflanzlichen und tierischen Ursprungs

Untersuchung auf P lycyclische ar matische K hlenwasserst ffe

Parameter	Meth de	Ergebnis	Einheit	Richtwert
Naphthalen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<1	µg/kg 88% TS	--
Acenaphthylen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<1	µg/kg 88% TS	--
Acenaphthen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<1	µg/kg 88% TS	--
Fluoren	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<1	µg/kg 88% TS	--
Phenanthren	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	23	µg/kg 88% TS	--
Anthracen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<1	µg/kg 88% TS	--
Fluoranthen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	1,3	µg/kg 88% TS	--
Pyren	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<1	µg/kg 88% TS	--
enzo(a)anthracen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<0,5	µg/kg 88% TS	--
Chrysen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	5,9	µg/kg 88% TS	--
enzo(b)fluoranthen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<0,5	µg/kg 88% TS	--
enzo(k)fluoranthen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<0,5	µg/kg 88% TS	--
enzo(a)pyren	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<0,5	µg/kg 88% TS	25 (QS-FUMI)
Dibenzo(ah)anthracen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<0,5	µg/kg 88% TS	--
enzo(ghi)perylen	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<0,5	µg/kg 88% TS	--
Indeno(1,2,3cd)pyren	analog ASU §64 LFG L 07.00-40, HPLC-UV/FLD	<0,5	µg/kg 88% TS	--

Untersuchung auf PCDD / PCDF ("Di xine") und di xinähnliche P lychl rierte Biphenyle (dl-PCB)

Parameter	Ergebnis	Meßunsicherheit	Einheit	Akti nswert	Höchstgehalt
PCDD/PCDF	0,0855	±0,021	ng WHO-TEQ/kg TS	--	--
PCDD/PCDF	0,0752	±0,019	ng WHO-TEQ/kg 88% TS	0,5 (RL 2002/32/EG)	0,75 (RL 2002/32/EG)
dioxinähnliche PC	0,0136	±0,0034	ng WHO-TEQ/kg TS	--	--
dioxinähnliche PC	0,0119	±0,0030	ng WHO-TEQ/kg 88% TS	0,35 (RL 2002/32/EG)	--
Summe PCDD/PCDF, dioxinähnliche PC	0,0990	±0,025	ng WHO-TEQ/kg TS	--	--
Summe PCDD/PCDF, dioxinähnliche PC	0,0871	±0,022	ng WHO-TEQ/kg 88% TS	--	1,25 (RL 2002/32/EG)

Bewertungsgrundlagen:

QS-FUMI QS-Leitfaden Futtermittelmonitoring in der aktuellen Fassung

RL 2002/32/EG Richtlinie 2002/32/EG über unerwünschte Stoffe in der Tierernährung in der aktuellen Fassung

Einzelergebnisse der Untersuchung auf PCDD / PCDF

Parameter	Meth de	Ergebnis	T xizitätsäqui-valent	Ergebnis
		ng/kg TS	WHO 2005	ng WHO-TEQ/kg TS
2,3,7,8 Tetra-CDD	DIN EN 16215 (Juli 2012)	<0,02	1	<0,02
1,2,3,7,8-Penta-CDD	DIN EN 16215 (Juli 2012)	<0,03	1	<0,03
1,2,3,4,7,8-Hexa-CDD	DIN EN 16215 (Juli 2012)	<0,03	0,1	<0,003
1,2,3,6,7,8-Hexa-CDD	DIN EN 16215 (Juli 2012)	<0,03	0,1	<0,003
1,2,3,7,8,9-Hexa-CDD	DIN EN 16215 (Juli 2012)	<0,03	0,1	<0,003
1,2,3,4,6,7,8-Hepta-CDD	DIN EN 16215 (Juli 2012)	<0,05	0,01	<0,0005
Octa-CDD	DIN EN 16215 (Juli 2012)	<0,10	0,0003	<0,00003
2,3,7,8-Tetra-CDF	DIN EN 16215 (Juli 2012)	<0,03	0,1	<0,003
1,2,3,7,8-Penta-CDF	DIN EN 16215 (Juli 2012)	<0,03	0,03	<0,0009
2,3,4,7,8-Penta-CDF	DIN EN 16215 (Juli 2012)	<0,03	0,3	<0,009
1,2,3,4,7,8-Hexa-CDF	DIN EN 16215 (Juli 2012)	<0,03	0,1	<0,003
1,2,3,6,7,8-Hexa-CDF	DIN EN 16215 (Juli 2012)	<0,03	0,1	<0,003
1,2,3,7,8,9-Hexa-CDF	DIN EN 16215 (Juli 2012)	<0,03	0,1	<0,003
2,3,4,6,7,8-Hexa-CDF	DIN EN 16215 (Juli 2012)	<0,03	0,1	<0,003
1,2,3,4,6,7,8-Hepta-CDF	DIN EN 16215 (Juli 2012)	<0,05	0,01	<0,0005
1,2,3,4,7,8,9-Hepta-CDF	DIN EN 16215 (Juli 2012)	<0,05	0,01	<0,0005
Octa-CDF	DIN EN 16215 (Juli 2012)	<0,10	0,0003	<0,00003
Summe PCDD/PCDF inkl. estimmungsgrenze zu 100% (Obergrenze)	DIN EN 16215 (Juli 2012)			0,0855
Summe PCDD/PCDF inkl. estimmungsgrenze zu 50% (Mittelwert)	DIN EN 16215 (Juli 2012)			0,0427
Summe PCDD/PCDF exkl. estimmungsgrenze (Unter-grenze)	DIN EN 16215 (Juli 2012)			0

