agromed

Agromed Austria GmbH
Bad Haller Strasse 23
4550 Kremsmünster
Austria

Kremsmünster, December 18th, 2020

Division of Animal Feeds (HFV-220)
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855

Re: CVM GRAS Notification for the substance Agromed's patented wood-based lignocellulose.

Dear Sir or Madam,

Under the Final Rule for the notification of self-determination of Generally Recognized as Safe (GRAS) ingredients, Agromed Austria GmbH is hereby submitting a notification for the substance Agromed's patented wood-based lignocellulose as a source of dietary fiber in animal food for food-processing animals (swine and poultry).

As discussed in detail in the enclosed dossier of information, the submission includes a determination, based on scientific procedures, that lignocellulose is GRAS for the intended conditions of use.

This submission is divided into seven parts according to 21 CFR 570.220 through 570.255. The complete data and information cited in the submission that served as the basis of this GRAS notification are available to the Food and Drug Administration upon request. Should you have any questions, please feel free to contact us via telephone (+43 7583 510550) or e-mail (grabherr@agromed.at).

Yours sincerely,

Helmut Grabherr
CEO, Agromed Austria GmbH

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Agromed Austria GmbH
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Generally Recognized As Safe (GRAS)

Notification

for

Agromed's patented wood-based Lignocellulose

Prepared for:

U.S. Food and Drug Administration

Center for Veterinary Medicine

Division of Animal Feed (HVF-220)

7519 Standish Place

Rockville, MD 20855

Notifier:

Agromed Austria GmbH

Bad Haller Strasse 23

4550 Kremsmünster

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Table of contents:

I. Part 1: Signed statements and certification

A. Submission of GRAS notification

Hereby we officially inform the Division of Animal Feeds (HFV-220), Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration that Agromed Austria GmbH is submitting a GRAS notification for the substance Agromed's patented wood-based lignocellulose in accordance with 21 CFR 570.225.

We further inform Division of Animal Feeds (HFV-220), Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration that all of Agromed's lignocellulose-based products are produced exclusively for Agromed Austria GmbH by the company (b) (4) (b) (4) (FDA registration no. (b) (4)) located in Germany.

B. Notifier

Agromed Austria GmbH
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T: +43 7583 5105-0
F: +43 7583 5105-40
M: office@agromed.at
W: www.agromed.at
Company Registration Number: FN 185370 d

Agromed Austria GmbH is registered as food facility (feed trade) in USA with reg.nr.: 19258067980.

Agromed Austria GmbH is GMP+ registered (GMP+ Registration Number: GMP022390). The DEKRA organization (DEKRA Certification GmbH, Stuttgart) audits Agromed Austria and issues the GMP + certificate.

Responsible Person:
Mr. Helmut Grabherr, CEO
M: grabherr@agromed.at

B.1. **Exclusive producer:**

Based on a sales and distribution agreement, wood-based lignocellulose for feed applications is solely and exclusively produced for Agromed Austria GmbH in the wood mill (b) (4) GmbH, in Germany since 2003.

The company (b) (4) is approved as a feed company in Germany and is certified in the international quality system GMP+ and the German quality system Q + S. Furthermore, (b) (4) is certified in the standards PEFC, Kosher and ISO 9001:2015. In addition, (b) (4) has also been registered at the FDA.

(b) (4)

(b) (4) GmbH is registered as food facility (feed trade) in USA with reg. nr: (b) (4).

(b) (4) GmbH is GMP+ certified (GMP+ Registration Number: (b) (4)). The DEKRA organization (DEKRA Certification GmbH, Stuttgart) audits (b) (4) and issues the GMP + certificate.

(b) (4) The DEKRA organization (DEKRA Certification GmbH, Stuttgart) audits (b) (4) GmbH and issues the GMP + certificate.

Responsible Person:
(b) (4)

C. Name of the notified product

Agromed's patented[1] wood-based lignocellulose, referred to as "Agromed's lignocellulose" in the present GRAS dossier.

D. Intended conditions of use

Agromed's lignocellulose is to be used as a dietary fiber source – rich in insoluble fibers - to be mixed in swine food and poultry food. The substance Agromed's lignocellulose is to be mixed with the compound feed.

E. Statutory basis

This GRAS determination is based upon the publicly available scientific literature pertaining to the safety of the Agromed's lignocellulose.

[1] Patent Nr.: US 8673383B2, full patent in Appendix B

F. Substance is exempt of premarket approval

Agromed Austria GmbH has determined that its Agromed lignocellulose is GRAS as a source of dietary fiber – rich in insoluble fibers - in swine and poultry food. Therefore, the substance Agromed's lignocellulose, under the conditions of its intended use, is exempt from premarket approval requirements of the Federal Food, Drug and Cosmetic Act.

G. Availability of information

Agromed Austria formally agrees that, if FDA asks to see the data and information that are the basis for its conclusion of GRAS status, either during or after evaluation of its notice, Agromed GmbH will:
(i) agree to make the data and information available to FDA; and
(ii) agree to both of the following procedures for making the data and information available to FDA:
(A) upon FDA's request, Agromed Austria GmbH will allow FDA to review and copy the data and information during customary business hours at the company address of Agromed Austria GmbH, Bad Haller Straße 23, A-4550 Kremsmünster, Austria/Europe; and
(B) upon FDA's request, Agromed Austria GmbH will provide a complete copy of the data and information either in an electronic format that is accessible for evaluation or on paper;

H. Data and Information exempt from disclosure

Agromed formally states that following data of the present GRAS dossier must remain confidential, and are not allowed to be disclosed to public:

- Part 2 "Identity, method of manufacture, specifications, and physical or technical effect"
- Part 3 "Target animal and human exposures"
- Part 6 "Narrative on the Safety of the substance"
- Part 7 "List of supporting data and information"

I. Certification

Agromed certifies that, to the best of its knowledge, the GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to Agromed Austria GmbH and pertinent to the evaluation of the safety and GRAS status of the use of the substance.

J. Signature

(b) (4)

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Cl Austria GmbH

Date: December 18th, 2020

II. Part 2: Identity, method of manufacture, specifications, and physical or technical effect

According to a generic definition, also relayed by the FAO[2], the term `lignocellulose´ refers to the combination of lignin, hemicellulose and cellulose that forms the structural framework of plant cell walls.

As a proportion of the total dry matter, lignocellulose varies widely in forages, depending on species and stage of maturity. In wood products, where stage of maturity has little meaning, the lignocellulose content is relatively constant within a species but may vary somewhat between species (Table 1) (Pigden and Heaney, 1969).

Table 1: Typical lignocellulose content of some plant materials

Plant material	Hemicellulose	Cellulose	Lignin	Total Lignocellulose
	Percent			
Western alfalfa (medium maturity)	6	25	7.2	38.2
Orchard grass (medium maturity)	40.0	32.0	4.7	76.7
Rye straw	27.2	34.0	14.2	75.4
Birch wood (Betula verrucose)	25.7	40.0	15.7	81.4
Spruce wood (Picea excelsa)	20.9	46.0	24.1	91.0

Lignin is an aromatic complex chemical compound which varies in content from about 2% in immature forages up to 15% in mature forages; in wood the percentage is somewhat higher (Table 1). Its main function is to supply strength and rigidity to plant materials.

Hemicelluloses are amorphous polysaccharides of short, highly branched chains of sugar. Hemicelluloses exist in close association with the cellulose and lignin in the plant cell walls. Hemicelluloses vary widely in content from one type of plant material to another with a range of about 6 to 40% (Table 1).

Cellulose is a polysaccharide consisting of a linear chain of several hundred to over ten thousand β-(1,4)-D-glucose units (Figure 1)[3]. It is a crystalline and strong component, resistant to hydrolysis polymer.

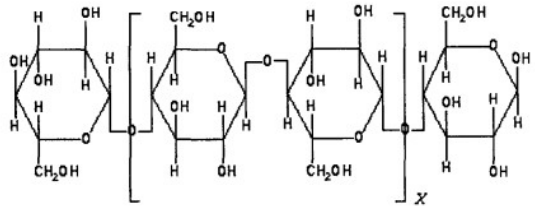


Figure 1: Chemical structure of cellulose

[2] FAO Term Portal http://www.fao.org/faoterm/viewentry/en/?entryId=170630, consulted on November 24th 2020.
[3] Extract from the GRAS Notice GRN No. 342: Oat hull fiber.

A. Typical chemical composition of Agromed's Lignocellulose

Based on the latest analysis from the Quality Control Plan of Agromed Austria, typical analytical values for Agromed's lignocellulose are (Table 2):

Table 2: Typical chemical composition of Agromed's lignocellulose

Parameter	Result	Result (On Dry)	Method of analysis
Moisture	(b) (4)		Gravimetric method acc. EC 152/2009 annex III-A and VDLUFA III (3.1)
Dry matter			calculated
Crude fat (XL)			Hydrolyze, Gravimetric method acc. EC 152/2009 annex III-H method B and VDLUFA III (5.1.1) procedure B
Crude ash (XA)			Gravimetric method acc. EC 152/2009 annex III-M and VDLUFA III (8.1)
Crude protein (XP)			Determination of protein content (Nx6.25) DUMAS, Oilseeds, animal feed and feeding stuffs eq to NEN-EN-ISO 16634-1 Grains, pulses and grain products eq to NEN-EN-ISO 16634-2
Crude fiber (XF)			Intermediate filtration acc NEN-EN-ISO 6865 eq EC 152/2009 annex III-I and VDLUFA III (6.1.1)
Nitrogen Free Extract			calculated
Σ			Addition of moisture, XL, XA, XP, XF
Neutral Detergent Fiber			LUFA 6.5.1 (on the model of Van Soest)
Acid Detergent Fiber			LUFA 6.5.2 (on the model of Van Soest)
Acid Detergent Lignin			LUFA 6.5.3 (on the model of Van Soest)
Neutral Detergent Fiber (NDF): hemicellulose, cellulose, lignin Acid Detergent Fiber (ADF): cellulose, lignin Acid Detergent Lignin (ADL): lignin			

Source: Report from (b) (4) *Laboratory dated October13th, 2020. Sample Seal Code 22971613. Report 1116630 v1. The FDA finds the complete report in Appendix A of the present GRAS dossier.*

Based on those analytical results, Agromed's lignocellulose (b) (4)

A.1. Limitations of analytical methods

The fiber analytical process used in a standard Weender feed analysis (crude fiber) is not designed for the analysis of wood. Comparably high levels of hemicellulose, cellulose and lignin are not found in other feedstuffs. Also, the extended fiber analysis according to Van Soest (NDF, ADF, ADL) has been developed for the analysis of roughage and not for wood-based lignocellulose. The analytical latitude for NDF at contents up to 58.0% (in fresh weight) is stated with 10% relative(VDLUFA, 2016). For ADF it is also 10% relative for contents up to 38.1% (in fresh weight) (VDLUFA, 2016). The ADF and NDF levels in Agromed's lignocellulose are higher and thus outside of the method of calibration, as a result of which, the measurement uncertainties are presumably higher than the stated 10%.

(b) (4)

. According to the current methods available, fiber analysis of wood fibers can only be regarded as unsatisfactory. (b) (4)

According to the current status, the fiber analysis of Agromed's lignocellulose is carried out via the Weender analysis (crude fiber) and the Van Soest analysis (NDF, ADF, ADL). These methods are only partially suitable for fiber analysis in Agromed's lignocellulose, but are international standards for the analysis of feed ingredients.

A.2. Technical effect of Agromed's lignocellulose

Due to the high crude fiber level in Agromed's lignocellulose product, the desired effect – increase of the dietary fiber concentration in the animal food – can be achieved with a supplementation at lower mixing rates than with other raw materials (Tables 3 and 4).

Table 3: Chemical composition of different feed ingredients

	DM	XA	XP	XF	XS
	%	% in dry matter			
Sugar beet pulp	(b) (4)				
Wheat bran					
Rice bran					
Rice hulls					
Soybean hulls					
Oat bran					
Oat hulls					
Agromed's lignocellulose					

DM = dry matter; XA = crude ash; XP = crude protein; XF = crude fiber; XS = crude starch
Source: Agromed Austria intern

Table 4: Necessary dosage to increase the raw fiber content in the animal food ration by 1%

Oats	Wheat bran	Sugar beet pulp	Soybean hulls	Agromed's lignocellulose
(b) (4)				%

Source: Agromed Austria intern

B. Source of the components of Agromed's lignocellulose

The formula of Agromed's lignocellulose has been patented (Patent No.: US 8,673,383 B2 dated March 18, 2014) See the whole patent in Appendix B. (b) (4)

Agromed's lignocellulose is composed exclusively of a mixture of (b) (4) and (b) (4) three species of (b) (4) ((b) (4)), (b) (4)((b) (4) and (b) (4)((b) (4)).

Based on our quality standards, it is excluded that processed wood (e.g. treated wood) is used in this mixture.

(b) (4)

For the production of Agromed's lignocellulose, (b) (4) .

B.4. Composition of Agromed's lignocellulose

A quantitative composition of the different components of Agromed's lignocellulose is given in Table 5.

Table 5: Quantitative composition of Agromed's lignocellulose

Starting materials	Quantitative fraction
(b) (4)	

C. Any known toxicants that could be in the source

Agromed Austria GmbH is GMP+ certified. The exclusive manufacturing partner – the company (b) (4) – is either GMP and QS (Quality System in Germany) certified. The QS-System – the quality assurance system for food in Germany – ensures the control of meat and meat products, fruits, vegetables and feed throughout production and processing.

Together, the companies Agromed Austria and (b) (4) developed a Quality Control Plan (detailed in Part II – E – E.2. of the present GRAS dossier) of its products suitable with the conditions of QS-System and (b) (4)

Following substances (presented in Table 6) are continuously tested and monitored in the Quality Control Plan.

Table 6: Substances analyzed in Agromed's Quality Control Plan

Substances	**Regulation fixing legally permitted limits**
Microbiology	(b) (4) Specific Feed Safety[4]
Heavy metals	Commission Regulation (EU) No. 2019/1869 amending Annex I to Directive 2002/32/EC[5]
Dioxins	Commission Regulation (EU) No. 277/2012 amending Annex I & II to Directive 2002/32/EC[6]
Pesticides	Regulation (EC) No. 396/2005[7] & Directive 2002/32/EG[8]

C.1. Monitoring of microbiology

The GMP guideline - GMP + BA1 "Specific Feed Safety Limits" – states limits for microbiological parameters (Table 7).

The microbiological analytical results of three non-consecutive batches of Agromed's lignocellulose are presented in Table 8.

[4] (b) (4) consulted on December 12, 2020

[5] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1869&from=EN, consulted on December 12, 2020

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012R0277&from=EN, consulted on December 12, 2020

[7] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32005R0396&from=EN, consulted on December 12, 2020

[8] https://eur-lex.europa.eu/resource.html?uri=cellar:aca28b8c-bf9d-444f-b470-268f71df28fb.0004.02/DOC_1&format=PDF, consulted on December 12, 2020

Table 7: Regulatory limits for microbiology parameters

Parameter	Legally permitted limit according to GMP+ BA1: Specific Feed Safety
Moulds	10^6 CFU/g
Yeast	10^6 CFU/g
Salmonella	Absence in 25g

Table 8: Analytical results for 3 non-consecutive batches of Agromed's lignocellulose

	Method	Unit	**Sample Seal Code 22971657 Report 1042444 v1, Feb. 2020**	**Sample Seal Code 22971663 Report 1005963 v 1, Nov. 2019**	**Sample Seal Code 20456433 Report 920816 v 1, Jan. 2019**	Legally permitted limits according to GMP+ BA1: Specific Feed Safety
Microbiological analysis						
Aerobic Plate Count	VDLUFA III, 28.1.2	cfu/g			(b) (4)	
Coliform	ISO 4831	cfu/g				
Moulds	VDLUFA III, 28.1.2	cfu/g				10^6
Yeast	VDLUFA III, 28.1.2	cfu/g				10^6
Salmonella	Eq NEN-EN-ISO-6579	cfu/g				Absence in 25g

(b) (4)

The complete analysis reports from external laboratories are to be found in Appendix C.

C.2. **Monitoring of heavy metals**

The European Regulation (Commission Regulation (EU) No. 2019/1869 amending Annex I to Directive 2002/32/EC) states limits for heavy metals (Table 9).

The heavy metals analysis for three non-consecutive batches of Agromed's lignocellulose are presented in Table 10. The complete analysis report from external laboratories are to be found in Appendix C.

Table 9: Regulatory limits for heavy metals

	Limits from Commission Regulation (EU) No 2019/1869 amending Annex I to Directive 2002/32/EC
Cd	1 mg/kg
Pb	10 mg/kg
As	2 mg/kg
Hg	0.1 mg/kg

Table 10: Analytical results for 3 non-consecutive batches of Agromed's lignocellulose

	Method	Unit	**Sample Seal Code 22971605 Report 1138916 v 1, Nov. 2020**	**Sample Seal Code 22971653 Report 1055092 v1, Mar. 2020**	**Sample Seal Code 22971662 Report 1009902 v 1, Nov. 2019**	Limits from Commission Regulation (EU) No 2019/1869 amending Annex I to Directive 2002/32/EC
Heavy metals						
Cd	ICP-MS; own method for food-stuffs: destruction cf NEN-EN 13805, Analysis acc. NEN-EN-15763	mg/kg		(b) (4)		1
Pb		mg/kg				10
As		mg/kg				2
Hg	Hg-analyser eq. NEN-EN 16277	mg/kg				0.1

C.3. **Monitoring of dioxins**

The European Regulation (Commission Regulation (EU) No. 277/2012 amending Annex I & II to Directive 2002/32/EC) states limits for dioxins (Table 11).

The dioxins analysis for three non-consecutive batches of Agromed's lignocellulose are presented in Table 12. The complete analysis report from external laboratories are to be found in Appendix C.

Table 11: Regulatory limits for dioxins

	Limits from Commission Regulation (EU) No 277/2012 amending Annexes I & II to Directive 2002/32/EC
WHO (PCDD/PCDF)TEQ 88%dm	0.75 ng WHO-PCDD/F-TEQ/kg
WHO (PCDD/F/PCB)TEQ 88%dm	1.25 ng WHO-PCDD/F-PCB-TEQ/kg

Table 12: Analytical results for 3 non-consecutive batches of Agromed's lignocellulose

	Method	Unit	**Sample Seal Code 22971605 Report 1138918 v 1, Nov. 2020**	**Sample Seal Code 22971653 Report 1055092 v1, Feb. 2020**	**Sample Seal Code 22971662 Report 1009902 v 1, Oct. 2019**	Limits from Commission Regulation
Dioxins						
WHO (PCDD/PCDF)TEQ 88%dm	Calculation feed of Toxic Equivalency Factors for dioxins and dioxinlike PCB's [WHO-2005]	ng/kg		(b) (4)		0.75
WHO (PCDD/F/PCB)TEQ 88%dm		ng/kg				1.25

C.4. **Monitoring of pesticides**

Regarding pesticides, the maximum residue levels of pesticides (MRL) are regulated by the following EU Regulations. These are:

• Regulation (EC) No. 396/2005. This regulation includes the MRLs for unprocessed products of vegetable and animal origin intended for human consumption and for feed. As much as the MRLs apply to feed they are applicable to both feed for food-producing animals and for nonfood-producing animals.

• Directive 2002/32/EG, Annex I, part IV regarding undesirable substances in feed. This Directive contains MRLs for certain specific Organochlorine compounds.

Agromed Austria's Quality Control Plan (cf. Table 18 of the present GRAS notice) includes pesticides analysis of the raw materials. Raw materials for pesticide analysis are defined in two categories: trunk wood and bark. The FDA finds several analysis reports for pesticides in Agromed's lignocellulose (non-consecutive batches) in Appendix C.

The precise and controlled monitoring of pesticides for the substance Agromed's lignocellulose shows that all pesticides in all raw materials are under the detection limits. That is why Agromed Austria can confirm that pesticides are not impacting the quality and toxicology of Agromed's lignocellulose.

The referent laboratory which analyzes pesticides residues in Agromed's lignocellulose is (b) (4) (referred to as (b) (4)), in The Netherlands. (b) (4) is accredited GMP+ and QS (among many other accreditations).

(b) (4) uses both gas chromatography/mass spectrometry (GC/MS) and liquid chromatography tandem mass spectrometry (LC/MS/MS) to analyze the pesticide residues.

Traditionally, pesticide residues are analyzed mainly by gas chromatography/mass spectrometry (GC/MS) methods (Hou et al., 2013; Kirchner et al., 2005), but GC is not a suitable technique for ionic and polar compounds. Liquid chromatography tandem mass spectrometry (LC/MS/MS) has become the method of choice for pesticide analysis due to its high selectivity and sensitivity as well as its suitability for a wide range of compounds in various sample matrices (Zhang et al., 2017; Wilkowska and Biziuk, 2011).

C.5. **FDA Regulation on pesticides**

The Food and Drug Administration is responsible under the Federal Food, Drug, and Cosmetic Act for enforcing tolerances established by the Environmental Protection Agency (EPA) for amounts of pesticide residues that may legally remain in food (including animal feed). The tolerances for pesticide chemicals are to be found in the Code of Federal Regulations (40 CFR Part 180[9]) and are updated once a year.

For a sample of 10 pesticide residues (5 measured with GC/MS method and 5 measured with LC/MS/MS method), Agromed Austria compared the following (Table 13):

[9] https://www.govinfo.gov/content/pkg/CFR-2014-title40-vol24/xml/CFR-2014-title40-vol24-part180.xml, consulted on December 12, 2020

- The tolerance of this pesticide residue according to the Code of Federal Regulations (40 CFR Part 180). The lowest defined tolerance established for the pesticide residue in agricultural commodities has been taken as standard value in Table 13.
- The detection limit of this pesticide residue as given from the external laboratory (b) (4) The FDA finds those detection limits in the complete pesticides analysis reports in Appendix C.

Table 13: Comparison between regulations for a sample of pesticide residues

Pesticide residue	Classification acc. 40 CFR Part 180 – Subpart C	Tolerance acc. 40 CFR Part 180 – Subpart C	Detection limit (b) (4) Lab.	Analytical results for Agromed's lignocellulose
Chlorothalonil	180.275	0.03 ppm	0.01 ppm	< 0.01 ppm
Cyfluthrin	180.436	0.01 ppm	0.01 ppm	< 0.01 ppm
Deltamethrin	180.435	0.02 ppm	0.01 ppm	< 0.01 ppm
Endosulfan	180.182	0.2 ppm	0.01 ppm	< 0.01 ppm
Famoxadone	180.587	0.02 ppm	0.01 ppm	< 0.01 ppm
Dimethoate	180.204	0.02 ppm	0.01 ppm	< 0.01 ppm
Malathion	180.111	0.1 ppm	0.01 ppm	< 0.01 ppm
Methomyl	180.253	0.1 ppm	0.01 ppm	< 0.01 ppm
Pirimiphos-methyl.	180.409	0.02 ppm	0.01 ppm	< 0.01 ppm
Thiodicarb	180.407	0.2 ppm	0.01 ppm	< 0.01 ppm

For the sample of pesticide residues studied, all analyzed residues in Agromed's lignocellulose are under the detection limit of the analytical method and under the tolerances defined by the EPA Regulation in the United States of America.

C.6. (b) (4) Risk Assessment

(b) (4) wrote a Risk Assessment of the substance `lignocellulose´. This Risk Assessment evaluation was made in order to evaluate `lignocellulose´ and see if (b) (4) could add it to its intern list for allowed ingredients in animal feed. In this generic Risk Assessment, `lignocellulose´ and `lignocellulose from bark´ have been evaluated from the early cultivation step in forestry up to the end product: Agromed's lignocellulose.

The complete report is made available to the FDA in Appendix D of the present GRAS dossier.

The Risk Assessment and the control audits that are regularly conducted at Agromed Austria, establish the basis of a continuous process of monitoring the quality of the end product Agromed's lignocellulose.

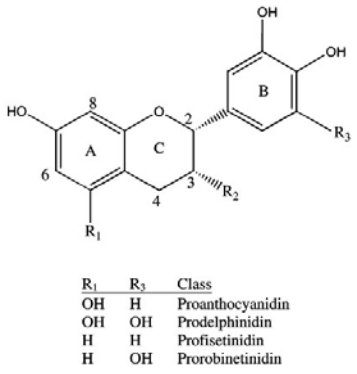
D. Other possible contaminants

Some substances may naturally be present in wood and therefore in Agromed's lignocellulose. Typically, such extractives consist of low molecular weight compounds (Schmitt et al. 2014) and may have aliphatic, alicyclic or aromatic structures. Some of them may protect wood against attacks from fungi, insects and bacteria, and may have toxic, irritant or sensitizing properties. Agromed Austria carried out in-depth studies of both the most common naturally present extractives (e.g. condensed tannins and volatile oils) and an organic extractive reported to have a potential negative effect on animal health (e.g. isocupressic acid).

Agromed Austria had first to develop adapted analytical methods in order to analyze the mentioned extractives in Agromed's lignocellulose. This project has been realized in collaboration with the (b) (4) Proper calibrations were developed, adapted to the matrix and the nature of Agromed's lignocellulose.

D.1. **Condensed tannins**

Condensed tannins (or proanthocyanidins, PAs) comprise a group of polyhydroxyflavan-3-ol oligomers and polymers linked by carbon-carbon bonds between flavanol subunits, figure 2 and 3 (Schofield *et al*, 2001).



R_1	R_3	Class
OH	H	Proanthocyanidin
OH	OH	Prodelphinidin
H	H	Profisetinidin
H	OH	Prorobinetinidin

Figure 2: The basic repeating unit in condensed tannins.

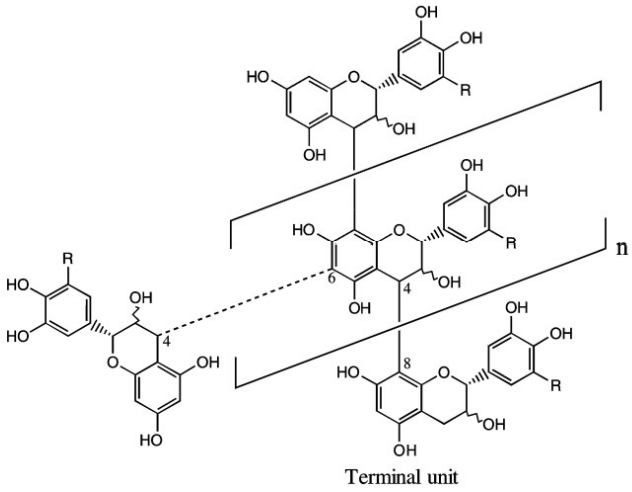


Figure 3: Model structure for a condensed tannin.

Plant condensed tannins (proanthocyanidins, PAs) are discussed to have both positive and negative effects on feed digestibility and animal performance, depending both on the quantity and the biological activity of the tannins that are present (Schofield *et al*, 2001).

The collaboration between the (b) (4) and Agromed lead to a method of analysis for the condensed tannins in Agromed's Lignocellulose. See Appendix E for the detailed method and the references which leaded to the development of the analytical method.

The absolute content of proanthocyanidins per sample of Agromed's lignocellulose in relation to a proanthocyanidin B2 standard (b) (4) is summarized in Table 14.

Table 14: Proanthocyanidin content determined by acid butanol assay in [mg/g]

Samples	Proanthocyanidine related to proanthocyanidine B2 standard (CAS: 29106-49-8)	
	Means value	Standard deviation
Opticell 12.2.	4.85	0.40
Opticell 22.2.	4.86	0.07
Opticell 24.2.	5.08	0.25

(Opticell® is a commercial brand name for the substance Agromed's lignocellulose.)

For comparison in food, grapes are one of the most concentrated fruit in polyphenols, and condensed tannins. Grape seeds have the highest concentration of bioactive molecules. Approximately 30% of total proanthocyanidins are stored in grape seeds and 15% in skin (Hanlin et al., 2011). Condensed tannins accumulate in grape skin during the maturation of the fruit. The color of grapes of different cultivars ranges from very dark nearly black purple to very light green, and are most often classified as red or white (Walker et al 2007). The color of red grapes is principally due to anthocyanins and other polyphenols. The condensed tannins derived from the grape berry play a significant role in wine astringency, bitterness, color stability, and aging potential (Hanlin and Downey, 2009).

Extracted forms of grapes (grape seed extract and grape pomace extract) are currently used in food processing, as antioxidant in juices and other beverages. A red grape pomace extract has been the topic of GRN No. 446 (food applications) and has been recognized as GRAS in 2013. In the mentioned dossier, the proanthocyanidin concentration of the product exGrape® (red grape pomace extract) was 49.21 % w/w (dry basis). The intended conditions of use for exGrape® are the application as an antioxidant in fruit juices and other mentioned beverages at a dosage up to 210 milligrams/kilogram.

A dosage of 2% of Agromed's lignocellulose in a swine diet, means that 2% x 5 mg/g = 0.1 mg Proanthocyanidin from Agromed's lignocellulose are present in 1 gram of the ration of a swine. (5mg/g being a mean value of the content of proanthocyanidin in Agromed's lignocellulose, cf. Table 14) With an average daily ration of 2,200 g, a fattening pig would eat about 220 mg proanthocyanidin in a day.

Red grapes and grapes seed are considered being rich in proanthocyanidins. According to a report of the USDA Database for the "Proanthocyanidin Content of Selected Foods" [10], there is in average about 60 mg proanthocyanidin in 100g of red grapes. For grape seeds, the value is about 373 mg per 100g.

There are no limits in eating quantities of grapes or other ingredients rich in polyphenols.

There is no evidence in literature linked with the risk of using tannin at the measured level of our product in animal or human nutrition.

[10] USDA Database for the Proanthocyanidin Content of Selected Foods: https://www.ars.usda.gov/ARSUserFiles/80400525/data/pa/pa.pdf, consulted on December 12, 2020

D.2. **Labdane acids (Isocupressic acid)**

Isocupressic acid is a labdane resin acid found in some tree species. Too high dosages of isocupressic acid has been found to lead to abortion in late term pregnant cows (Gardner et al, 1994). A chemical survey was conducted to determine the phytochemical distribution of isocupressic acid in selected North American shrub and tree species with possible association with cattle abortions (Gardner and James, 1999).

The results of this study are presented in table 15.

Table 15: Isocupressic acid content of selected North American gymnosperms

Species	Sample collection site, state (county)	Isocupressic acid content (% dry weight)[a]
Abies lasiocarpa	Colorado (Gilpin, Gilpin)	n.d.[b] n.d.
	Idaho (Bonner)	0.04
	Oregon (Umatilla)	n.d.
	Utah (Cache)	n.d.
Abies grandis	Idaho (Bonner)	n.d.
	Oregon (Umatilla)	n.d. n.d.
Abies concolor	Arizona (Coconino)	n.d.
	California (Pumas, Fresno, Tulare)	n.d. n.d. n.d.
	Colorado (Custer)	0.04
	Utah (Cache)	n.d.
Cupressus macrocarpa	California (El Dorado)[c]	n.d.
Juniperus scopulorum	Arizona (Coconino)	0.42
	New Mexico (Union)	0.33
	Utah (Cache)	0.84
Juniperus osteosperma	Arizona (Yavapai)	n.d.
	Colorado (Montrose)	n.d.
	Nevada (White Pine)	0.07
	Utah (Cache)	n.d.
Juniperus monosperma	Arizona (Coconino)	0.14
	New Mexico (Union)	n.d.
Juniperus communis	Colorado (Park, Delta)	2.88 2.05
Picea pungens	Colorado (Park, Boulder)	n.d. n.d.
	Utah (Summit)	0.17
Picea engelmannii	California (El Dorado)[c]	0.27
	Colorado (Gilpin, Park)	n.d. n.d.
	Idaho (Bonner)	0.04
	Montana (Gallatin)	0.31
	Oregon (Umatilla)	n.d.
	Utah (Cache)	n.d.
Pinus arizonica	California (El Dorado)[c]	n.d.
Pinus contorta	Colorado (Montrose, Gilpin)	0.47 0.29
	Idaho (Bonner)	0.11
	Oregon (Umatilla)	0.28
	Utah (Cache)	0.66
Pinus echinata	Arkansas (Logan)	n.d. n.d.
Pinus edulis	Arizona (Coconino)	n.d.
	Colorado (Montrose)	0.12
	New Mexico (Union)	0.10
	Utah (San Juan)	0.45
Pinus elliottii	Arkansas (Logan)	n.d. n.d.
Pinus flexilis	Colorado (Gilpin, Grand, Grand)	n.d. 0.06 n.d.
	Utah (Cache)	n.d.
Pinus jeffreyi	California (Plumas)	0.54 0.04
Pinus monophylla	Nevada (White Pine)	0.32
Pinus montezume	California (El Dorado)[c]	n.d.
Pinus palustris	Arkansas (Logan)	n.d. n.d,
Pinus ponderosa	Arizona (Coconina)	0.49
	California (Plumas, Tulare, Plumas)	0.42 0.45 0.08
	California (El Dorado)[c]	0.72 1.35
	Colorado (Weld)	0.49 0.58
	Oregon (Deschutes)	0.74
	Utah (San Juan)	0.51
Pinus taeda	Arkansas (Logan)	n.d. n.d.
Pseudotsuga menziesii	California (Plumas, Plumas)	n.d. n.d.
	Colorado (Park)	0.05
	Idaho (Bonner)	n.d.
	Oregon (Deschutes)	n.d.
	Utah (Cache)	0.04

[a] Multiple entries in this column represent results from different collections of the same species from the same location and are not replicate analyses of the same sample.
[b] n.d. = not detected (<0.01%).
[c] Collections made from El Dorado county were made from the forest plots of the USFS, Pacific Southwest Research Station, Institute of Forest Genetics, Placerville, CA.

Significant isocupressic acid levels are defined as those comparable to the level found in ponderosa pine, i.e. >0.50% on a dry weight basis.

The mentioned study from Gardner and James is the first report of the detection of isocupressic acid in many of these species and in particular for jeffrey pine, lodgepole pine and Rocky Mountain juniper. Isocupressic acid had previously been isolated from common juniper (Teresa et al., 1980; San Feliciano et al., 1991; Kagawa et al., 1993), but not from any North American collections. The detection of isocupressic acid in jeffrey pine was not unexpected as this

species is closely related to ponderosa pine. Jeffrey pine is considered to be a separate species from P. ponderosa, but was at one time classified as a subspecies (Munz and Keck, 1959).

Direct association of jeffrey pine with plant-induced abortions in cattle could not be made. Current cattle grazing and management practices in regions where jeffrey pine is abundant may not provide opportunity for late-term pregnant cattle to have access to pine needles of jeffrey pine.

There are no formally reported incidences of cattle abortions resulting from consumption of lodgepole pine (*P. contorta*), but field reports from several individual cattle operators concerning abortions that might have occurred after animals had access to lodgepole pine needles. Isocupressic acid was detected in all collections of lodgepole pine needles, although at slightly lower concentrations than that generally found in ponderosa pine. The detection of isocupressic acid in lodgepole pine needles would seem to lend credibility to the reports that cattle may abort after eating these pine needles.

The southern pines (*P. echinata, P. taeda, P. palustris, P. elliotti*) and the firs ((b) (4)) contained extremely low or undetectable levels of isocupressic acid.

Some reports have been made with reference to juniper trees and abortions in livestock (Norris and Valentine, 1954; Kingsbury, 1964). Juniper was reported to cause abortions in sheep; however, the experimental results could not be repeated in a second feeding trial (Johnson et al., 1976). In the presented study from Gardner and James, the content of isocupressie acid was 0.84% (dry weight) in Rocky Mountain juniper (*Juniperus scopulorum*). These results would further implicate this tree as a potential abortifacient plant in cattle. One-seed juniper (*J. monosperma*) and Utah juniper (*J. osteosperma*) contained little to no isocupressic acid. The highest levels of isocupressic acid were measured in samples of common juniper (*J. communis*), but no cattle abortion cases have been associated to this species. Common juniper is a low growing shrub that typically grows at higher elevations (2000–3300 m) in the mountains of the western United States. During the spring calving periods cattle in late gestation most likely do not graze lands at this altitude.

Despite the potential effect of abortion that some species of Juniperus may have, some coniferous trees of the genus Juniperus have been the subject of deeper investigations. Indeed, rising feed costs and recurring feed shortages necessitate the investigation into alternative and underutilized feed resources. Nutritional characteristics of Juniperus species are either unknown or limited to needles and ground material from small stems. Therefore, a deeper study on the analysis of nutritional characteristics of the entire woody plant material of 4 Juniperus species - *Juniperus pinchotii*, *Juniperus monosperma*, *Juniperus ashei*, and *Juniperus virginiana* - has been done (Stewart et al, 2015).

