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JRC F.5/CvH/ZE/AS/Ares

**Evaluation Report on the Analytical Methods submitted
in connection with the Application for Authorisation of a
Feed Additive according to Regulation (EC) No 1831/2003**

Botanically defined flavourings group BDG 18 – Coniferales, Ginkgoales
(FAD-2010-0320; CRL/100216)

**Evaluation Report on the Analytical Methods submitted
in connection with the Application for Authorisation of a
Feed Additive according to Regulation (EC) No 1831/2003**

Dossier related to: **FAD-2010-0320 - CRL/100216**

Name of Feed Additives: ***BDG 18 – Coniferales, Ginkgoales -
Juniper oil, juniper berry extract (wb),
juniper tincture, cedarwood texas oil,
pine oil, pine tincture, pine oil white, pine
needle oil, ginkgo extract (wb) and ginkgo
tincture***

Phytochemical markers: **Pin-2(3)-ene, pin-2(10)-ene,
cis-thujopsene, tanins and total flavone
glycosides**

Rapporteur Laboratory: **European Union Reference Laboratory for
Feed Additives (EURL-FA)
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Date: **14/03/2023**

EXECUTIVE SUMMARY

In the present grouped application an authorisation is sought under Articles 4 and 10 for *juniper oil*, *juniper berry extract (wb)*, *juniper tincture*, *cedarwood texas oil*, *pine oil*, *pine tincture*, *pine oil white*, *pine needle oil*, *ginkgo extract (wb)* and *ginkgo tincture* from *botanically defined flavourings group 18 (BDG 18)*, under the category/functional group 2(b) 'sensory additives'/flavouring compounds', according to Annex I of Regulation (EC) No 1831/2003. The authorisation is sought for all animal species.

However, after withdrawal of *juniper berry extract (wb)*, *pine oil* and *pine needle oil* from this grouped application, the EURL focused on the evaluation of the remaining seven *feed additives*.

The *feed additives* are intended to be incorporated into *compound feed* or *water* for drinking directly or through flavouring *premixtures*. Depending on the product and species the Applicant proposed maximum inclusion levels ranging from 15 to 750 mg/kg *compound feed*.

For the determination of the phytochemical markers in the following products: *pin-2(3)-ene* in *juniper oil*, *cis-thujopsene* in *cedarwood Texas oil* and *pin-2(3)-ene* and *pin-2(10)-ene* in the *feed pine oil white* the Applicant proposed the methods of gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 8897, ISO 4725 and ISO 11020 standards, respectively) and provided experimental evidences of the applicability of the methods. Based on the available data, the EURL recommends for official control the proposed GC-FID methods for the determination of the phytochemical markers (*pin-2(3)-ene*, *cis-thujopsene* and *pin-2(10)-ene*) in the corresponding products (*juniper oil*, *cis-thujopsene* and *cedarwood Texas oil*).

For the characterisation of *pine tincture* and *ginkgo tincture*, the Applicant proposed the spectrophotometric method based on the European Pharmacopoeia monograph (01/2008:20814) for the determination of *total polyphenols* in the products and the methods of high performance thin-layer chromatography (HPTLC) for the determination of *total phenolic acids* and *total flavonoids* in *pine tincture* and *ginkgo tincture*, respectively. In addition, experimental evidences were provided demonstrating the applicability of the methods. Based on the available data, the EURL recommends for official control the proposed spectrophotometric and HPTLC methods for the characterisation of *pine tincture* and *ginkgo tincture*.

For the determination of the phytochemical marker *total flavone glycosides* in *ginkgo tincture* the Applicant proposed the methods of high performance liquid chromatography with spectrophotometric detection (HPLC-UV) based on the European Pharmacopoeia monograph (01/2011:1828) and provided experimental evidences of the applicability of the method.

Based on the available data, the EURL recommends for official control the proposed HPLC-UV method for the determination of the phytochemical marker *total flavone glycosides* in *ginkgo tincture*.

For the determination of the phytochemical marker *total flavone glycosides* in *ginkgo extract* the Applicant proposed the HPLC-UV methods of the US Pharmacopoeia monograph 35-NF30 (powdered ginkgo extract) and of the European Pharmacopoeia monograph (04/2008:1827) providing experimental evidences of the applicability of the methods. Based on the available data, the EURL recommends for official control the proposed HPLC-UV methods for the determination of the phytochemical marker *total flavone glycosides* in *ginkgo extract*.