Einzelergebnisse der Untersuchung auf di xinähnliche P lychl rierte Biphenyle (dl-PCB)

Parameter	Meth de	Ergebnis	T xizitätsäqui-valent	Ergebnis
		ng/kg TS	WHO 2005	ng WHO-TEQ/kg TS
PC 77	DIN EN 16215 (Juli 2012)	0,39	0,0001	0,000039
PC 81	DIN EN 16215 (Juli 2012)	<0,1	0,0003	<0,00003
PC 126	DIN EN 16215 (Juli 2012)	<0,1	0,1	<0,01
PC 169	DIN EN 16215 (Juli 2012)	<0,1	0,03	<0,003
PC 105	DIN EN 16215 (Juli 2012)	1,3	0,00003	0,000038
PC 114	DIN EN 16215 (Juli 2012)	<0,5	0,00003	<0,000015
PC 118	DIN EN 16215 (Juli 2012)	9,5	0,00003	0,00029
PC 123	DIN EN 16215 (Juli 2012)	<0,5	0,00003	<0,000015
PC 156	DIN EN 16215 (Juli 2012)	2,9	0,00003	0,000088
PC 157	DIN EN 16215 (Juli 2012)	<0,5	0,00003	<0,000015
PC 167	DIN EN 16215 (Juli 2012)	1,0	0,00003	0,000031
PC 189	DIN EN 16215 (Juli 2012)	<0,5	0,00003	<0,000015
Summe dioxinähnliche PC inkl. estimmungsgrenze zu 100% (Obergrenze)	DIN EN 16215 (Juli 2012)			0,0136
Summe dioxinähnliche PC inkl. estimmungsgrenze zu 50% (Mittelwert)	DIN EN 16215 (Juli 2012)			0,00703
Summe dioxinähnliche PC exkl. estimmungsgrenze (Untergrenze)	DIN EN 16215 (Juli 2012)			0,000481

Bewertung: Die untersuchte Probe ist hinsichtlich der geprüften mikrobiologischen Parameter nicht zu beanstanden.

Die durch die Richtlinie 2002/32/EG v rgegebenen Höchstmengen für unerwünschte Stoffe in Futtermitteln werden eingehalten.
Der Richtwert an enzo(a)pyren der polyzyklischen aromatischen Kohlenwasserstoffe (PAK) nach GMP+ Feed Certification scheme für fettarme Futtermittel (<10%) wird eingehalten.

Es sind keine Verarbeitungsfaktoren veröffentlicht, um aus den Pflanzenschutzmittel-Gehalten in Karottentrester auf den Gehalt im Rohstoff Karotte zurückrechnen zu können. Unter der Annahme eines Verarbeitungsfaktors von 1 (kein Abbau und keine Aufkonzentrierung während der Verarbeitung) werden die gesetzlichen Höchstmengen gemäß Verordnung (EG) 396/2005 eingehalten.