Agromed developed – in partnership with the (b) (4) - an analytical method to analyze isocupressic acid in Agromed's Lignocellulose. The detailed analytical method is described in Appendix E.

Isosupressic acid was investigated as a representative of the labdane acids (resin acids, ref: Gardner et al, 1999). In comparison with a defined isocupressic standard, isocupressic acid could not be detected in any of the samples (Table 16). OptiCell® is a brand name for Agromed's lignocellulose.

Table 16: Content of isocupressic acid (labdane acid) determined with isocupressic standard [mg/g]

Samples	Isocupressic acid (Labdane acid) rel. to Isocupressic standard (99%, Logan)
	Means value
OptiCell 12.2.	not detected
OptiCell 22.2.	not detected
OptiCell 24.2.	not detected

D.3. **Volatile oils**

The diverse applications (e.g. bactericidal, medicinal, cosmetic) of volatile oils are currently used in several types of industries through the enriched form of essential oils.

The chemical production of essential oils made via an extraction – mostly by distillation from aromatic plants – enrich essential oils with volatile molecules, such as terpenes.

In vitro physicochemical assays characterize most of the essential oils as antioxidants. However, recent work (Bakkali et al, 2008) shows that in eukaryotic cells, essential oils can act as prooxidants affecting inner cell membranes. Depending on type and concentration, they exhibit cytotoxic effects on living cells but are usually nongenotoxic. These findings suggest that, at least in part, the encountered beneficial effects of essential oils are due to prooxidant effects on the cellular level (Bakkali et al, 2008).

As a conclusion of their review work, Bakkali and co-writers (Bakkali et al, 2008) indicate that in the future, essential oils could make their way from the traditional into the modern medical domain. Indeed, many tumor cells are characterized by severe changes in energy metabolism, mitochondrial overproduction and permanent oxidative stress (Czarnecka et al., 2006). Essential oils, due to their capacity to interfere with mitochondrial functions, may add prooxidant effects and thus become genuine antitumor agents. Many radical producing agents are in fact used in antitumor treatments. In the case of essential oils, radical production could be very well controlled and targeted without presenting by itself any toxic or mutagenic side-effects to healthy tissues.

It is clear to Agromed Austria that the content of volatile oils naturally present in Agromed's lignocellulose cannot be compared with contents present in extracted essential oils, bringing the toxicity of those molecules to a non-relevant matter for Agromed's lignocellulose.

As volatile oils are to be found in Agromed's lignocellulose, Agromed Austria studied the quantification of those volatile oils in its product. In partnership with the (b) (4) (b) (4) Agromed developed a method to analyze terpenes and aldehydes in Agromed's lignocellulose. You can find the detailed method of analysis in Appendix E. The volatile aldehydes and terpenes determined by SPME-GC/MS are summed up in Table 17 as TIC*. The TVOC (Total Volatile Organic Compounds) is shown as reference.

*The total ion current (TIC) chromatogram represents the summed intensity across the entire range of masses being detected at every point in the analysis.

Table 17: Volatile aldehydes and terpenes measured with SPME-GC/MS [TIC]

Substance	Opticell 12.2.	Opticell 22.2.	Opticell 24.2.
Hexanal	3.0E+07	2.9E+07	3.3E+07
p-Xylol	0.0E+00	0.0E+00	0.0E+00
Alpha Pinen	2.4E+07	2.4E+07	1.6E+07
Camphene	2.5E+06	2.4E+06	1.5E+06
Verbenene	1.3E+06	1.2E+06	8.3E+05
Benzaldehyd	2.0E+06	2.4E+06	9.2E+06
Benzene, 1,2,3,4-tetramethyl	2.9E+06	2.9E+06	2.0E+06
Beta Pinen	9.9E+06	9.3E+06	8.9E+06
2-Pentylfuran	1.0E+07	1.0E+07	6.4E+06
Oktanal	1.1E+07	1.2E+07	2.2E+07
3-Carene	9.0E+06	8.8E+06	1.3E+07
Capronsäure	0.0E+00	0.0E+00	0.0E+00
p-Cymene	7.7E+06	7.7E+06	4.0E+06
D-Limonene	1.3E+07	1.3E+07	6.0E+06
3-Octene 2-on	0.0E+00	0.0E+00	0.0E+00
2-Oktanal	7.9E+06	9.3E+06	1.2E+07
p-Cymenene	7.6E+05	1.1E+06	1.5E+06
ähnlich p-Cymenene	3.1E+06	3.0E+06	1.4E+06
Nonanal	1.7E+07	1.8E+07	3.1E+07
.alpha.-Campholenal	1.7E+06	1.7E+06	1.1E+06
n.i.	1.4E+06	1.5E+06	1.6E+06
Terpene n.i.	5.8E+05	5.7E+05	1.4E+06
n.i.	1.2E+06	2.5E+06	1.8E+06
Pinocamphone	1.7E+06	1.9E+06	2.5E+06
Pinocarvone	3.5E+06	3.5E+06	2.1E+06
Terpinen-4-ol	4.7E+06	4.8E+06	3.9E+06
n.i.	0.0E+00	9.3E+05	2.2E+06
n.i.	2.3E+06	2.2E+06	1.7E+06
Alpha Terpineol	8.5E+06	9.2E+06	5.0E+06
(1R)-Myrtenal	3.9E+06	4.0E+06	2.8E+06
Dodecan	0.0E+00	0.0E+00	0.0E+00
l-Verbenone	6.1E+06	6.4E+06	4.9E+06
2 decanal	3.1E+06	3.5E+06	8.6E+06
Bornylacetate	1.6E+06	1.8E+06	1.6E+06
car-3-ene-2,5-dione	3.9E+05	1.5E+06	8.0E+05
Alpha Cubebene	0.0E+00	1.7E+06	1.6E+06
Undecan	1.5E+06	0.0E+00	0.0E+00
α-Longipinene	1.6E+06	1.7E+06	1.2E+06
Cyclosativene	8.0E+05	7.8E+05	6.9E+05
Longicylene	1.9E+06	1.8E+06	1.3E+06
Beta Cubebene	0.0E+00	8.0E+05	8.7E+05
Tetradecan	7.8E+05	0.0E+00	0.0E+00
Longifolene	1.2E+07	1.1E+07	7.1E+06
Gamma Muurolene	2.6E+06	2.2E+06	1.4E+06
Alpha Muurolene	2.4E+06	2.4E+06	1.3E+06
Gamma Carinene	1.5E+06	1.5E+06	1.0E+06
Delta Cadinene	1.4E+06	1.8E+06	1.6E+06
Manool oxide	1.3E+06	1.5E+06	1.3E+06
Manool oxide	1.2E+06	1.5E+06	1.3E+06
n.i.	9.3E+05	9.6E+05	8.4E+05
TVOC	***2.2E+08***	***2.3E+08***	***2.3E+08***

E. Regulatory status:

Wood-based lignocellulose is permitted for use as an animal feed material by the European Community under the Registration Number 7.8.1[11] in the Catalog of Feed Materials VO (EU) No. 2017/1017 (7.8.1), without any restriction (target species, limited use). In addition, wood-based lignocellulose is listed in the German Positive List for ingredients to use in animal feed.

The FAO - in its Code of Practice on Good Animal Feeding[12] – ranks wood as an animal feed ingredient. Indeed, most livestock will consume a portion of their bedding. "Bedding material such as wood shavings should also be managed in the same manner as animal feed ingredients." (Section 6, 6.1, 54).

In its 12th edited FAO Animal Production and Health Paper, the FAO has selected some of the most meaningful articles from the World Animal Review about ruminant nutrition. One selected article is about the use of several kinds of lignocelluloses (among which wood-based lignocellulose) in a ruminant nutrition strategy (Prigden and Bender, 1972). To integrate a wood-based ingredient into a ration of a food-processing animal is a studied nutritional strategy presented by experts in animal nutrition.

[11] Link to European Catalog of Feed Materials VO (EU) No. 2017/1017: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R1017&from=EN

[12] The Codex Code of practice on good animal feeding, Section 6, Code of practice on good animal feeding, CAC/RCP 54-2004, http://www fao.org/3/i1379e/i1379e06.pdf

F. Method of manufacture

(b) (4)

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F.1. **Global Flowchart Manufacturing Process**

(b) (4)

The FDA will find in Appendix F a detailed description of each process step and the quality controls that apply.

In the mentioned appendix, Agromed Austria GmbH focuses also on sharing information on the quality of the starting materials.

(b) (4) This is confirmed by the numerous published scientific trials where Agromed's lignocellulose has been used, the non-published trials made by Agromed Austria GmbH in association with Universities as well as the current customers using Agromed's lignocellulose on a daily basis.

F.2. **Quality Control Plan**

(b) (4) is certified in the QS quality system in Germany. The QS-System – the quality assurance system for food in Germany – ensures the control of meat and meat products, fruits, vegetables and feed throughout production and processing.

(b) (4) developed a Quality Control Plan of its products suitable with the conditions of QS-System.

Following examinations are to be integrated in the inspection of raw materials and finished materials. (Table 18)

Table 18: Analysis to be made on raw material per defined batch

Volume in tons / Parameter	Lignocellulose (per 16 000 tons produced)	Lignocellulose from bark (per 2 000 tons produced)
Dioxin (finished material)	1	1
Dioxinlike PCB (finished material)	1	1
Non dioxinlike PCB (finished material)	1	1
Salmonella (finished material)	1	1
Heavy metals (Pb, Cd, As, Hg) (finished material)	1	1
Pesticides (raw material)	1	1

Besides the above mentioned analysis, Agromed Austria GmbH has decided to carry out more inspections on the finished products (Table 19).

Table 19: Analysis to be made on finished product per year

ANALYSIS	**Observed criteria**
Microbiology	Aerobic Plate Count

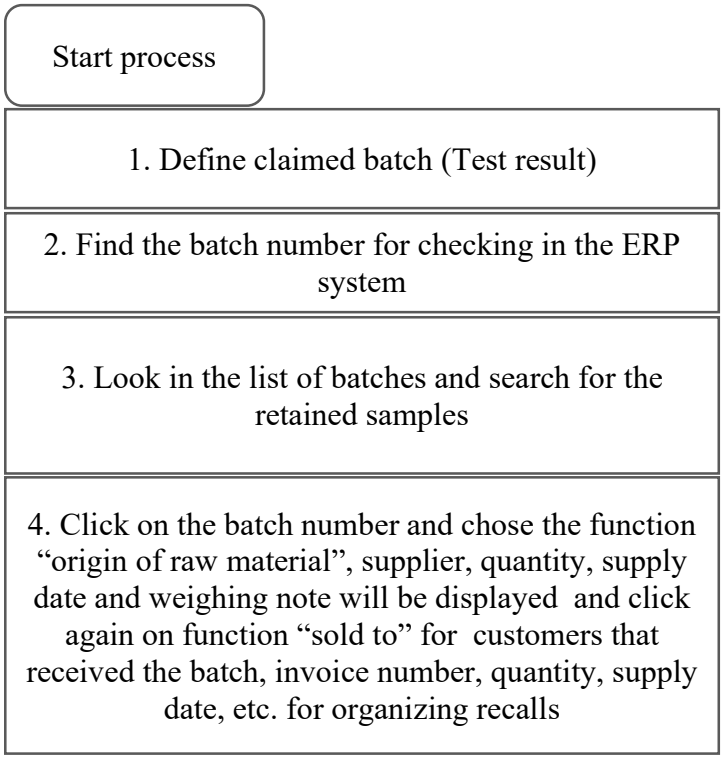
	Coliform Yeast Moulds
Simple Weender	Dry matter Crude protein Crude fat Crude fibre Crude ash N-free extract substances
Advanced Weender	NDF, ADF, ADL
Minerals	Sodium, potassium, magnesium, calcium, phosphor
Trace elements	Copper, iron, zinc, manganese

As a reminder, the FDA can find some reports of the above-mentioned analysis in Appendix C of the present GRAS dossier.

F.3. **Acceptance criteria of a produced batch**

The measurements of humidity together with the monitoring of the two analysis control plans (on raw materials and on finished products) constitute the acceptance criteria of the produced batches. Is there a batch where the analytical values are outside the acceptance zone? The Quality Process "Tracking and Tracing" stands for the traceability throughout the manufacturing process.

Figure 4: Quality Process: Tracking and Tracing



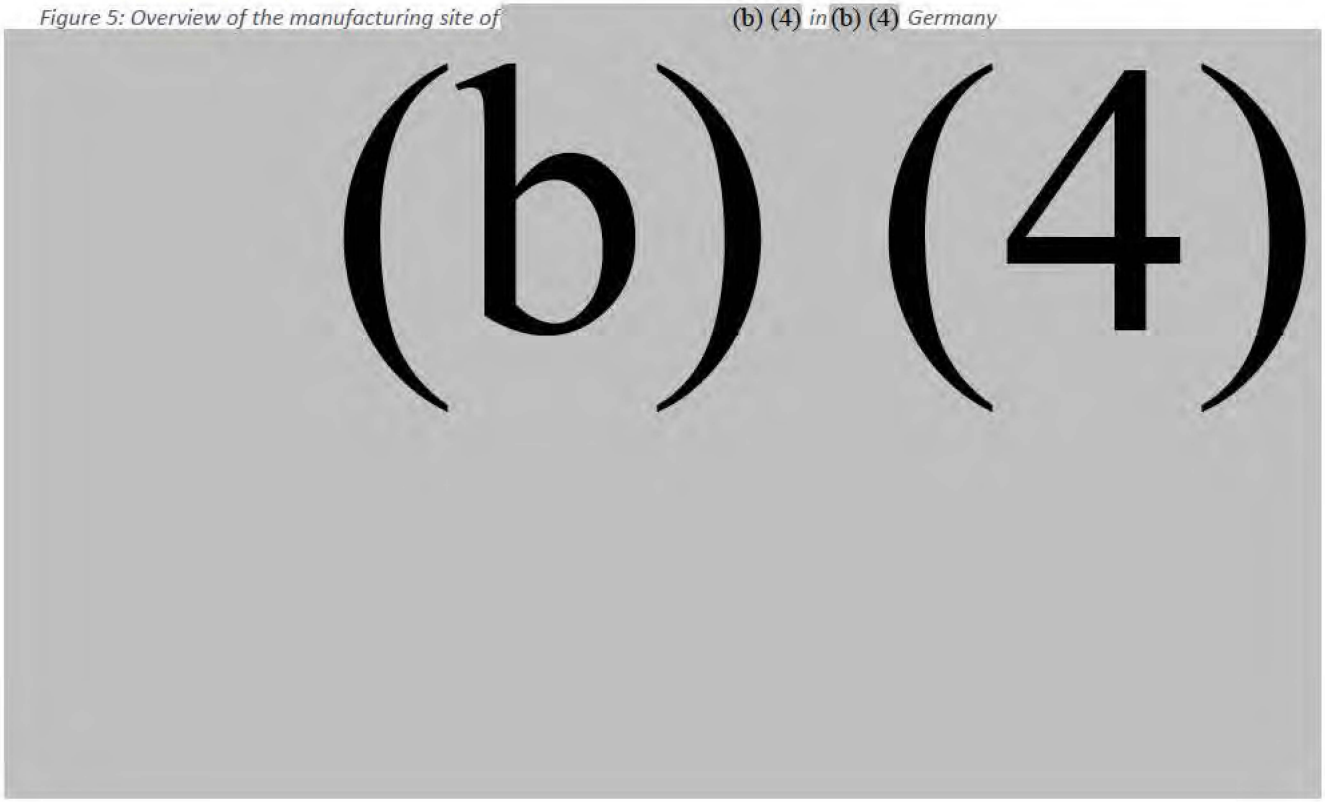
5. Check again the retained samples in the intern laboratory and with external laboratories

6. When results are still outside the acceptance zone, follow Quality Process: Crisis Management

End process

F.4. **Gallery**

Figure 5: Overview of the manufacturing site of (b) (4) *in* (b) (4) *Germany*



G. Specifications

(b) (4)

The feed grade specifications for Agromed's lignocellulose are presented in Table 20.

Table 20: Specifications of Agromed's wood-based lignocellulose, cutout from the last version of the Specification Sheet 16/E/05.03.2018

Parameter	Assay Method	Specification
Physical Characteristics		
Appearance	Visual	powder or free flowing granules
Granulometry	Air jet Sieving	(b) (4)
Odor	Visual	Typical of wood
Color	Visual	brown
Chemical Characteristics		
(b) (4)	Gravimetric method acc. EC 152/2009 annex III-A and VDLUFA III (3.1)	(b) (4)
Crude fat	Hydrolyse, Gravimetric method acc. EC 152/2009 annex III-H method B and VDLUFA III (5.1.1) procedure B	
Crude ash	Gravimetric method acc. EC 152/2009 annex III-M and VDLUFA III (8.1)	
Crude protein	Determination of protein content (Nx6.25) DUMAS, Oilseeds, animal feed and feedingstuffs eq to NEN-EN-ISO 16634-1 Grains, pulses and grain products eq to NEN-EN-ISO 16634-2	
Crude fiber	Intermediate filtration acc NEN-EN-ISO 6865 eq EC 152/2009 annex III-I and VDLUFA III (6.1.1)	

The analytical results of 3 non-consecutive lots of Agromed's lignocellulose (Table 21) shows that the substance – object of the present GRAS dossier – meets its chemical specifications.

Table 21: Analytical results for 3 non-consecutive lots of Agromed's Lignocellulose: Specifications

Parameter	Assay Method	Sample Seal Code 22971613 Report 1116630 v 1, dated August 2020	Sample Seal Code 22971656 Report 1051502 v 1, dated January 2020	Sample Seal Code 22971662 Report 1005966 v 2, dated October 2019
(b) (4)	Cf. table 19	(b) (4)		
Crude fat	Cf. table 19			
Crude ash	Cf. table 19			
Crude protein	Cf. table 19			
Crude fiber	Cf. table 19			

* the measured value for crude protein is above the specification value. The specification values have tolerances on the model of tolerances for the compositional labelling of feed materials or compound feed (Commission Regulation (EU) No 939/2010 amending Annex IV to Regulation (EC) No 767/2009). The crude protein content in the specifications of Agromed's lignocellulose can vary ± 1 unit of the total mass or volume, that is to say from a range of [0.2%;2.2%].

H. References:

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III. Part 3: Target animal and human exposures

A. Exposing food-processing animals to Agromed's lignocellulose

As previously mentioned, Agromed's wood-based lignocellulose is proposed for integrating dietary fibers in swine and poultry food. The amount of Agromed's lignocellulose that target animal species are likely to consume in animal food (including drinking water) as part of the animal's total diet are the following recommended dosages:

Sow: up to 4%
Pig: up to 2%
Piglet: up to 2%
Broiler: up to 2%
Laying hen: up to 2%
Turkey: up to 2%

A.1. **Estimated Daily Intake (EDI)**

The Estimated Daily Intake (EDI) of Agromed's Lignocellulose has been estimated in Table 22 for all species of the intended use of the substance.

Daily Feed Intakes have been taken from a guidance note from the European Food Safety Authority (EFSA, 2017). They are representative of populations of animals generally, and may not be specific to particular categories of food-producing animals raised under specific conditions. The quantity of food consumed per day per animal may not be representative of food intakes for a specific period of time during growth, but rather reflect an average that approximates intakes over an expected lifetime.

Table 22: Estimated Daily Intake in g/day of Agromed's lignocellulose for the target animal species

	Feed Intake (g DM/day)	Dosage of Agromed's Lignocellulose	EDI (g/day)
Gestating sow	2,500	4%	100
Lactating sow	5,280	2%	105.6
Fattening pig	2,200	2%	44
Piglet	880	2%	17.6
Broiler	158	2%	3.16
Laying hen	106	2%	2.12
Turkey	176	2%	3.52

Limits on the fiber content in animal feed rations do not exist. There is no maximal limit for the daily intake of fiber.

In practice, food-processing animals are fed with industrial by-product containing fibers. Diet rations are calculated on a basis of energy and protein content, the fiber content results from the by-products used as fiber source. In practice, there is a lack of fiber in the rations of food-processing animals. Animal Welfare principles remember to supply animals with enough fibre in their diet, in order to support a healthier digestion process.

In Germany, according to the Animal Welfare and Usage Regulations, pregnant sows must have a minimum content of crude fiber in the ration or, more precisely, a minimum consumption of crude fiber (200g / animal, day).

A typical German ration for gestating sow would have a crude fiber content of about 71g/kg ration (Table 23), that is to say 177.5 g crude fiber/day. The supplementation of Agromed's lignocellulose (with a typical crude fiber content of 60%) on top, without any modification of the ration, would lead to an average daily intake of 222.5g crude fiber /day. This crude fiber value is more in line with European Welfare standards. There are no maximal limits in the crude fiber content of a ration for food-processing animals. A balanced dosage of dietary fibers in a ration has to take several factors in consideration such as: energy dilution, total ingestion capacity (satiety) and economics. Fibers are usually underdosed in rations because of only considering the energy dilution factor.

Table 23: Example of typical German diet for gestating sow

Feed ingredients	%
Barley	35
Vegetable oil	1
Soja derivates	10
Wheat bran	7
Dry beet pulp	7
Calcium carbonate	2
Mais	10
Soybean hull	7
Soft wheat	21
	100

A.2. **Possible interactions of Agromed's lignocellulose with other constituents of the feed**

By adding Agromed's Lignocellulose in the feed of food-producing animals, there is no chemical interaction to be noticed.

B. Human Exposure to Agromed's lignocellulose

B.1. **Residues of the notified substance in edible animal tissues**

Insoluble fibers (e.g., lignin, cellulose, certain hemicelluloses) generally pass through the intestinal tract of monogastric animals largely unchanged. Their effect is to stimulate intestinal motility, but are not expected to be absorbed within the digestive tract of either type of animal, and will completely be eliminated in the feces. Insoluble fiber significantly increases fecal bulk, decreases intestinal transit time, delays glucose absorption, and slows down the hydrolysis of starch (Williams and Bollella, 1995).

It should be noted that the majority of the dietary fiber content of Agromed's Lignocellulose is insoluble fiber: above 71,3% of Agromed's lignocellulose based on the typical ADF value measuring the cellulose and lignin fraction summarized in Table 2. Parts of the hemicelluloses are also insoluble (Arabinogalactans, Arabinoxylan, Glucoronoxylan, Xyloglucan and Galactomannans), and should also be counted in the insoluble fiber fraction of Agromed's lignocellulose.

A part of the insoluble fermentable fiber fractions is broken down in the large intestine by the physiological intestinal flora to form lactic acid and short-chain fatty acids (Cuervo et al, 2013). These are normal, physiological digestive processes that do not lead to any residues in the animal product intended for human consumption.

On the other hand, soluble fibers (some hemicelluloses, pectin, beta-glucans, etc…) are metabolized by the enzymatic action of anaerobic bacteria in the colon (Vergara et al, 2013; Williams and Bollella, 1995). Soluble fiber increases stool size moderately, delays intestinal transit time, gastric emptying, and glucose absorption. Soluble fibers are mainly found in fruits, vegetables, and some grains such as oats and barley. In Agromed's lignocellulose, the soluble and fermentable fiber part is smaller than the insoluble fraction. It is estimated to be comprised between: [TDF value (Table 24) – NDF (Table 2) and TDF (Table 24) – ADF (Table 2)], that is to say [0%;12.8%]. There is no literature recalling toxicological effects of soluble fiber fractions.

Table 24: Total Dietary Fiber analysis of Agromed's lignocellulose

Parameter	Method	Sample Report 1732718-614149 – LUFA ITL, dated October 2015
Total Dietary Fibre (TDF)	§ 64 of the German Food, Commodities and Feed Code (LFGB) L 00.00-18	84.1%

As described above, the major effects of dietary fiber occur in the colon. Both soluble and insoluble dietary fiber interacts with the microbiota, the colonic mucosa and muscle to produce several possible effects. The actions of an individual fiber source depend to a large extent on its fermentability. The least fermentable fibers (insoluble fiber such as cellulose) are the most likely to increase stool output (Wenck, 2001). Soluble fiber, which is highly fermentable, is unlikely to have much effect on stool output but will affect bacterial fermentation products in the proximal colon (FAO/WHO, 1997).

It is pertinent to consider that the dietary fiber components from Agromed's lignocellulose either is inert and leaves the animal body or is fermented in the gastrointestinal tract of the targeted animal and generate beneficial molecules. No transmission of dietary fibers in the edible parts of food-processing animals can relevantly be considered.

B.2. **Occurrence of tannin, isocupressic acid and volatile oils in human food items**

There is no evidence that any of the toxicants studied in Part 2 – Section D of the present GRAS notice is being transferred into the edible part of a food-producing animal.

Even in the case of a 1:1 transmission into the edible parts of food-processing animals, the contents of those specific toxicants are so low, in comparison to contents found in food articles, that it excludes any toxicological risk.

See discussion lead in Part 2 – C – C.1. "Condensed tannins" of the present GRAS dossier for the condensed tannins.

There is no evidence linked with the risk of using tannin at the measured level found in Agromed's lignocellulose in animal or human nutrition.

The evaluation of volatile oils in scientific reviews does not suggest harmful effect on the health of human beings. On the opposite, modern medicine plan to use those molecules even more (e.g., cancer treatments).

There are examples of essential oils used in food as flavor ingredients, like coriander (Burdock and Carabin, 2009).

Terpenes are absents (not to be found) in the samples of Agromed's Lignocellulose.

Therefore, Agromed Austria comes to the conclusion that those extractives do not represent a risk in the application of Agromed's lignocellulose in swine and poultry food. Agromed's lignocellulose, in its intended condition of use, has no toxicological effect whatsoever in edible parts of its target animals.

B.3. **Current Research on wood with applications in human medicine**

To relate to the question of the toxicity of the substance on persons, it is worth to say that the Scientific Community is studying at the moment several aspects from wood biochemicals, in order to use them for the protection of human health in various application.

Dr. Lauri Polari refers in a published study (Polari, L. 2015) to the health-promoting effects of wood-derived biochemicals.

The results suggest that some bacteria can utilize hemicellulose and thus it has potential as a prebiotic compound. Also, the efficacy of pine polyphenols to inhibit the growth of prostate cancer was of main interest. It was found that lignans inhibited the proliferation of various cancer cells, and reduced the growth of prostate cancer xenografts in mice. It was found that dietary pine knot extract alleviated the obesity-induced inflammation in adipose tissue.

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IV. Part 4: Self-limiting levels of use

Agromed's Lignocellulose is considered to be self-limiting for technical reasons such as product texture and processability.

There is no scientifically documented health issues related to effect of higher dosages of Agromed's lignocellulose. Scientific work done with 10% lignocellulose prove that such dosage could be given to broilers without any collateral damages (Röhe et al, 2020), (Röhe et al, 2017) – in Part 6, paragraph B of the present GRAS dossier.

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V. Part 5: Experience based on common use in food before 1958.

Plant fibers have always been part of the natural feed source of swine and poultry. Plant fibers in general are characterized by ratios of soluble/insoluble, fermentable/non-fermentable fiber fractions. Since Agromed's lignocellulose is a standardized mix of wood sources, with defined and measurable fiber fractions, it is comparable in a way to other forms of natural plant fiber.

A. Woody material usage in animal nutrition

Agromed Austria found general available information on usages made with woody materials for applications in animal nutrition. Agromed would like to share an overview of feeding experiments done with wood materials. The earliest experiments start before 1958. With the time, the occurrence of such experiments increased.

Agromed Austria does not intend to justify the GRAS status of the substance only through the argumentation on the common use of wood material as feedstuffs before 1958; but this chronological overview should reinforce the view of Agromed's wood-based lignocellulose as a fully-fledged ingredient in animal nutrition.

Wood residues such as wood pulp and bark have been used as energy sources for ruminants during periods of critical feed shortages, but due to their poor energy balance they have never been generally recognized as alternatives for conventional feedstuffs under normal economic conditions.

More than 1.5 million tons sulfate and sulfite pulps from spruce, pine, and fir were fed to cattle and horses in the Scandinavian countries during World War II, when feed supplies were limited.

Feeding of wood-derived feedstuffs in North America has been largely experimental, with the exception of isolated situations in which wood residues have been fed on a commercial scale (National Research Council, 1983).

Research to utilize wood in animal feeds began with the work of the Forest Products Laboratory of the United States Department of Agriculture, located at the University of Wisconsin, on the utilization of wood wastes. An improved process of hydrolyzing sawdust coming from eastern white pine has been developed. The finished product has been fed to dairy cows (Sherrard and Blanco, 1921).

Similar wood sawdust (sources: eastern white pine, Douglas fir) was used in several feeding experiments with sheep and dairy cows (Archibald, 1926; Morrison et al. 1922).

Already in 1959, Stranks proved the digestibility of wood residues (Stranks, 1959), followed by Millett et al. (Millet et al., 1970) which showed the digestibility of 27 species of trees. Nehring and Schramm (Nehring and Schramm, 1951 a & b) reported the advantages of certain tree species for sheep in comparison to others. Nehring and Schütte (Nehring and Schütte, 1950) proved the different digestibility of different parts of trees, i.e., bark and stem.

In 1975, the in vitro digestibility of poplar bark was studied further (Gharib et al., 1975)

Even the presence and positive value of natural amounts of oligosaccharides and phenolic glycosides were proven (Millet et al., 1970).

In 1969, tests were performed regarding chemical compositions of different tree species in regards to digestibility and nutritional value (Enzmann et al., 1969).

In a study performed on 1971, goats showed good effects after being fed with air dried bark (Mellenberger et al., 1971).

Additional studies regarding the performance of animals were done in 1969 and 1975 showing no negative effects on the test animals by feeding them wood bark in the daily diet presented in the study performed in South Dakota (Enzmann et al., 1969; Fritschel et al., 1976; Singh and Kamstra, 1981).

In USA the usability of tree remnants after pulp manufacture as lamb feed has been observed in 1979 (Lemieux and Wilson, 1979).

Lignocellulose is being used worldwide since 2005 as a high quality dietary fiber source with a sold amount of 600,000 tons and used by approximately 15 million animals without a single adverse effect shown since the start of the product in animal nutrition.

B. Woody material as a part of human nutrition

Scientific literature describes the use of e.g. pine bark as food in Scandinavia, northern parts of Russia and North America. The indigenous peoples of Sami (North Scandinavia), the Gitxsan and Dakelh (British Columbia, Canada) as well as the Kutenai (border of Canada – USA: British Columbia; Washington, Montana, Idaho) ate pine bark as basic food regularly and in mentionable amounts.

For the Sami, bark is consistently described as a normal basic food in the 17th and 18th centuries. Pine bark was a regular food both in times with good food supply and in famine years.

Similar the situation in North America: for the Gitxsan, Dakelh and Kutenai, pine bark was a basic food and in some cases medicine and delicacy. Bark was eaten fresh, roasted or dried and ground into flour, which was mixed into other kinds of food. This way bark pine was eaten all year long. The most important nutritional constituents in pine cambium are carbohydrates, vitamins (esp. Vit. C), fiber and minerals (esp. calcium); they made pine bark an important additional component to the protein- and fat-dominated food like fish, meat and reindeer milk.

Pine bark as food in the Americas was first recorded in 1792 among the Carrier people (Dakelh people). Archaeological finds also indicate a much longer tradition of pine bark eating in North America. For both continents it is evident that pine bark was used till the 19th century. The end of pine bark as food was caused mainly by the better availability of alternative food sources (sugar, meal, dried fruit) (Östlund et al., 2009).

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VI. Part 6: Narrative on the Safety of the substance

A. Dietary fibers

It is commonly recognized that dietary fiber is an important component of a healthful diet. In general, nutritionists recommend a diet high in fiber (20-35 g fiber/day). The Nutrition Facts panel required under 21 C.F.R. §I 101.77 provides a good reference, stating as a goal 25 g of total dietary fiber daily. According to the National Center for Health Statistics, consumers average only 14-15 g fiber intake/day, far below moderate levels of dietary fiber. FDA recognizes the importance of fiber in the diet by requiring that fiber occupy a prominent position on the Nutrition Facts label on food labels.

The situation is not any different in animal food. Food-producing animal are often fed high-density nutrients diets (especially high protein and high energy levels). When consuming diets high in protein and energy, an adequate supply with dietary fiber is of particular interest. In Germany, according to the Animal Welfare and Usage Regulations, pregnant sows must have a minimum content of crude fiber in the ration or, more precisely, a minimum consumption of crude fiber (200 g / animal, day).

A joint FAO/WHO Expert Committee on Food Additives (JECFA) Consultation Report (FAO/WHO, 1997) addressed the physiological effects of dietary fiber and stated that it is well established that dietary fiber reaches the large intestine and is fermented by the colonic microbiota resulting in the production of short chain fatty acids (SCFA), hydrogen, carbon dioxide and biomass. Furthermore, the fermentative process dominates human large bowel function and allows for energy to be obtained from carbohydrates not digested in the small bowel, through absorption of SCFA.

Dietary fibers have positive benefits on animal and human health. The major effects of dietary fiber occur in the colon. Both soluble and insoluble dietary fiber interacts with the microflora, and the colonic mucosa and muscle to produce several possible effects. The actions of an individual fiber source depend to a large extent on its fermentability. The least fermentable fibers (insoluble fiber such as cellulose) are the most likely to increase stool output. Soluble fiber, which is highly fermentable, is unlikely to have much effect on stool output but will affect bacterial fermentation products in the proximal colon (FAO/WHO, 1997). Animal gut health is enhanced, and alternatively gut perturbation (e.g., diarrhea in young animals) is also improved (Montagne et al., 2003).

Other sources of fibers (e.g. wheat, sugar beet, soy, rice bran, potato, pea, oat hull, corn hull) have been evaluated by the FDA in a review collecting scientific evidence identified for certain non-digestible carbohydrates that are not listed as a dietary fiber in 21 CFR 101.9(c)(6)(i). Scientific conclusions could be drawn as well about physiological effects that are beneficial to human health (Science Review FDA; 2016).

Purified dietary fibers may reduce acutely the absorption of some vitamins and minerals by binding or entrapping them in the small intestinal lumen. However, there is little evidence that population groups (including children) consuming nutritionally adequate diets rich in high fiber foods, such as vegetarians, have any problems with vitamin or mineral deficiencies (FAO/WHO, 1997; Williams and Bollella, 1995).

Williams and Bollella (1995) reviewed the scientific literature related to the safety of consumption of high fiber diets in children. They concluded that a small loss of energy, protein, and fat may occur with a high intake of dietary fiber. However, the small loss of energy was unlikely to be significant to children consuming adequate levels of major nutrients. They proposed that even with a doubling of the current dietary fiber intake, there is unlikely to be an adverse effect on serum vitamin and mineral concentrations in healthy US children consuming a balanced diet containing adequate levels of nutrients. In addition, they reported that even though studies linking dietary fiber with increased intestinal gas and stomach distress are lacking, fiber supplements have been shown to reduce the symptoms of chronic recurrent stomach pain in childhood.

Consumption of dietary fiber also may lead to many health benefits, including lower risk of obesity, diabetes, and various gastro-intestinal (GI) diseases. Total fiber intake influences several metabolic functions, including the absorption of nutrients and carbohydrates. Increased fiber consumption benefits a number of GI disorders including: constipation (insoluble fibers helping to promote regular bowel movements), duodenal ulcer, and gastroesophageal reflux disease.

The Institute of Medicine (IOM, 2002) has not established a tolerable upper intake level for dietary or functional fiber. Some of the fibers such as guar gum, inulin and oligofructose, fructooligosaccharides, polydextrose, resistant starch, and psyllium have been found to cause gastrointestinal distress, including abdominal cramping, bloating, gas, and diarrhea (IOM, 2002).

Available evidence also indicates that abrupt increase in the intake of dietary fiber in some people may result in abdominal cramping, bloating or gas. These symptoms can be minimized or avoided by increasing intake of fiber-rich foods gradually and increasing fluid intake to ~2 liters/day. In general, dietary fiber as part of a balanced diet has not been found to adversely affect the calcium, magnesium, iron, or zinc status of healthy people at recommended intake levels (IOM, 2002).

B. In vivo animal studies with Agromed's lignocellulose

An intensive search on the general available published studies should support the safety of the use of Agromed's lignocellulose in the targeted animal diets.

This section provides a summary of in vivo animal studies utilizing Agromed's lignocellulose to evaluate the safety of the substance. Researches underline some potential positive effects occurring from the use of Agromed's lignocellulose on animal digestive health, but Agromed Austria does not want to claim those effects. The only interest of mentioning the following in vivo studies is the proof that the substance Agromed's lignocellulose is safe for use in the targeted animals. Agromed Austria does not intend to claim any nutritional effect.