For the determination of the phytochemical marker *tannins* in *juniper tincture* the Applicant proposed the spectrophotometric method of the European Pharmacopoeia monograph (01/2008:20814) and provided experimental evidences of the applicability of the method. Based on the available data, the EURL recommends for official control the proposed spectrophotometric method of the European Pharmacopoeia monograph (01/2008:20814) for the determination of the phytochemical marker *tannins* in *juniper tincture*.

The Applicant did not provide any methods or data for the determination of the *feed additives* from this botanically defined group in *premixtures*, *compound feed* and *water* as the accurate determination of these products in the mentioned matrices is not achievable experimentally. Therefore, the EURL cannot evaluate or recommend any method for official control for the determination of the *feed additives* of this botanically defined group in *premixtures*, *compound feed* and *water*.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.

KEYWORDS

Juniper oil, *juniper berry extract (wb)*, *juniper tincture*, *cedarwood texas oil*, *pine oil*, *pine tincture*, *pine oil white*, *pine needle oil*, *ginkgo extract (wb)* and *ginkgo tincture* from *botanically defined flavourings group 18 (BDG 18)*, sensory additives, flavouring compounds, all animal species.

1. BACKGROUND

In the present grouped application an authorisation is sought under Articles 4(1) (new use in water) and 10(2) (re-evaluation of additives already authorised under the provisions of the Council Directive 70/524/EEC) for *juniper oil*, *juniper berry extract (wb)*, *juniper tincture*, *cedarwood texas oil*, *pine oil*, *pine tincture*, *pine oil white*, *pine needle oil*, *ginkgo extract (wb)* and *ginkgo tincture* from *botanically defined flavourings group 18 (BDG 18)*, under the category/functional group 2(b) 'sensory additives'/flavouring compounds', according to Annex I of Regulation (EC) No 1831/2003 [1]. The authorisation is sought for all animal species [1].

However, upon requests from the Applicant, the European Commission has accepted to withdraw three *feed additives* from this grouped application, namely *juniper berry extract (wb)*, *pine oil* and *pine needle oil* [2,3]. Therefore, in this report, the EURL focused on the evaluation of the remaining seven *feed additives*, namely *juniper oil*, *cedarwood texas oil*, *pine oil white*, *pine tincture*, *ginkgo tincture*, *ginkgo extract* and *juniper tincture*.

In the technical dossier the Applicant presented the description of each *feed additive* [4], including phytochemical marker(s) and their content, which were further consolidated and updated in the frame of the supplementary information [5-12] as shown in Table 1.

Table 1. The updated specifications of the *feed additives* under the evaluation from botanically defined group BDG 18

Additive	Plant species	Phytochemical marker (or major component)	Content of phytochemical marker	Reference
Juniper oil	<i>Juniperus communis</i> L.	Pin-2(3)-ene	25 – 45 (*)	[5]
Cedarwood Texas oil	<i>Juniperus mexicana</i> Schiede	cis-Thujopsene	25 – 35 (*)	[6]
Pine oil white	<i>Pinus pinaster</i> Aiton. (<i>Pinus pinaster</i> Soland.) or <i>Pinus massoniana</i>	Pin-2(3)-ene	70 – 85 (*)	[7]
		Pin-2(10)-ene	11 – 20 (*)	
Pine tincture	<i>Pinus sylvestris</i> L.	Total polyphenols and total phenolic acids	-	[8]
Ginkgo tincture	<i>Ginkgo biloba</i> L.	Total polyphenols and total flavonoids	-	[9]
		Total flavone glycosides	≤ 500 (**)	[10]
Ginkgo extract	<i>Ginkgo biloba</i> L.	Total flavone glycosides	22 – 27 (***)	[11]
Juniper tincture	<i>Juniperus communis</i> L.	Tannins	20 – 200 (****)	[12]

The content of the phytochemical markers is expressed in terms of: relative response of the marker (response of the signal of the marker divided by the sum of the signals of all components), expressed as % (*); mass fraction, using a standard substance, expressed as mg/L (**); mass fraction, using a standard substance, expressed as % (***) ; mass fraction, using a standard substance, expressed as mg/kg (****).