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Julius-Hofmann-Straße 2
97469 Gochsheim

Ihr Ansprechpartner:
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Prüfbericht zum Auftrag Nr. F 19172 - 19

Dokumenten-Nr. F2019-019172-0

Auftraggeber:	Mainfrucht GmbH & Co. KG Julius-Hofmann-Straße 2, 97469 Gochsheim
Probenumfang:	1 Probe
Probenart:	Futtermittelausgangserzeugnisse (1x)
Probenahme:	Auftraggeber, 10.09.2019
Probeneingang:	12.09.2019
Prüfzeitraum:	12.09.2019 bis 04.10.2019

Bemerkung: Prüfergebnisse beziehen sich ausschließlich auf untersuchte Proben. Die auszugsweise Vervielfältigung des Prüfberichts bedarf der schriftlichen Genehmigung durch die SYNLAB Analytics & Services Germany GmbH. Dieser Prüfbericht wurde durch unten stehende Person validiert und freigegeben. Durchführung am SYNLAB Standort Jena, sofern nicht anders vermerkt.
Die Entnahme der mit "Probenahme: Auftraggeber" gekennzeichneten Proben erfolgte im Verantwortungsbereich des Kunden. Die Angaben zur Probenahme und alle damit verbundenen Werte (Angaben zur Probe, Vor-Ort-Werte, Volumenangaben etc.) erfolgten durch den Kunden und wurden wie übermittelt übernommen. Die Ergebnisse gelten für die Probe wie erhalten.

Abkürzungen, Symbole: --: nicht bestimmt / nicht anwendbar, (F): Fremdvergabe in akkreditierte Laboratorien, (SY): Durchführung an anderem SYNLAB Standort; (N): nicht-akkreditiertes Prüfverfahren, BG: Bestimmungsgrenze, FG: Frischgewicht, n.best.: nicht bestimmt, n.a.: nicht anwendbar, n.n.: nicht nachgewiesen, n.v.: nicht verfügbar, OF: Oberfläche, OS: Originalsubstanz, TM: Trockenmasse, TS: Trockensubstanz; ↑↓: Grenzwert-/Warnwert über-/unterschritten, ↗↘: Richtwert über-/unterschritten, ‡: durch Kunden bereitgestellte Angaben

Jena, den 04.10.2019

Frank Tischendorf
stellv. Arbeitsgruppenleiter
Arbeitsgruppe Futtermittel

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Labor-Nr.: L1
Produkt: Futtermittelausgangserzeugnisse
Probenbezeichnung: Karottentrester, 4.02.02‡
Probenahme: Auftraggeber, 10.09.2019‡
Probentransport: Kurier
Probenzustand: einwandfrei
Eingangsdatum: 12.09.2019
QS-Proben-ID: **KE00000766-0000000004**
Ursprungsland: Deutschland‡
Betriebsinterne Bezeichnung: Karottentrester orange frisch KW 37 2019‡
Prüfzeitraum: 12.09.2019 - 04.10.2019

Mikrobiologische Untersuchungen

Parameter	Methode	Ergebnis	Einheit	Warnwert
Salmonellen	ASU L 00.00-20:2018-03, DIN EN ISO 6579-1:2017-07	n.n.	in 25 g	n.n.

Chemisch-physikalische Untersuchung

Parameter	Methode	Ergebnis	Einheit
Trockensubstanz	VO (EG) 152/2009, III, A	13,3	% OS

Ergebnisse der Elementmessungen

Parameter	Methode	Ergebnis	Einheit	Höchstgehalt
Probenvorbereitung HNO3-Druckaufschluss	ASU § 64 LFGB L00.00-19/1 und DIN EN 13805:2014-12	--		--
Arsen	DIN EN ISO 17294-2: 2017-01	0,014	mg/kg 88% TS	2 (RL 2002/32/EG)
Blei	DIN EN ISO 17294-2: 2017-01	0,13	mg/kg 88% TS	10 (RL 2002/32/EG)
Cadmium	DIN EN ISO 17294-2: 2017-01	0,064	mg/kg 88% TS	1 (RL 2002/32/EG)
Quecksilber	DIN EN 15763:2010-04	0,0041	mg/kg 88% TS	0,1 (RL 2002/32/EG)