Worldwide, experts from the scientific community lead several studies on the use of Agromed's lignocellulose in animal feed. This, as a sign of the attested security regarding the use of Agromed's Lignocellulose as a feed ingredient in the food of food processing-animals. No adverse effects associated with Agromed's lignocellulose were reported in the published literature.

B.1. Eubiotic Lignocellulose Supplementation in Sows Reduced Dry Period and Preweaning Mortality of Piglets (Reyes et al., 2015)

Aim of the study

A feeding trial was conducted in a commercial swine farm in order to evaluate the efficacy of supplementing eubiotic lignocellulose (Agromed's lignocellulose) on reproductive performance of breeder sows.

Material and method

Seventy (70) Landrace x Large White female pigs were allotted to two (2) dietary treatments (control and Agromed's lignocellulose) following randomized complete block design, with parity as blocking factor. Agromed's lignocellulose supplementation was given at 25 and 10kg/ton add-on at gestating and lactating diets, respectively. Gestating diets were provided after the first insemination until two (2) weeks before expected date of farrowing. Lactating diets were provided fourteen (14) days before expected date of farrowing, after sows were moved to the farrowing house until the next insemination after weaning.

Average gestating and lactating feed intake based on farm records were 2.51 kg and 5.56 kg, respectively. Controlled feeding (three (3) times a day) was practiced and no feed refusal was observed throughout the feeding trial. The trial duration was about six (6) months and three (3) weeks.

Results and conclusion for the present GRAS dossier

Agromed's lignocellulose supplementation during gestation and lactation reduced preweaning mortality of piglets and dry period of sows. However, supplementation had no significant effect on other variables measured (length of parturition, litter size born alive, mummified fetus, still birth, birth weight, among others). This indicates that increasing the fiber content of the diet by adding Agromed's lignocellulose during gestating and lactating stages enhances piglet survival and indirectly improves the reproductive performance of sows by shortening the dry period.

For the purpose of the present GRAS notice, it is worth notifying that Agromed's lignocellulose did not present any adverse effect and was safe for the animals in this trial.

B.2. Additional data on the use of Agromed's lignocellulose in sows

In the published study of da Silva et al. (da Silva et al., 2012) named „Effects of dietary fibers with different physicochemical properties on feeding motivation in adult female pigs", sows are fed with a low inclusion diet (five (5)% of a similar wood-based lignocellulose) during seven (7) days and a high inclusion diet (ten (10)% of a similar wood-based lignocellulose) during seven (7) days. No negative effects are to be noticed from such dosages, which states for the safety of such product.

An experimental trial named "Inducing satiety in sows through nutritional manipulation of gastrointestinal tract volume and volatile fatty acid production" (Muller et al., 2015) was published in Animal Production Science. But for some reason, its complete report is untraceable on the internet. There is only a summary available online. Agromed Austria does not possess the complete report for this experiment. In this mentioned experiment, Agromed's lignocellulose was given to sows at a dosage of 4% for a period of two (2) weeks. No negative effects on the health of the animals were noted.

A non-published trial (Sarandan et al., 2008) listed in Part7 – Section B "unpublished data", employs a dosage of 3% of Agromed's lignocellulose (under the brand name OptiCell®) for gestating sows and 0.5% for lactating sows during one reproductive cycle from insemination until weaning. Again, using Agromed's lignocellulose was safe in this experiment and contributes to attest the safety of using Agromed's lignocellulose for the targeted animals.

B.3. Effects of soybean hulls and lignocellulose on performance, nutrient digestibility, microbial metabolites and immune response in piglets (Slama et al., 2020)

Aim of the published study

A feeding trial with ninety-six (96) piglets was performed to investigate the effect of added soluble and insoluble dietary fiber sources on performance, apparent total tract digestibility (ATTD), concentration of microbial metabolites and pro-inflammatory marker genes as indicators for immune response.

Materials and methods

Piglets were allotted to four (4) treatments: control, with soybean hulls and two different kinds of lignocellulose from Agromed Austria GmbH (one of them being Agromed's lignocellulose). All diets were calculated with a similar total dietary fiber content, being isofibrous. However, soybean hulls contained more soluble dietary fibers compared to lignocelluloses.

A starter diet was fed the first fourteen (14) days after weaning followed by a grower diet up to the end of the trial (day fifty-four (54)). The diets were isoenergetic and were calculated to reach or exceed given recommendations. For the evaluation of ATTD of various nutrients, titanium dioxide (TiO_2) was included as inert marker in the grower diet at 0.5%.

Results and conclusion for the present GRAS dossier

Finally, no impact on immune response was detected. In conclusion, soybean hulls affected the apparent total tract digestibility positively and lignocellulose prevented the formation of cadaverine. No overall direct response of soluble nor of insoluble dietary fiber for the inclusion level were observed.

But the practicability of the dosages proposed for Agromed's lignocellulose and its safety in this study are demonstrated.

B.4. Additional data on the use of Agromed's lignocellulose in piglets

An additional study (Pluske et al., 2014) evaluated dosages up to 9% of Agromed's lignocellulose (under the brand name OptiCell®) given to piglets during a period of two (2) weeks after weaning, with no damaging effects observed on animals. This as a statement of the safety of the substance for its use in swine nutrition.

An additional non-published trial (Sun et al., 2019) listed in Part7 – Section B "unpublished data", mentions a trial done with a diet supplemented with 2% fiber. The added fiber in the experiment is Agromed's lignocellulose. In the experiment, there was no assumption made suggesting any toxicological effect of Agromed's lignocellulose used at a dosage of 2%. This experiment gives an additional proof of the safety of Agromed's lignocellulose used at the mentioned dosage of 2% in piglets.

This experimental trial (Jenkins et al., 2015) was published in Animal Production Science, but for some reason, its complete report is untraceable on the internet. There is only a summary available online. Agromed Austria does not possess the complete report for this experiment. In this mentioned experiment, Agromed's lignocellulose (under the brand name OptiCell®) was given to weaner pigs at a dosage up to 5.1% with no damaging effects on animal health.

B.5. Effects of dietary supplementation of the lignocelluloses FibreCell and OptiCell on performance, expression of inflammation-related genes and the gut microbiome of broilers (Zeitz et al, 2019)

Aim of the published study

This study investigated the hypothesis that dietary supplementation of wood-based lignocellulose in broilers influences the gut bacterial population, and, through these changes, influences broiler performance positively.

Objective and description

Ninety-six (96) day-old male Cobb500 broilers were allotted to three (3) experimental groups and fed three (3) different maize-wheat-soybean meal-based basal diets during days one (1) to ten (10), eleven (11) to twenty-one (21), and twenty-two (22) to thirty-five (35). The basal diets were fed to the control group and were supplemented with 0.8% of two (2) different kinds of wood-based lignocellulose (one of them being Agromed's lignocellulose).

Body weight and feed consumption were determined, and at slaughter (day thirty-five (35)), carcass and gizzard weights and gizzard content pH were recorded, and samples of jejunum, cecum, and colon mucosa and of cecum digesta were collected from fifteen (15) birds/group.

Results and conclusion for the present GRAS dossier

Growth performance and feed intake were not influenced. The data obtained from this study indicate that the susceptibility of lignocellulose to fermentation is crucial for mediating its effects on the bacterial population in the cecum.

Again, Agromed's lignocellulose was safe to use in the diet of day-old broilers at a dosage of 0.8%. This as an example of the safety in use of Agromed's lignocellulose.

B.6. Additional data on the use of Agromed's lignocellulose in broilers

The published study (Abdollahi et al., 2018) employs a similar wood-based lignocellulose at a dosage of 1%, with no negative effects on the animals, reinforcing the non-toxicological argumentation of Agromed's lignocellulose.

The additional recently published study (Hou et al., 2020) mentions the use of Agromed's lignocellulose at a dosage up to 4% in broilers.
The mentioned dosages of this study (up to 4%) are superior to the dosages presented for broilers in the present GRAS notice, and still do not show any adverse effects or risk for the health of the animals, but promote some health benefits and is safe in practice.

This scientific experiment (Röhe et al., 2020) uses a similar wood-based lignocellulose at dosages up to 10%, without noticing any damageable effects on animal health. This as a statement of the safety of wood-based lignocelluloses such as Agromed's lignocellulose.

B.7. **Supplementing the feeds of layer pullets at different ages with two different fiber sources improves immune function (Hussein et al, 2017)**

Aim of the published study

The purpose of this study was to study the effects of lignocellulose supplementation on immune function in layer pullets at different stages of growth. Two (2) separate experiments were conducted.

Materials and methods

In one of the experiments, Hy-Line Brown layer grower pullets aged ten (10) weeks were kept in a house containing eighteen (18) pens. The three (3) experimental diets were: control diet (a commercial grower diet with no fiber added), the control diet supplemented with 1.5% OptiCell C5 (OptiCell® is a brand name for Agromed's lignocellulose), and the control diet supplemented with 1.5% of a similar wood-based lignocellulose. Fresh water was available at all times.

Results and conclusion for the present GRAS dossier

With a dosage of Agromed's lignocellulose up to 1.5%, positive effects can be seen on the immune system of young and grower pullets.

For the present GRAS dossier, it is essential to underline that no negative effects on the health of animals were noticed, attesting the safety of the use of Agromed's lignocellulose at 1.5% for layers.

C. Conclusion to scientific research

None of the published studies and other part-published or unpublished experiments mentioned any toxicological effect or health risk linked to the use of Agromed's lignocellulose in the targeted animal species. The dosages used in the mentioned experiments reinforce the validity and consistency of the dosages defined in the Part 3 "Toxicology" of the present GRAS dossier.

Especially, studies in broilers at higher dosages (Hou et al., 2020; Röhe et al., 2020) shows that using a wood-based lignocellulose – like Agromed's lignocellulose – in a fragile organism at dosages up to 10% does not lead to health risks. Similar dosages used for layers and turkeys follow the same principle of risk devaluation.

Also, studies in piglets evaluating higher dosages (up to 9%; Pluske et al., 2014) attest the security of using Agromed's lignocellulose at lower dosages for piglets but also pigs and sows.

A thorough review of the publicly available scientific literature as well as other part-published and unpublished experiments failed to reveal evidence of any adverse effects associated with consumption of Agromed's lignocellulose.

D. A qualitative source of dietary fiber

Traditional fiber sources bring automatically an amount of soluble/insoluble fibers in the ration. The ratio soluble/insoluble varies from one cereal to another and can slightly vary from one harvest to another. Modifying the quantity of those ingredients in the diet of a sow or a pig for example will strongly impact the physical properties of the digesta, with effects on the digestive process.

Agromed's wood-based lignocellulose has a standardized recipe. Generally, the monitoring of nutritional values shows that the different fiber fractions (e.g. NDF, ADF, ADL) remain stable (Table 26).

Table 25: Cutout of the monitoring plan of the fiber fractions in Agromed's lignocellulose

Parameters	Unit	**Sample Seal Code 22971656 Report 1051502 v1, dated March 2020**	**Sample Seal Code 22971655 Report 1047988 v1, dated March 2020**	**Sample Seal Code 22971613 Report 1116630 v1, dated October 2020**
Fiber fractions according to Van Soest				
NDF	%, on dry			(b) (4)
ADF	%, on dry			
ADL	%, on dry			

E. Similarity/Comparability with other GRAS products

E.1. **Dietary fibers**

Since Agromed's lignocellulose is a standardized mix of wood sources, with defined and measurable fiber fractions, it is comparable to other forms of natural plant fiber. Currently there are 11 fiber sources possessing a GRAS status with applications in food. Most of those ingredients are currently used in animal feeding quite commonly (table 27).

Table 26: Fiber food ingredients possessing a GRAS Dossier

GRN No.	Substance	Date of closure
646	Pecan shell fiber	Oct 12, 2016
599	Citrus fiber	Feb 17, 2016
541	Insoluble fiber from citrus peel	Mar 24, 2015
525	Pea fiber	Sep 24, 2014
478	Rice hull fiber	Sep 14, 2015
430	Sugar beet fiber	Mar 6, 2013
427	Corn hull fiber	Sep 12, 2012
373	Rice bran fiber	Aug 19, 2011
344	Barley fiber	May 23, 2011
342	Oat hull fiber	Dec 23, 2010
310	Potato fiber	Jun 10, 2010

Lignocellulose is contained in all those substances, with variation in its proportion. Thus lignocellulose, per se, can be considered as GRAS. Lignocellulose is the main ingredient of Agromed's lignocellulose.

E.2. **Insoluble fiber from citrus peel**

A numerous amount of GRAS notifications referring to dietary fibers already have been approved by the FDA. Among others, we can find the citrus fiber (GRAS No. 599) and particularly the insoluble fiber from citrus peel (GRAS No. 541) which is rich in insoluble dietary fibers under comparable conditions as Agromed's lignocellulose (Table 28).

Table 27: Fiber types comparison

Parameter	Units	Results		Reference method
		Insoluble fiber from citrus peel	Agromed's lignocellulose	
NDF	%	95.05	(b) (4)	Van Soest
ADF	%	80.73		Van Soest
ADL	%	13.16		Van Soest

Source: GRAS No. 541 and Table 2 from this dossier.

The insoluble fiber from citrus peel has been evaluated as safe for the intended use of a moisture retention agent, flavor enhancing agent, or processing aid in baked goods, pastas, salad dressings, confectionery, processed cheese spreads, frozen food entrees, and comminuted and whole muscle meat and poultry products at a maximum level of 5%; and as a flavor enhancer in non-carbonated beverages and fruit drinks; as a seasoning in brine and in comminuted and whole muscle meat and poultry products, and as an ingredient in salads, sauces, meats, fillings, dips, baked goods, dairy products, fruit- and vegetable based products, and pizza at a maximum level of 5%.

The GRAS notice 541 "insoluble fiber from citrus peel" has been closed in March 2015 with "FDA has no questions".

E.3. **Cellulose derivates**

Naturally occurring cellulose is the major carbohydrate of green plants, and thus, is a regular component of the normal human diet. Cellulose, a major component of Agromed's lignocellulose (about 42,2% according to table 2), as well as modified forms of cellulose (i.e., carboxymethyl cellulose, hydroxpropylmethyl cellulose, methylcellulose, and sodium carboxymethyl cellulose) have been recognized as GRAS substances since 1973 (LSRO, 1973).

The committee that evaluated the health aspects of cellulose and cellulose derivatives as food ingredients concluded:

> "There is no evidence in the available information on pure and regenerated cellulose, including microcrystalline cellulose, that demonstrates or suggests reasonable grounds to suspect, a hazard

to the public where they are used at levels that are now current, or that might reasonably be expected in the future."

JECFA established a group acceptable daily intake (ADI) of "not specified" for cellulose and modified celluloses at its thirty-fifth meeting (JECFA, 1989). The modified celluloses included ethyl cellulose, ethyl hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, methyl ethyl cellulose, and sodium carboxymethyl cellulose; cross-linked sodium carboxymethyl cellulose was added at the fifty-ninth meeting in 2002 (JECFA, 2002). The toxicological monograph for the JECFA evaluation concluded that modified celluloses as a group are of very low toxicity.

The safety of naturally occurring cellulose and cellulose derivatives is very well established and supported by the scientific community.

Ethyl Cellulose has been considered safe for its intended use as a viscosity modifier, thickener, film-former, stabilizer, filler and actor in the thermal gelation in grain products, vegetables, fruits, milk and milk products, legumes, nuts and seeds, fats and oils, sugars and sweets, and beverages at level ranging from 0.0075 to 5%, by the FDA. The corresponded GRAS notification (GRN No. 470) has been evaluated in 2013. Wood pulp is used as a starting material to produce ethyl cellulose, which happens chemically by aid of ethyl chloride. Among ethyl cellulose, there are numerous other cellulose derivatives for which the GRAS status has been confirmed by the FDA. The following cellulose derivatives are listed either as GRAS or permitted for direct addition to food as food additives: sodium carboxymethyl cellulose; methyl cellulose; cellulose acetate; ethyl cellulose and hydroxypropylmethyl cellulose. The current regulatory approvals of cellulose and its derivatives, including ethyl cellulose, are summarized in Table 29.

Table 28:Regulatory Status of Cellulose Derivatives

Ingredient Name	Regulatory Status	Food uses	Specifications
Ethyl cellulose	21 CFR § 172.868; 73.1	Binder, filler in vitamins; tablet coating; fixative in flavorings	FCC; USP
	21 CFR §182.90 (GRAS 470)	Substances migrating to food from paper and paperboard products.	
	21 CFR §73.1	Diluents in color additive mixtures for food use exempt from certification. For marking foods and for coloring egg shell	

Methyl cellulose	21 CFR §182.1480	Multipurpose food use	FCC; USP
Methyl ethyl cellulose	21 CFR §172.872	In food generally consistent with GMP	21 CFR 172.872(b)
Hydroxypropyl cellulose	21 CFR §172.870; (GRN 190)	In food generally consistent with GMP	
Hydroxypropyl methyl cellulose	21 CFR §172.874; (GRN 213)	In food generally consistent with GMP	FCC
Carboxymethyl cellulose	21 CFR §175.105; §175.300; §182.70; unpublished GRAS for direct food uses	Multipurpose food use	
Sodium carboxymethyl cellulose	21 CFR §182.1745	Multipurpose food use	FCC; USP

Source: GRAS No. 470 – Ethyl Cellulose

F. Research Projects on the use of wood-based feed ingredients in the United States

Rising feed costs and recurring feed shortages necessitate the investigation into alternatives and underutilized feed resources. Wood-based solutions have been explored recently by different teams of American researchers. The acknowledgement of using wood-based products as feed ingredients has already been made by the scientific community.

For example, with the tree genus Juniperus, from which nutritional characteristics are either unknown or limited to leaves and ground material from small stems. A deeper study on the analysis of nutritional characteristics of the entire woody plant material of 4 Juniperus species - *Juniperus pinchotii*, *Juniperus monosperma*, *Juniperus ashei*, and *Juniperus virginiana* - has shown interesting nutritional values (Stewart et al, 2015).

Two years later, an evaluation of the use of ground Juniperus as a feed ingredient for ewe with effects on the animal performance was done. The objective of this research was to evaluate effects of replacing sorghum × Sudangrass hay with ground Juniper in gestating ewe supplements on pre- and postpartum growth performance, serum metabolites and hormonal concentrations, milk fatty acid composition, and progeny preweaning performance. (Stewart et al., 2017)

The effects of replacing cottonseed hulls with dry redberry Juniper leaves in Rambouillet lambs diets were studied, in a study with 2 feeding periods. Effects on birth weight, average daily gain and average daily dry matter intake (among others) have been seen. (Whitney et al, 2010).

Also, the effects of using ground redberry juniper and dried distillers grains with solubles in Rambouillet lamb feedlot diets on growth, blood serum, fecal, and wool characteristics were evaluated (Whitney et al, 2014).

And also, the effects of using ground woody plants from different Juniperus species in Rambouillet wether lamb feedlot diets on growth performance, blood serum, and rumen parameters were evaluated (Whitney et al, 2017).

G. Safety Determination

The subject of the present GRAS determination is the use of Agromed's lignocellulose as a dietary fiber source to be added in swine and poultry food.

Agromed's lignocellulose is composed of fibers from non-processed tree parts (trunk and bark). Agromed's lignocellulose is consistently manufactured with current Good Manufacturing Practice (GMP) for feed. The manufacturing process does not involve any chemical processing aid.

Lignocellulose products are in use for animal nutrition in Europe, Asia, Latin America and Australia since 2005 without any negative side effects. In the European Union lignocellulose is a feed material listed in the Catalog of Feed Materials VO (EU) No. 2017/1017 (7.8.1). Agromed Austria GmbH can provide feeding trials to evaluate the recommended dosage presented in the Part 3 "Toxicology" of the present GRAS dossier, in accordance with animal age and agricultural use.

There is common knowledge of a history of animal and human consumption of products derived from wood.

In the food industry, wood has a long tradition of use in many food contact applications.

Consumption of dietary fiber leads to many health benefits. Total fiber intake influences several metabolic functions.

As per the toxicity of Agromed's lignocellulose, dietary fibers are no components disposing of toxicological effects.

The evaluation of some possible toxicants (condensed tannins, volatile oil and isocupressic acid) has been made and even in the case those molecules would pass unchanged (there is no evidence of that) in the animal products destined to human consumption, the naturally present levels of those molecules are too low to generate any toxicological effects.

An extensive literature search for safety and toxicity information on wood-based lignocellulose was conducted and was utilized for this review. Based on a critical evaluation of the pertinent data and information summarized, Agromed Austria GmbH has determined through scientific procedures that the addition of Agromed's Lignocellulose meeting the specification cited in the present dossier and manufactured according to current Good Manufacturing Practice is Generally Recognized As Safe (GRAS).

In coming to its conclusion that Agromed's lignocellulose is GRAS, Agromed Austria GmbH relied upon the findings that neither Agromed's lignocellulose nor any of its constituents pose any toxicological hazards or safety concerns at the intended use levels, as well as on published safety studies and other articles relating to the safety of the product. Other qualified and competent scientists, reviewing the same publicly available toxicological and safety information, would reach the same conclusion.

VII. Part 7: List of supporting data and information

A. Generally available scientific data and information

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B. Unpublished data

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Analytical Report

(b) (4)
(b)(6)
(b) (4)

Reportnr. : **1116630 version 1**
Product recognized as
Product Specification : OptiCell C5
Reference
AWB / BarCode
Packing : Plastic, ambient
Sample Type : Sample

Disponent Number
(b) (4) Date : 26 Aug-2020
Samplesize (kg) : 0,768
Sealed / Seal Code : Yes / 22971613
Sample Arrival Date : 23 Sep-2020 11:31
ReportDate Version : **13-Oct-2020 10:52**

Composition Determination

Weender

Parameter	Result (as received)		Result (On Dry)		Result (12% moisture)	
Moisture - 103	(b) (4)	%			Q	R
Dry Matter (calculated):		%				
Fat / Oil B (acid hydrolyse)		%	(b) (4)	%	Q	R
Fiber		%		%	Q	R
Ash (550°C)		%		%	Q	R
NDF (Neutral detergent fiber)		g/kg		g/kg		O
Proteine (Nx6,25) .		%		%	Q	

Common

Parameter	Result (as received)		Result (On Dry)		Result (12% moisture)	
ADF	(b) (4)	g/kg	(b) (4)	g/kg		O
ADL		g/kg		g/kg		O

Q - Analyses ISO 17
R - Carried out by (b) (4)
O - Outsourced

Requested 23-Sep 2020 by (b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1116630 version 1**	Disponent Number	
Product recognized as			
Product Specification	: OptiCell C5	Sampling Date	: 26-Aug 2020
Reference		Samplesize (kg)	: 0,768
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Packing	: Plastic, ambient	Sample Arrival Date	: 23 Sep 2020 11:31
Sample Type	: Sample	ReportDate Version	: **13-Oct-2020 10:52**

ANNEX

Method Descriptions

Composition Determination

Weender

Method Description	Method Code
Determination of ash; gravimetric method acc EC 152/2009 annex III-M and VDLUFA III (8.1)	acc EC 152/2009
Determination of crude fibre content intermediate filtration acc NEN-EN-ISO 6865 eq EC 152/2009 annex III I and VDLUFA III (6.1.1)	acc NEN-EN-ISO 6865
Determination of fat (hydrolyse); gravimetric method; acc EC 152/2009 annex III-H method B and VDLUFA III (5.1.1) procedure B	acc. EC 152/2009
Determination of moisture, gravimetric method; acc EC 152/2009 annex III-A and VDLUFA III (3.1)	acc. EC 152/2009
Determination of NDF (Neutral detergent fiber)	LUFA 6.5.1.
Determination of Proteine content (Nx6,25) DUMAS, Oilseeds, animal feed and feedingstuffs eq to NEN EN ISO 16634 1 Grains, pulses and grain products eq to NEN EN ISO 16634 2	

Common

Method Description	Method Code
Determination of ADF (Acid detergent fiber)	LUFA 6.5.2
Determination of ADL (Acid detergent Lignin)	LUFA 6.5.3

Abbreviations:

acc: in accordance with

eq: Equivalent to

US008673383B2

(12) **United States Patent**
Neufeld

(10) **Patent No.: US 8,673,383 B2**
(45) **Date of Patent: Mar. 18, 2014**

(54) **ROUGHAGE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 626 days.

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A23L 1/212	(2006.01)
A23L 1/30	(2006.01)
A23K 1/18	(2006.01)
A23K 3/00	(2006.01)
A21D 4/00	(2006.01)
A23B 7/154	(2006.01)
A23C 3/00	(2006.01)
A23L 3/34	(2006.01)
C12H 1/10	(2006.01)

(52) **U.S. Cl.**
USPC **426/615**; 426/2; 426/53; 426/54; 426/72; 426/321; 527/103

(58) **Field of Classification Search**
USPC 426/615; 527/103
See application file for complete search history.

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(57) **ABSTRACT**

The invention relates to dietary fiber for human and animal nutrition and more particularly to roughage consisting of a fiber formulation containing lignocellulose. Said formulation contains a fraction of a fibrous substance that is fermentable in the digestive tract and a fraction of a fibrous substance that is poorly or non-fermentable in the digestive tract.

26 Claims, No Drawings

ROUGHAGE

CROSS REFERENCE TO RELATED APPLICATIONS

This application is the US national phase of PCT application PCT/EP2007/009791, filed 13 Nov. 2007, published 22 May 2008 as WO2008/058698, and claiming the priority of Austrian patent application A1875/2006 itself filed 13 Nov. 2006, whose entire disclosures are herewith incorporated by reference.

The invention relates to additives for human and animal nutrition and more particularly to roughage.

The importance of roughage for human and animal health, digestive stability and well-being is indisputable. In the area of farm animal nutrition, this fact has been incorporated as part of an EU guideline in effect since Aug. 4, 2006 (for the Federal Republic of Germany: Federal Law Gazette, Volume 2006 Part I No. 37 §25(6)]. In all-purpose feed for pregnant gilts and sows, a crude fiber content of at least 8% on a dry basis is prescribed by this guideline. In any case, when feeding animals, care must be taken that an intake of at least 200 g of crude fiber per day is guaranteed up to one week before the farrow date.

The colloquial expression "roughage" is to some degree problematic. First of all, because the so-named feed components are not at all useless ballast as the expression suggests, and secondly since the material in question involves a complex group of substances with manifold physiological effects. A common characteristic is that they pass through the intestines undigested. All roughage materials are polysaccharides with the exception of lignin, a polymer of phenylpropane. However, the definition and further classification of roughage is inconsistent. According to the "biological" definition, roughage materials are carbohydrates that are not enzymatically decomposed in the small intestines and consequently reach the large intestines, plus lignin. This definition also encompasses the starch fraction that is not enzymatically decomposed in the small intestines (resistant starch), and is fermented by the flora in the large intestines, thus resulting in a biological effect in the large intestines. One "chemical" definition states as follows: roughage includes non starch polysaccharides ("structural carbohydrates" as they are called in German) plus lignin. The latter definition does not include the resistant starches, which results in the effect of such a starch fraction, which transfers to the colon, remaining unaccounted for.

If the origins of roughage are considered, it can be classified into the following: a) fibers designed to maintain plant structure, b) plant mucilage and c) stored polysaccharides. Roughage of an animal origin, such as cutine, is practically meaningless. The fact that roughage has some fibrous structure in it has led to the terms vegetable fiber, fiber and the increasingly popular term dietary fiber, as is used in the English language. Unfortunately, these terms are also confusing since not all roughage contains fibrous structures, as can be seen in the above list. Also worth mentioning is the term "crude fiber", which includes various structural materials that are insoluble in dilute acids and bases as determined through Weender analysis. The crude fiber fraction is usually much lower than the roughage fraction, with the ratio of these two values fluctuating depending on the feed composition. To understand the physiological effect, it makes sense to classify roughage into soluble/insoluble fractions and easily fermentable/difficult-to-ferment or totally impossible-to-ferment fractions.

The most common roughage components include cellulose, hemicelluloses, lignin, inulin, fructooligosaccharides and plant hydrocolloids.

Cellulose is the characteristic component of plant cell walls and determines the structure thereof for the most part. It is the most widespread macromolecule on earth. Cellulose is made up exclusively of 1,4-linked β-glucose units, being a high molecular weight polysaccharide with an un-branched chain-like molecular structure. Cellulose is water-insoluble and has a high water-binding capacity.

Hemicelluloses are polysaccharides consisting of pentoses (arabinose, xylose) and hexoses (glucose, mannose, galactose). Chain molecules form the base structure of hemicelluloses, these chain molecules, in contrast to cellulose, containing short side chains consisting of various sugars or sugar acid radicals, but which can also be slightly branched. The large amount of hydrophilic groups in hemicelluloses explains their strong ability to swell.

Lignin is a three-dimensional macromolecule that is constructed from phenylpropane units to form a polymeric compound. Lignin has far fewer polar groups than the polysaccharides and is therefore hydrophobic and not water-soluble.

Due to the high water-binding capacity of cellulose and hemicelluloses, they increase the volume stimulus in the intestines, which triggers peristalsis and accelerates passage through the large intestines. This is how they counteract constipation.

Inulin and fructooligosaccharides are polysaccharides that are formed from many plants and used as reserve material. Inulin and fructooligosaccharides are water-soluble.

Plant hydrocolloids such as pectin and locust bean gum [carob gum] are also included in the roughage group. They are water-soluble, gel-formers and as such increase the viscosity of the bolus. This increase in viscosity presumably causes delay in passage through the stomach and small intestines.

Fermentable roughage such as inulin, fructooligo-saccharides and pectin are quickly and almost completely decomposed in the colon by bacteria, since they are nutrition for intestinal flora. This in turn creates short-chained fatty acids, primarily acetic acid, propionic acid and butyric acid, which have positive effects on the intestinal tract and overall health of the animal. These short-chained fatty acids lower the pH value of the ingesta, thereby stabilizing the flora of the large intestines, preventing bacterial migration of pathogenic microbes to areas of the large intestine, and thereby guarding against diarrheic illnesses. In addition, these short-chained fatty acids stimulate reabsorption of sodium and water from the colon. This is another mechanism that is a prophylactic against diarrhea. The butyric acid that is formed acts as an energy-supplying substrate for the cells of the mucous membrane of the large intestine, thereby promoting the regenerative capacity of the mucous membrane and keeping it healthy. The lowering of the pH as described, and the influence on the intestinal flora causes the concentration of ammonia in the large intestine to decrease. This is very important for intestinal health since ammonia is a highly toxic metabolic product that causes inflammation and cell damage that can result in permanent damage to the intestinal epithelium. The damaging effect of ammonia is also not limited to the intestinal tract; ammonia extends to the entire organism and can thus damage other organs as well. It is also worth mentioning that the short-chained fatty acids that arise from the fermentation process make their way to the bloodstream and are available to the animal as an additional useful energy source.

Roughage is of great practical important in general for both animal as well as human nutrition. Usually, it is assumed that roughage accelerates the time of passage in the intestinal

tract. However, this only applies to the area of the large intestines, whereas in the stomach and small intestines the time of passage is not affected or is even slowed. Both soluble and insoluble roughage is described as being capable of reducing the emptying frequency of the stomach. The scientific literature mentions that this has a positive effect on protein digestion due to the longer time for stomach acids and enzymes to take effect.

To maintain a healthy intestinal environment, it is important to combine fermentable and less-fermentable roughage.

In practice, in particular for animal nutritional purposes, frequently used crude fiber substrates include wheat bran, dry forage, dried greens and crude fiber products comprised of lignocellulose.

Wheat bran is characterized by its low energy content with a relatively high crude fiber content. The percentage of bacterially fermentable roughage is also high. Due to its high phosphorous content and low calcium content, wheat bran is a suitable crude fiber substrate in support of MMA prophylaxis (i.e. mastitis-metritis-agalactia prophylaxis) in sows during the birth preparation phase, for example. Nevertheless, wheat bran can be heavily laden with mycotoxins, which are known to lead to health problems.

Dry forage also has a high crude fiber content and large percentage of bacterially fermentable roughage. The moist, slimy droppings in swine caused by dry forage feed and the high calcium content, which promotes urinary tract infections due to an increase in the urine pH and thus promotes the occurrence of MMA, are detrimental to the birth preparation process. Therefore, the use of dry forage in large amounts is somewhat problematic with respect to breeding sows.

Dried greens have a low energy content and high crude fiber content, and have a high percentage of bacterially fermentable roughage. Mycotoxin exposure is possible.

Recently, crude fiber products comprised of lignocellulose have been proven useful to farm animal nutrition. Lignocellulose is understood to mean cellulose and hemicelluloses with stored lignin in it, in other words lignified plant material. The advantages of these products are their standardized crude fiber content, the fact that they are free of mycotoxins and their thermal hygienization in the production process.

Use of these crude fiber products has already proven useful in sow feed. A high crude fiber content leads to good satiation stimulus, which has a calming influence on the behavior of animals as a result. It is well documented that these crude fiber products comprised of lignocellulose help to counteract obstipation due to the accelerated passage through the large intestine and thus contribute significantly to MMA prophylaxis without exposing the animals to the risk of mycotoxin exposure, which is the case in other crude fiber substrates.

The use of wood or wood flours in animal nutrition is a well-known method. In EP 1 542 545 B1, a feed additive is disclosed that consists of a so-called crude fiber concentrate of "fibrillated" lignocellulose. The use of cellulose fibrils in feed is described in EP 0 819 787 A2.

The lignocellulose-based crude fiber products currently being marketed consist of insoluble, difficult-to-ferment roughage. However, from a nutritional-physiological point of view, it is important to use a combination of difficult-to-ferment or unfermentable roughage and fermentable roughage. Fermentable roughage results in the formation of organic acids in the intestines, in particular lactic acid, as well as volatile fatty acids, with butyric acid being of greatest importance to the metabolism of villi and for water reabsorption in the intestines. However, excess intake of fermentable fibrous substances (roughage) results in a worsening of the stool consistency and significant gas build-up in the lumen of the intestines. An increase in gas build-up is considered adverse to farm animals from an energetic point of view since it results in a loss of energy.

Thus, it is not possible to achieve an optimum effect on the metabolic activity or digestive health of the organism either through the sole use of fermentable fibrous substances or through the sole use of difficult-to-ferment or unfermentable fibrous substances as roughage; rather, a balanced combination of these elements is necessary.

The invention proposes an improved roughage that comprises a lignocellulosic fiber formulation containing a portion of fibrous substance that is fermentable in the intestinal tract and a portion of fibrous substance that is difficult-to-ferment or unfermentable in the intestinal tract.

A fibrous substance that is fermentable in the intestinal tract is understood to mean fibrous substances that are partially or wholly decomposed microbially in the intestinal tract, resulting in the formation of acids. Fibrous substances that are difficult-to-ferment or unfermentable in the intestinal tract are understood to mean fibrous substances that are not microbially decomposed, or else slowly or with difficulty, in the intestinal tract of animals with single-chamber stomachs (monogastric organisms) and in humans. In expert circles, it is commonly assumed that fibrous substances that are difficult-to-ferment or unfermentable are insoluble, whereas easily fermentable fibrous substances are soluble.

The ratio between the fermentable and difficult-to-ferment or unfermentable fraction can vary within a wide range in the roughage according to the invention, depending on the application. The ratio can be between 1:100 and 100:1, for example.

According to the invention, the lignocellulosic material can be used in unprocessed form or in processed form. The lignocellulosic material according to the invention can be used in purified and prepared form.

According to one feature of the invention, the roughage according to the invention can contain a lignocellulosic material that is made up of one portion of fibrous substance that is fermentable in the intestinal tract and one portion that is difficult-to-ferment or unfermentable in the intestinal tract.

Possible raw materials for such a roughage according to the invention can include barks from softwoods, barks from hardwoods and the wood from larches (*Larix* spp.), for example. Preferred bark material according to the invention includes such materials from pines (*Pinus* spp.), for example.

Other raw materials that are easily fermented in the intestinal tract can be used as fermentable fiber components, such as oligosaccharides, pectins, inulin and plant material that contains these fermentable fibrous substances, such as chicory, topinambur, etc.

According to another feature of the invention, the roughage according to the invention can contain bark material that is selected from the group consisting bark material from softwoods, bark material from hardwoods or mixtures thereof. A preferred roughage according to the invention can contain bark material from pines.

According to another feature of the invention, the roughage according to the invention can contain larch wood.

According to another feature of the invention, the roughage according to the invention can contain larch wood and bark material from softwoods and/or bark material from hardwoods. A preferred roughage according to the invention can contain bark material from pines and larch wood.

According to another feature of the invention, the roughage according to the invention can comprise a mixture of

- at least one lignocellulosic raw material that comprises a portion of fibrous substance that is fermentable in the intestinal tract, and
- at least one lignocellulosic raw material that comprises a portion of fibrous substance that is difficult-to-ferment or unfermentable in the intestinal tract.