The *feed additives* are intended to be incorporated into *compound feed* or *water* for drinking directly or through flavouring *premixtures*. Initially, the Applicant suggested the typical maximum inclusion levels of the *feed additives* of 25 mg/kg *compound feed* [13], which were further updated in the frame of the supplementary information for the different products. Depending on the product and species the levels for the products were ranging from 15 to 750 mg/kg *compound feed* [5-12].

2. TERMS OF REFERENCE

In accordance with Article 5 of Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761, on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and the tasks of the European Union Reference Laboratory concerning applications for authorisations of feed additives, the EURL is requested to submit a full evaluation report to the European Food Safety Authority for each application or group of applications. For this particular dossier, the methods of analysis submitted in connection with *Botanically defined flavourings group 18 (BDG 18) - Coniferales, Ginkgoales* and their suitability to be used for official controls in the frame of the authorisation were evaluated.

3. EVALUATION

Description of the analytical methods for the determination of the active substance in the feed additive, premixtures, feedingstuffs and when appropriate water (section 2.6.1 of the dossier - Annex II of Commission Regulation (EC) No 429/2008)

Juniper oil

For the determination of the phytochemical marker *pin-2(3)-ene* in *juniper oil* the Applicant proposed a method based on gas chromatography coupled with flame ionisation detection (GC-FID) [14]. The method is based on the standard ISO 8897:2010 for "Oil of juniper berry (*Juniperus communis* L.)" [15].

According to the specific analytical procedure, 25 µl of the *juniper oil* is dissolved in 1 ml of hexane and 1 µl of the solution is injected into the GC. The eluted compounds are detected by FID and the quantification is performed using the normalisation approach for the estimation of the area percentage of individual components (including also the phytochemical marker) in the chromatogram [14]. In addition, the Applicant presented the typical chromatogram of *juniper oil* demonstrating a good separation of the marker [14]. Also, the Applicant presented the range of the phytochemical marker *pin-2(3)-ene* in *juniper oil* from the analysis of five batches, which was ranging from 41.0 to 42.0 % [5]. The latter range is within the one as specified in the above mentioned ISO 8897:2010 standard [15].

Given the available performance characteristics and data, the EURL recommends for official control the GC-FID method based on the ISO 8897:2010 standard for the determination of the phytochemical marker *pin-2(3)-ene* in *juniper oil*.

Cedarwood Texas oil

For the determination of the phytochemical marker *cis-thujopsene* in *cedarwood Texas oil* the Applicant proposed a method based on GC-FID [16]. The method is based on the standard ISO 4725:2004 for "Oil of cedarwood, Texas (*Juniperus mexicana* Schiede)" [17].

According to the specific analytical procedure, 1 µl of the oil is injected into the GC using split ratio 100:1. The eluted compounds are detected by FID and the quantification is performed using the normalisation approach for the estimation of the area percentage of individual components (including also the phytochemical marker) in the chromatogram [16].

In addition, the Applicant presented the typical chromatogram of *cedarwood Texas oil* demonstrating a good separation of the marker [16]. Also, the Applicant presented the range of the phytochemical marker *cis-thujopsene* in *cedarwood Texas oil* from the analysis of five batches, which was ranging from 26.8 to 31.0 % [6]. The latter range is within the one as specified in the above mentioned ISO 4725:2004 standard [17].

Given the available performance characteristics and data, the EURL recommends for official control the GC-FID method based on the ISO 4725:2004 standard for the determination of the phytochemical marker *cis-thujopsene* in *cedarwood Texas oil*.

Pine oil white

For the determination of the phytochemical markers *pin-2(3)-ene* and *pin-2(10)-ene* in *pine oil white* the Applicant proposed a method based on GC-FID [18]. The method is based on the standard ISO 11020:1998 for "Oil of turpentine, Iberian type (*Pinus pinaster* Sol.)" [19].

According to the specific analytical procedure, 1 µl of the *Pine oil white* is injected into the GC at a split ratio of 1:100. The eluted compounds are detected by FID and the quantification is performed using the normalisation approach for the estimation of the area percentage of individual components (including also the phytochemical markers) in the chromatogram [18].