Untersuchung auf Mycotoxine

Parameter	Methode	Ergebnis	Einheit	Höchstgehalt
Aflatoxin B1	DIN EN ISO 17375:2006-09	<0,1	µg/kg 88% TS	20 (RL 2002/32/EG)

Bewertungsgrundlagen:
RL 2002/32/EG Richtlinie 2002/32/EG über unerwünschte Stoffe in der Tierernährung in der aktuellen Fassung

Untersuchung auf Pflanzenschutzmittel: Multimethode

Die Untersuchung auf Pflanzenschutzmittel umfasste die in angehängter Wirkstoffliste zum Pflanzenschutzmittel-Screening aufgeführten Substanzen mit den dort angegebenen Bestimmungsgrenzen (BG).

Parameter	Methode	Ergebnis	Einheit
Pflanzenschutzmittel	QuEChERS DIN EN 15662:2018-07, Bestimmung mit GC-MS/MS und LC-MS/MS	n.n.	

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Untersuchung auf Pflanzenschutzmittel: Einzelmethoden

Parameter	Methode	Ergebnis	Einheit
Dithiocarbamate (als Summe CS2)	DIN EN 12396-2, BG: 0,02 mg/kg	n.n.	mg/kg

Untersuchung auf nicht-dioxinähnliche Polychlorierte Biphenyle (ndl-PCB)

Parameter	Methode	Ergebnis	Einheit	Höchstgehalt
PCB 28	DIN EN 16215 (Juli 2012), GC-HRMS	<0,1	µg/kg 88% TS	--
PCB 52	DIN EN 16215 (Juli 2012), GC-HRMS	<0,1	µg/kg 88% TS	--
PCB 101	DIN EN 16215 (Juli 2012), GC-HRMS	0,10	µg/kg 88% TS	--
PCB 153	DIN EN 16215 (Juli 2012), GC-HRMS	0,10	µg/kg 88% TS	--
PCB 138	DIN EN 16215 (Juli 2012), GC-HRMS	<0,1	µg/kg 88% TS	--
PCB 180	DIN EN 16215 (Juli 2012), GC-HRMS	<0,1	µg/kg 88% TS	--
Summe Indikator PCB	DIN EN 16215 (Juli 2012), GC-HRMS	0,60	µg/kg 88% TS	10 (RL 2002/32/EG)

Untersuchung auf PCDD / PCDF ("Dioxine") und dioxinähnliche Polychlorierte Biphenyle (dl-PCB)

Parameter	Ergebnis	Meßunsicher-heit	Einheit	Aktionswert	Höchstgehalt
PCDD/PCDF	0,0855	±0,021	ng WHO-TEQ/kg TS	--	--
PCDD/PCDF	0,0752	±0,019	ng WHO-TEQ/kg 88% TS	0,5 (RL 2002/32/EG)	0,75 (RL 2002/32/EG)
dioxinähnliche PCB	0,0161	±0,0040	ng WHO-TEQ/kg TS	--	--
dioxinähnliche PCB	0,0141	±0,0035	ng WHO-TEQ/kg 88% TS	0,35 (RL 2002/32/EG)	--
Summe PCDD/PCDF, dioxinähnliche PCB	0,102	±0,025	ng WHO-TEQ/kg TS	--	--
Summe PCDD/PCDF, dioxinähnliche PCB	0,0893	±0,022	ng WHO-TEQ/kg 88% TS	--	1,25 (RL 2002/32/EG)

Bewertungsgrundlagen:

RL 2002/32/EG Richtlinie 2002/32/EG über unerwünschte Stoffe in der Tierernährung in der aktuellen Fassung

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Einzelergebnisse der Untersuchung auf PCDD / PCDF