As contemplated by the present invention, possible raw materials with primarily unfermentable fibrous substance include hardwoods and softwoods but also other plant components containing difficult-to-ferment or unfermentable plant fibers (lignocelluloses such as reeds, straw, etc.).

According to another feature of the invention, the roughage can comprise at least one wood selected from the group consisting of softwood, hardwood and mixtures thereof and at least one bark material selected from the group consisting of bark material of softwoods, bark material of hardwoods and mixtures thereof.

According to another feature of the invention, the roughage can comprise a softwood selected from the group consisting of spruce wood (*Picea* spp.), pine wood (*Pinus* spp.), larch wood (*Larix* spp.) and mixtures thereof and a bark material selected from the group consisting of bark material of softwoods, bark material of hardwoods and mixtures thereof.

According to another feature of the invention, the roughage according to the invention can comprise a softwood selected from the group consisting of spruce wood, pine wood, larch wood and mixtures thereof and a bark material of pines.

According to another feature of the invention, the roughage according to the invention can comprise a bark material selected from the group consisting of bark material of softwoods, bark material of hardwoods and mixtures thereof and at least one hardwood. For example, according to the invention beech (*Fagus* spp.), poplar (*Populus* spp.), birch (*Betula* spp.) and the like can be used in the hardwood component. According to a preferred embodiment of the invention, the roughage comprises bark material of conifers and a hardwood selected from beech, poplar, birch and mixtures thereof.

According to another feature of the invention, the roughage can comprise a mixture of larch wood and other softwoods.

According to another feature of the invention, the roughage can comprise larch wood and a softwood selected from the group consisting of spruce wood, pine wood and mixtures thereof.

According to another feature of the invention, the roughage can comprise a mixture of larch wood and at least one hardwood. For example, according to the invention beech, poplar, birch and the like can be used in the hardwood component.

According to a particularly preferred embodiment of the invention, the roughage can comprise a mixture of bark material, preferably pine bark, with larch wood and at least one other softwood, in particular spruce wood and/or pine wood.

According to another particularly preferred embodiment of the invention, the roughage can comprise a mixture of bark material, preferably pine bark, with a mixture of pine wood and spruce wood.

According to another feature of the invention, the roughage can comprise isoquinoline alkaloids, in particular benzophenanthridine alkaloids. The alkaloids can be comprised in the form of plant materials, such as rhizomes, leaves, stems and the like.

For example, papaveraceae plant materials can be used for the present invention. Possible especially preferred plants can include *sanguinaria canadensis, macleaya cordata, chelidonium majus, hydrastis canadensis*, etc., for example. The papaveraceae contain isoquinoline alkaloids, in particular benzophenanthridine alkaloids such as sanguinarine and chelerythrine.

According to the invention, extracts of plant materials can also be included, such as those of *sanguinaria canadensis* or *macleaya cordata* or from other papaveraceae. According to a preferred embodiment of the invention, extracts of *macleaya cordata* are used.

Suitable plant material extracts according to the invention can be obtained through any known extraction process, such as aqueous extraction, alcoholic extraction, CO2 extraction and the like.

According to the invention, the roughage can comprise salts or derivatives of isolated isoquinoline alkaloids or their synthetic analogs.

The roughage according to the invention is preferred to comprise benzophenanthridine alkaloids, in particular sanguinarine and chelerythrine, wherein the dosage of sanguinarine can vary between 0.00001 wt.-% and 50 wt.-% of the overall weight of the roughage, for example. According to a preferred embodiment, the ratio of sanguinarine to chelerythrine can be about 2:1.

Benzophenanthridine alkaloids are known for their performance-enhancing and appetite enhancing effect in animals. Surprisingly, an increase in satiation stimulus was achieved with an alkaloid-containing roughage according to the present invention. This effect is particularly important in breeding sows. It is also of interest for other animals, in particular dogs and cats, for which the roughage according to the invention can be used to dampen appetite, particularly in connection with prophylaxis and treatment of obesity. However, the roughage according to the invention can even be successfully used for domestic pets of normal weight; these animals can often be quite annoying to owners due to their appetency to food (begging).

The present invention also pertains to a method of preparing roughage according to the invention.

According to one feature of the invention, the method can comprise the following steps:

(a) Cleaning the components of the roughage, which are selected from the group consisting of bark material from hardwoods, bark material from softwoods, larch wood, softwoods, hardwoods and mixtures thereof, and removal of foreign fractions,

(b) Drying the components to a dry matter fraction of about 3 to 12%,

(c) Comminution of the components and if necessary screening to a desired particle size,

(d) Compacting of the individual components,

(e) Crumbling the components in a crumbler to the desired particle size and then mixing the components.

According to another features of the invention, prior to compacting in step (d) at least one of the components can be admixed with a plant material containing isoquinoline alkaloids or an isoquinoline alkaloid extract can be sprayed onto at least one of the components.

According to another feature of the invention, when the crumbled components are mixed in step (e) a plant material containing isoquinoline alkaloids can be admixed or an isoquinoline alkaloid extract can be sprayed thereon.

According to another feature of the invention, the method can comprise the following steps:

(i) Cleaning the components of the roughage, which are selected from the group consisting of bark material from hardwoods, bark material from softwoods, larch wood, softwoods, hardwoods and mixtures thereof, and removal of foreign fractions,

(ii) Drying the components to a dry matter fraction of about 3 to 12%,

(iii) Comminution of the components and if necessary screening to a desired particle size,

(iv) Mixing the comminuted and if necessary screened components,

(v) Compacting the mixture and then crumbling the components in a crumbler to the desired particle size.

According to another feature of the invention, when the components are mixed in step (iv) a plant material containing isoquinoline alkaloids can be admixed or an isoquinoline alkaloid is extract can be sprayed thereon.

According to another feature of the invention, a plant material containing isoquinoline alkaloids can be admixed with the crumbled mixture from step (v) or an isoquinoline alkaloid extract can be sprayed thereon.

According to another embodiment of the invention, a feed material can be provided that comprises a roughage as defined above. The feed material comprises at least one feed component selected from the group consisting of protein substrates, carbohydrate substrates, raw feed, green fodder preserves (silage), fats, vitamins, minerals, and trace elements. Examples of carbohydrate substrates can include grain, grain products, corn and the like. Examples of protein substrates can include meat and bone meals, soy products, lactoproteins, rapeseed products such as rape cake or rape meal, and the like. Examples of raw feed contained in feed materials for ruminants, rodents and types of hares, for example, can include hay, straw and the like, and moreover all types of silage.

The amount of roughage according to the invention in the feed material can vary within a wide range. According to the invention, the feed material can contain 0.01 to 50 wt.-% of roughage based on the total weight of the feed material.

According to another feature of the invention, a feed material additive can be provided to prepare a feed material as defined above, wherein the feed material additive comprises a roughage according to the invention.

According to another feature of the invention, a feed material premixture can be provided to prepare a feed material as defined above, wherein the feed material premixture comprises a roughage according to the invention. Possible feed material premixtures include supplemental feed material as well. Up to >99% roughage according to the invention can make up such feed material premixtures or supplemental feed materials.

According to the invention, the feed material or feed material additive or feed material premixture to prepare a feed material comprises an isoquinoline alkaloid-containing roughage according to the invention, said roughage being use to reduce appetite, increase satiation stimulus and if necessary for weight reduction.

The roughage according to the invention can be mixed into a conventional animal feed substance either in powdered, granulated or crumbled form. The roughage can also be designed in the form of a chew object, such as chew bones. In the process, the roughage according to the invention can be used by itself or together with conventional feed material components such as protein substrates, carbohydrate substrates, oils, fats, vitamin substrates, mineral substrates, technical additives, etc.

The present invention is explained in detail below with the aid of examples.

EXAMPLE 1

Preparation of a roughage according to the invention Raw materials used include pine bark, larch wood and spruce wood or pine wood or a mixture of spruce wood and pine wood at a ratio of about 30% pine bark, about 20% larch wood and about 50% spruce wood or pine wood or spruce wood-pine wood mixture. The raw materials are cleaned and foreign fractions removed, and then dried to a dry matter fraction of 10% and comminuted. If necessary, screening to a desired grain size can be done. Then, the individual components are compacted, crumbled in a crumbler to the desired particle size and then mixed together.

Alternatively, the ground starting components can be mixed together prior to compacting.

If necessary, an isoquinoline alkaloid extract is sprayed thereon or plant material that contains isoquinoline alkaloid is mixed in. A soluble form of the extract can also be finally sprayed onto the finished product.

EXAMPLE 2

Preparation of a roughage according to the invention Spruce wood or a spruce wood-pine wood mixture is used together with pine bark at a mixture ratio of 1:1. Processing is done as in Example 1.

EXAMPLE 3

Preparation of a roughage according to the invention 100% pine bark is used as the raw material. Processing is done as in Example 1.

EXAMPLE 4

Preferred Formulations of the Roughage According to the Invention

Formulation 1:

50% of the product consists of spruce wood or pine wood or a mixture thereof, 30% of the product consists of pine bark and 20% consists of larch wood.

The woods and the barks are ground as follows, for example: 0% of particles are >0.28 mm, 4-8% of particles are >0.20 mm, 52-68% of particles are >0.08 mm, 20-32% of particles are ≤0.08 mm.

The components are mixed and then used as a flour product.

Formulation 2:

The proportions of barks and woods are the same as that in Formulation 1.

The ingredients of the formulation are compacted and then crumbled, and it makes no difference whether the components are mixed before or after compacting or even not until the end of the production process, i.e. in already crumbled form. The compacted and crumbled product can have the following particle size distribution, for example: 0% of particles are >2.0 mm, 60-63% of particles are >1.0 mm, 32-34% of particles are >0.5 mm, 5-70 of particles are <0.5 mm.

Formulation 3:

The portions of barks and woods are the same as in Formulation 1.

The ingredients of the formulation are compacted and then crumbled. The components can be mixed before or after compacting or even not until the end of the production process, i.e. in already crumbled form The compacted and crumbled product can have the following particle size distribution, for example: 0% of particles are >8.0 mm, 78-83% of particles are >3.15 mm, 15-18% of particles are >2.0 mm, 0-1% of particles are <2.0 mm.

The three formulations of the roughage according to the invention can have a moisture content of 8.5-9.3%, for example. All three formulations are further characterized in

that they have a liquid binding capacity that corresponds to at least 5 times their own weight. Furthermore, all three formulations have a total dietary fiber content of 85% (tdf).

The very high total dietary fiber (tdf) content as described is especially good from a nutrition-physiological point of view and cannot be accomplished in this form with any of the roughage substrates known from the prior art. One trained in the art assumes from the prior art that fibrous formulations based on lignocellulose are not fermented, or are fermented only to a small extent, in the intestinal tract of animals with single-chamber stomachs. Therefore, it is surprising that roughage formulations according to the invention comprising lignocellulosic material in the combinations set forth according to the invention are fermented in the intestinal tract, resulting in a massive generation of organic acids, in particular lactic acid, far in excess of the values obtained from conventional crude fiber substrates.

EXAMPLE 5

Lactic Acid Generation Capacity of Roughage According to the Invention

In a test, various formulations of the roughage according to the invention were incubated together with the blind gut contents of poultry in an in vitro testing system, and the influence of different fibrous products on lactic acid generation capacity, the generation of volatile fatty acids and other parameters was investigated. As expected, this test determined that conventional products based on lignocelluloses rarely resulted in the generation of lactic acid, which is why they are considered to be difficult-to-ferment, or non-fermentable fibrous substances, as one trained in the art knows.

Surprisingly, the results obtained from various roughage formulations according to the invention showed an increase in lactic acid production of up to nearly 30 times that of conventional lignocellulose products. The results are summarized in Table 1 below:

TABLE 1

	Average measured value D-Lactate in mg/l	Fermentation - D-Lactate generation in mg/l (measured value minus zero)
Zero	2.25	
Lignocellulose	3.85	1.60
Invention 1*	21.90	19.65
Invention 2*	47.10	44.85
Invention 3*	48.50	46.25
Invention 4*	34.50	32.25
Feed	14.00	11.75
Corn Starch	31.90	29.65
Beet Slices	8.52	6.27
Citrus Fiber	9.32	7.07
Fruit Fiber 1	16.50	14.25
Fruit Fiber 2	3.07	0.82

*Invention 1: roughage according to the invention comprising larch wood + larch bark;
Invention 2: roughage according to the invention comprising pine bark;
Invention 3: roughage according to the invention comprising hardwood + hardwood bars;
Invention 4: roughage according to the invention comprising 20% larch wood + 30% pine bark + 50% spruce wood + pine wood.

From a nutrition-physiological point of view, the lactic acid generated is very important since it results in a protective effect against certain microbes, in particular pathogenic microbes, in the intestinal lumen. An especially important effect of the roughage according to the invention can be explained by the fact that lignocellulosic substances result in a surface accumulation of such pathogenic microbes due to the adsorptive effect of the substances; these microbes can then be deactivated or their multiplication can be restricted by means of the locally increased lactic acid production in the roughage particles. For example, bacteria such as coli bacteria, clostridia, etc. attach to the roughage particles. Especially the lactic acid bacteria are promoted by the fermentable portion of the material. They generate lactic acid and the lactic acid surrounds the roughage particles. This produces a very localized lactic acid halo around the particles so that the pathogenic or damaging microbes accumulated there are counteracted. This particularly advantageous effect of the present invention is not observed in roughages of the prior art.

Moreover, lignocellulosic substances are adsorbents for various pollutants, in particular ammonia. As a result of the local influence of the acid, this ammonia is converted to the non-toxic ammonium ion after its attachment. This is very important for general animal health, intestinal health in particular, but also for general barn climate.

EXAMPLE 6

Composition of a Preferred Roughage According to the Invention

The analysis of the roughage according to the invention, comprising 20% larch wood, 30% pine bark and 50% spruce wood+pine wood (Formulation 1 in Example 4, "Invention 4" of Table 1 of Example 5), yields the product specification listed in the following Table 2 (data given in %):

TABLE 2

Crude fiber	53 ± 2
TDF (total dietary fiber)	85 ± 2
ADL (acid detergent lignin)	30 ± 2
Crude protein	1.0
Crude ash	1.6
Crude fat	0.7
Moisture	9 ± 1

The roughage formulation according to the invention is a combination of fermentable and difficult-to-ferment or non-fermentable fibrous substances, said combination being favorable from a nutritional-physiological point of view; this combination results on the one hand in the non-fermentable fibrous portion shifting the fermentation process of the fermentable food fraction to regions of the intestinal lumen where the volatile fatty acids produced, in particular butyric acid, can be put to use primarily for energetic metabolism of the intestinal epithelium and for water reabsorption and not just act as an energy substrate for the body through reabsorption. Tests with the roughage according to the invention have shown that the water reabsorption in the intestinal lumen is optimized, thus increasing the dry matter fraction in the stool.

As part of diarrhea prophylaxis in piglets, a clear improvement in stool consistence has been shown. In comparison with conventional formulations comprised of lignocelluloses, the fibrous formulation according to the invention results in a further improvement in effectiveness, expressed on the one hand in an improvement in stool dry fraction as a result of optimized water reabsorption. This is especially important in piglets and poultry, but also in an optimized satiation stimulus in sows or even domestic animals such as dogs and cats; this satiation stimulus can even be accomplished at lower concentrations than in conventional lignocellulose products. Moreover, the decrease in the production of ammonia leads to a lower occurrence of inflammation in the colon, which also has a positive effect on the water reabsorption (a damaged

mucous membrane cannot reabsorb enough water) and overall a positive effect on the health of the animals. In addition, the accelerated colon passage makes it more difficult for pathogenic microbes to ascend to the small intestine.

In numerous studies of broilers and turkey hens, a much more positive effect on the stool dry matter fraction was found. The stool dry matter fraction of the test group was up to 20% higher in comparison to the control group by fattening periods or phases. This understandably had a positive effect on the litter quality and as a consequence on general health. In these practical studies, considerable savings were achieved in the area of treatment and litter costs.

The feed according to the invention is of considerable importance especially in breeding sows since in this application feeding is limited due to MMA prophylaxis (metritis-mastitis-aglactia), whereas the satiation stimulus of the animal should still be satisfied. This is usually achieved by increasing the intake of crude fiber, but recently lignocellulose-based crude fiber formulations have frequently been used. The usual dosage for lignocellulose products in satiation feeding of breeding sows is about 4-5%. These necessarily high dosages are satisfactory neither from an economical point of view nor from a nutritional-physiological point of view since this leads to a decreased intake of other important nutrients. Interestingly, a significant improvement in satiation stimulus was achieved using the roughage according to the invention, in particular using the formulation with a high proportion of pine bark or pine bark alone, even at much lower dosages than the 4-5% listed for the usual lignocellulose products. This is presumably due to the combined effect of the roughage according to the invention since the lactic acid generated leads to an optimization of the satiation stimulus due to its hydrogen ion content.

EXAMPLE 7

Feed Recommendations for the Roughage According to the Invention from Example 6

Table 3 below provides examples of the roughage content according to the invention from Example 6 in the feed during the feeding of various farm animals.

TABLE 3

(Roughage content indicated in % of the ration)	
Pregnant breeding sows: rationed feeding	2-3
satiation feeding (ad lib.)	2-5
Fattened pigs	0.5-1.5
Piglets	1-2
Broilers	0.5-1.5
Turkey hens	1-2
Rabbits	2-5

Table 4 below shows an example of a ration with the roughage according to the invention from Example 6 in the raising of piglets:

TABLE 4

4%	Mineral/active ingredient mixture
22%	Soy grits
24.5%	Barley
15%	Wheat
28%	Corn
5%	Whey fat concentrate
1.5%	Roughage according to the invention

Table 5 below shows an example of a ration with the roughage according to the invention from Example 6 in a feed for pregnant breeding sows:

TABLE 5

39%	Barley
10%	Corn
10%	Wheat
11%	Rapeseed grits or sunflower grits
15%	Wheat feed meal
5%	Wheat bran
5%	Dry forage
3%	Mineral/active ingredient mixture
2%	Roughage according to the invention

Table 6 below shows an example of a ration with the roughage according to the invention from Example 6 in a feed for fattened pigs:

TABLE 6

60%	Whole grain silage or grain corn silage
17.5%	Wheat
18%	Soy grits
3%	Mineral/active ingredient mixture
1.5%	Roughage according to the invention

Table 7 below shows an example of a ration with the roughage according to the invention from Example 6 in rabbit feed:

TABLE 7

20%	Alfalfa meal
10%	Sunflower grits
15%	Soy grits
30%	Barley
3%	Mineral/active ingredient
10%	Wheat bran
8%	Wheat feed meal
4%	Roughage according to the invention

Table 8 below shows an example of a ration with the roughage according to the invention from Example 6 in fattened broiler feed.

TABLE 8

50%	Corn
9%	Wheat
32%	Soy grits
3%	Mineral/active ingredient mixture
5%	Oil/fat
1%	Roughage according to the invention

Table 9 below shows an example of a ration with the roughage according to the invention from Example 6 in a feed for fattened calves:

TABLE 9

99%	Mixed milk replacement drink for calves
1%	Roughage according to the invention

According to another embodiment of the invention, the roughage according to the invention can be used as a food additive in human food. The roughage according to the invention can be contained in particular in dietary food. For example, the use of the roughage according to the invention in food can bring about an appetite reduction and/or increase in satiation stimulus and therefore support weight reduction.

The invention claimed is:

1. A lignocellulosic fiber roughage formulation, which comprises a mixture of:

(a) at least one comminuted lignocellulosic raw material comprising one portion of fibrous substance that is fermentable in the intestinal tract of a human or animal with a single-chamber stomach, said material comprising at least one bark material selected from the group consisting of bark material from softwoods, bark material from hardwoods, and mixtures thereof and

(b) at least one comminuted lignocellulosic raw material that comprises a portion of fibrous substance that is more difficult-to-ferment than said fermentable fibrous substance or that is unfermentable in the intestinal tract of a human or animal with a single-chamber stomach, said material comprising at least one wood selected from the group consisting of softwood, hardwood, and mixtures thereof,

wherein the fermentable fibrous substance and the fibrous substance that is more difficult-to-ferment than said fermentable fibrous substance or that is unfermentable are present in a ratio between 1:100 and 100:1,

wherein 0% of said comminuted lignocellulosic raw materials have a particle size greater than 2 mm.

2. The lignocellulosic fiber roughage formulation according to claim 1, which comprises a softwood selected from the group consisting of spruce wood, pine wood, larch wood and mixtures thereof and a bark material selected from the group consisting of bark material from softwoods, bark material from hardwoods and mixtures thereof.

3. The lignocellulosic fiber roughage formulation according to claim 2, which comprises a softwood selected from the group consisting of spruce wood, pine wood, larch wood and mixtures thereof and a bark material from pines.

4. The lignocellulosic fiber roughage formulation according to claim 1, which comprises a mixture of larch wood and other softwoods.

5. The lignocellulosic fiber roughage formulation according to claim 4, which comprises larch wood and another softwood selected from the group consisting of spruce wood, pine wood, and mixtures thereof.

6. The lignocellulosic fiber roughage formulation according to claim 1, which comprises a bark material that is selected from the group consisting of bark material from softwoods, bark material from hardwoods and mixtures thereof and at least one hardwood.

7. The lignocellulosic fiber roughage formulation according to claim 6, which comprises a bark material that is selected from the group consisting of bark material from softwoods, bark material from hardwoods and mixtures thereof and hardwood selected from beech, poplar, birch and mixtures thereof.

8. The lignocellulosic fiber roughage formulation according to claim 1, which comprises larch wood and at least one hardwood.

9. The lignocellulosic fiber roughage formulation according to claim 8, which comprises larch wood and a hardwood selected from beech, poplar, birch and mixtures thereof.

10. The lignocellulosic fiber roughage formulation according to claim 1, which comprises an isoquinoline alkaloid.

11. The lignocellulosic fiber roughage formulation according to claim 10, wherein the isoquinoline alkaloid is a benzophenanthridine alkaloid.

12. The lignocellulosic fiber roughage formulation according to claim 10, wherein the isoquinoline alkaloid is contained in a plant part selected from the group consisting of rhizomes, leaves, and stems, or in an extract of said plant part or as a salt or derivative of the isoquinoline alkaloid or in the form of a synthetic analog of the isoquinoline alkaloid.

13. The lignocellulosic fiber roughage formulation according to claim 12, wherein the isoquinoline alkaloid is contained in a plant part of papaveraceae.

14. The lignocellulosic fiber roughage formulation according to claim 12, wherein the isoquinoline alkaloid is contained in the form of an extract of a plant part of papaveraceae.

15. The lignocellulosic fiber roughage formulation according to claim 13, wherein the papaveraceae plant part is from a plant selected from the group consisting of sanguinaria canandensis, macleaya cordata, chelidonium majus, hydrastis canadensis and mixtures thereof.

16. The lignocellulosic fiber roughage formulation according to claim 10, which comprises sanguinarine or chelerythrine or a mixture thereof as the isoquinoline alkaloid.

17. The lignocellulosic fiber roughage formulation according to claim 16, wherein sanguinarine is contained in the formulation in an amount of 0.00001 wt.- % to 50 wt.- %, based on the total weight of the roughage.

18. The lignocellulosic fiber roughage formulation according to claim 16, wherein in the mixture of sanguinarine and chelerythrine, the sanguinarine and chelerythrine are contained at a ratio of about 2:1.

19. A method of preparing a lignocellulosic fiber roughage formulation, as defined in claim 1, which comprises the following steps:

(a) cleaning the components of the roughage and removing foreign fractions,

(b) drying the components,

(c) comminuting the components and if necessary screening to a desired particle size, and either

(d1) compacting the individual components, crumbling the components to the desired particle size, and then mixing the components, or

(d2) mixing the comminuted components, which are optionally sieved, compacting the mixture and then crumbling it to a desired particle size.

20. An animal feed which comprises the lignocellulosic fiber roughage formulation according to claim 1, said animal feed further comprising at least one feed component selected from the group consisting of protein substrates, carbohydrate substrates, raw feed, green fodder preserves (silage), fats, vitamins, minerals and trace elements.

21. The animal feed according to claim 20, in which the lignocellulosic fiber roughage formulation which is present in said animal feed is present in an amount of between 0.01 and 50 wt. %, based on the total weight of the feed.

22. The An animal feed premixture which comprises the lignocellulosic fiber roughage formulation according to claim 1, said animal feed premixture further comprising at least one feed component selected from the group consisting of protein substrates, carbohydrate substrates, raw feed, green fodder preserves (silage), fats, vitamins, minerals and trace elements.

23. The animal feed premixture according to claim 22 which comprises the lignocellulosic fiber roughage formulation in an amount making up to >99% of the animal feed premixture.

24. The lignocellulosic fiber roughage formulation according to claim 1 which is used for providing dietary roughage to a human in need thereof.

25. The lignocellulosic fiber roughage formulation according to claim 10 which is used for one or more of the purposes of appetite reduction, increasing satiation stimulus, or weight reduction.

26. The lignocellulosic fiber roughage formulation according to claim 1 wherein the formulation has a moisture content of 8.5 to 9.3%.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.	:	8,673,383 B2
APPLICATION NO.	:	12/514588
DATED	:	March 18, 2014
INVENTOR(S)	:	Klaus Neufeld

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the Title Page:

The first or sole Notice should read --

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 1297 days.

Signed and Sealed this

Twenty-ninth Day of September, 2015

Michelle K. Lee

Michelle K. Lee

Director of the United States Patent and Trademark Office

(b) (4)

Analytical Report

(b) (4)
(b)(6)
(b) (4)

Reportnr.	: **1042444 version 1**	Disponent Number	:
Product recognized as	:		
Product Specification	: OptiCell C5	Sampling Date	: 29-Jan-2020
Reference	: Docucare: 22971657	Samplesize (kg)	: 0,266
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971657
Packing	: Plastic, ambient	Sample Arrival Date	: 05-Feb-2020 10:00
Sample Type	: Sample	ReportDate Version	: **10-Feb-2020 15:48**

Microbiological Determination

Common

Parameter	Result (as received)			
Yeasts, osmotolerant	(b) (4)	cfu/g	Q	R
Moulds,		cfu/g	Q	R
Aerobic plate count		cfu/g	Q	R
Coliforms		cfu/g	Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4) location Rotterdam

(b) (4)

Requested 05-Feb-2020 by (b) (4)
Analyses according to annex

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1042444 version 1**	Disponent Number	:
Product recognized as	:		
Product Specification	: OptiCell C5	Sampling Date	:29-Jan-2020
Reference	: Docucare: 22971657	Samplesize (kg)	:0,266
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971657
Packing	: Plastic, ambient	Sample Arrival Date	:05-Feb-2020 10:00
Sample Type	: Sample	ReportDate Version	:**10-Feb-2020 15:48**

ANNEX

Analyses	**Start date**
Aerobic plate count/ Other	05-02-2020
Moulds & Yeast; dry products	05-02-2020

Method Descriptions

Microbiological Determination

Common

Method Description	**Method Code**
Enumeration of Coliforms;[AFNOR 01/2-09/89A]	Eq. NEN-EN-ISO 4832
Enumeration of micro-organisms (Aerobic plate count) at 30°C; [AFNOR 01/1-09/89]	Eq.NEN-EN-ISO 4833-1
Enumeration of osmotolerant yeasts and moulds; colony-count technique DG18	Acc. NEN-ISO 21527-2

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

(b) (4)

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1005963 version 1**	Disponent Number	: Opticel C5
Product recognized as	:		
Product Specification	: Lignocellulose Dunkel	Sampling Date	: 25-Oct-2019
Reference	:	Samplesize (kg)	: 0,472
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971663
Packing	: Plastic, ambient	Sample Arrival Date	: 29-Oct-2019 15:53
Sample Type	: Sample	ReportDate Version	: **04-Nov-2019 14:57**

Microbiological Determination

Common

Parameter	Result (as received)			
Yeasts, osmotolerant	(b) (4)	cfu/g	Q	R
Moulds,		cfu/g	Q	R
Aerobic plate count		cfu/g	Q	R
Coliforms		cfu/g	Q	R
Salmonella	Not detected / 25g		Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1005963 version 1**	Disponent Number	: Opticel C5
Product recognized as	:		
Product Specification	: Lignocellulose Dunkel	Sampling Date	: 25-Oct-2019
Reference	:	Samplesize (kg)	: 0,472
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971663
Packing	: Plastic, ambient	Sample Arrival Date	: 29-Oct-2019 15:53
Sample Type	: Sample	ReportDate Version	: **04-Nov-2019 14:57**

ANNEX

Analyses	**Start date**
Aerobic plate count/ Other	29-10-2019
Moulds & Yeast; dry products	29-10-2019
Salmonella standaard /25 g PCR	29-10-2019

Method Descriptions

Microbiological Determination

Common

Method Description	**Method Code**
Detection of Salmonella (RT-PCR); [Microval 2011-LR40]	Eq NEN-EN-ISO- 6579
Enumeration of Coliforms;[AFNOR 01/2-09/89A]	Eq. NEN-EN-ISO 4832
Enumeration of micro-organisms (Aerobic plate count) at 30°C; [AFNOR 01/1-09/89]	Eq.NEN-EN-ISO 4833-1
Enumeration of osmotolerant yeasts and moulds; colony-count technique DG18	Acc. NEN-ISO 21527-2

Abbreviations:

acc: in accordance with
eq: Equivalent to

(b) (4)

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **920816 version 1**	Disponent Number	:20456433
Product recognized as	:		
Product Specification	: OptiCell C5	Sampling Date	:18-Jan-2019
Reference	:	Samplesize (kg)	:0,398
AWB / BarCode	:	Sealed / Seal Code	: Yes /20456433
Packing	: Plastic, ambient	Sample Arrival Date	:24-Jan-2019 12:49
Sample Type	: Sample	ReportDate Version	:**29-Jan-2019 14:43**

Microbiological Determination

Common

Parameter	Result (as received)			
Yeasts, osmotolerant	(b) (4)	cfu/g	Q	R
Moulds, osmotolerant		cfu/g	Q	R
Aerobic plate count		cfu/g	Q	R
Coliforms		cfu/g	Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

Analytical Report

Reportnr.	: **920816 version 1**	Disponent Number	:20456433
Product recognized as	:		
Product Specification	: OptiCell C5	Sampling Date	:18-Jan-2019
Reference	:	Samplesize (kg)	:0,398
AWB / BarCode	:	Sealed / Seal Code	: Yes /20456433
Packing	: Plastic, ambient	Sample Arrival Date	:24-Jan-2019 12:49
Sample Type	: Sample	ReportDate Version	:**29-Jan-2019 14:43**

ANNEX

Analyses	**Start date**
Aerobic plate count/ Other	24-01-2019
Moulds & Yeast; dry products	24-01-2019

Method Descriptions

Microbiological Determination

Common

Method Description	**Method Code**
Enumeration of Coliforms;[AFNOR 01/2-09/89A]	Eq. NEN-EN-ISO 4832
Enumeration of micro-organisms (Aerobic plate count) at 30°C; [AFNOR 01/1-09/89]	Eq.NEN-EN-ISO 4833-1
Enumeration of osmotolerant yeasts and moulds; colony-count technique DG18	Acc. NEN-ISO 21527-2

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **933953 version 1**	Disponent Number	:F00002315-0-20456863
Product recognized as	: Diervoeders / Animalfeed		
Product Specification	: OptiCell C5	Sampling Date	:18-Feb-2019
Reference	:	Samplesize (kg)	:0,682
AWB / BarCode	:	Sealed / Seal Code	:Yes /20456863
Packing	: Plastic, ambient	Sample Arrival Date	:22-Feb-2019 13:03
Sample Type	: Sample	ReportDate Version	:**28-Feb-2019 16:22**

Microbiological Determination

Common

Parameter	Result (as received)	
Salmonella	Not detected / 25g	Q R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

Requested 22-Feb-2019 by (b) (4)
Analyses according to annex

Analytical Report

Reportnr.	: **933953 version 1**	Disponent Number	:F00002315-0-20456863
Product recognized as	: Diervoeders / Animalfeed		
Product Specification	: OptiCell C5	Sampling Date	:18-Feb-2019
Reference	:	Samplesize (kg)	:0,682
AWB / BarCode	:	Sealed / Seal Code	:Yes /20456863
Packing	: Plastic, ambient	Sample Arrival Date	:22-Feb-2019 13:03
Sample Type	: Sample	ReportDate Version	:**28-Feb-2019 16:22**

ANNEX

Method Descriptions

Microbiological Determination

Common

Method Description	Method Code
Detection of Salmonella (RT-PCR); [Microval 2011-LR40]	Eq NEN-EN-ISO- 6579

Abbreviations:

acc: in accordance with

eq: Equivalent to

Analytical Report

(b) (4)

Germany

Reportnr.	: **1055091 version 1**	Disponent Number	: F00002315-22971653
Product recognized as	:		
Product Specification	: Lignocellulose, 12,08,01	Sampling Date	: 25-Feb-2020
Reference	:	Samplesize (kg)	: 0,621
AWB / BarCode	:	Sealed / Seal Code	: Yes / 22971653
Packing	: Plastic, ambient	Sample Arrival Date	: 28-Feb-2020 16:46
Sample Type	: Parcel Sample	ReportDate Version	: **17-Mar-2020 09:50**
		Origin	: Germany

Microbiological Determination

Common

Parameter	Result (as received)		
Salmonella	Not detected / 25g	Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1055091 version 1**	Disponent Number	:F00002315-22971653
Product recognized as	:		
Product Specification	:Lignocellulose, 12,08,01	Sampling Date	:25-Feb-2020
Reference	:	Samplesize (kg)	:0,621
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971653
Packing	:Plastic, ambient	Sample Arrival Date	:28-Feb-2020 16:46
Sample Type	:Parcel Sample	ReportDate Version	:**17-Mar-2020 09:50**

ANNEX

Method Descriptions

Microbiological Determination

Common

Method Description	Method Code
Detection of Salmonella (RT-PCR); [Microval 2011-LR40]	Eq NEN-EN-ISO- 6579

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1055090 version 1**	Disponent Number	:F00002315-22971653
Product recognized as	:		
Product Specification	:Lignocellulose, 12,08,01	Sampling Date	:25-Feb-2020
Reference	:	Samplesize (kg)	:0,621
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971653
Packing	:Plastic, ambient	Sample Arrival Date	:28-Feb-2020 16:46
Sample Type	:Parcel Sample	ReportDate Version	:**17-Mar-2020 09:50**
		Origin	:Germany

Composition Determination

Metal and other elements

Parameter	Result (as received)			
Cd (Cadmium)	0,427	mg/kg	Q	R
Pb (Lead)	1,07	mg/kg	Q	R
As (Arsenic)	0,148	mg/kg	Q	R
Hg (Mercury)	0,010	mg/kg	Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1055090 version 1**	Disponent Number	:F00002315-22971653
Product recognized as	:		
Product Specification	:Lignocellulose, 12,08,01	Sampling Date	:25-Feb-2020
Reference	:	Samplesize (kg)	:0,621
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971653
Packing	:Plastic, ambient	Sample Arrival Date	:28-Feb-2020 16:46
Sample Type	:Parcel Sample	ReportDate Version	:**17-Mar-2020 09:50**

ANNEX

Method Descriptions

Composition Determination

Metal and other elements

Method Description	Method Code
Determination of arsenic (As), Cadmium (Cd), Lead (Pb); ICP-MS; ***Foodstuffs:destruction Acc. NEN-EN 13805,Analysis Acc NEN-EN-15763	Own method***
Determination of Mercury (Hg); Hg-analyser Animalfeed/feedingstuff : eq. NEN-EN16277 Food : eq. NEN-EN15763	

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1138916 version 1**		
Sample Arrival Date	: 11-Nov-2020 10:34	Sampling Date *	: 27-Oct-2020
ReportDate Version	: **20-Nov-2020 11:44**	Samplesize (kg)	: 0,701
Packing	: Plastic, ambient		

Sample information *

Disponent Number	: Docucare 22971605	Product specification	: OptiCell C5
Sealed / Seal Code	: No /	AWB / BarCode	: CY752999927DE

*** Information supplied by customer (TLR takes no responsibility for this information).**

Composition Determination

Metal and other elements

Parameter	Result (as received)			
Cd (Cadmium)	0,332	mg/kg	Q	R
Pb (Lead)	1,22	mg/kg	Q	R
As (Arsenic)	0,136	mg/kg	Q	R
Hg (Mercury)	0,011	mg/kg	Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