In addition, the Applicant presented the typical chromatogram of *Pine oil white* demonstrating a good separation of the markers [18]. Also, the Applicant presented the range of the phytochemical markers (*pin-2(3)-ene* and *pin-2(10)-ene*) in *pine oil white* from the analysis of five batches, which was ranging from 71.0 to 72.2 % and from 17.7 to 19.2 %, respectively [7]. The latter range is within the range as specified in the above mentioned ISO 11020:1998 standard [19].

Given the available performance characteristics and data, the EURL recommends for official control the GC-FID method based on the ISO 11020:1998 standard for the determination of the phytochemical markers *pin-2(3)-ene* and *pin-2(10)-ene* in *pine oil white*.

Pine tincture

For the determination of *total polyphenols* the Applicant proposed a spectrophotometric method [20], which is based on a similar method described in the European Pharmacopoeia monograph for the determination of tannins in herbal drugs [21]. According to the method, the *pine tincture* is diluted and derivatised with the Folin-Ciocalteu's reagent. The resulting reaction products are measured at 760 nm. The *total polyphenols* content is quantified by an external standard calibration using a *gallic acid* as the calibration standard [20].

For the determination of *total phenolic acids* the Applicant proposed high performance thin-layer chromatography (HPTLC) method, where *chlorogenic acid* is used as a calibration standard and the *total phenolic acids* content is therefore expressed as *chlorogenic acid* equivalents [20].

The Applicant has provided the results of the analysis of five different batches of the *feed additive* characterised by applying the above mentioned methods [8,22]. A summary of the results is shown in Table 2. These analyses led to average values of 0.09 % (w/w) for *total polyphenols* and of 0.02 % (w/w) for *total phenolic acids* [8,22].

Furthermore, the Applicant proposed the use of the HPTLC profiles of *phenolic acids* in *pine tincture* as a tool for the unequivocal identification of the *feed additive* [8].

Based on the experimental evidences provided the EURL recommends for official control the above mentioned methods based on spectrophotometry and high performance thin-layer chromatography (HPTLC) for the characterisation of the *feed additive (pine tincture)*.

Table 2. Batch-to-batch results for pine tincture [8,22]

Batch	total polyphenols (gallic acid equivalent)		total phenolic acids (chlorogenic acid equivalent)	
	(mg/L)	(%, w/w)	(mg/L)	(%, w/w)
1	934	0.0962	349	0.0360
2	987	0.1016	366	0.0377
3	990	0.1019	361	0.0372
4	694	0.0716	-	-
5	674	0.0695	-	-

Ginkgo tincture

For the determination of *total polyphenols* the Applicant proposed the above mentioned spectrophotometric method [23] based on a similar method described in the European Pharmacopoeia monograph for the determination of tannins in herbal drugs [21]. According to the method, the *ginkgo tincture* is diluted and derivatised with the Folin-Ciocalteu's reagent and the resulting reaction products are measured at 760 nm. The *total polyphenols* content is quantified by an external standard calibration using a *gallic acid* as the calibration standard [23].

For the determination of *total flavonoids* the Applicant proposed HPTLC method, where *rutin* is used as a calibration standard and the *total flavonoids* content is therefore expressed as *rutin* equivalents [23].

The Applicant has provided the results of the analysis of five different batches of the *feed additive* characterised by applying the above mentioned methods [9,24]. A summary of the results is shown in Table 3. These analyses led to average values of 0.11 % (w/w) for *total polyphenols* and of 0.10 % (w/w) for *total flavonoids* [9,24].

Furthermore, the Applicant proposed the use of the HPTLC profiles of *total flavonoids* in *ginkgo tincture* as a tool for the unequivocal identification of the *feed additive* [9].

Based on the experimental evidences provided the EURL recommends for official control the above mentioned methods based on spectrophotometry and high performance thin-layer chromatography (HPTLC) for the characterisation of the *ginkgo tincture* product.

For the determination of the phytochemical marker *total flavone glycosides* in the other *ginkgo tincture* product the Applicant submitted the method based on high performance liquid chromatography with spectrophotometric detection (HPLC-UV) [25], which is based on the HPLC-UV method dedicated for analysis of flavonoids described in European Pharmacopoeia monograph for Ginkgo leaf (01/2011:1828) [26].