Parameter	Methode	Ergebnis	Toxizitätsäquivalent	Ergebnis
		ng/kg TS	WHO 2005	ng WHO-TEQ/kg TS
2,3,7,8 Tetra-CDD	DIN EN 16215 (Juli 2012), GC-HRMS	<0,02	1	<0,02
1,2,3,7,8-Penta-CDD	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	1	<0,03
1,2,3,4,7,8-Hexa-CDD	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,1	<0,003
1,2,3,6,7,8-Hexa-CDD	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,1	<0,003
1,2,3,7,8,9-Hexa-CDD	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,1	<0,003
1,2,3,4,6,7,8-Hepta-CDD	DIN EN 16215 (Juli 2012), GC-HRMS	<0,05	0,01	<0,0005
Octa-CDD	DIN EN 16215 (Juli 2012), GC-HRMS	<0,10	0,0003	<0,00003
2,3,7,8-Tetra-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,1	<0,003
1,2,3,7,8-Penta-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,03	<0,0009
2,3,4,7,8-Penta-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,3	<0,009
1,2,3,4,7,8-Hexa-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,1	<0,003
1,2,3,6,7,8-Hexa-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,1	<0,003
1,2,3,7,8,9-Hexa-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,1	<0,003
2,3,4,6,7,8-Hexa-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,03	0,1	<0,003
1,2,3,4,6,7,8-Hepta-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,05	0,01	<0,0005
1,2,3,4,7,8,9-Hepta-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,05	0,01	<0,0005
Octa-CDF	DIN EN 16215 (Juli 2012), GC-HRMS	<0,10	0,0003	<0,00003
Summe PCDD/PCDF inkl. Bestimmungs-grenze zu 100% (Obergrenze)	DIN EN 16215 (Juli 2012), GC-HRMS			0,0855
Summe PCDD/PCDF inkl. Bestimmungs-grenze zu 50% (Mittelwert)	DIN EN 16215 (Juli 2012), GC-HRMS			0,0427
Summe PCDD/PCDF exkl. Bestimmungs-grenze (Untergrenze)	DIN EN 16215 (Juli 2012), GC-HRMS			0

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Einzelergebnisse der Untersuchung auf dioxinähnliche Polychlorierte Biphenyle (dl-PCB)

Parameter	Methode	Ergebnis	Toxizitätsäquivalent	Ergebnis
		ng/kg TS	WHO 2005	ng WHO-TEQ/kg TS
PCB 77	DIN EN 16215 (Juli 2012), GC-HRMS	2,4	0,0001	0,00024
PCB 81	DIN EN 16215 (Juli 2012), GC-HRMS	0,14	0,0003	0,000042
PCB 126	DIN EN 16215 (Juli 2012), GC-HRMS	<0,1	0,1	<0,01
PCB 169	DIN EN 16215 (Juli 2012), GC-HRMS	<0,1	0,03	<0,003
PCB 105	DIN EN 16215 (Juli 2012), GC-HRMS	20	0,00003	0,00061
PCB 114	DIN EN 16215 (Juli 2012), GC-HRMS	<0,5	0,00003	<0,000015
PCB 118	DIN EN 16215 (Juli 2012), GC-HRMS	57	0,00003	0,0017
PCB 123	DIN EN 16215 (Juli 2012), GC-HRMS	9,8	0,00003	0,00029
PCB 156	DIN EN 16215 (Juli 2012), GC-HRMS	3,8	0,00003	0,00011
PCB 157	DIN EN 16215 (Juli 2012), GC-HRMS	0,94	0,00003	0,000028
PCB 167	DIN EN 16215 (Juli 2012), GC-HRMS	<0,5	0,00003	<0,000015
PCB 189	DIN EN 16215 (Juli 2012), GC-HRMS	<0,5	0,00003	<0,000015
Summe dioxinähnliche PCB inkl. Bestimmungsgrenze zu 100% (Obergrenze)	DIN EN 16215 (Juli 2012), GC-HRMS			0,0161
Summe dioxinähnliche PCB inkl. Bestimmungsgrenze zu 50% (Mittelwert)	DIN EN 16215 (Juli 2012), GC-HRMS			0,00955
Summe dioxinähnliche PCB exkl. Bestimmungsgrenze (Untergrenze)	DIN EN 16215 (Juli 2012), GC-HRMS			0,00303

Bewertung: **Die untersuchte Probe ist hinsichtlich der geprüften mikrobiologischen Parameter nicht zu beanstanden.**

Die durch die Richtlinie 2002/32/EG vorgegebenen Höchstmengen für unerwünschte Stoffe in Futtermitteln werden eingehalten.