Analytical Report

Reportnr.	: **1138916 version 1**		
Sample Arrival Date	: 11-Nov-2020 10:34	Sampling Date	*:27-Oct-2020
ReportDate Version	: **20-Nov-2020 11:44**	Samplesize (kg)	: 0,701
Packing	: Plastic, ambient		

ANNEX

Method Descriptions

Composition Determination

Metal and other elements

Method Description	Method Code
Determination of arsenic (As), Cadmium (Cd), Lead (Pb); ICP-MS; ***Foodstuffs:destruction Acc. NEN-EN 13805,Analysis Acc NEN-EN-15763	Own method***
Determination of Mercury (Hg); Hg-analyser Animalfeed/feedingstuff : eq. NEN-EN16277 Food : eq. NEN-EN15763	

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1009901 version 1**	Disponent Number	:
Product recognized as	:		
Product Specification	: Opticel C5	Sampling Date	: 25-Oct-2019
Reference	:	Samplesize (kg)	: 0,741
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971662
Packing	: Plastic, ambient	Sample Arrival Date	: 29-Oct-2019 15:57
Sample Type	: Sample	ReportDate Version	: **08-Nov-2019 15:28**

Composition Determination

Metal and other elements

Parameter	Result (as received)			
Cd (Cadmium)	0,285	mg/kg	Q	R
Pb (Lead)	0,90	mg/kg	Q	R
As (Arsenic)	0,097	mg/kg	Q	R
Hg (Mercury)	0,008	mg/kg	Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4) location Rotterdam

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1009901 version 1**	Disponent Number	:
Product recognized as	:		
Product Specification	: Opticel C5	Sampling Date	:25-Oct-2019
Reference	:	Samplesize (kg)	:0,741
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971662
Packing	: Plastic, ambient	Sample Arrival Date	:29-Oct-2019 15:57
Sample Type	: Sample	ReportDate Version	:**08-Nov-2019 15:28**

ANNEX

Method Descriptions

Composition Determination

Metal and other elements

Method Description	Method Code
Determination of arsenic (As), Cadmium (Cd), Lead (Pb); ICP-MS; ***Foodstuffs:destruction Acc. NEN-EN 13805,Analysis Acc NEN-EN-15763	Own method***
Determination of Mercury (Hg); Hg-analyser Animalfeed/feedingstuff : eq. NEN-EN16277 Food : eq. NEN-EN15763	

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1138918 version 1**		
Sample Arrival Date	: 11-Nov-2020 10:34	Sampling Date *	: 27-Oct-2020
ReportDate Version	: **20-Nov-2020 11:44**	Samplesize (kg)	: 0,701
Packing	: Plastic, ambient		

Sample information *

Disponent Number	: Docucare 22971605	Product specification	: OptiCell C5
Sealed / Seal Code	: No /	AWB / BarCode	: CY752999927DE

*** Information supplied by customer (TLR takes no responsibility for this information).**

Contaminations

EFSA/TEF- calculation with moisture content 12%

Parameter	Result (as received)			
WHO (PCDD/PCDF) TEQ 88%dm.	0,136	ng/kg	Q	R
WHO (PCDD/F/PCB) TEQ 88%dm	0,264	ng/kg	Q	R
WHO (PCB)-TEQ 88%dm	0,128	ng/kg	Q	R
Sum ndl-PCB's (ICES-6) Up.bound	3,0	µg/kg	Q	R
Moisture tbv Dioxines	8,87	%		R

EFSA/TEF- calculation wet weight

Parameter	Result (as received)			
WHO-PCDD/PCDF-TEQ Up.bound	0,141	ng/kg	Q	R
WHO-PCB- TEQ Up.bound	0,132	ng/kg	Q	R
WHO-PCDD/F-PCB-TEQ Up.boun	0,273	ng/kg	Q	R

Dioxins, dl PCBs, ndl PCBs

Parameter	Result (as received)			
PCB-77	1,6	ng/kg	Q	R
PCB-81	< 1,0	ng/kg	Q	R
PCB-126	< 1,0	ng/kg	Q	R
PCB-169	< 1,0	ng/kg	Q	R
PCB-105	< 5	ng/kg	Q	R
PCB-114	< 10	ng/kg	Q	R
PCB-118	< 20	ng/kg	Q	R
PCB-123	< 5	ng/kg	Q	R
PCB-156	< 5	ng/kg	Q	R
PCB-157	< 5	ng/kg	Q	R
PCB-167	< 5	ng/kg	Q	R
PCB-189	< 5	ng/kg	Q	R
WHO (PCB-TEQ) Medium bound	0,07	ng/kg	Q	R
WHO (PCB-TEQ) Lower bound	< 0,00	ng/kg	Q	R

Dioxins

Parameter	Result (as received)			
2,3,7,8-TCDD	< 0,04	ng/kg	Q	R
1,2,3,7,8-PeCDD	< 0,04	ng/kg	Q	R

(b) (4)

Analytical Report

Reportnr.	: **1138918 version 1**		
Sample Arrival Date	: 11-Nov-2020 10:34	Sampling Date	*:27-Oct-2020
ReportDate Version	: **20-Nov-2020 11:44**	Samplesize (kg)	: 0,701
Packing	: Plastic, ambient		

1,2,3,4,7,8-HxCDD	< 0,05	ng/kg	Q	R
1,2,3,6,7,8-HxCDD	< 0,05	ng/kg	Q	R
1,2,3,7,8,9-HxCDD	< 0,05	ng/kg	Q	R
1,2,3,4,6,7,8-HpCDD	0,33	ng/kg	Q	R
OCDD	2,6	ng/kg	Q	R
2,3,7,8-TCDF	< 0,04	ng/kg	Q	R
1,2,3,7,8-PeCDF	< 0,04	ng/kg	Q	R
2,3,4,7,8-PeCDF	< 0,04	ng/kg	Q	R
1,2,3,4,7,8-HxCDF	< 0,05	ng/kg	Q	R
1,2,3,6,7,8-HxCDF	< 0,05	ng/kg	Q	R
1,2,3,7,8,9-HxCDF	< 0,05	ng/kg	Q	R
2,3,4,6,7,8-HxCDF	< 0,05	ng/kg	Q	R
1,2,3,4,6,7,8-HpCDF	0,23	ng/kg	Q	R
1,2,3,4,7,8,9-HpCDF	< 0,15	ng/kg	Q	R
OCDF	< 2,0	ng/kg	Q	R
WHO-PCDD/PCDF-TEQ Med.boun	0,07	ng/kg	Q	R
WHO-PCDD/PCDF-TEQ Low.boun	0,006	ng/kg	Q	R
WHO-PCDD/F-PCB-TEQ Med.bou	0,140	ng/kg	Q	R
WHO-PCDD/F-PCB-TEQ Low.bou	0,007	ng/kg		R

Poly Chlorinated Biphenyls

Parameter	Result (as received)			
PCB 28	< 0,50	µg/kg	Q	R
PCB 52	< 0,50	µg/kg	Q	R
PCB 101	< 0,50	µg/kg	Q	R
PCB 138	< 0,50	µg/kg	Q	R
PCB 153	< 0,50	µg/kg	Q	R
PCB 180	< 0,50	µg/kg	Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

Analytical Report

Reportnr.	: **1138918 version 1**		
Sample Arrival Date	: 11-Nov-2020 10:34	Sampling Date	*:27-Oct-2020
ReportDate Version	: **20-Nov-2020 11:44**	Samplesize (kg)	: 0,701
Packing	: Plastic, ambient		

ANNEX

Method Descriptions

Contaminations

EFSA/TEF- calculation with moisture content 1

Method Description	Method Code
Calculation feed of Toxic Equivalency Factors for dioxins and dioxinlike PCB's [WHO-2005]	.

EFSA/TEF- calculation wet weight

Method Description	Method Code
Calculation food of Toxic Equivalency Factors for dioxins and dioxinlike PCB's [WHO-2005]	.
Determination of dioxines and dioxinlike PCB's in food and animal feedings stuff According to NEN-EN 16215 - EC 709/2014	--

Dioxins

Method Description	Method Code
Determination of dioxines and dioxinlike PCB's in food and animal feedings stuff According to NEN-EN 16215 - EC 709/2014	--
The mediumbound conc: For the calculation of the total TEQ, the values lower than LOQ, were regarded as the value of half of LOQ The lowerbound conc: For the calculation of the TEQ, the values lower than LOQ, were regarded as zero.	.-

Poly Chlorinated Biphenyls

Method Description	Method Code
Determination of the content of PCBs; GPC-LC-GCMS method	Own method

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1055092 version 1**	Disponent Number	:F00002315-22971653
Product recognized as	:		
Product Specification	:Lignocellulose, 12,08,01	Sampling Date	:25-Feb-2020
Reference	:	Samplesize (kg)	:0,621
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971653
Packing	:Plastic, ambient	Sample Arrival Date	:28-Feb-2020 16:46
Sample Type	:Parcel Sample	ReportDate Version	:**17-Mar-2020 09:50**
		Origin	:Germany

Contaminations

EFSA/TEF- calculation with moisture content 12%

Parameter	Result (as received)			
WHO (PCDD/PCDF) TEQ 88%dm.	0,138	ng/kg	Q	R
WHO (PCDD/F/PCB) TEQ 88%dm	0,266	ng/kg	Q	R
WHO (PCB)-TEQ 88%dm	0,128	ng/kg	Q	R
Sum ndl-PCB's Up.Bound	6,0	µg/kg	Q	R
Moisture tbv Dioxines	9,28	%		R

EFSA/TEF- calculation wet weight

Parameter	Result (as received)			
WHO-PCDD/PCDF-TEQ Up.bound	0,142	ng/kg	Q	R
WHO-PCB- TEQ Up.bound	0,132	ng/kg	Q	R
WHO-PCDD/F-PCB-TEQ Up.boun	0,274	ng/kg	Q	R

Dioxins, dl PCBs, ndl PCBs

Parameter	Result (as received)			
PCB-77	1,1	ng/kg	Q	R
PCB-81	< 1,0	ng/kg	Q	R
PCB-126	< 1,0	ng/kg	Q	R
PCB-169	< 1,0	ng/kg	Q	R
PCB-105	5	ng/kg	Q	R
PCB-114	< 10	ng/kg	Q	R
PCB-118	< 20	ng/kg	Q	R
PCB-123	< 5	ng/kg	Q	R
PCB-156	< 5	ng/kg	Q	R
PCB-157	< 5	ng/kg	Q	R
PCB-167	< 5	ng/kg	Q	R
PCB-189	< 5	ng/kg	Q	R
WHO (PCB-TEQ) Medium bound	0,07	ng/kg	Q	R
WHO (PCB-TEQ) Lower bound	< 0,00	ng/kg	Q	R

Dioxins

Parameter	Result (as received)			
2,3,7,8-TCDD	< 0,04	ng/kg	Q	R
1,2,3,7,8-PeCDD	< 0,04	ng/kg	Q	R

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1055092 version 1**	Disponent Number	:F00002315-22971653
Product recognized as	:		
Product Specification	:Lignocellulose, 12,08,01	Sampling Date	:25-Feb-2020
Reference	:	Samplesize (kg)	:0,621
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971653
Packing	:Plastic, ambient	Sample Arrival Date	:28-Feb-2020 16:46
Sample Type	:Parcel Sample	ReportDate Version	:**17-Mar-2020 09:50**

1,2,3,4,7,8-HxCDD	< 0,05	ng/kg		Q	R
1,2,3,6,7,8-HxCDD	< 0,05	ng/kg		Q	R
1,2,3,7,8,9-HxCDD	< 0,05	ng/kg		Q	R
1,2,3,4,6,7,8-HpCDD	0,44	ng/kg		Q	R
OCDD	2,8	ng/kg		Q	R
2,3,7,8-TCDF	< 0,04	ng/kg		Q	R
1,2,3,7,8-PeCDF	< 0,04	ng/kg		Q	R
2,3,4,7,8-PeCDF	< 0,04	ng/kg		Q	R
1,2,3,4,7,8-HxCDF	< 0,05	ng/kg		Q	R
1,2,3,6,7,8-HxCDF	< 0,05	ng/kg		Q	R
1,2,3,7,8,9-HxCDF	< 0,05	ng/kg		Q	R
2,3,4,6,7,8-HxCDF	< 0,05	ng/kg		Q	R
1,2,3,4,6,7,8-HpCDF	0,26	ng/kg		Q	R
1,2,3,4,7,8,9-HpCDF	< 0,15	ng/kg		Q	R
OCDF	< 2,0	ng/kg		Q	R
WHO-PCDD/PCDF-TEQ Med.boun	0,08	ng/kg		Q	R
WHO-PCDD/PCDF-TEQ Low.boun	0,008	ng/kg		Q	R
WHO-PCDD/F-PCB-TEQ Med.bou	0,141	ng/kg		Q	R
WHO-PCDD/F-PCB-TEQ Low.bou	0,008	ng/kg			R

Poly Chlorinated Biphenyls

Parameter	Result (as received)			
PCB 28	< 1,0	µg/kg	Q	R
PCB 52	< 1,0	µg/kg	Q	R
PCB 101	< 1,0	µg/kg	Q	R
PCB 138	< 1,0	µg/kg	Q	R
PCB 153	< 1,0	µg/kg	Q	R
PCB 180	< 1,0	µg/kg	Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

Analytical Report

Reportnr.	: **1055092 version 1**	Disponent Number	: F00002315-22971653
Product recognized as	:		
Product Specification	: Lignocellulose, 12,08,01	Sampling Date	: 25-Feb-2020
Reference	:	Samplesize (kg)	: 0,621
AWB / BarCode	:	Sealed / Seal Code	: Yes / 22971653
Packing	: Plastic, ambient	Sample Arrival Date	: 28-Feb-2020 16:46
Sample Type	: Parcel Sample	ReportDate Version	: **17-Mar-2020 09:50**

ANNEX

Method Descriptions

Contaminations

EFSA/TEF- calculation with moisture content 1

Method Description	Method Code
Calculation feed of Toxic Equivalency Factors for dioxins and dioxinlike PCB's [WHO-2005]	.

EFSA/TEF- calculation wet weight

Method Description	Method Code
Calculation food of Toxic Equivalency Factors for dioxins and dioxinlike PCB's [WHO-2005]	.
Determination of dioxines and dioxinlike PCB's in food and animal feedings stuff According to NEN-EN 16215 - EC 709/2014	--

Dioxins

Method Description	Method Code
Determination of dioxines and dioxinlike PCB's in food and animal feedings stuff According to NEN-EN 16215 - EC 709/2014	--
The mediumbound conc: For the calculation of the total TEQ, the values lower than LOQ, were regarded as the value of half of LOQ The lowerbound conc: For the calculation of the TEQ, the values lower than LOQ, were regarded as zero.	.-

Poly Chlorinated Biphenyls

Method Description	Method Code
Determination of the content of PCBs; GPC-LC-GCMS method	Own method

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1009902 version 1**	Disponent Number	:
Product recognized as	:		
Product Specification	: Opticel C5	Sampling Date	:25-Oct-2019
Reference	:	Samplesize (kg)	:0,741
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971662
Packing	: Plastic, ambient	Sample Arrival Date	:29-Oct-2019 15:57
Sample Type	: Sample	ReportDate Version	:**08-Nov-2019 15:28**

Contaminations

EFSA/TEF- calculation with moisture content 12%

Parameter	Result (as received)			
WHO (PCDD/PCDF) TEQ 88%dm.	0,146	ng/kg	Q	R
WHO (PCDD/F/PCB) TEQ 88%dm	0,273	ng/kg	Q	R
WHO (PCB)-TEQ 88%dm	0,126	ng/kg	Q	R
Sum ndl-PCB's Up.Bound	6,0	µg/kg	Q	R
Moisture tbv Dioxines	7,80	%		R

EFSA/TEF- calculation wet weight

Parameter	Result (as received)			
WHO-PCDD/PCDF-TEQ Up.bound	0,153	ng/kg	Q	R
WHO-PCB- TEQ Up.bound	0,132	ng/kg	Q	R
WHO-PCDD/F-PCB-TEQ Up.boun	0,286	ng/kg	Q	R

Dioxins, dl PCBs, ndl PCBs

Parameter	Result (as received)			
PCB-77	1,7	ng/kg	Q	R
PCB-81	< 1,0	ng/kg	Q	R
PCB-126	< 1,0	ng/kg	Q	R
PCB-169	< 1,0	ng/kg	Q	R
PCB-105	7	ng/kg	Q	R
PCB-114	< 10	ng/kg	Q	R
PCB-118	< 20	ng/kg	Q	R
PCB-123	< 5	ng/kg	Q	R
PCB-156	< 5	ng/kg	Q	R
PCB-157	< 5	ng/kg	Q	R
PCB-167	< 5	ng/kg	Q	R
PCB-189	< 5	ng/kg	Q	R
WHO (PCB-TEQ) Medium bound	0,07	ng/kg	Q	R
WHO (PCB-TEQ) Lower bound	< 0,00	ng/kg	Q	R

Dioxins

Parameter	Result (as received)			
2,3,7,8-TCDD	< 0,04	ng/kg	Q	R
1,2,3,7,8-PeCDD	< 0,04	ng/kg	Q	R
1,2,3,4,7,8-HxCDD	< 0,05	ng/kg	Q	R
1,2,3,6,7,8-HxCDD	0,08	ng/kg	Q	R

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1009902 version 1**	Disponent Number	:
Product recognized as	:		
Product Specification	: Opticel C5	Sampling Date	: 25-Oct-2019
Reference	:	Samplesize (kg)	: 0,741
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971662
Packing	: Plastic, ambient	Sample Arrival Date	: 29-Oct-2019 15:57
Sample Type	: Sample	ReportDate Version	: **08-Nov-2019 15:28**

1,2,3,7,8,9-HxCDD	< 0,05	ng/kg	Q	R
1,2,3,4,6,7,8-HpCDD	0,93	ng/kg	Q	R
OCDD	7,7	ng/kg	Q	R
2,3,7,8-TCDF	< 0,04	ng/kg	Q	R
1,2,3,7,8-PeCDF	< 0,04	ng/kg	Q	R
2,3,4,7,8-PeCDF	< 0,04	ng/kg	Q	R
1,2,3,4,7,8-HxCDF	0,06	ng/kg	Q	R
1,2,3,6,7,8-HxCDF	< 0,05	ng/kg	Q	R
1,2,3,7,8,9-HxCDF	< 0,05	ng/kg	Q	R
2,3,4,6,7,8-HxCDF	< 0,05	ng/kg	Q	R
1,2,3,4,6,7,8-HpCDF	0,34	ng/kg	Q	R
1,2,3,4,7,8,9-HpCDF	< 0,15	ng/kg	Q	R
OCDF	< 2,0	ng/kg	Q	R
WHO-PCDD/PCDF-TEQ Med.boun	0,09	ng/kg	Q	R
WHO-PCDD/PCDF-TEQ Low.boun	0,029	ng/kg	Q	R
WHO-PCDD/F-PCB-TEQ Med.bou	0,158	ng/kg	Q	R
WHO-PCDD/F-PCB-TEQ Low.bou	0,029	ng/kg		R

Poly Chlorinated Biphenyls

Parameter	Result (as received)			
PCB 28	< 1,0	µg/kg	Q	R
PCB 52	< 1,0	µg/kg	Q	R
PCB 101	< 1,0	µg/kg	Q	R
PCB 138	< 1,0	µg/kg	Q	R
PCB 153	< 1,0	µg/kg	Q	R
PCB 180	< 1,0	µg/kg	Q	R

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1009902 version 1**	Disponent Number	:
Product recognized as	:		
Product Specification	: Opticel C5	Sampling Date	:25-Oct-2019
Reference	:	Samplesize (kg)	:0,741
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971662
Packing	: Plastic, ambient	Sample Arrival Date	:29-Oct-2019 15:57
Sample Type	: Sample	ReportDate Version	:**08-Nov-2019 15:28**

ANNEX

Method Descriptions

Contaminations

EFSA/TEF- calculation with moisture content 1

Method Description	Method Code
Calculation feed of Toxic Equivalency Factors for dioxins and dioxinlike PCB's [WHO-2005]	.

EFSA/TEF- calculation wet weight

Method Description	Method Code
Calculation food of Toxic Equivalency Factors for dioxins and dioxinlike PCB's [WHO-2005]	.
Determination of dioxines and dioxinlike PCB's in food and animal feedings stuff According to NEN-EN 16215 - EC 709/2014	–

Dioxins

Method Description	Method Code
Determination of dioxines and dioxinlike PCB's in food and animal feedings stuff According to NEN-EN 16215 - EC 709/2014	–
The mediumbound conc: For the calculation of the total TEQ, the values lower than LOQ, were regarded as the value of half of LOQ The lowerbound conc: For the calculation of the TEQ, the values lower than LOQ, were regarded as zero.	.-

Poly Chlorinated Biphenyls

Method Description	Method Code
Determination of the content of PCBs; GPC-LC-GCMS method	Own method

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1116620 version 1**	Disponent Number	:F00002315-0-22971612
Product recognized as	:		
Product Specification	:Lignocellulose Rohware (hell)	Sampling Date	:28-Sep-2020
Reference	:	Samplesize (kg)	:0,176
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971612
Packing	:Plastic, ambient	Sample Arrival Date	:06-Oct-2020 09:22
Sample Type	:Parcel Sample	ReportDate Version	:**13-Oct-2020 10:46**
		Origin	:Germany

Contaminations

Pesticides

Parameter	Result (as received)		
Pesticides GCMS	Performed according annex, nothing detected	Q	R
Pesticides LCMSMS	Performed according annex, nothing detected	Q	R

(b) (4)

Analytical Report

Reportnr.	: **1116620 version 1**	Disponent Number	: F00002315-0-22971612
Product recognized as	:		
Product Specification	: Lignocellulose Rohware (hell)	Sampling Date	: 28-Sep-2020
Reference	:	Samplesize (kg)	: 0,176
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971612
Packing	: Plastic, ambient	Sample Arrival Date	: 06-Oct-2020 09:22
Sample Type	: Parcel Sample	ReportDate Version	: **13-Oct-2020 10:46**

Analysed Contamination / Pesticides below detection limits

Pesticides GCMSMS

		Azinphos-ethyl	< 0,010 mg/kg	Q	Bitertanol	< 0,010 mg/kg	Q	Brompropylate	< 0,010 mg/kg	Q
Chlorothalonil.	< 0,010 mg/kg	Chlorpyrifos-methyl	< 0,010 mg/kg	Q	Cyfluthrin (sum isomers)	< 0,010 mg/kg		Cyfluthrin I	< 0,010 mg/kg	Q
Cyfluthrin II	< 0,010 mg/kg	Q Cyfluthrin III	< 0,010 mg/kg	Q	Cyhalothrin (Lambda)	< 0,010 mg/kg	Q	Cypermethrin (sum)	< 0,010 mg/kg	Q
Deltamethrin	< 0,010 mg/kg	Q Dichlorvos.	< 0,010 mg/kg		Diphenylamine	< 0,010 mg/kg	Q	Disulfoton	< 0,010 mg/kg	Q
Endosulfan (sum)	< 0,010 mg/kg	Endosulfan-a.	< 0,010 mg/kg		Endosulfan-ß	< 0,010 mg/kg	Q	Endosulfansulphate	< 0,010 mg/kg	Q
Famoxadone	< 0,010 mg/kg	Q Fenvalerate (es)	< 0,010 mg/kg	Q	Folpet (sum)	< 0,010 mg/kg		Folpet.	< 0,010 mg/kg	
Iprodione	< 0,010 mg/kg	Q Nitrofen	< 0,010 mg/kg	Q	Parathion-methyl	< 0,010 mg/kg	Q	Permethrin (sum isomers)	< 0,010 mg/kg	
Permethrin I	< 0,010 mg/kg	Q Permethrin II	< 0,010 mg/kg	Q	Procymidone	< 0,010 mg/kg	Q	Profenophos	< 0,010 mg/kg	Q
Resmethrin	< 0,010 mg/kg	Q Vinchlozolin	< 0,010 mg/kg	Q						

Pesticides LCMSMS (neg. ionisation)

		Hexaconazole	< 0,010 mg/kg	Q							

Pesticides LCMSMS (pos. ionisation)

		Azoxystrobin	< 0,010 mg/kg	Q	Carbaryl	< 0,010 mg/kg	Q	Carbendazim	< 0,010 mg/kg	Q
Carbendazim (sum)	< 0,010 mg/kg	Chlorpyriphos	< 0,010 mg/kg	Q	Cyprodinil	< 0,010 mg/kg	Q	Demeton-S-methyl-sulfon	< 0,010 mg/kg	Q
Dimethoate	< 0,010 mg/kg	Q Fenpropidin	< 0,010 mg/kg	Q	Imazalil	< 0,010 mg/kg	Q	Kresoxim-methyl	< 0,010 mg/kg	Q
Malathion	< 0,010 mg/kg	Q Mecarbam	< 0,010 mg/kg	Q	Metalaxyl	< 0,010 mg/kg	Q	Methidathion	< 0,010 mg/kg	Q
Methomyl	< 0,010 mg/kg	Q Myclobutanil	< 0,010 mg/kg	Q	Oxydemeton-methyl	< 0,010 mg/kg	Q	Oxydemeton-methyl (sum)	< 0,010 mg/kg	
Paraoxon-methyl	< 0,010 mg/kg	Q Parathion-ethyl	< 0,010 mg/kg	Q	Pendimethalin	< 0,010 mg/kg	Q	Phosphamidon	< 0,010 mg/kg	Q
Pirimiphos-methyl.	< 0,010 mg/kg	Prochloraz	< 0,010 mg/kg	Q	Propiconazole	< 0,010 mg/kg	Q	Spiroxamine	< 0,010 mg/kg	Q
Thiodicarb	< 0,010 mg/kg	Q Triadimefon	< 0,010 mg/kg	Q	Triadimenol	< 0,010 mg/kg	Q	Triazophos	< 0,010 mg/kg	Q
Trichlorfon	< 0,010 mg/kg	Q								

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

Analytical Report

Reportnr.	: **1116620 version 1**	Disponent Number	: F00002315-0-22971612
Product recognized as	:		
Product Specification	: Lignocellulose Rohware (hell)	Sampling Date	: 28-Sep-2020
Reference	:	Samplesize (kg)	: 0,176
AWB / BarCode	:	Sealed / Seal Code	: Yes / 22971612
Packing	: Plastic, ambient	Sample Arrival Date	: 06-Oct-2020 09:22
Sample Type	: Parcel Sample	ReportDate Version	: **13-Oct-2020 10:46**

ANNEX

Method Descriptions

Contaminations

Pesticides

Method Description	Method Code
Flexscope:Determination of the pesticide content ; GC-MS method	Own method
Flexscope:Determination of the pesticide content; LC-MS-MS method	Own method

Abbreviations:

acc: in accordance with
eq: Equivalent to

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1089579 version 1**	Disponent Number	:22971621
Product recognized as	:		
Product Specification	:Lignocellulose Rohmaterial	Sampling Date	:30-Jun-2020
Reference	:	Samplesize (kg)	:0,177
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971621
Packing	:Plastic, ambient	Sample Arrival Date	:15-Jul-2020 12:25
Sample Type	:Sample	ReportDate Version	:**17-Jul-2020 14:00**

Contaminations

Pesticides

Parameter	Result (as received)		
Pesticides GCMS	Performed according annex, nothing detected	Q	R
Pesticides LCMSMS	Performed according annex, nothing detected	Q	R

(b) (4)

Analytical Report

Reportnr.	: **1089579 version 1**	Disponent Number	:22971621
Product recognized as	:		
Product Specification	:Lignocellulose Rohmaterial	Sampling Date	:30-Jun-2020
Reference	:	Samplesize (kg)	:0,177
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971621
Packing	:Plastic, ambient	Sample Arrival Date	:15-Jul-2020 12:25
Sample Type	:Sample	ReportDate Version	:**17-Jul-2020 14:00**

Analysed Contamination / Pesticides below detection limits

Pesticides GCMSMS

		4-chloro-3-methylphenol.	< 0,010 mg/kg	Aclonifen.	< 0,010 mg/kg	Acrinathrin.	< 0,010 mg/kg
Aldrin and Dieldrin (sum)	< 0,010 mg/kg	Aldrin.	< 0,010 mg/kg	Anthraquinone.	< 0,010 mg/kg	Atrazine.	< 0,010 mg/kg
Azinphos-ethyl.	< 0,010 mg/kg	Barban.	< 0,010 mg/kg	Benazolin-ethyl-ester	< 0,010 mg/kg Q	Benfluralin	< 0,010 mg/kg Q
Bifenox.	< 0,010 mg/kg	Bifenthrin	< 0,010 mg/kg Q	Binapacryl.	< 0,010 mg/kg	Biphenyl.	< 0,010 mg/kg
Bitertanol.	< 0,010 mg/kg	Bromocyclen.	< 0,010 mg/kg	Bromophos-ethyl	< 0,010 mg/kg Q	Bromophos-methyl	< 0,010 mg/kg Q
Brompropylate	< 0,010 mg/kg Q	Butafenacil	< 0,010 mg/kg Q	Captafol.	< 0,010 mg/kg	Captan (sum)	< 0,010 mg/kg
Carbophenothion	< 0,010 mg/kg Q	Chinomethionat.	< 0,010 mg/kg	Chlorbenside.	< 0,010 mg/kg	Chlorbufam.	< 0,010 mg/kg
Chlordane-cis.	< 0,010 mg/kg	Chlordane-trans.	< 0,010 mg/kg	Chlordeconhydrate.	< 0,010 mg/kg	Chlorfenapyr	< 0,010 mg/kg Q
Chlorfenson	< 0,010 mg/kg Q	Chlorfenvinphos	< 0,010 mg/kg Q	Chlormephos.	< 0,010 mg/kg	Chlorobenzilate	< 0,010 mg/kg Q
Chloroneb	< 0,010 mg/kg Q	Chlorothalonil	< 0,010 mg/kg Q	Chlorpropham.	< 0,010 mg/kg	Chlorpyrifos-methyl	< 0,010 mg/kg Q
Chlorthal-dimethyl (DCPA)	< 0,010 mg/kg Q	Chlorthion	< 0,010 mg/kg	Chlozolinate	< 0,010 mg/kg Q	Cyanophos.	< 0,010 mg/kg
Cyfluthrin I.	< 0,010 mg/kg	Cyfluthrin II.	< 0,010 mg/kg	Cyfluthrin III.	< 0,010 mg/kg	Cyhalofop butyl.	< 0,010 mg/kg
Cyhalothrin (Lambda).	< 0,010 mg/kg	Cypermethrin (sum).	< 0,010 mg/kg	Deltamethrin.	< 0,010 mg/kg	Diallate	< 0,010 mg/kg Q
Dichlobenil.	< 0,010 mg/kg	Dichlofop methyl	< 0,010 mg/kg Q	Dichloraniline, 3,5-.	< 0,010 mg/kg	Dichloroaniline.3.4-.	< 0,010 mg/kg
Dichlorobenzophenone,2,4-	< 0,010 mg/kg Q	Dichlorvos.	< 0,010 mg/kg	Dicloran.	< 0,010 mg/kg	Dicofol	< 0,010 mg/kg Q
Dieldrin.	< 0,010 mg/kg	Dinobuton	< 0,010 mg/kg Q	Dioxabenzofos.	< 0,010 mg/kg	Dioxathion	< 0,010 mg/kg Q
Diphenylamine.	< 0,010 mg/kg	Disulfoton	< 0,010 mg/kg Q	Endosulfan (sum)	< 0,010 mg/kg	Endosulfan-a.	< 0,010 mg/kg
Endosulfan-ß.	< 0,010 mg/kg	Endosulfansulphate.	< 0,010 mg/kg	Endrin.	< 0,010 mg/kg	EPN	< 0,010 mg/kg Q
EPTC.	< 0,010 mg/kg	Etridiazole.	< 0,010 mg/kg	Etrimfos	< 0,010 mg/kg Q	Famoxadone.	< 0,010 mg/kg
Fenchlorfos (Ronnel)	< 0,010 mg/kg Q	Fenitrothion.	< 0,010 mg/kg	Fenpropathrin	< 0,010 mg/kg Q	Fenson	< 0,010 mg/kg Q
Fenthion-oxon.	< 0,010 mg/kg	Fenvalerate (es)	< 0,010 mg/kg Q	Fenvalerate (sum)	< 0,010 mg/kg Q	Fluchloralin	< 0,010 mg/kg Q
Flucythrinate.	< 0,010 mg/kg	Fluvalinate.	< 0,010 mg/kg	Folpet	< 0,010 mg/kg Q	Folpet (sum)	< 0,010 mg/kg
HCH-a.	< 0,005 mg/kg	HCH-d.	< 0,005 mg/kg	HCH-ß.	< 0,005 mg/kg	HCH-y.	< 0,005 mg/kg
Heptachlor.	< 0,005 mg/kg	Heptachloroepoxide-cis	< 0,010 mg/kg Q	Heptachloroepoxide-trans.	< 0,005 mg/kg	Hexachlorobenzene (HCB).	< 0,005 mg/kg
Iodofenfos.	< 0,010 mg/kg	Iprodione.	< 0,010 mg/kg	Isodrin.	< 0,010 mg/kg	Leptophos.	< 0,010 mg/kg
Methacrifos	< 0,010 mg/kg Q	Methoxychlor.	< 0,010 mg/kg	Naled.	< 0,010 mg/kg	Nitrofen.	< 0,010 mg/kg
Nitrothal-isopropyl (Nitrothal)	< 0,010 mg/kg Q	Nonachlor (cis + trans).	< 0,010 mg/kg	o,p-DDD.	< 0,005 mg/kg	o,p-DDE.	< 0,005 mg/kg
o,p-DDT.	< 0,005 mg/kg	Oxadiazon.	< 0,010 mg/kg	Oxychlordane.	< 0,010 mg/kg	Oxyfluorfen	< 0,010 mg/kg Q
p,p-DDD.	< 0,005 mg/kg	p,p-DDE.	< 0,005 mg/kg	p,p-DDT.	< 0,010 mg/kg	Parathion-methyl.	< 0,010 mg/kg
Pentachloorbenzene.	< 0,010 mg/kg	Pentachloroaniline.	< 0,010 mg/kg	Pentachloroanisole.	< 0,010 mg/kg	Perchlordecone (mirex).	< 0,010 mg/kg Q
Permethrin I.	< 0,010 mg/kg	Permethrin II.	< 0,010 mg/kg	Perthane (Ethylan)	< 0,010 mg/kg Q	Phenothrin (peak 1)	< 0,010 mg/kg
Phenothrin (peak 2)	< 0,010 mg/kg	Phenothrin (sum)	< 0,010 mg/kg Q	Phenthoate	< 0,010 mg/kg Q	Phenylphenol,2-	< 0,010 mg/kg Q
Phorate	< 0,010 mg/kg Q	Phtalimide.	< 0,010 mg/kg	Piperonylbutoxide	< 0,010 mg/kg Q	Procymidone	< 0,010 mg/kg Q
Profenophos.	< 0,010 mg/kg	Propham.	< 0,010 mg/kg	Pyrethrins (sum)	< 0,010 mg/kg	Quintozene (sum).	< 0,010 mg/kg
Resmethrin.	< 0,010 mg/kg	Silafluofen.	< 0,010 mg/kg	Tebupirimfos	< 0,010 mg/kg Q	Tecnazene.	< 0,010 mg/kg
Tefluthrin	< 0,010 mg/kg Q	Terbufos	< 0,010 mg/kg Q	Tetradifon	< 0,010 mg/kg Q	Tetrahydrophthalimide (THPI).	< 0,010 mg/kg
Tetramethrin.	< 0,010 mg/kg	Thiometon.	< 0,010 mg/kg	Toxaphen P26.	< 0,010 mg/kg	Toxaphen P50.	< 0,010 mg/kg
Toxaphen P62.	< 0,010 mg/kg	Trifluralin	< 0,010 mg/kg Q	Vinchlozolin	< 0,010 mg/kg Q		

Pesticides LCMSMS

		Alachlor.	< 0,010 mg/kg	Etofenprox	< 0,010 mg/kg Q	Fluxapyroxad	< 0,010 mg/kg Q
Malathion (sum)	< 0,010 mg/kg						

Pesticides LCMSMS (neg. ionisation)

(b) (4)

Analytical Report

Reportnr.	: **1089579 version 1**	Disponent Number	:22971621
Product recognized as	:		
Product Specification	:Lignocellulose Rohmaterial	Sampling Date	:30-Jun-2020
Reference	:	Samplesize (kg)	:0,177
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971621
Packing	:Plastic, ambient	Sample Arrival Date	:15-Jul-2020 12:25
Sample Type	:Sample	ReportDate Version	:**17-Jul-2020 14:00**