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Test report for order no. F 19001 - 20

document no. F2020-019001-1

customer:	Mainfrucht GmbH & Co. KG Julius-Hofmann-Straße 2, 97469 Gochsheim
no. of samples:	1 sample
sample type:	feed materials (1x)
sampling:	customer, Margarete Glawe, 09-09-2020
date of sample receipt:	11-09-2020
test period:	11-09-2020 to 28-09-2020

remark:

The test results relate only to the items tested. This report shall not be reproduced, except in full, without written consent of SGS Analytics Germany GmbH. This test report has been validated and cleared by the person mentioned below. All tests were conducted at the SGS site in Jena unless stated otherwise.

Samples marked with "Sampling: Client" have been taken within the responsibility of the customer. The details of the sampling and all associated data (information on the sample, on-site values, volume information, etc.) were provided by the customer. They were taken over as transmitted. All results apply to the sample as received.

abbreviations, symbols:

--: not determined, not applicable, (S) subcontraction to an accredited laboratory, (SGS) conducted at different SGS site; (N) non-accredited test method, loq: limit of quantification, n.determ.: not determined, n.a.: not applicable, n.d.: not detected, n.av.: not available, DM: dry mass, DS: dry substance, FS: fresh substance, OS: original substance, SF: surface, ‡: information provided by the customer

Jena, 10-08-2021

Dr. Karla Jochmann
Division Manager
Division Feedingstuff

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lab no.: L1
Produkt: feed materials
beperbter_article: Karottentrester, 04.02.02‡
sampling: customer, Margarete Glawe, 09-09-2020‡
sample transport: courier
sample state: flawless
date of sample receipt: 11-09-2020
QS sample ID: **KE00000766-0000000005**
internal labelling: Karottentrester orange frisch KW 37 2020‡
test period: 11-09-2020 - 28-09-2020

Microbiological analyses

parameter	method	result	unit	warning threshold value
salmonella	ASU L 00.00-20:2018-03, DIN EN ISO 6579-1:2017-07	not detected	in 25 g	not detected

Physicochemical analyses

parameter	method	result	unit
dry matter	VO (EG) 152/2009, III, A	11,7	% OS

Results of element measurements

parameter	method	result	unit	maximum residue level
sample preparation HNO3-pressure digestion	ASU § 64 LFGB L00.00-19/1 and DIN EN 13805:2014-12	--		--
As	DIN EN ISO 17294-2: 2017-01	0,010	mg/kg 88% DM	2 (RL 2002/32/EG)
Pb	DIN EN ISO 17294-2: 2017-01	0,068	mg/kg 88% DM	10 (RL 2002/32/EG)
Cd	DIN EN ISO 17294-2: 2017-01	0,084	mg/kg 88% DM	1 (RL 2002/32/EG)
Hg	DIN EN 15763:2010-04	0,0083	mg/kg 88% DM	0,1 (RL 2002/32/EG)

basis of evaluation:
RL 2002/32/EG Directive 2002/32/EC on undesirable substances in animal feed in its current version

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Analysis of mycotoxins

parameter	method	result	unit	maximum residue level
aflatoxin B1	DIN EN ISO 17375:2006-09	<0,1	µg/kg 88% DM	20 (RL 2002/32/EG)
aflatoxin B2	DIN EN ISO 17375:2006-09	<0,1	µg/kg 88% DM	--
aflatoxin G1	DIN EN ISO 17375:2006-09	<0,1	µg/kg 88% DM	--
aflatoxin G2	DIN EN ISO 17375:2006-09	<0,1	µg/kg 88% DM	--
total aflatoxins	DIN EN ISO 17375:2006-09	not detected	µg/kg 88% DM	--

basis of evaluation:

RL 2002/32/EG Directive 2002/32/EC on undesirable substances in animal feed in its current version

Analysis of pesticides: Screening

The analysis of pesticides covered all substances listed in the attached pesticide screening list with limits of quantification mentioned therein.

parameter	method	result	unit	maximum residue level
pesticides	QuEChERS DIN EN 15662:2018-07, determination by GC-MS/MS and LC-MS/MS	detected		--
difenoconazole	QuEChERS DIN EN 15662:2018-07, determination by GC-MS/MS and LC-MS/MS	0,032	mg/kg	0,4 (VO (EG) 396/2005)

basis of evaluation:

VO (EG) 396/2005 Regulation (EC) No. 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin in its current version

Analysis of non dioxin-like polychlorinated biphenyls (ndl-PCBs)

parameter	method	result	unit	maximum residue level
PCB 28	DIN EN 16215 (Mai 2020), GC-HRMS	<0,1	µg/kg 88% DM	--
PCB 52	DIN EN 16215 (Mai 2020), GC-HRMS	<0,1	µg/kg 88% DM	--
PCB 101	DIN EN 16215 (Mai 2020), GC-HRMS	<0,1	µg/kg 88% DM	--
PCB 153	DIN EN 16215 (Mai 2020), GC-HRMS	<0,1	µg/kg 88% DM	--
PCB 138	DIN EN 16215 (Mai 2020), GC-HRMS	<0,1	µg/kg 88% DM	--
PCB 180	DIN EN 16215 (Mai 2020), GC-HRMS	<0,1	µg/kg 88% DM	--

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parameter	method	result	unit	maximum residue level
sum not-dioxin-like PCBs incl. LOQ for not quantified congeners (upper bound value)	DIN EN 16215 (Mai 2020), GC-HRMS	0,60	µg/kg 88% DM	10 (RL 2002/32/EG)
sum not-dioxin-like PCBs incl. half the LOQ for not quantified congeners (medium bound value)	DIN EN 16215 (Mai 2020), GC-HRMS	0,300	µg/kg 88% DM	--
sum not-dioxin-like PCBs incl. limit of quantification to 0% (lower bound value)	DIN EN 16215 (Mai 2020), GC-HRMS	0,00	µg/kg 88% DM	--

basis of evaluation:

RL 2002/32/EG Directive 2002/32/EC on undesirable substances in animal feed in its current version

Analysis of PCDDs / PCDFs ("dioxins") and dioxin-like polychlorinated biphenyls (dl-PCBs)

parameter	result	measurement uncertainty	unit	action level	maximum residue level
PCDDs/PCDFs	0,0855	±0,021	ng WHO-TEQ/kg DM	--	--
PCDDs/PCDFs	0,0752	±0,019	ng WHO-TEQ/kg 88% DM	0,5 (RL 2002/32/EG)	0,75 (RL 2002/32/EG)
dioxin-like PCBs	0,0133	±0,0033	ng WHO-TEQ/kg DM	--	--
dioxin-like PCBs	0,0117	±0,0029	ng WHO-TEQ/kg 88% DM	0,35 (RL 2002/32/EG)	--
sum of PCDDs/PCDFs, dioxin-like PCBs	0,0988	±0,025	ng WHO-TEQ/kg DM	--	--
sum of PCDDs/PCDFs, dioxin-like PCBs	0,0870	±0,022	ng WHO-TEQ/kg 88% DM	--	1,25 (RL 2002/32/EG)

basis of evaluation:

RL 2002/32/EG Directive 2002/32/EC on undesirable substances in animal feed in its current version

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Individual results of the analyses of PCDDs / PCDFs

parameter	method	result	toxic equiva-lent	result
		ng/kg DM	WHO 2005	ng WHO-TEQ/kg DM
2,3,7,8 Tetra-CDD	DIN EN 16215 (Mai 2020), GC-HRMS	<0,02	1	<0,02
1,2,3,7,8-Penta-CDD	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	1	<0,03
1,2,3,4,7,8-Hexa-CDD	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,1	<0,003
1,2,3,6,7,8-Hexa-CDD	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,1	<0,003
1,2,3,7,8,9-Hexa-CDD	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,1	<0,003
1,2,3,4,6,7,8-Hepta-CDD	DIN EN 16215 (Mai 2020), GC-HRMS	<0,05	0,01	<0,0005
Octa-CDD	DIN EN 16215 (Mai 2020), GC-HRMS	<0,10	0,0003	<0,00003
2,3,7,8-Tetra-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,1	<0,003
1,2,3,7,8-Penta-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,03	<0,0009
2,3,4,7,8-Penta-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,3	<0,009
1,2,3,4,7,8-Hexa-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,1	<0,003
1,2,3,6,7,8-Hexa-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,1	<0,003
1,2,3,7,8,9-Hexa-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,1	<0,003
2,3,4,6,7,8-Hexa-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,03	0,1	<0,003
1,2,3,4,6,7,8-Hepta-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,05	0,01	<0,0005
1,2,3,4,7,8,9-Hepta-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,05	0,01	<0,0005
Octa-CDF	DIN EN 16215 (Mai 2020), GC-HRMS	<0,10	0,0003	<0,00003
sum of PCDDs/PCDFs incl. LOQ for not quantified congeners (upper bound)	DIN EN 16215 (Mai 2020), GC-HRMS			0,0855
sum of PCDDs/PCDFs incl. half the LOQ for not quantified congeners (medium bound)	DIN EN 16215 (Mai 2020), GC-HRMS			0,0427
sum of PCDDs/PCDFs excl. LOQ for not quantified congeners (lower bound)	DIN EN 16215 (Mai 2020), GC-HRMS			0