		2,4-D.	< 0,010 mg/kg	Bentazone	< 0,010 mg/kg	Bentazone-6-hydroxy.	< 0,010 mg/kg
Bentazone-8-hydroxy.	< 0,010 mg/kg	Bromoxynil	< 0,010 mg/kg	Carbetamide	< 0,010 mg/kg Q	Chlorbromuron	< 0,010 mg/kg Q
Chlorfluazuron	< 0,010 mg/kg Q	Chloroxuron	< 0,010 mg/kg Q	Clethodim (sum)	< 0,010 mg/kg	Clethodim.	< 0,010 mg/kg
Cyantraniliprole	< 0,01 mg/kg Q	Cyclanilide	< 0,010 mg/kg	Cythioate	< 0,010 mg/kg Q	Dichlorophen	< 0,010 mg/kg
Dichlorprop	< 0,010 mg/kg	Diflubenzuron	< 0,010 mg/kg Q	Diflufenican.	< 0,010 mg/kg	Dinoseb	< 0,010 mg/kg Q
Dinoterb.	< 0,010 mg/kg	Diuron	< 0,010 mg/kg Q	DMSA (N,N-dimethyl-N'-fenyls	< 0,010 mg/kg	DNOC	< 0,010 mg/kg Q
Fenoxaprop-P-ethyl	< 0,010 mg/kg Q	Fenpiclonil	< 0,010 mg/kg Q	Fipronil	< 0,005 mg/kg Q	Fipronil (sum)	< 0,005 mg/kg Q
Fipronil sulfon	< 0,005 mg/kg Q	Fluazinam.	< 0,010 mg/kg	Flubendiamide	< 0,010 mg/kg Q	Flucycloxuron (E+Z).	< 0,010 mg/kg
Fludioxonil	< 0,010 mg/kg Q	Flufenoxuron	< 0,010 mg/kg Q	Fluometuron	< 0,010 mg/kg Q	Flutolanil	< 0,010 mg/kg Q
Halofenozide.	< 0,010 mg/kg	Hexaconazole	< 0,010 mg/kg Q	Hexaflumuron	< 0,010 mg/kg Q	Imazamethabenz-methyl	< 0,010 mg/kg Q
Isocarbophos	< 0,010 mg/kg Q	Isoxaflutole	< 0,010 mg/kg Q	Lufenuron	< 0,010 mg/kg Q	MCPA	< 0,010 mg/kg
MCPA & MCPB (sum)	< 0,010 mg/kg	MCPB.	< 0,010 mg/kg	Mecoprop	< 0,010 mg/kg	Mepronil	< 0,010 mg/kg Q
Methoprene.	< 0,010 mg/kg	Monuron	< 0,010 mg/kg Q	Neburon	< 0,010 mg/kg Q	Norflurazon	< 0,010 mg/kg Q
Noviflumuron	< 0,010 mg/kg Q	Phosmet	< 0,010 mg/kg Q	Picolinafen.	< 0,010 mg/kg	Propanil	< 0,010 mg/kg Q
Prothioconazole (sum)	< 0,010 mg/kg	Prothioconazole.	< 0,010 mg/kg	Silthiofam	< 0,010 mg/kg Q	Sulfosulfuron	< 0,010 mg/kg Q
Teflubenzuron	< 0,010 mg/kg Q	Terbacil	< 0,010 mg/kg Q	Triasulfuron	< 0,010 mg/kg Q	Triflumuron	< 0,010 mg/kg Q
Triflusulfuron-methyl.	< 0,010 mg/kg	Warfarin	< 0,010 mg/kg Q				

Pesticides LCMSMS (pos. ionisation)

		Acephate.	< 0,010 mg/kg	Acetamiprid	< 0,010 mg/kg Q	Acetochlor	< 0,010 mg/kg Q
Acibenzolar-S-methyl.	< 0,010 mg/kg	Aldicarb sulphone	< 0,010 mg/kg Q	Aldicarb.	< 0,010 mg/kg	Aldicarb-sulfoxide.	< 0,010 mg/kg
Allethrin	< 0,010 mg/kg Q	Ametoctradin	< 0,010 mg/kg Q	Ametryn.	< 0,010 mg/kg	Aminobenzimidazole,2-.	< 0,010 mg/kg
Aminocarb	< 0,010 mg/kg Q	Aminopyralid	< 0,010 mg/kg Q	Azaconazole	< 0,010 mg/kg Q	Azadirachtin.	< 0,010 mg/kg
Azamethiphos	< 0,010 mg/kg Q	Azimsulfuron	< 0,010 mg/kg	Azinphos-methyl	< 0,010 mg/kg Q	Aziprotryne.	< 0,010 mg/kg
Azoxystrobin	< 0,010 mg/kg Q	Benalaxyl	< 0,010 mg/kg Q	Bendiocarb	< 0,010 mg/kg Q	Benfuracarb.	< 0,005 mg/kg
Benodanil	< 0,010 mg/kg Q	Benomyl.	< 0,010 mg/kg	Benthiavalicarb-isopropyl	< 0,010 mg/kg Q	Benzoximate.	< 0,010 mg/kg
Benzoyl-prop-ethyl	< 0,010 mg/kg Q	Bifenazate.	< 0,010 mg/kg	Boscalid	< 0,010 mg/kg Q	Bromacil	< 0,010 mg/kg Q
Bromuconazole	< 0,010 mg/kg Q	Bufencarb	< 0,010 mg/kg Q	Bupirimate	< 0,010 mg/kg Q	Buprofezin.	< 0,010 mg/kg
Butocarboxim sulfoxide.	< 0,010 mg/kg	Butoxycarboxim.	< 0,010 mg/kg	Butralin.	< 0,010 mg/kg	Buturon	< 0,010 mg/kg Q
Butylate.	< 0,010 mg/kg	Cadusafos.	< 0,010 mg/kg	Carbaryl	< 0,010 mg/kg Q	Carbendazim	< 0,010 mg/kg Q
Carbendazim (sum)	< 0,010 mg/kg	Carbofuran	< 0,002 mg/kg Q	Carbofuran (sum)	< 0,002 mg/kg	Carbofuran-3-hydroxy	< 0,002 mg/kg Q
Carbofuran-3-keto	< 0,002 mg/kg Q	Carboxin	< 0,010 mg/kg Q	Carfentrazone-ethyl	< 0,010 mg/kg Q	Carpropamide	< 0,010 mg/kg Q
Chlorantraniliprole	< 0,010 mg/kg Q	Chloridazon (sum)	< 0,010 mg/kg	Chloridazon.	< 0,010 mg/kg	Chloroaniline,3-.	< 0,010 mg/kg
Chlorotoluron	< 0,010 mg/kg Q	Chlorpyriphos.	< 0,010 mg/kg	Chlorthiamid.	< 0,010 mg/kg	Chlorthiophos.	< 0,010 mg/kg
Climbazol	< 0,010 mg/kg Q	Clodinafop-propargyl	< 0,010 mg/kg Q	Clofentezine.	< 0,010 mg/kg	Clomazone	< 0,010 mg/kg Q
Clopyralid.	< 0,010 mg/kg	Cloquintocet - mexyl.	< 0,010 mg/kg	Clothianidin	< 0,010 mg/kg Q	Coumaphos	< 0,010 mg/kg Q
Crimidine	< 0,010 mg/kg Q	Cruformate	< 0,010 mg/kg Q	Cyanazine	< 0,010 mg/kg Q	Cyanofenphos	< 0,010 mg/kg Q
Cyazofamid	< 0,010 mg/kg Q	Cycloate.	< 0,010 mg/kg	Cycloxydim,	< 0,010 mg/kg	Cyflufenamid	< 0,010 mg/kg Q
Cymiazole	< 0,010 mg/kg Q	Cymoxanil	< 0,010 mg/kg Q	Cyproconazole	< 0,010 mg/kg Q	Cyprodinil.	< 0,010 mg/kg
Cyprofuram	< 0,010 mg/kg Q	Cyromazine.	< 0,010 mg/kg	Daminozide.	< 0,010 mg/kg	Dazomet	< 0,010 mg/kg Q
Demeton O & S.	< 0,010 mg/kg	Demeton-S-methyl	< 0,010 mg/kg Q	Demeton-S-methyl-sulfon	< 0,010 mg/kg Q	Desmedipham	< 0,010 mg/kg Q
Desmetryn	< 0,010 mg/kg Q	Diafenthiuron.	< 0,010 mg/kg	Dialifos	< 0,010 mg/kg Q	Diazinon.	< 0,010 mg/kg
Dichlofluanid.	< 0,010 mg/kg	Diclobutrazol	< 0,010 mg/kg Q	Dicrotophos	< 0,010 mg/kg Q	Diethatyl-ethyl	< 0,010 mg/kg Q
Diethofencarb	< 0,010 mg/kg Q	Diethyltoluamid (DEET)	< 0,010 mg/kg Q	Difenoconazole	< 0,010 mg/kg Q	Difenoxuron	< 0,010 mg/kg Q
Dimefox	< 0,010 mg/kg Q	Dimefuron	< 0,010 mg/kg Q	Dimethachlor	< 0,010 mg/kg Q	Dimethirimol.	< 0,010 mg/kg
Dimethoate	< 0,010 mg/kg Q	Dimethoate and omethoate (s	< 0,010 mg/kg	Dimethomorph	< 0,010 mg/kg Q	Dimoxystrobin	< 0,010 mg/kg Q

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1089579 version 1**	Disponent Number	:22971621
Product recognized as	:		
Product Specification	:Lignocellulose Rohmaterial	Sampling Date	:30-Jun-2020
Reference	:	Samplesize (kg)	:0,177
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971621
Packing	:Plastic, ambient	Sample Arrival Date	:15-Jul-2020 12:25
Sample Type	:Sample	ReportDate Version	:**17-Jul-2020 14:00**

Diniconazole	< 0,010 mg/kg Q	Dinotefuran.	< 0,010 mg/kg	Dioxacarb	< 0,010 mg/kg Q	Diphenamid	< 0,010 mg/kg Q
Dipropetryn.	< 0,010 mg/kg	Disulfoton (sum)	< 0,010 mg/kg	Disulfoton-sulfone.	< 0,010 mg/kg	Ditalimfos	< 0,010 mg/kg Q
DMST (Dimethylsulftoluidide)	< 0,010 mg/kg Q	Dodemorph-cis	< 0,010 mg/kg Q	Dodemorph-trans	< 0,010 mg/kg Q	Dodine.	< 0,010 mg/kg
Edifenphos.	< 0,010 mg/kg	Emamectin	< 0,010 mg/kg Q	Epoxiconazole	< 0,010 mg/kg Q	Etaconazole	< 0,010 mg/kg Q
Ethiofencarb	< 0,010 mg/kg Q	Ethiofencarb sulfone	< 0,010 mg/kg Q	Ethion	< 0,010 mg/kg Q	Ethiprole	< 0,010 mg/kg Q
Ethirimol.	< 0,010 mg/kg	Ethofumesate	< 0,010 mg/kg Q	Ethoprofos.	< 0,010 mg/kg	Ethoprop.	< 0,010 mg/kg
Ethoxyquin.	< 0,010 mg/kg	Ethoxysulfuron	< 0,010 mg/kg Q	Etoxazol.	< 0,010 mg/kg	Fenamidone	< 0,010 mg/kg Q
Fenamiphos	< 0,010 mg/kg Q	Fenamiphos (sum)	< 0,010 mg/kg	Fenamiphos sulphone	< 0,010 mg/kg Q	Fenamiphos sulphoxide	< 0,010 mg/kg Q
Fenarimol	< 0,010 mg/kg Q	Fenazaquin.	< 0,010 mg/kg	Fenbuconazole	< 0,010 mg/kg Q	Fenfuram	< 0,010 mg/kg Q
Fenhexamid	< 0,010 mg/kg Q	Fenobucarb	< 0,010 mg/kg Q	Fenothiocarb	< 0,010 mg/kg Q	Fenoxycarb	< 0,010 mg/kg Q
Fenpropidin	< 0,010 mg/kg Q	Fenpropimorph	< 0,010 mg/kg Q	Fenpyroximat.	< 0,010 mg/kg	Fensulfothion	< 0,010 mg/kg Q
Fenthion	< 0,010 mg/kg Q	Fenthion-sulfoxide	< 0,010 mg/kg Q	Fenuron	< 0,010 mg/kg Q	Flamprop-isopropyl.	< 0,010 mg/kg
Flamprop-methyl	< 0,010 mg/kg Q	Flazasulfuron	< 0,010 mg/kg Q	Flonicamid (sum incl. metaboli	< 0,010 mg/kg Q	Florasulam.	< 0,010 mg/kg
Fluazifop (free acid).	< 0,010 mg/kg	Fluazifop (sum)	< 0,010 mg/kg	Fluazifop-p-butyl	< 0,010 mg/kg Q	Flufenacet	< 0,010 mg/kg Q
Fluopicolide.	< 0,010 mg/kg	Fluopyram	< 0,010 mg/kg Q	Fluoxastrobin	< 0,010 mg/kg Q	Fluquinconazole	< 0,010 mg/kg Q
Flurochloridone	< 0,010 mg/kg Q	Fluroxypyr-meptyl	< 0,010 mg/kg Q	Flusilazole	< 0,010 mg/kg Q	Flutriafol	< 0,010 mg/kg Q
Fonofos.	< 0,010 mg/kg	Foramsulfuron	< 0,010 mg/kg Q	Forchlorfenuron	< 0,010 mg/kg Q	Formetanate.	< 0,010 mg/kg
Formothion.	< 0,010 mg/kg	Fosthiazate	< 0,010 mg/kg Q	Fuberidazole.	< 0,010 mg/kg	Furalaxyl	< 0,010 mg/kg Q
Furathiocarb	< 0,005 mg/kg Q	Furmecyclox.	< 0,010 mg/kg	Haloxyfop	< 0,010 mg/kg Q	Haloxyfop-2-ethoxyethyl	< 0,010 mg/kg Q
Haloxyfop-methyl	< 0,010 mg/kg Q	Heptenophos	< 0,010 mg/kg Q	Hexazinone	< 0,010 mg/kg Q	Hexythiazox.	< 0,010 mg/kg
Hymexazole.	< 0,010 mg/kg	Imazalil	< 0,010 mg/kg Q	Imazamox	< 0,01 mg/kg Q	Imazapic.	< 0,010 mg/kg
Imazapyr.	< 0,010 mg/kg	Imidacloprid.	< 0,010 mg/kg	Indoxacarb	< 0,010 mg/kg Q	Iodosulfuron methyl	< 0,010 mg/kg Q
Iprobenphos	< 0,010 mg/kg Q	Iprovalicarb	< 0,010 mg/kg Q	Isazofos	< 0,010 mg/kg Q	Isofenphos-ethyl.	< 0,010 mg/kg
Isofenphos-methyl	< 0,010 mg/kg Q	Isofenphos-oxon	< 0,010 mg/kg Q	Isoprocarb	< 0,010 mg/kg Q	Isoprothiolane	< 0,010 mg/kg Q
Isoproturon	< 0,010 mg/kg Q	Isopyrazam.	< 0,010 mg/kg	Isouron	< 0,010 mg/kg Q	Isoxathion.	< 0,010 mg/kg
Kresoxym-methyl.	< 0,010 mg/kg	Lenacil	< 0,010 mg/kg Q	Linuron	< 0,010 mg/kg Q	Malaoxon	< 0,010 mg/kg Q
Malathion	< 0,010 mg/kg Q	Mandipropamid	< 0,010 mg/kg Q	Mecarbam	< 0,010 mg/kg Q	Mefenacet	< 0,010 mg/kg Q
Mepanipyrim.	< 0,010 mg/kg	Mephosfolan	< 0,010 mg/kg Q	Mesosulfuron-methyl	< 0,010 mg/kg Q	Mesotrione.	< 0,010 mg/kg
Metaflumizone.	< 0,010 mg/kg	Metalaxyl	< 0,010 mg/kg Q	Metamitron	< 0,010 mg/kg Q	Metazachloor	< 0,010 mg/kg Q
Metconazole.	< 0,010 mg/kg	Methabenzthiazuron	< 0,010 mg/kg Q	Methamidophos	< 0,010 mg/kg Q	Methidathion	< 0,010 mg/kg Q
Methiocarb	< 0,010 mg/kg Q	Methiocarb sulfone	< 0,010 mg/kg Q	Methiocarb sulfoxide	< 0,010 mg/kg Q	Metholachlor.	< 0,010 mg/kg
Methomyl	< 0,010 mg/kg Q	Methoprotryne	< 0,010 mg/kg Q	Methoxyfenozide	< 0,010 mg/kg Q	Metobromuron	< 0,010 mg/kg Q
Metolachlor	< 0,010 mg/kg Q	Metolcarb	< 0,010 mg/kg Q	Metoxuron	< 0,010 mg/kg Q	Metrafenone.	< 0,010 mg/kg
Metribuzin	< 0,010 mg/kg Q	Metsulfuron methyl.	< 0,010 mg/kg	Mevinphos	< 0,010 mg/kg Q	Mexacarbate	< 0,010 mg/kg Q
Monalide	< 0,010 mg/kg Q	Monocrotophos.	< 0,010 mg/kg	Monolinuron	< 0,010 mg/kg Q	Myclobutanil	< 0,010 mg/kg Q
Naphthylacetamide,1-.	< 0,010 mg/kg	Napropamide	< 0,010 mg/kg Q	Nicosulfuron.	< 0,010 mg/kg	Nitenpyram.	< 0,010 mg/kg
Novaluron	< 0,010 mg/kg Q	Nuarimol	< 0,010 mg/kg Q	Ofurace	< 0,010 mg/kg Q	Omethoate.	< 0,010 mg/kg
Orbencarb.	< 0,010 mg/kg	Oxadixyl	< 0,010 mg/kg Q	Oxamyl.	< 0,010 mg/kg	Oxasulfuron	< 0,010 mg/kg Q
Oxycarboxin	< 0,010 mg/kg Q	Oxydemeton-methyl	< 0,010 mg/kg Q	Paclobutrazol	< 0,010 mg/kg Q	Paraoxon-Ethyl	< 0,010 mg/kg Q
Paraoxon-methyl	< 0,010 mg/kg Q	Parathion-ethyl	< 0,010 mg/kg Q	Penconazole	< 0,010 mg/kg Q	Pencycuron	< 0,010 mg/kg Q
Pendimethalin.	< 0,010 mg/kg Q	Pentanochlor	< 0,010 mg/kg Q	Penthiopyrad	< 0,01 mg/kg Q	Phenmedipham	< 0,010 mg/kg Q
Phorate sulfone	< 0,010 mg/kg Q	Phorate sulfoxide	< 0,010 mg/kg Q	Phosalone	< 0,010 mg/kg Q	Phosphamidon	< 0,010 mg/kg Q
Phoxim	< 0,010 mg/kg Q	Picoxystrobin	< 0,010 mg/kg Q	Pirimicarb	< 0,010 mg/kg Q	Pirimidifen.	< 0,010 mg/kg
Pirimiphos-ethyl.	< 0,010 mg/kg	Pirimiphos-methyl.	< 0,010 mg/kg	Prochloraz	< 0,010 mg/kg Q	Promecarb	< 0,010 mg/kg Q
Prometryn.	< 0,010 mg/kg	Propachlor	< 0,010 mg/kg Q	Propamocarb	< 0,010 mg/kg Q	Propaphos	< 0,010 mg/kg Q
Propaquizafop	< 0,010 mg/kg Q	Propargite.	< 0,010 mg/kg	Propazine.	< 0,010 mg/kg	Propetamphos.	< 0,010 mg/kg
Propiconazole	< 0,010 mg/kg Q	Propoxur	< 0,010 mg/kg Q	Propoxycarbazone sodium.	< 0,010 mg/kg	Propyzamide	< 0,010 mg/kg Q

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1089579 version 1**	Disponent Number	:22971621
Product recognized as	:		
Product Specification	:Lignocellulose Rohmaterial	Sampling Date	:30-Jun-2020
Reference	:	Samplesize (kg)	:0,177
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971621
Packing	:Plastic, ambient	Sample Arrival Date	:15-Jul-2020 12:25
Sample Type	:Sample	ReportDate Version	:**17-Jul-2020 14:00**

Proquinazid.	< 0,010 mg/kg	Prosulfocarb.	< 0,010 mg/kg	Prosulfuron	< 0,010 mg/kg Q	Prothiofos.	< 0,010 mg/kg
Prothoate	< 0,010 mg/kg Q	Pymetrozine.	< 0,010 mg/kg	Pyracarbolid	< 0,010 mg/kg Q	Pyraclofos	< 0,010 mg/kg Q
Pyraclostrobin.	< 0,010 mg/kg	Pyraflufen-ethyl	< 0,010 mg/kg Q	Pyrazophos	< 0,010 mg/kg Q	Pyridaben.	< 0,010 mg/kg
Pyridafol	< 0,010 mg/kg Q	Pyridaphenthion	< 0,010 mg/kg Q	Pyridate (sum)	< 0,01 mg/kg	Pyridate.	< 0,010 mg/kg
Pyrifenox	< 0,010 mg/kg Q	Pyrimethanil.	< 0,010 mg/kg	Pyriproxyfen.	< 0,010 mg/kg	Pyroquilon	< 0,010 mg/kg Q
Quinalphos.	< 0,010 mg/kg	Quinclorac	< 0,010 mg/kg Q	Quinmerac	< 0,010 mg/kg Q	Quinoclamine	< 0,010 mg/kg Q
Quinoxyfen.	< 0,010 mg/kg	Quizalofop-ethyl.	< 0,010 mg/kg	Rimsulfuron	< 0,010 mg/kg Q	Rotenone	< 0,010 mg/kg Q
Saflufenacil	< 0,010 mg/kg Q	Sedaxane	< 0,010 mg/kg Q	Simazine	< 0,010 mg/kg Q	Spinetoram	< 0,010 mg/kg Q
Spinosyn A	< 0,010 mg/kg Q	Spinosyn D	< 0,010 mg/kg Q	Spirodiclofen.	< 0,010 mg/kg	Spiromesifen.	< 0,010 mg/kg
Spirotetramat (sum incl. 4 met	< 0,010 mg/kg	Spirotetramat.	< 0,010 mg/kg	Spirotetramat-cis-enol	< 0,010 mg/kg Q	Spirotetramat-cis-keto-hydrox	< 0,010 mg/kg Q
Spirotetramat-enol-glucoside.	< 0,010 mg/kg	Spirotetramat-mono-hydroxy	< 0,010 mg/kg Q	Spiroxamine	< 0,010 mg/kg Q	Sulcotrione.	< 0,010 mg/kg
Sulfotep.	< 0,010 mg/kg	Sulfoxaflor	< 0,010 mg/kg Q	Sulprofos.	< 0,010 mg/kg	Tebuconazol	< 0,010 mg/kg Q
Tebufenozide.	< 0,010 mg/kg	Tebufenpyrad.	< 0,010 mg/kg	Tebuthiuron	< 0,010 mg/kg Q	TEPP,O,O-	< 0,010 mg/kg Q
TEPP,O,S-	< 0,010 mg/kg Q	Terbumeton	< 0,010 mg/kg Q	Terbuthylazine.	< 0,010 mg/kg	Terbutryn.	< 0,010 mg/kg
Tetrachlorvinphos	< 0,010 mg/kg Q	Tetraconazole.	< 0,010 mg/kg	TFNA.	< 0,010 mg/kg	TFNA-AM	< 0,010 mg/kg Q
TFNG.	< 0,010 mg/kg	Thiabendazole.	< 0,010 mg/kg	Thiacloprid	< 0,010 mg/kg Q	Thiadiazuron	< 0,010 mg/kg Q
Thiamethoxam	< 0,010 mg/kg Q	Thifensulfuron methyl.	< 0,010 mg/kg	Thiobencarb.	< 0,010 mg/kg	Thiocyclam hydrogen oxal.	< 0,010 mg/kg
Thiodicarb	< 0,010 mg/kg Q	Thiofanox.	< 0,010 mg/kg	Thiofanox-sulfone.	< 0,010 mg/kg	Thiofanox-sulfoxide.	< 0,010 mg/kg
Thiophanate-methyl.	< 0,010 mg/kg	Tolclofos-methyl.	< 0,010 mg/kg	Tolfenpyrad.	< 0,010 mg/kg	Tolyfluanid (sum)	< 0,01 mg/kg
Tolylfluanid.	< 0,010 mg/kg	Triadimefon	< 0,010 mg/kg Q	Triadimenol	< 0,010 mg/kg Q	Triallate.	< 0,010 mg/kg
Triapenthenol	< 0,010 mg/kg Q	Triazophos	< 0,010 mg/kg Q	Trichlorfon	< 0,010 mg/kg Q	Tricyclazole	< 0,010 mg/kg Q
Trietazine.	< 0,010 mg/kg	Trifloxystrobin.	< 0,010 mg/kg	Triflumizole	< 0,010 mg/kg Q	Triforine.	< 0,010 mg/kg
Trimethacarb,3,4,5-	< 0,010 mg/kg	Trinexapac	< 0,010 mg/kg Q	Triticonazole	< 0,010 mg/kg Q	Vamidothion	< 0,010 mg/kg Q
Vernolat.	< 0,010 mg/kg	XMC (3,5-Xylyl MethylCarbam	< 0,010 mg/kg Q				

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4) location Rotterdam

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1089579 version 1**	Disponent Number	:22971621
Product recognized as	:		
Product Specification	:Lignocellulose Rohmaterial	Sampling Date	:30-Jun-2020
Reference	:	Samplesize (kg)	:0,177
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971621
Packing	:Plastic, ambient	Sample Arrival Date	:15-Jul-2020 12:25
Sample Type	:Sample	ReportDate Version	:**17-Jul-2020 14:00**

ANNEX

Method Descriptions

Contaminations

Pesticides

Method Description	Method Code
Flexscope:Determination of the pesticide content ; GC-MS method	Own method
Flexscope:Determination of the pesticide content; LC-MS-MS method	Own method

Abbreviations:

acc: in accordance with
eq: Equivalent to

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **1019751 version 1**	Disponent Number	: F00002315-0-22971660
Product recognized as	:		
Product Specification	: Lignocullulose, 12.08.01	Sampling Date	: 19-Nov-2019
Reference	:	Samplesize (kg)	: 0,157
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971660
Packing	: Plastic, ambient	Sample Arrival Date	: 30-Nov-2019 11:47
Sample Type	: Parcel Sample	ReportDate Version	: **04-Dec-2019 21:47**
		Origin	: Germany

Contaminations

Pesticides

Parameter	Result (as received)		
Pesticides GCMS	performed according to annex	Q	R
Pesticides LCMSMS	performed according to annex	Q	R

(b) (4)

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1019751 version 1**	Disponent Number	: F00002315-0-22971660
Product recognized as	:		
Product Specification	: Lignocullulose, 12.08.01	Sampling Date	: 19-Nov-2019
Reference	:	Samplesize (kg)	: 0,157
AWB / BarCode	:	Sealed / Seal Code	: Yes / 22971660
Packing	: Plastic, ambient	Sample Arrival Date	: 30-Nov-2019 11:47
Sample Type	: Parcel Sample	ReportDate Version	: **04-Dec-2019 21:47**

Analysed Contamination / Pesticides below detection limits

Pesticides GCMSMS

		Azinphos-ethyl	< 0,010 mg/kg	Q	Bitertanol	< 0,010 mg/kg	Q	Brompropylate	< 0,010 mg/kg	Q
Chlorothalonil.	< 0,010 mg/kg	Chlorpyrifos-methyl	< 0,010 mg/kg	Q	Cyfluthrin (sum isomers)	< 0,010 mg/kg		Cyfluthrin I	< 0,010 mg/kg	Q
Cyfluthrin II	< 0,010 mg/kg	Q Cyfluthrin III	< 0,010 mg/kg	Q	Cyhalothrin (Lambda)	< 0,010 mg/kg	Q	Cypermethrin (sum)	< 0,010 mg/kg	Q
Deltamethrin	< 0,010 mg/kg	Q Dichlorvos.	< 0,010 mg/kg		Diphenylamine	< 0,010 mg/kg	Q	Disulfoton	< 0,010 mg/kg	Q
Endosulfan (sum)	< 0,010 mg/kg	Endosulfan-a.	< 0,010 mg/kg		Endosulfan-ß	< 0,010 mg/kg	Q	Endosulfansulphate	< 0,010 mg/kg	Q
Famoxadone	< 0,010 mg/kg	Q Fenvalerate (es)	< 0,010 mg/kg	Q	Folpet (sum)	< 0,010 mg/kg		Folpet.	< 0,010 mg/kg	
Iprodione	< 0,010 mg/kg	Q Nitrofen	< 0,010 mg/kg	Q	Parathion-methyl	< 0,010 mg/kg	Q	Permethrin (sum isomers)	< 0,010 mg/kg	
Permethrin I	< 0,010 mg/kg	Q Permethrin II	< 0,010 mg/kg	Q	Procymidone	< 0,010 mg/kg	Q	Profenophos	< 0,010 mg/kg	Q
Resmethrin	< 0,010 mg/kg	Q Vinchlozolin	< 0,010 mg/kg	Q						

Pesticides LCMSMS (neg. ionisation)

		Hexaconazole	< 0,010 mg/kg	Q							

Pesticides LCMSMS (pos. ionisation)

		Azoxystrobin	< 0,010 mg/kg	Q	Carbaryl	< 0,010 mg/kg	Q	Carbendazim	< 0,010 mg/kg	Q
Carbendazim (sum)	< 0,010 mg/kg	Chlorpyriphos	< 0,010 mg/kg	Q	Cyprodinil	< 0,010 mg/kg	Q	Demeton-S-methyl-sulfon	< 0,010 mg/kg	Q
Dimethoate	< 0,010 mg/kg	Q Fenpropidin	< 0,010 mg/kg	Q	Imazalil	< 0,010 mg/kg	Q	Kresoxim-methyl	< 0,010 mg/kg	Q
Malathion	< 0,010 mg/kg	Q Mecarbam	< 0,010 mg/kg	Q	Metalaxyl	< 0,010 mg/kg	Q	Methidathion	< 0,010 mg/kg	Q
Methomyl	< 0,010 mg/kg	Q Myclobutanil	< 0,010 mg/kg	Q	Oxydemeton-methyl	< 0,010 mg/kg	Q	Oxydemeton-methyl (sum)	< 0,010 mg/kg	
Paraoxon-methyl	< 0,010 mg/kg	Q Parathion-ethyl	< 0,010 mg/kg	Q	Pendimethalin	< 0,010 mg/kg	Q	Phosphamidon	< 0,010 mg/kg	Q
Pirimiphos-methyl.	< 0,010 mg/kg	Prochloraz	< 0,010 mg/kg	Q	Propiconazole	< 0,010 mg/kg	Q	Spiroxamine	< 0,010 mg/kg	Q
Thiodicarb	< 0,010 mg/kg	Q Triadimefon	< 0,010 mg/kg	Q	Triadimenol	< 0,010 mg/kg	Q	Triazophos	< 0,010 mg/kg	Q
Trichlorfon	< 0,010 mg/kg	Q								

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4) location Rotterdam

(b) (4)

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **1019751 version 1**	Disponent Number	:F00002315-0-22971660
Product recognized as	:		
Product Specification	:Lignocullulose, 12.08.01	Sampling Date	:19-Nov-2019
Reference	:	Samplesize (kg)	:0,157
AWB / BarCode	:	Sealed / Seal Code	:Yes /22971660
Packing	:Plastic, ambient	Sample Arrival Date	:30-Nov-2019 11:47
Sample Type	:Parcel Sample	ReportDate Version	:**04-Dec-2019 21:47**

ANNEX

Method Descriptions

Contaminations

Pesticides

Method Description	Method Code
Flexscope:Determination of the pesticide content ; GC-MS method	Own method
Flexscope:Determination of the pesticide content; LC-MS-MS method	Own method

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **995972 version 1**	Disponent Number	: F00002315-0-22971666
Product recognized as	:		
Product Specification	: Lignocullulose aus Rinde, 12.08.05	Sampling Date	: 18-Sep-2019
Reference	:	Samplesize (kg)	: 0,194
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971666
Packing	: Plastic, ambient	Sample Arrival Date	: 26-Sep-2019 09:50
Sample Type	: Parcel Sample	ReportDate Version	: **03-Oct-2019 17:26**
		Origin	: Germany

Contaminations

Pesticides

Parameter	Result (as received)		
Pesticides GCMS	No pesticides detected above LOQ. Method and accrediation in infosheet available by (b) (4)	Q	R
Pesticides LCMSMS	No pesticides detected above LOQ. Method and accreditation in infosheet available b (b) (4)	Q	R
Pesticides LCMSMS (neg. ionisatio	No pesticides detected above LOQ. Method and accreditation in infosheet available by (b) (4)	Q	R

(b) (4)

Analytical Report

Reportnr.	: **995972 version 1**	Disponent Number	: F00002315-0-22971666
Product recognized as	:		
Product Specification	: Lignocullulose aus Rinde, 12.08.05	Sampling Date	: 18-Sep-2019
Reference	:	Samplesize (kg)	: 0,194
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971666
Packing	: Plastic, ambient	Sample Arrival Date	: 26-Sep-2019 09:50
Sample Type	: Parcel Sample	ReportDate Version	: **03-Oct-2019 17:26**

Analysed Contamination / Pesticides below detection limits

Pesticides GCMSMS

		Azinphos-ethyl	< 0,010 mg/kg	Q	Bitertanol	< 0,010 mg/kg	Q	Brompropylate	< 0,010 mg/kg	Q
Chlorothalonil.	< 0,010 mg/kg	Chlorpyrifos-methyl	< 0,010 mg/kg	Q	Cyfluthrin (sum isomers)	< 0,010 mg/kg		Cyfluthrin I	< 0,010 mg/kg	Q
Cyfluthrin II	< 0,010 mg/kg	Q Cyfluthrin III	< 0,010 mg/kg	Q	Cyhalothrin (Lambda)	< 0,010 mg/kg	Q	Cypermethrin (sum)	< 0,010 mg/kg	Q
Deltamethrin	< 0,010 mg/kg	Q Dichlorvos.	< 0,010 mg/kg		Diphenylamine	< 0,010 mg/kg	Q	Disulfoton	< 0,010 mg/kg	Q
Endosulfan (sum)	< 0,010 mg/kg	Endosulfan-a.	< 0,010 mg/kg		Endosulfan-ß	< 0,010 mg/kg	Q	Endosulfansulphate	< 0,010 mg/kg	Q
Famoxadone	< 0,010 mg/kg	Q Fenvaleraat (es)	< 0,010 mg/kg	Q	Folpet (sum)	< 0,010 mg/kg		Folpet.	< 0,010 mg/kg	
Iprodione	< 0,010 mg/kg	Q Nitrofen	< 0,010 mg/kg	Q	Parathion-methyl	< 0,010 mg/kg	Q	Permethrin (sum isomers)	< 0,010 mg/kg	
Permethrin I	< 0,010 mg/kg	Q Permethrin II	< 0,010 mg/kg	Q	Procymidone	< 0,010 mg/kg	Q	Profenophos	< 0,010 mg/kg	Q
Resmethrin	< 0,010 mg/kg	Q Vinchlozolin	< 0,010 mg/kg	Q						

Pesticides LCMSMS (neg. ionisation)

		Hexaconazole	< 0,010 mg/kg	Q							

Pesticides LCMSMS (pos. ionisation)

		Azoxystrobin	< 0,010 mg/kg	Q	Carbaryl	< 0,010 mg/kg	Q	Carbendazim	< 0,010 mg/kg	Q
Carbendazim (sum)	< 0,010 mg/kg	Chlorpyriphos	< 0,010 mg/kg	Q	Cyprodinil	< 0,010 mg/kg	Q	Demeton-S-methyl-sulfon	< 0,010 mg/kg	Q
Dimethoate	< 0,010 mg/kg	Q Fenpropidin	< 0,010 mg/kg	Q	Imazalil	< 0,010 mg/kg	Q	Kresoxim-methyl	< 0,010 mg/kg	Q
Malathion	< 0,010 mg/kg	Q Mecarbam	< 0,010 mg/kg	Q	Metalaxyl	< 0,010 mg/kg	Q	Methidathion	< 0,010 mg/kg	Q
Methomyl	< 0,010 mg/kg	Q Myclobutanil	< 0,010 mg/kg	Q	Oxydemeton-methyl	< 0,010 mg/kg	Q	Oxydemeton-methyl (sum)	< 0,010 mg/kg	
Paraoxon-methyl	< 0,010 mg/kg	Q Parathion-ethyl	< 0,010 mg/kg	Q	Pendimethalin	< 0,010 mg/kg	Q	Phosphamidon	< 0,010 mg/kg	Q
Pirimiphos-methyl.	< 0,010 mg/kg	Prochloraz	< 0,010 mg/kg	Q	Propiconazole	< 0,010 mg/kg	Q	Spiroxamine	< 0,010 mg/kg	Q
Thiodicarb	< 0,010 mg/kg	Q Triadimefon	< 0,010 mg/kg	Q	Triadimenol	< 0,010 mg/kg	Q	Triazophos	< 0,010 mg/kg	Q
Trichlorfon	< 0,010 mg/kg	Q								

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam

(b) (4)

Analytical Report

Reportnr.	: **995972 version 1**	Disponent Number	: F00002315-0-22971666
Product recognized as	:		
Product Specification	: Lignocullulose aus Rinde, 12.08.05	Sampling Date	: 18-Sep-2019
Reference	:	Samplesize (kg)	: 0,194
AWB / BarCode	:	Sealed / Seal Code	: Yes /22971666
Packing	: Plastic, ambient	Sample Arrival Date	: 26-Sep-2019 09:50
Sample Type	: Parcel Sample	ReportDate Version	: **03-Oct-2019 17:26**

ANNEX

Method Descriptions

Contaminations

Pesticides

Method Description	Method Code
Flexscope:Determination of the pesticide content ; GC-MS method	Own method
Flexscope:Determination of the pesticide content; LC-MS-MS (negative mode) method	Own method
Flexscope:Determination of the pesticide content; LC-MS-MS method	Own method

Abbreviations:

acc: in accordance with

eq: Equivalent to

Analytical Report

(b) (4)

Germany

Reportnr.	: **895257 version 1**	Disponent Number	: F00002315-0-20456881
Product recognized as	:		
Product Specification	: Lignocellulose Rohware Dunkel - DE	Sampling Date	:05-Nov-2018
Reference	: Debasafe 20456881	Samplesize (kg)	:0,136
AWB / BarCode	:	Sealed / Seal Code	: Yes / 20456881
Packing	: Plastic, ambient	Sample Arrival Date	: 12-Nov-2018 11:44
Sample Type	: Sample	ReportDate Version	: **15-Nov-2018 12:45**

Contaminations

Pesticides

Parameter	Result (as received)		
Pesticides GCMS	No pesticides detected above LOQ. Method and accrediation in infosheet available by (b) (4)	Q	R
Pesticides LCMSMS (pos. ionisatio	No pesticides detected above LOQ. Method and accrediation in infosheet available by (b) (4)	Q	R
Pesticides LCMSMS (neg. ionisatio	No pesticides detected above LOQ. Method and accrediation in infosheet available by (b) (4)	Q	R

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **895257 version 1**	Disponent Number	: F00002315-0-20456881
Product recognized as	:		
Product Specification	: Lignocellulose Rohware Dunkel - DE	Sampling Date	: 05-Nov-2018
Reference	: Debasafe 20456881	Samplesize (kg)	: 0,136
AWB / BarCode	:	Sealed / Seal Code	: Yes / 20456881
Packing	: Plastic, ambient	Sample Arrival Date	: 12-Nov-2018 11:44
Sample Type	: Sample	ReportDate Version	: **15-Nov-2018 12:45**

Analysed Contamination / Pesticides below detection limits

Pesticides GCMSMS

		Azinphos-ethyl	< 0,010 mg/kg Q	Bitertanol	< 0,010 mg/kg Q	Brompropylate	< 0,010 mg/kg Q
Chlorothalonil.	< 0,010 mg/kg	Chlorpyrifos-methyl	< 0,010 mg/kg Q	Cyfluthrin (sum isomers)	< 0,010 mg/kg	Cyfluthrin I	< 0,010 mg/kg Q
Cyfluthrin II	< 0,010 mg/kg Q	Cyfluthrin III	< 0,010 mg/kg Q	Cyhalothrin (Lambda)	< 0,010 mg/kg Q	Cypermethrin (sum)	< 0,010 mg/kg Q
Deltamethrin	< 0,010 mg/kg Q	Dichlorvos.	< 0,010 mg/kg	Diphenylamine	< 0,010 mg/kg Q	Disulfoton	< 0,010 mg/kg Q
Endosulfan (sum)	< 0,010 mg/kg	Endosulfan-a.	< 0,010 mg/kg	Endosulfan-ß	< 0,010 mg/kg Q	Endosulfansulphate	< 0,010 mg/kg Q
Famoxadone	< 0,010 mg/kg Q	Fenvaleraat (es)	< 0,010 mg/kg Q	Folpet (sum)	< 0,010 mg/kg	Folpet.	< 0,010 mg/kg
Iprodione	< 0,010 mg/kg Q	Nitrofen	< 0,010 mg/kg Q	Parathion-methyl	< 0,010 mg/kg Q	Permethrin (sum isomers)	< 0,010 mg/kg
Permethrin I	< 0,010 mg/kg Q	Permethrin II	< 0,010 mg/kg Q	Procymidone	< 0,010 mg/kg Q	Profenophos	< 0,010 mg/kg Q
Resmethrin	< 0,010 mg/kg Q	Vinchlozolin	< 0,010 mg/kg				

Pesticides LCMSMS (neg. ionisation)

		Hexaconazole	< 0,010 mg/kg				

Pesticides LCMSMS (pos. ionisation)

		Azoxystrobin	< 0,010 mg/kg Q	Carbaryl	< 0,010 mg/kg Q	Carbendazim	< 0,010 mg/kg Q
Carbendazim (sum)	< 0,010 mg/kg	Chlorpyriphos	< 0,010 mg/kg Q	Cyprodinil	< 0,010 mg/kg Q	Demeton-S-methyl-sulfon	< 0,010 mg/kg Q
Dimethoate	< 0,010 mg/kg Q	Fenpropidin	< 0,010 mg/kg	Imazalil	< 0,010 mg/kg Q	Kresoxim-methyl	< 0,010 mg/kg Q
Malathion	< 0,010 mg/kg Q	Mecarbam	< 0,010 mg/kg Q	Metalaxyl	< 0,010 mg/kg Q	Methidathion	< 0,010 mg/kg Q
Methomyl	< 0,010 mg/kg Q	Myclobutanil	< 0,010 mg/kg Q	Oxydemeton-methyl	< 0,010 mg/kg Q	Oxydemeton-methyl (sum)	< 0,010 mg/kg
Paraoxon-methyl	< 0,010 mg/kg Q	Parathion-ethyl	< 0,010 mg/kg Q	Pendimethalin	< 0,010 mg/kg	Phosphamidon	< 0,010 mg/kg Q
Pirimiphos-methyl.	< 0,010 mg/kg	Prochloraz	< 0,010 mg/kg Q	Propiconazole	< 0,010 mg/kg Q	Spiroxamine	< 0,010 mg/kg Q
Thiodicarb	< 0,010 mg/kg Q	Triadimefon	< 0,010 mg/kg Q	Triadimenol	< 0,010 mg/kg Q	Triazophos	< 0,010 mg/kg Q
Trichlorfon	< 0,010 mg/kg Q						

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4) location Rotterdam

(b) (4)

(b) (4)

Analytical Report

Reportnr.	: **895257 version 1**	Disponent Number	: F00002315-0-20456881
Product recognized as	:		
Product Specification	: Lignocellulose Rohware Dunkel - DE	Sampling Date	: 05-Nov-2018
Reference	: Debasafe 20456881	Samplesize (kg)	: 0,136
AWB / BarCode	:	Sealed / Seal Code	: Yes / 20456881
Packing	: Plastic, ambient	Sample Arrival Date	: 12-Nov-2018 11:44
Sample Type	: Sample	ReportDate Version	: **15-Nov-2018 12:45**

ANNEX

Method Descriptions

Contaminations

Pesticides

Method Description	Method Code
Flexscope:Determination of the pesticide content ; GC-MS method	Own method
Flexscope:Determination of the pesticide content; LC-MS-MS (negative mode) method	Own method
Flexscope:Determination of the pesticide content; LC-MS-MS (positive mode)method	Own method

Abbreviations:

acc: in accordance with

eq: Equivalent to

(b) (4)

Analytical Report

(b) (4)

Germany

Reportnr.	: **873492 version 1**	Disponent Number	: F00002315-0-20456894
Product recognized as	:		
Product Specification	: Lignocellulose Rohware (hell)	Sampling Date	:06-Sep-2018
Reference	:	Samplesize (kg)	:0,202
AWB / BarCode	:	Sealed / Seal Code	: Yes / 20456894
Packing	: Plastic, ambient	Sample Arrival Date	: 13-Sep-2018 16:39
Sample Type	: Sample	ReportDate Version	: **18-Sep-2018 16:51**

Contaminations

Pesticides

Parameter	Result (as received)	
Pesticides GCMS	No pesticides detected above LOQ. Method and accrediation in infosheet available by (b) (4)	R
Pesticides LCMSMS (pos. ionisatio	No pesticides detected above LOQ. Method and accrediation in infosheet available by (b) (4)	R
Pesticides LCMSMS (neg. ionisatio	No pesticides detected above LOQ. Method and accrediation in infosheet available by (b) (4)	R
Pesticides according QS list	Not detected above limit of quantification	O

(b) (4)

Analytical Report

Reportnr.	: **873492 version 1**	Disponent Number	: F00002315-0-20456894
Product recognized as	:		
Product Specification	: Lignocellulose Rohware (hell)	Sampling Date	: 06-Sep-2018
Reference	:	Samplesize (kg)	: 0,202
AWB / BarCode	:	Sealed / Seal Code	: Yes / 20456894
Packing	: Plastic, ambient	Sample Arrival Date	: 13-Sep-2018 16:39
Sample Type	: Sample	ReportDate Version	: **18-Sep-2018 16:51**

Analysed Contamination / Pesticides below detection limits

Pesticides GCMSMS

		Azinphos-ethyl	< 0,010 mg/kg	Bitertanol	< 0,010 mg/kg	Brompropylate	< 0,010 mg/kg
Chlorothalonil.	< 0,010 mg/kg	Chlorpyrifos-methyl	< 0,010 mg/kg	Cyfluthrin (sum isomers)	< 0,010 mg/kg	Cyfluthrin I	< 0,010 mg/kg
Cyfluthrin II	< 0,010 mg/kg	Cyfluthrin III	< 0,010 mg/kg	Cyhalothrin (Lambda)	< 0,010 mg/kg	Cypermethrin (sum)	< 0,010 mg/kg
Deltamethrin	< 0,010 mg/kg	Dichlorvos.	< 0,010 mg/kg	Diphenylamine	< 0,010 mg/kg	Disulfoton	< 0,010 mg/kg
Endosulfan (sum)	< 0,010 mg/kg	Endosulfan-a.	< 0,010 mg/kg	Endosulfan-ß	< 0,010 mg/kg	Endosulfansulphate	
Famoxadone	< 0,010 mg/kg	Fenvaleraat (es)	< 0,010 mg/kg	Folpet (sum)	< 0,010 mg/kg	Folpet.	< 0,010 mg/kg
Iprodione	< 0,010 mg/kg	Nitrofen	< 0,010 mg/kg	Parathion-methyl	< 0,010 mg/kg	Permethrin (sum isomers)	< 0,010 mg/kg
Permethrin I	< 0,010 mg/kg	Permethrin II	< 0,010 mg/kg	Procymidone	< 0,010 mg/kg	Profenophos	< 0,010 mg/kg
Resmethrin	< 0,010 mg/kg	Vinchlozolin	< 0,010 mg/kg				

Pesticides LCMSMS

		Chlorpyriphos	< 0,010 mg/kg				

Pesticides LCMSMS (neg. ionisation)

		Hexaconazole	< 0,010 mg/kg				

Pesticides LCMSMS (pos. ionisation)

		Azoxystrobin	< 0,010 mg/kg	Carbaryl	< 0,010 mg/kg	Carbendazim	< 0,010 mg/kg
Carbendazim (sum)	< 0,010 mg/kg	Cyprodinil	< 0,010 mg/kg	Demeton-S-methyl-sulfon	< 0,010 mg/kg	Dimethoate	< 0,010 mg/kg
Fenpropidin	< 0,010 mg/kg	Imazalil	< 0,010 mg/kg	Kresoxim-methyl	< 0,010 mg/kg	Malathion	< 0,010 mg/kg
Mecarbam	< 0,010 mg/kg	Metalaxyl	< 0,010 mg/kg	Methidathion	< 0,010 mg/kg	Methomyl	< 0,010 mg/kg
Myclobutanil	< 0,010 mg/kg	Oxydemeton-methyl	< 0,010 mg/kg	Oxydemeton-methyl (sum)	< 0,010 mg/kg	Paraoxon-methyl	< 0,010 mg/kg
Parathion-ethyl	< 0,010 mg/kg	Pendimethalin..	< 0,010 mg/kg	Phosphamidon	< 0,010 mg/kg	Pirimiphos-methyl.	< 0,010 mg/kg
Prochloraz	< 0,010 mg/kg	Propiconazole	< 0,010 mg/kg	Spiroxamine	< 0,010 mg/kg	Thiodicarb	< 0,010 mg/kg
Triadimefon	< 0,010 mg/kg	Triadimenol	< 0,010 mg/kg	Triazophos	< 0,010 mg/kg	Trichlorfon	< 0,010 mg/kg

Q - Analyses ISO 17025 accredited by RvA (ILAC)
R - Carried out by (b) (4), location Rotterdam
O - Outsourced

Analytical Report

Reportnr.	: **873492 version 1**	Disponent Number	: F00002315-0-20456894
Product recognized as	:		
Product Specification	: Lignocellulose Rohware (hell)	Sampling Date	:06-Sep-2018
Reference	:	Samplesize (kg)	: 0,202
AWB / BarCode	:	Sealed / Seal Code	: Yes / 20456894
Packing	: Plastic, ambient	Sample Arrival Date	: 13-Sep-2018 16:39
Sample Type	: Sample	ReportDate Version	: **18-Sep-2018 16:51**

ANNEX

Method Descriptions

Contaminations

Pesticides

Method Description	Method Code
Determination of pesticides; performed by (b) (4)	.
Flexscope:Determination of the pesticide content ; GC-MS method	Own method
Flexscope:Determination of the pesticide content; LC-MS-MS (negative mode) method	Own method
Flexscope:Determination of the pesticide content; LC-MS-MS (positive mode)method	Own method

(b) (4)

Risk assessment: Lignocellulose

With respect to the risks associated with (b) (4) risk assessment (b) (4) applies.

Version: 16/05/2014

code: 121

(b) (4)

(b) (4)

DISCLAIMER: This risk assessment is a shortened version from the Feed Safety Database Risk Assessments whereby the information from the digital database is always leading. (b) (4) is not liable for any inaccuracies in the risk assessments.

(b) (4)

(b) (4)

Content

Datasheet

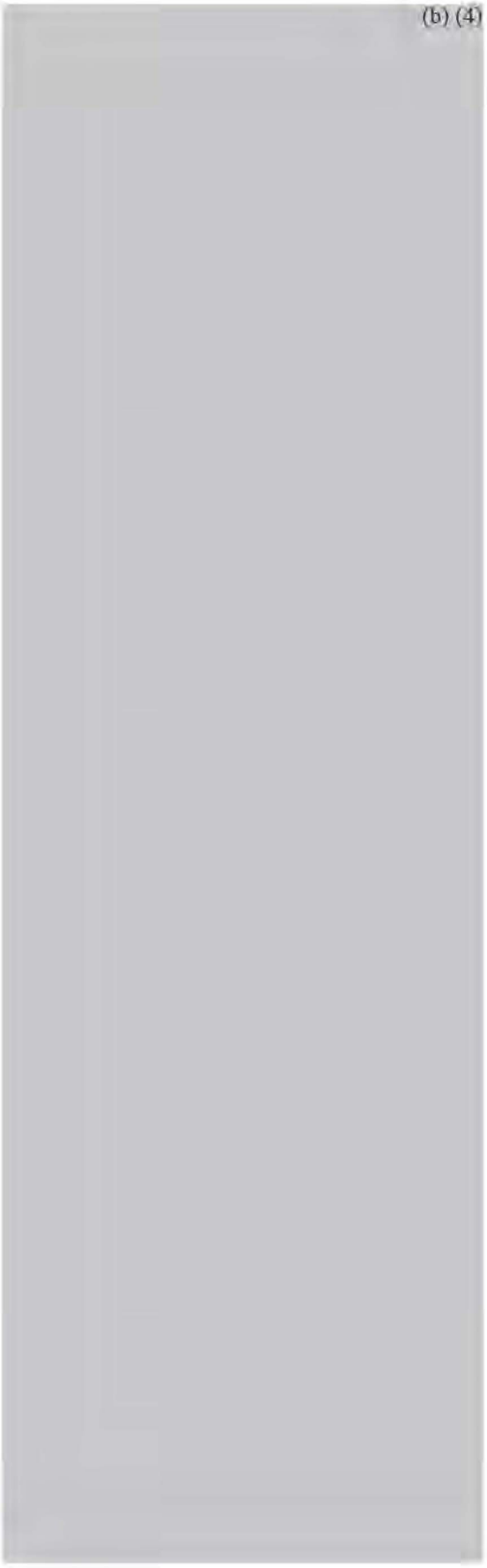
code	Product	Synonyms	Definition
7.034	Lignocellulose		Product which is only obtained through the mechanical treatment of natural wood.
7.035	Lignocellulose from bark		Product obtained by means of mechanical processing (drying, milling and pressing) of fresh purified bark and which predominantly consists of lignocellulose.

Processing aids used during treatment and processing *)
Not identified

*) For the processing aids used in production it must be demonstrated by way of a hazards analysis that the unintentional but technically unavoidable presence of residues of these processing aids or their derivatives in the end product has no detrimental effects on animal health, human health or the environment and no technological effect at all on the end product. Attention should also be paid in carrying out the analysis to the hazards of overdosage of processing aids and the presence of contaminants in the processing aids used. In the event of use as a feed additive then the above does not apply and there should be compliance with the applicable community legislation and the compatible national legislation.

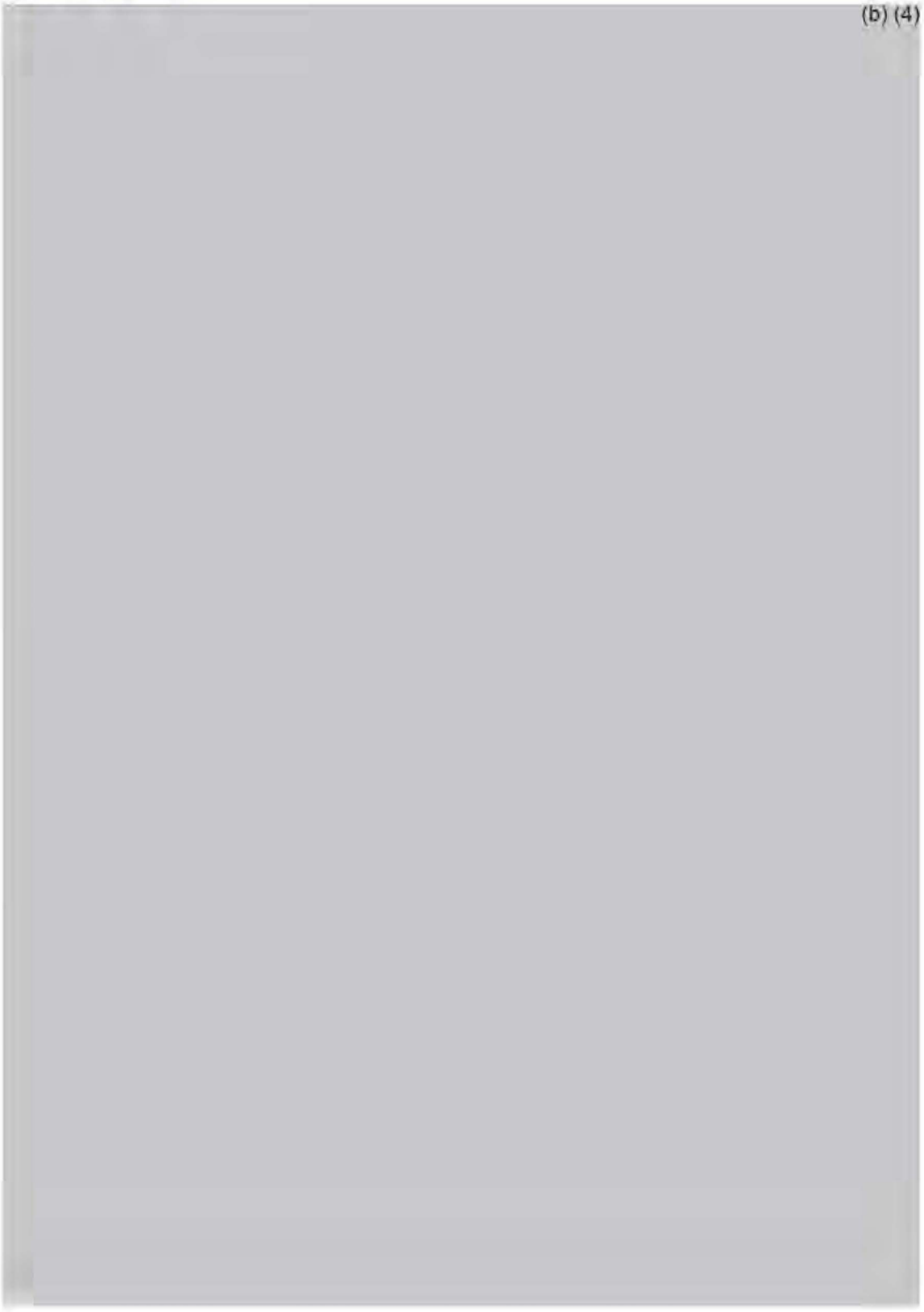
Global
Flowchart Lignocellulose

(b) (4)



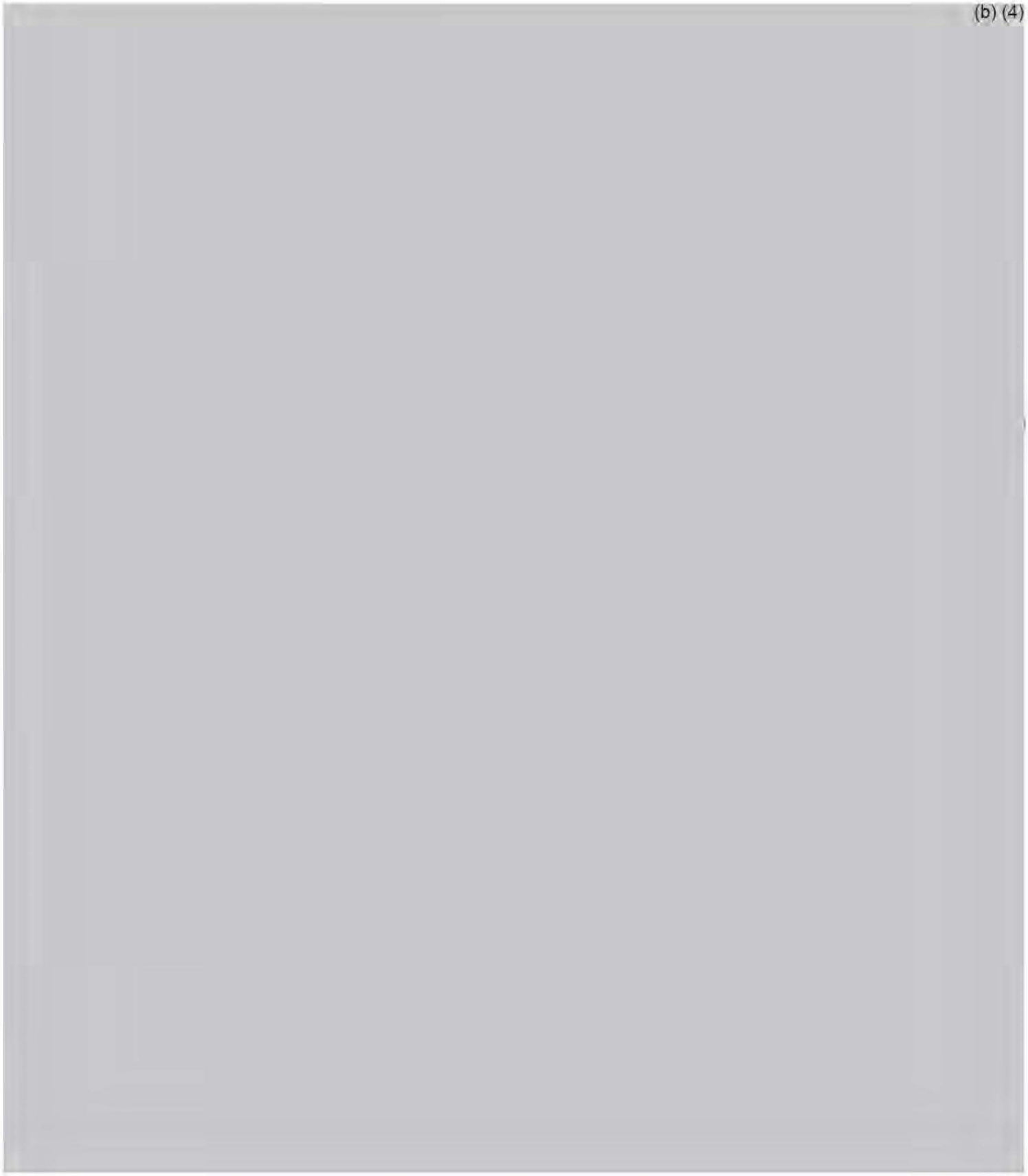
Detail 1
Flowchart Lignocellulose

(b) (4)



(b) (4)

Detail 2
Flowchart Lignocellulose



(b) (4)

Detail 3
Flowchart Lignocellulose

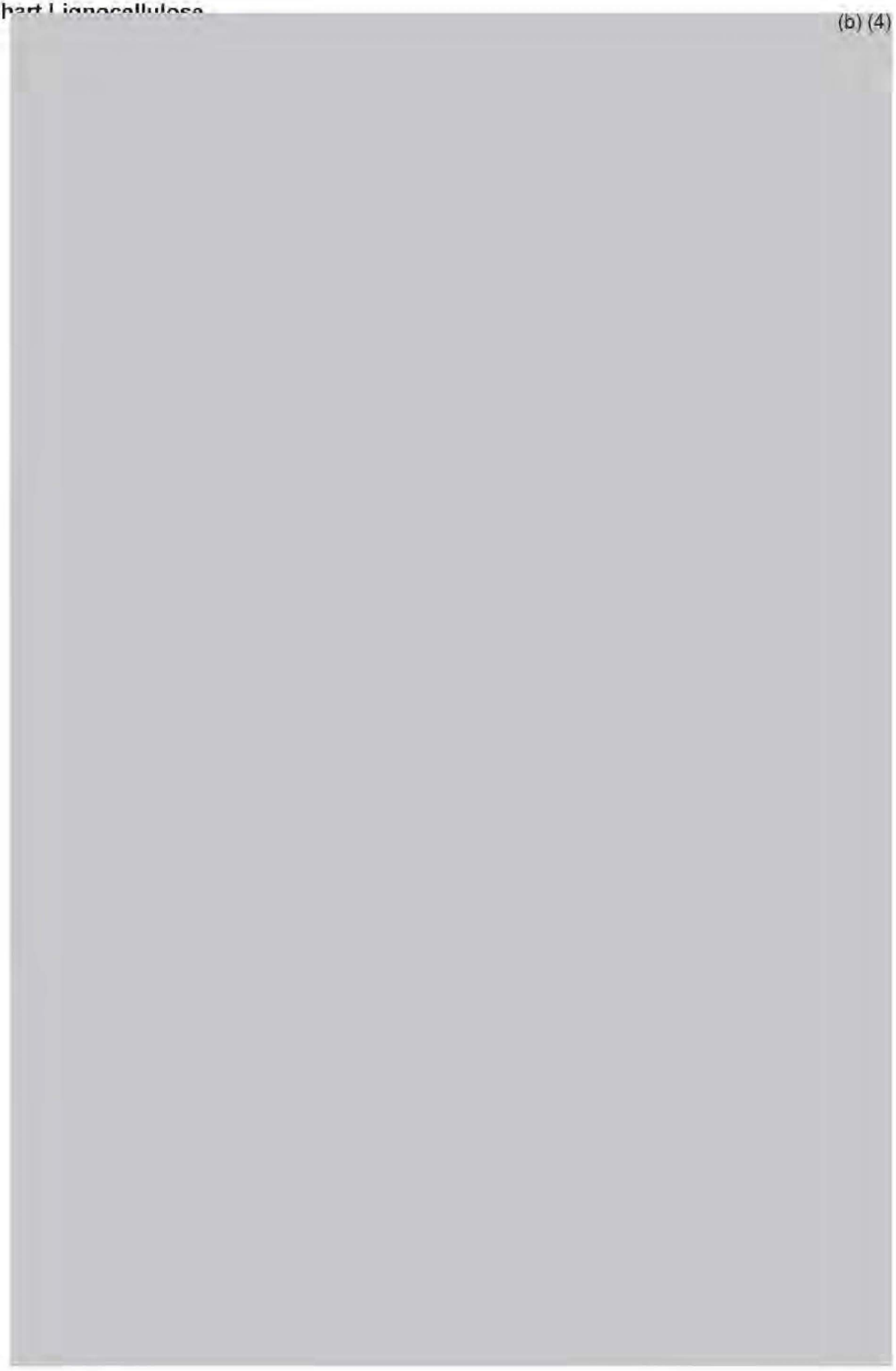
(b) (4)

(b) (4)

Detail 4

Flowchart Lignocellulose

(b) (4)

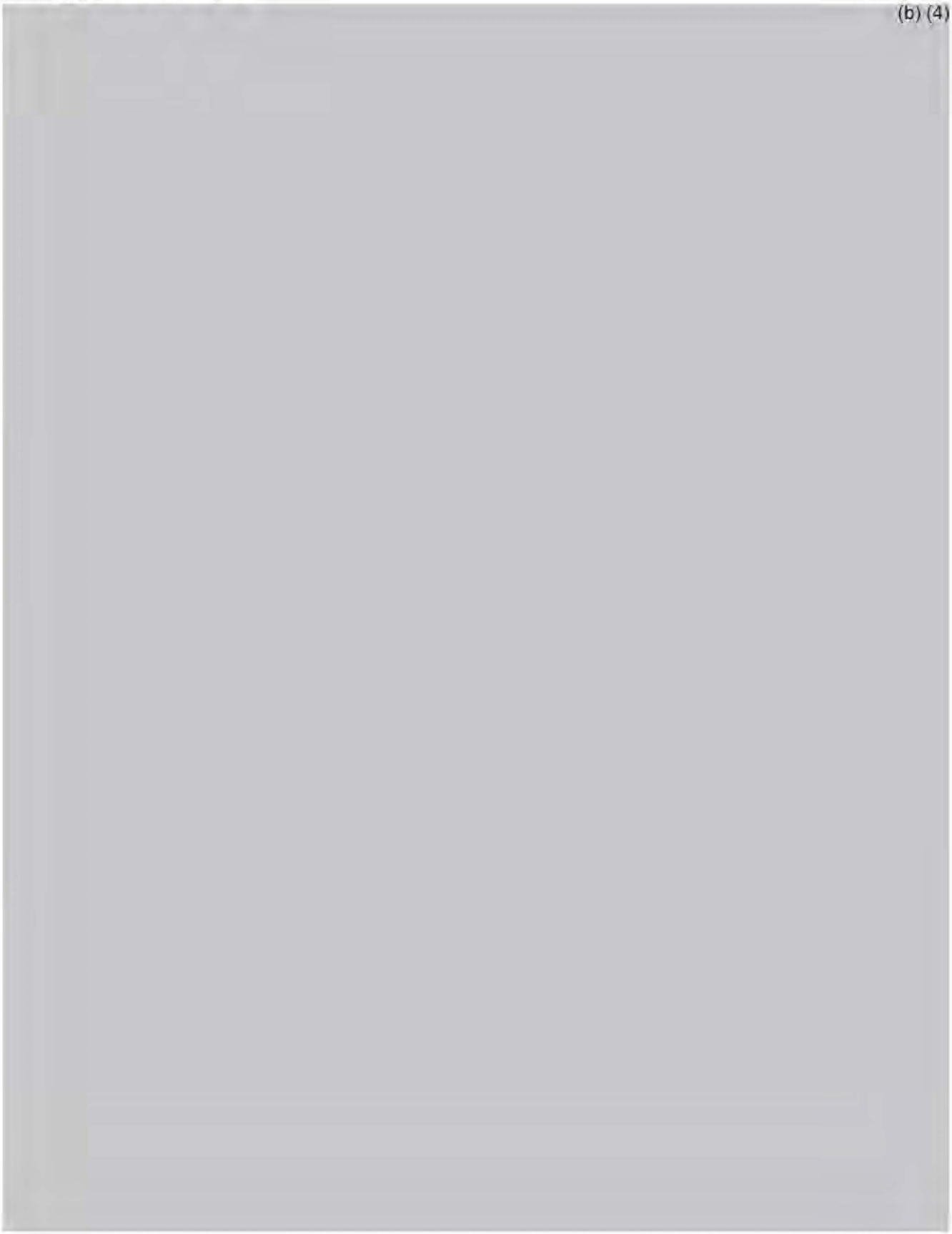


(b) (4)

Detail_5

Flowchart Lignocellulose from bark

(b) (4)



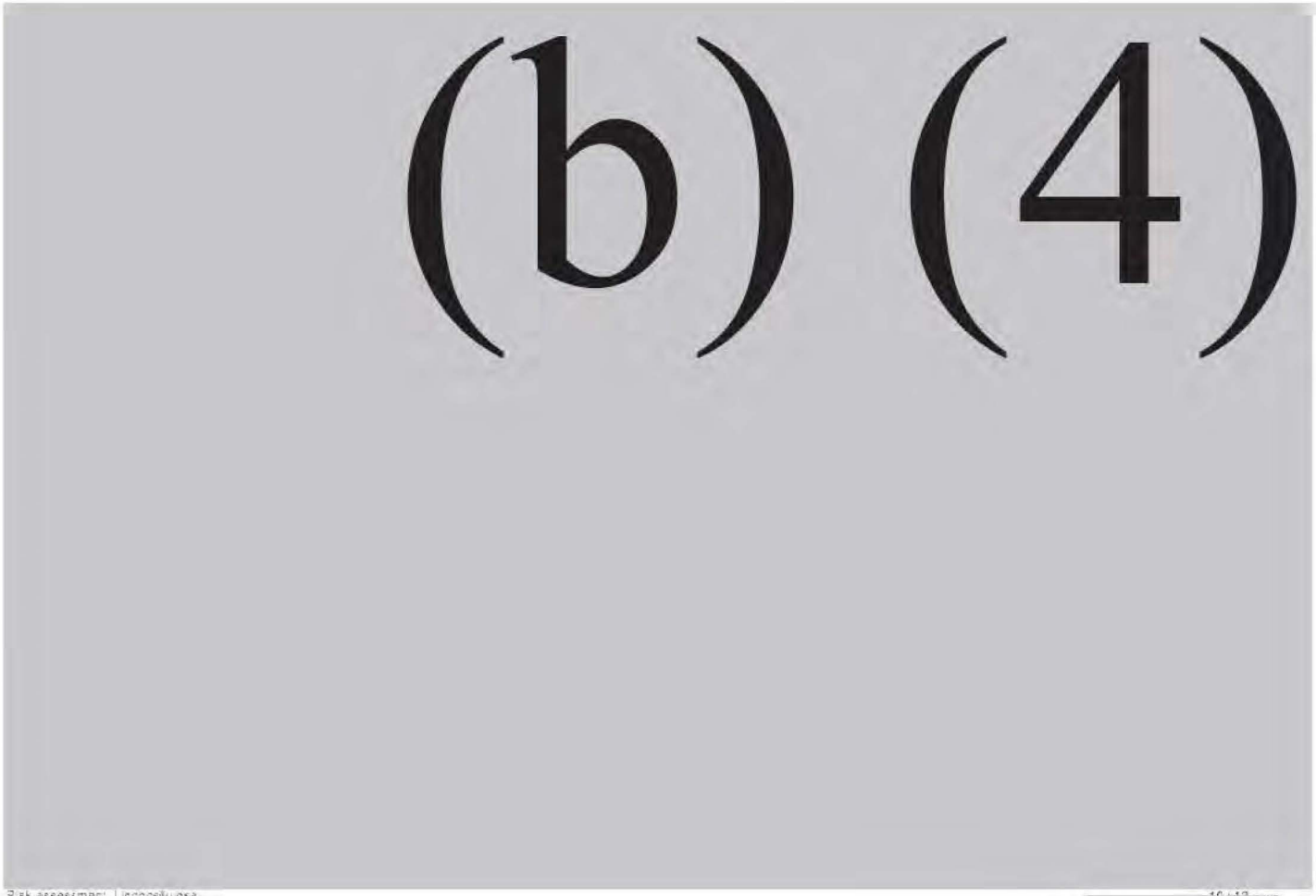
(b) (4)