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Individual results of the analyses of dioxin-like PCBs (dl-PCBs)

parameter	method	result	toxic equiva-lent	result
		ng/kg DM	WHO 2005	ng WHO-TEQ/kg DM
PCB 77	DIN EN 16215 (Mai 2020), GC-HRMS	0,35	0,0001	0,000035
PCB 81	DIN EN 16215 (Mai 2020), GC-HRMS	<0,1	0,0003	<0,00003
PCB 126	DIN EN 16215 (Mai 2020), GC-HRMS	<0,1	0,1	<0,01
PCB 169	DIN EN 16215 (Mai 2020), GC-HRMS	<0,1	0,03	<0,003
PCB 105	DIN EN 16215 (Mai 2020), GC-HRMS	1,5	0,00003	0,000046
PCB 114	DIN EN 16215 (Mai 2020), GC-HRMS	<0,5	0,00003	<0,000015
PCB 118	DIN EN 16215 (Mai 2020), GC-HRMS	4,9	0,00003	0,00015
PCB 123	DIN EN 16215 (Mai 2020), GC-HRMS	<0,5	0,00003	<0,000015
PCB 156	DIN EN 16215 (Mai 2020), GC-HRMS	<0,5	0,00003	<0,000015
PCB 157	DIN EN 16215 (Mai 2020), GC-HRMS	<0,5	0,00003	<0,000015
PCB 167	DIN EN 16215 (Mai 2020), GC-HRMS	<0,5	0,00003	<0,000015
PCB 189	DIN EN 16215 (Mai 2020), GC-HRMS	<0,5	0,00003	<0,000015
sum of dioxin-like PCBs incl. LOQ for not quantified congeners (upper bound)	DIN EN 16215 (Mai 2020), GC-HRMS			0,0133
sum of dioxin-like PCBs incl. half the LOQ for not quantified congeners (medium bound)	DIN EN 16215 (Mai 2020), GC-HRMS			0,00679
sum of dioxin-like PCBs excl. LOQ for not quantified congeners (lower bound)	DIN EN 16215 (Mai 2020), GC-HRMS			0,000228

note: *** maximum residue level for unprocessed Carrots - Specification for orientation.**

evaluation: With regard to the analyzed microbiological parameters the tested sample is satisfactory.

The maximum permitted residue levels (MRL) specified in directive 2002/32/EC setting maximum levels for undesirable substances in animal feed are not exceeded.

From: Richard Lane
To: Hall, Karen
Subject: [EXTERNAL] Re: Question Regarding GRN 000972
Date: Friday, October 1, 2021 4:32:27 PM

Karen,

The folks in The Netherlands must have been working late. I can confirm that the notified substance will not be used in any USDA-regulated products.

Regards,
Richard
Richard W Lane, PhD
Lane Toxicology Consulting, LLC
Tel: 201/452-5816
richardlanephd@gmail.com

On Fri, Oct 1, 2021 at 10:07 AM Hall, Karen <Karen.Hall@fda.hhs.gov> wrote:

> Good Morning Richard,
>
> I hope your day is going well. We have one additional question.
>
> On page 42 Table 14 of your GRAS notice, NutriLeads states that pectin hydrolysate is not intended for use in meat products. Could you confirm that pectin hydrolysate is not intended for use in any products regulated by the USDA?
>
> Thank you and have a nice weekend.
>
> Kind Regards,
>
> Karen
>
> **Karen Hall**

Regulatory Review Scientist

Division of Food Ingredients
Office of Food Additive Safety

Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Karen.Hall@fda.hhs.gov