Detail 6

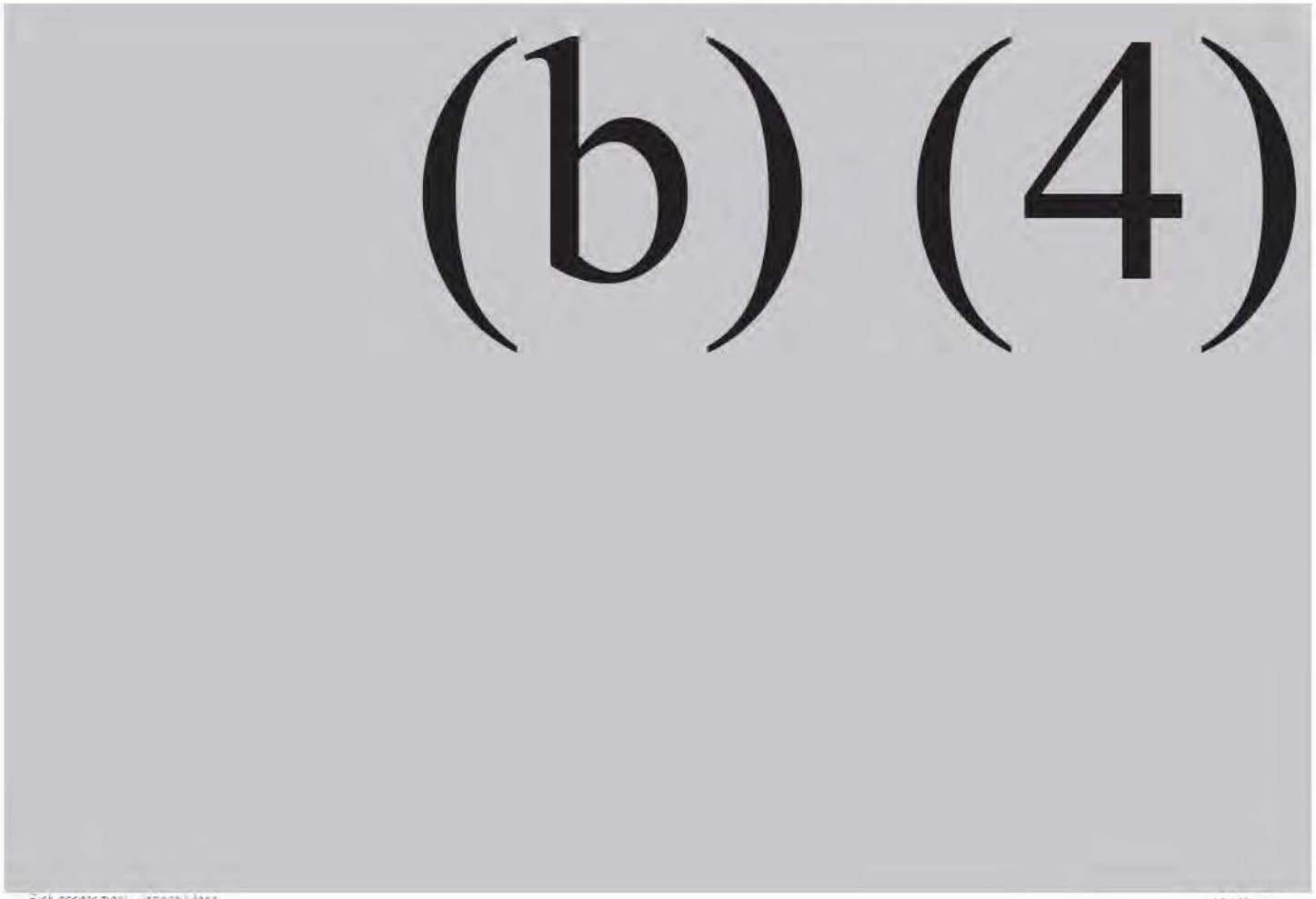
Flowchart Lignocellulose from bark

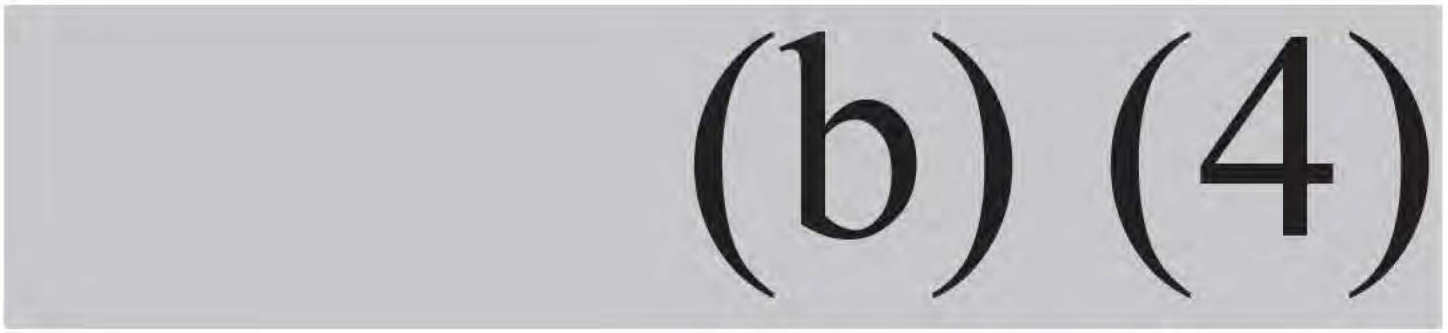
(b) (4)

(b) (4)



(b) (4)


(b) (4)


(b) (4)

Appendix E:

Preparation of samples:

Sample list:

Sample	Sample ID	Date
Opticell	20000214	12.2.20
Opticell	20000284	22.2.20
Opticell	20000285	24.2.20
Opticell	Ch. 1	2.4.2014
Opticell	Ch. 2	2.4.2014
Opticell	C5	2.4.2014

Table 30: List of samples used for wet chemical analyses

All samples were available as (b) (4). The date given is the date the sample was sent (day/month/year).

Drying

(b) (4)

Wet chemical processes

All measurements were performed in triple determination. It should be noted that the analytical methods are not directly comparable. The moisture content of the samples was determined and included before the extractions. All values refer to g dry wood.

Extraction procedure:

(b) (4)

Analysis - Hemicellulose content:

(b) (4)

Analysis - Determination of proanthocyanidin content - acid butanol assay

(b) (4)

(b) (4)

Analysis - Determination of labdane acid (repr: isocupressic acid)

(b) (4)

Analysis - SPME Analysis

(b) (4)

REFERENCES:

1. Folin, O. and Ciocalteu, V. Journal for Biological Chemistry, (1927). 73, p. 627

2. Gardner, D. R. and James, L F. (1999). Pine Needle Abortion in Cattle: Analysis of Isocupressic Acid in North American Gymnosperms, Phytochemical analysis 10, 132-136.

3. Gessner, M.O. and Steiner, D. (2005). Acid butanol assay for proanthocyanidins (condensed tannins). in: Methods to study litter decomposition, Springer, pp. 107-114.

4. Schwanninger, M.;Hinterstoisser, B. (2002): Klason Lignin: Modifications to Improve the Precision of the Standardized Determination. Holzforschung. 56**:** 161.

5. Sundberg, A., et al. (1996): Determination of hemicelluloses and pectins in wood and pulp fibers by acid methanolysis and gas chromatography. Nordic Pulp & Paper Research Journal 11, 216-219

6. TAPPI – T 222: Acid-insoluble lignin in wood and pulp, January 2002, Technical Association of the Pulp and Paper Industry.

7. Willför, S., et al. (2003a): Phenolic and Lipophilic Extractives in Scots Pine Knots and Stemwood. Holzforschung 57, 4, 359-372.

8. Willför, S., et al. (2003b): Lignans and Lipophilic Extractives in Norway Spruce Knots and Stemwood. Holzforschung 57, 1, 27-36.

Agromed's lignocellulose

Manufacturing process and quality controls

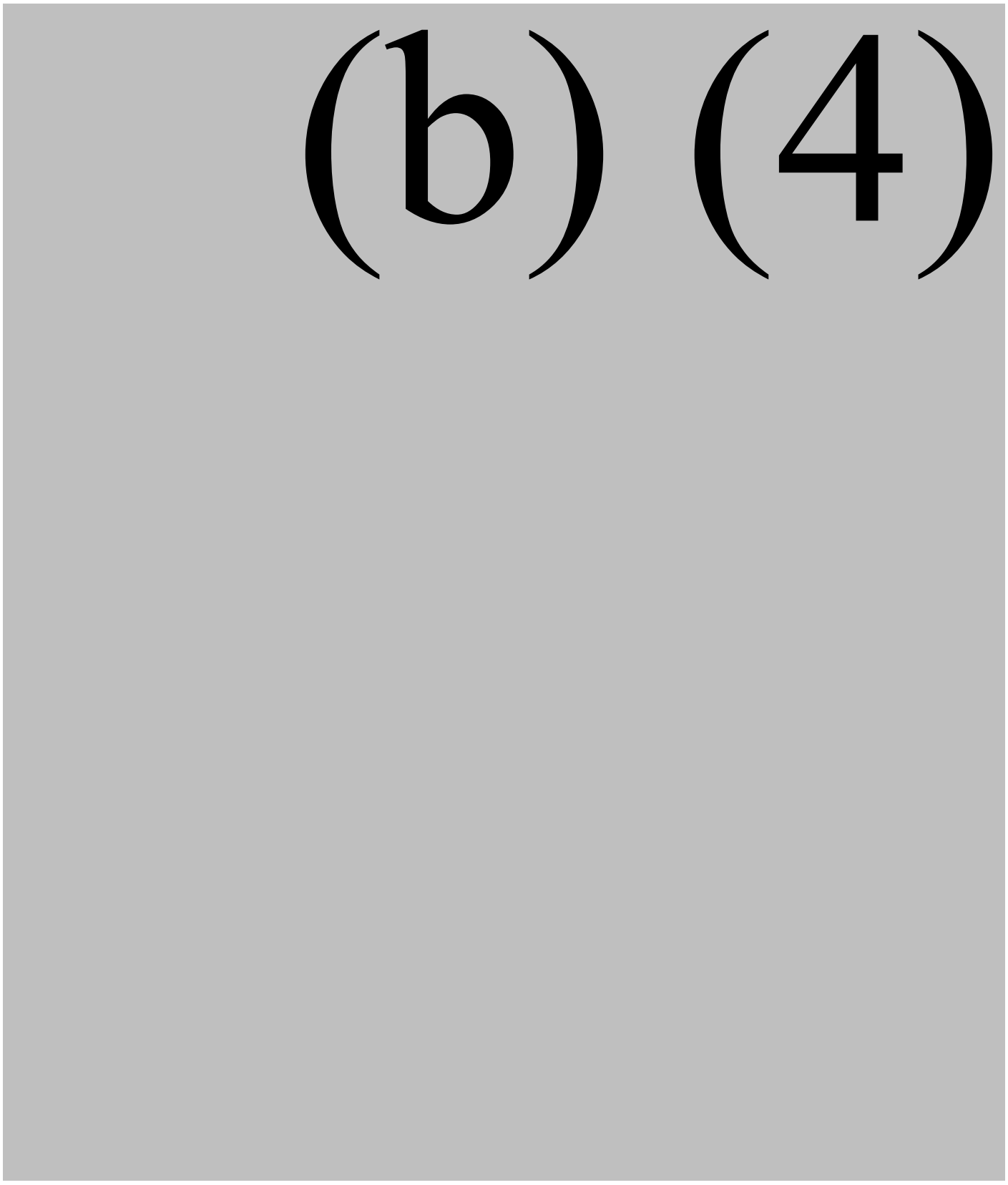
Version 1

Date: 05.08.2020

Author: (b)(6), Regulatory Department Agromed Austria GmbH

Agromed Austria GmbH
Bad Haller Straße 23
A-4550 Kremsmünster
Austria
info@agromed.at
www.agromed.at

DISCLAIMER: The manufacturing process and quality controls documentation here presented are prove to be valid at the time of publication. Any implementation occurring afterwards will constitute a new version of the document, invalidating the previous version.


(b) (4)

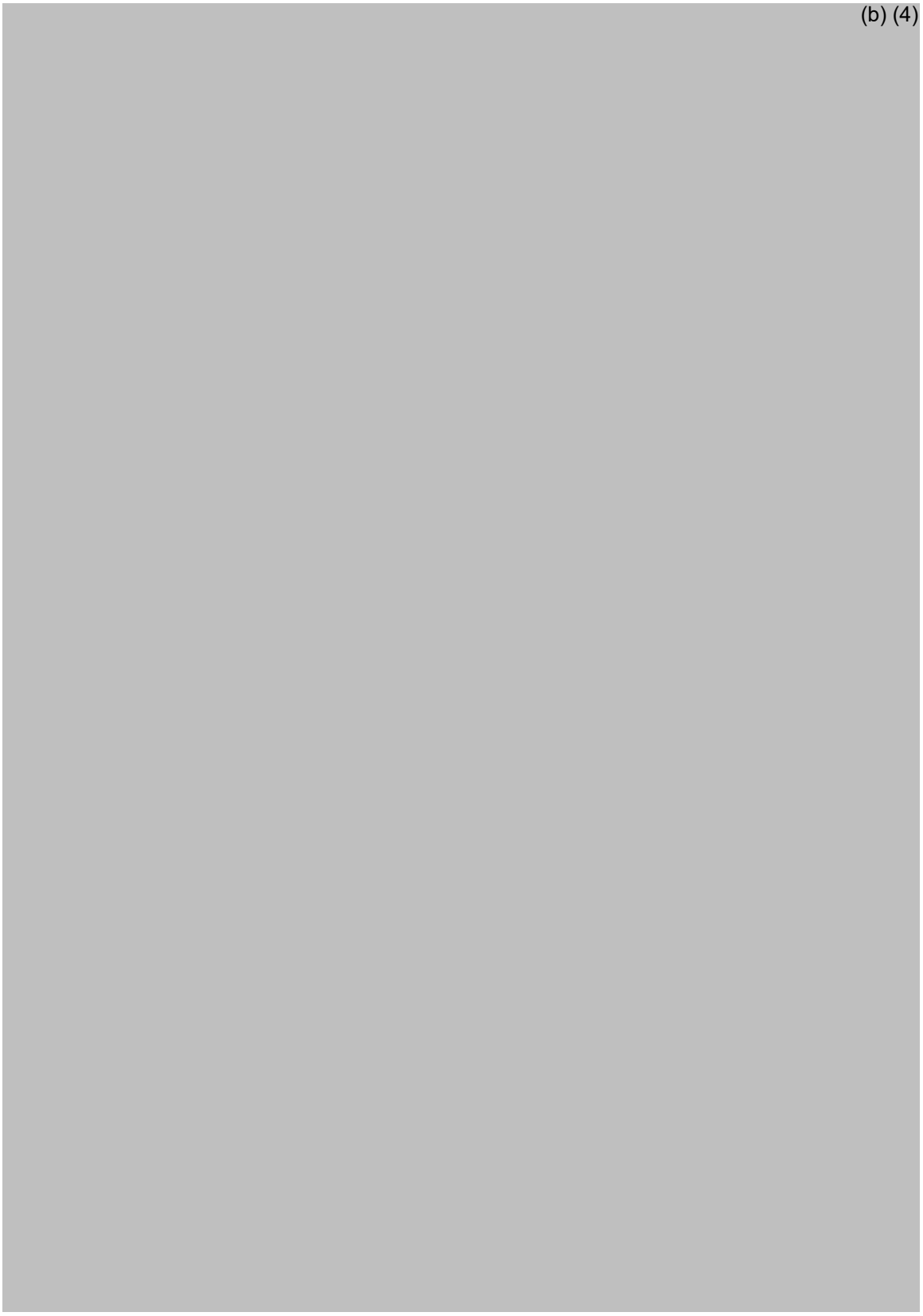
1 Global

1.1 Flowchart Manufacturing Description

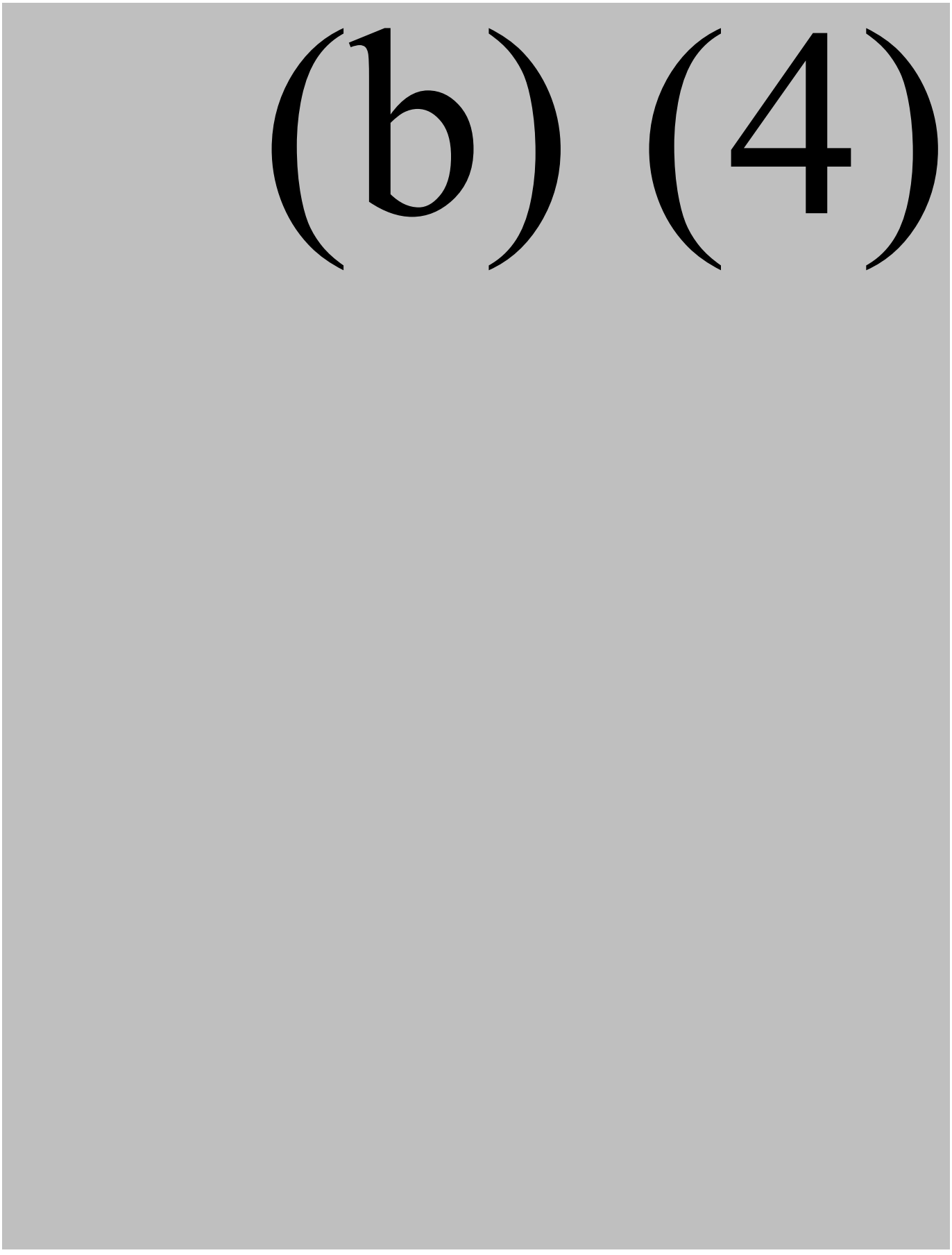
2 Process Description: A. Reception of raw materials

2.1 Flowchart

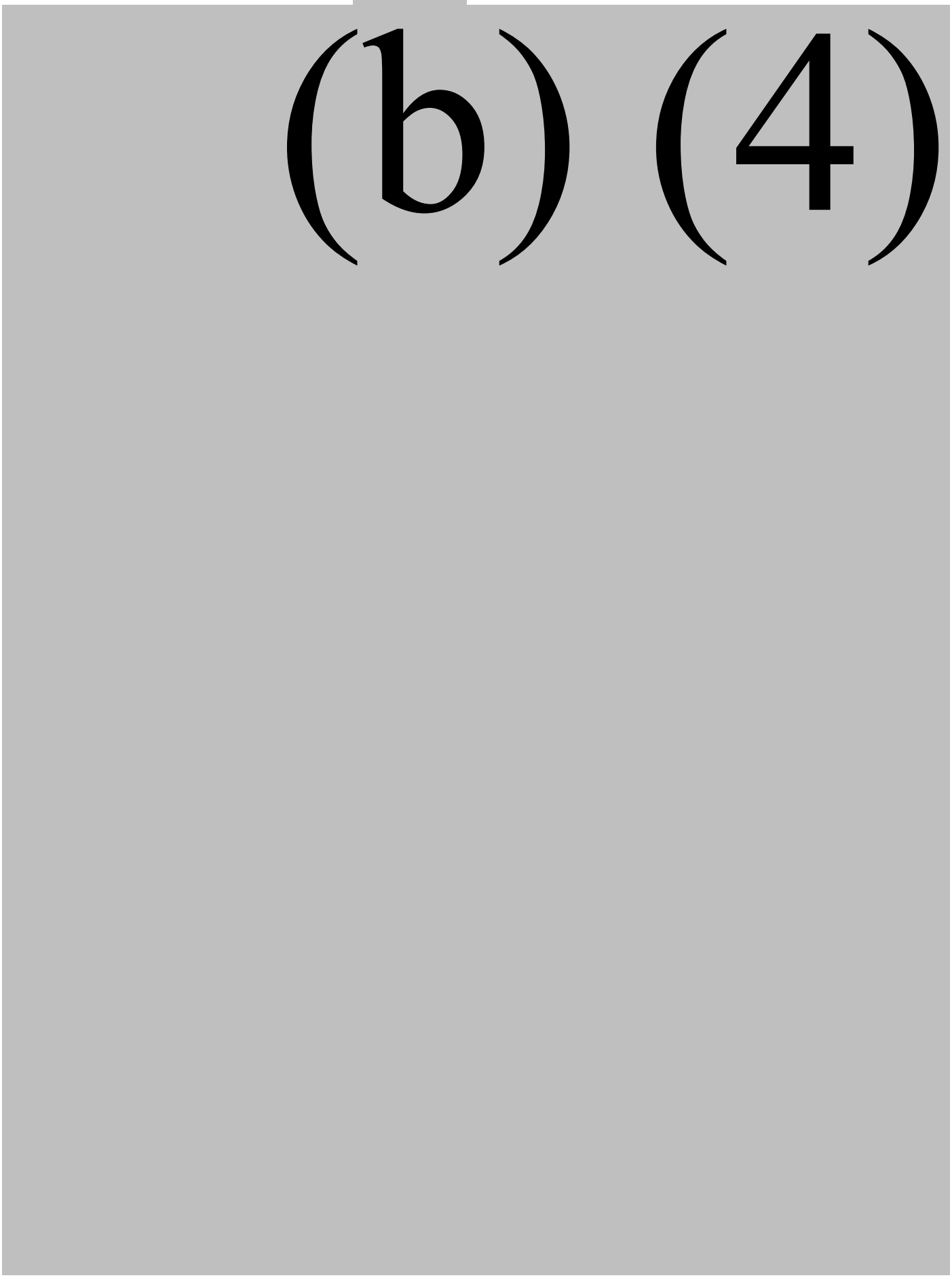
(b) (4)

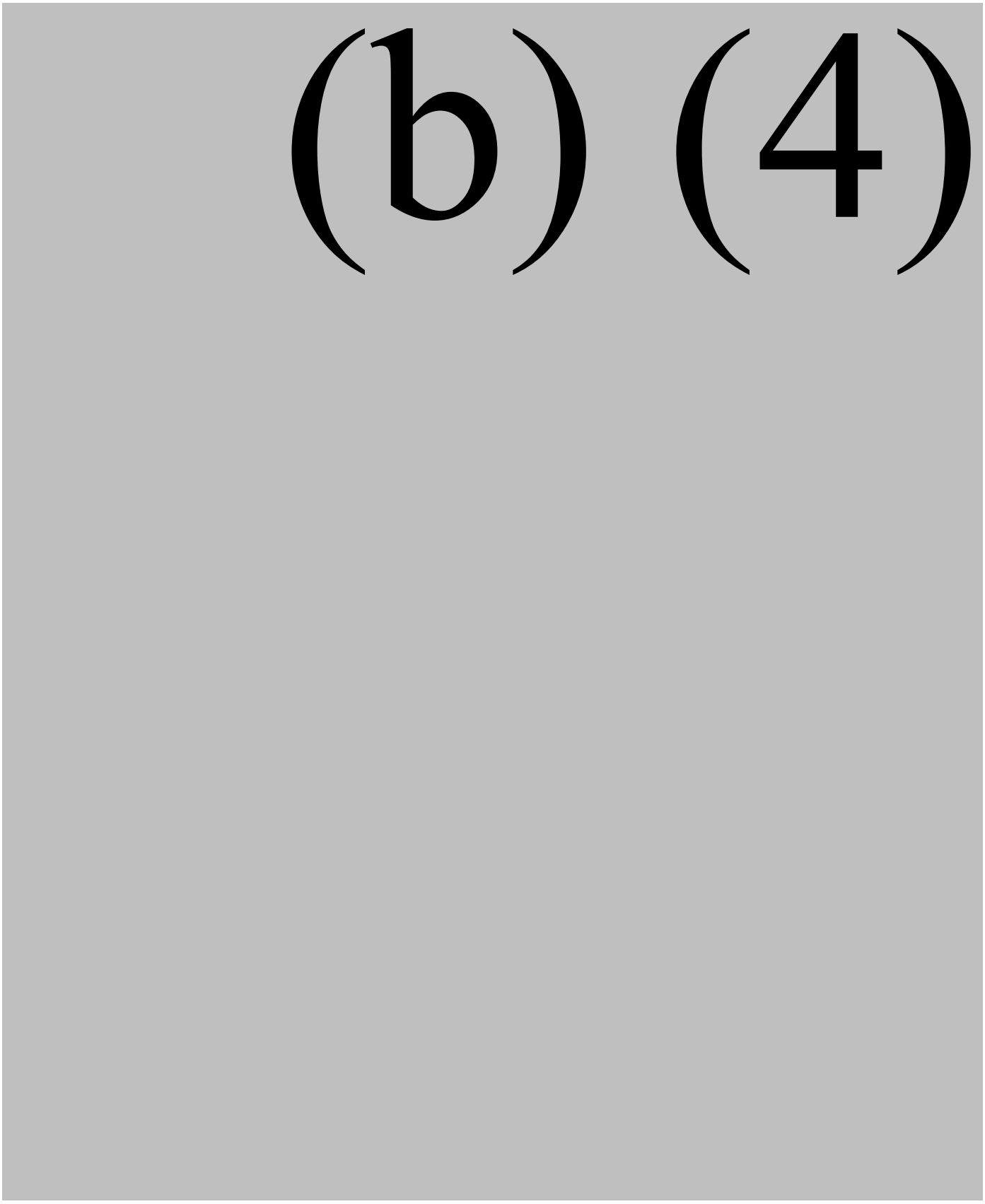


2.2 Description of the process



3 Process Description: B. (b) (4)

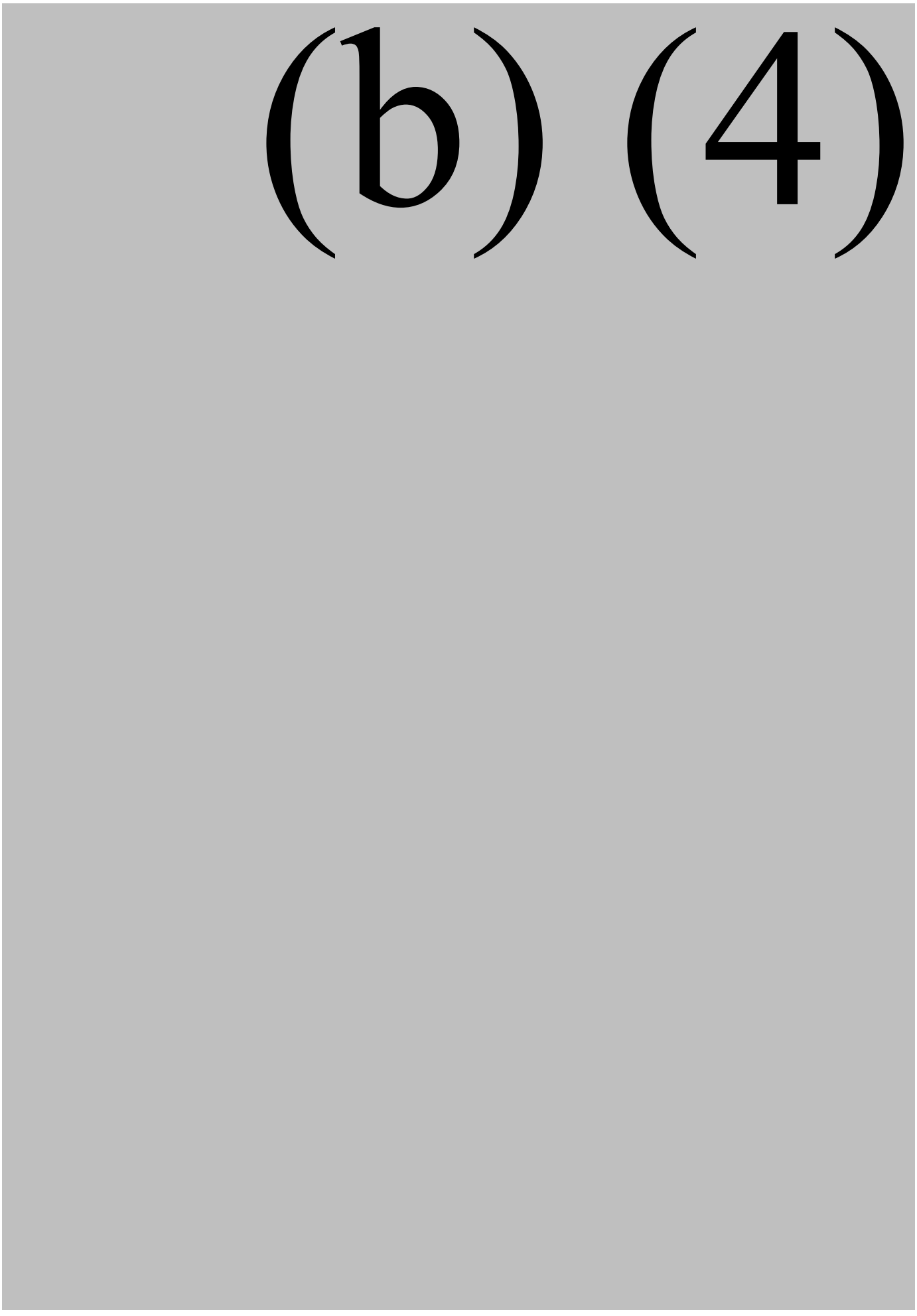



(b) (4)

(b) (4)

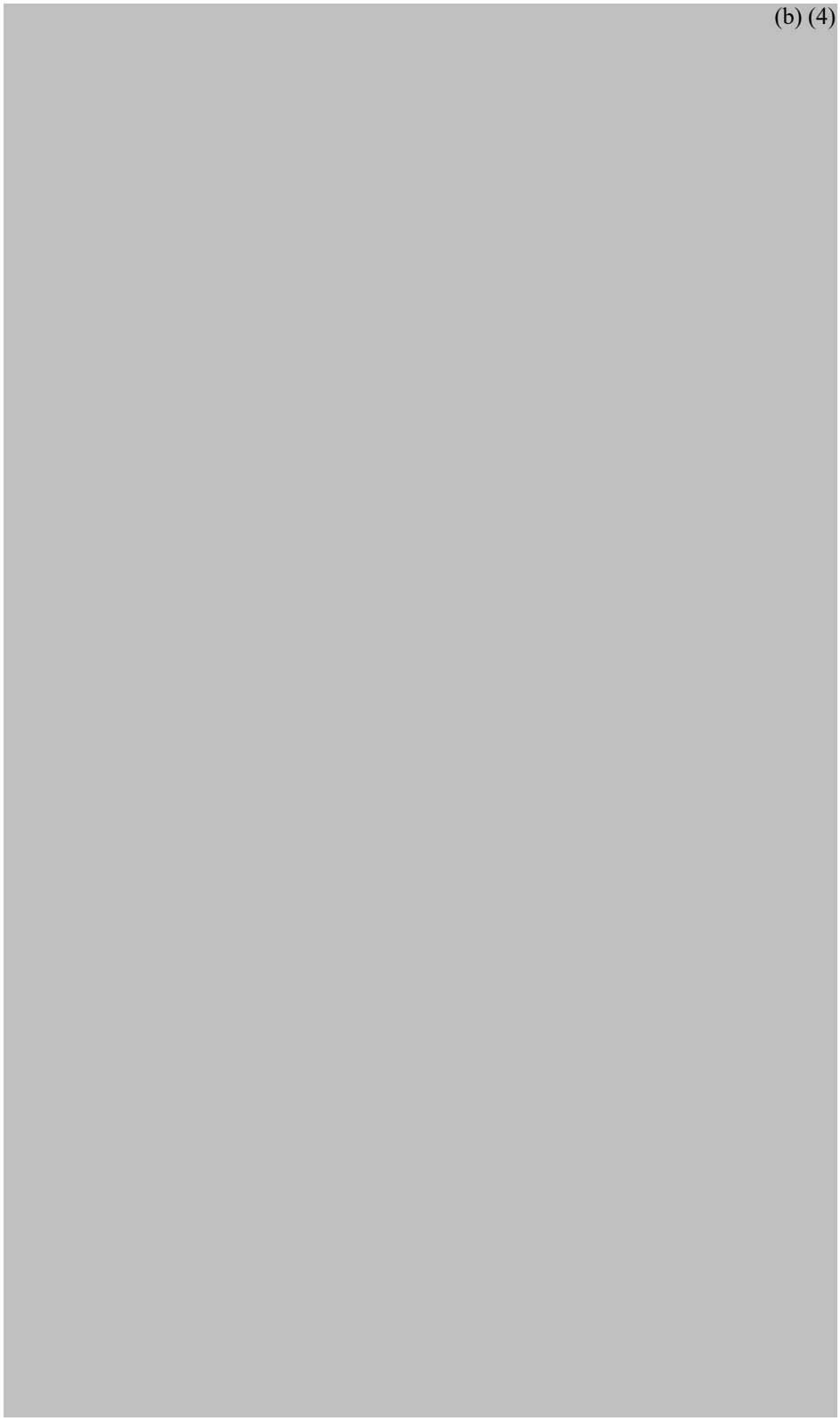
(b) (4)

6 Process Description: E. (b) (4)



8 Quality Process: Sample taking and retained samples

(b) (4)



(b) (4)

9 Quality Process: (b) (4)

9 1 Description

(b) (4)

10 Analysis Plan

10.1 (b) (4)

(b) (4)

(b) (4)

11 Acceptance criteria of a produced batch

11.1 (b) (4)

(b) (4)

11.2 (b) (4)

(b) (4)

(b) (4)

agromed
natural effects

Kremsmünster, 13.09.2021

GRAS Notice No. 46

Ms. Megan Hall, M.S.
Administrative Reviewer
Division of Animal Feeds
Center for Veterinary Medicine
12225 Wilkins Avenue
Rockville, Maryland 20852
United States

Via e-mail to: Animalfood-premarket@fda.hhs.gov

Dear Ms. Hall,

This e-mail is in response to the reception of the meeting minutes (received per e-mail on September 10th) of our meeting of September 8th.

Agromed Austria GmbH[1] – Mr. Helmut Grabherr being its legal representant – **requests CVM to cease the evaluation** of the GRAS Notice AGRN #46.
Herewith, we consider that CVM will stop to proceed with evaluation of the GRAS Notice AGRN #46.

If you have any questions concerning this letter, please contact Agromed Austria GmbH (Ms. Marie Wiesinger[2]).

(b)(6)

Sincer

DI Hel
CEO A
e-mail

[1] Bad Haller Straße 23, A-4550 Kremsmünster, Austria
[2] Regulatory Department; P.: +43 7583 5105825; wiesinger@agromed.at