Table 3. Batch-to-batch results for ginkgo tincture [9,24]

Batch	total polyphenols (gallic acid equivalent)		total flavonoids (rutin equivalent)
	(mg/L)	(%, w/w)	(%, w/w)
1	803	0.0818	0.0922
2	1215	0.1247	0.1185
3	1466	0.1505	0.1075
4	1063	0.1085	0.0997
5	1028	0.1049	0.1004

According to the specific protocol [25], the sample is evaporated to dryness and the residue is dissolved in methanol. After the addition of hydrochloric acid, the mixture after the dilution with water is centrifuged. An aliquot of the supernatant at first is heated in a water bath and then cooled down before the chromatographic analysis. The eluted compounds are detected at 370 nm and the quantification of *total flavone glycosides* is performed by an external standard calibration using quercetin as a calibration standard [25].

The Applicant has provided the results of the analysis of five different batches of the *feed additive*, where the content of *total flavone glycosides* was ranging from 853 to 1154 mg/L *ginkgo tincture* [10,27].

Given the available data, the EURL recommends for official control the HPLC-UV method based on European Pharmacopeia monograph (01/2011:1828), for the determination of the phytochemical marker *total flavone glycosides* in the *ginkgo tincture* product.

Ginkgo extract

For the determination of the phytochemical marker in *ginkgo extract* the Applicant proposed the methods of US Pharmacopeia 35-NF 30 monograph for powdered ginkgo extract [28] and of European Pharmacopeia monograph for ginkgo dry extract, refined and quantified (04/2008:1827) [29], which are based on HPLC-UV.

Following the protocols of the method, the sample is treated with aqueous solutions of hydrochloric acid and alcohol/methanol in hot water bath and then cooled down before the chromatographic analysis. The eluted compounds are detected at 370 nm and the quantification of *total flavone glycosides* is performed by an external standard calibration using quercetin as a calibration standard [28,29].

The Applicant has provided the results of the analysis of four different batches of the *feed additive*, where the content of *total flavone glycosides* in the product was ranging from 27.6 to 29.9 % (w/w) [11].

Given the available data, the EURL recommends for official control the HPLC-UV method of the above mentioned US Pharmacopeia or European Pharmacopeia monographs for the determination of the phytochemical marker *total flavone glycosides* in *ginkgo extract*.

Juniper tincture

For the determination of *tannins* in the *feed additive* the Applicant proposed [12,30] a spectrophotometric method of the European Pharmacopoeia monograph (01/2008:20814) for the determination of *tannins* in herbal drugs [21]. According to the method, the sample is derivatised with phosphomolybdotungstic reagent and the reaction products are measured at

760 nm. The content of *tannins* is determined by an external standard calibration using *pyrogallol* as a calibration standard [21].

The Applicant has provided the results of the analysis of two sets of batches of the *feed additive*, where the content of *tannins* and *polyphenols* were ranging from 90 to 470 mg/kg [12] and the content of *tannins* was ranging from 40 to 80 mg/kg [30].

Given the available data, the EURL recommends for official control the spectrophotometric method of the European Pharmacopoeia monograph (01/2008:20814) for the determination of the phytochemical marker *tannins* in *juniper tincture*.

The Applicant did not provide any methods or data for the determination of the *feed additives* from this botanically defined group in *premixtures*, *compound feed* and *water* as the accurate determination of these products in the mentioned matrices is not achievable experimentally. Therefore, the EURL cannot evaluate or recommend any method for official control for the determination of the *feed additives* of this botanically defined group in *premixtures*, *compound feed* and *water*.

Methods of analysis for the determination of the residues of the additive in food (section 2.6.2 of the dossier - Annex II of Commission Regulation (EC) No 429/2008)

An evaluation of corresponding methods of analysis is not relevant for the present application.

Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761) is not considered necessary.

4. CONCLUSIONS AND RECOMMENDATIONS

In the frame of this authorisation the EURL recommends for official control: (i) the methods of gas chromatography coupled with flame ionisation detection (GC-FID) (based on ISO 8897, ISO 4725 and ISO 11020 standards, respectively) for the determination of *pin-2(3)-ene* in *juniper oil*; *cis-thujopsene* in *cedarwood Texas oil*; and *pin-2(3)-ene* and *pin-2(10)-ene* in the *feed pine oil white*; ii) the spectrophotometric method based on the European Pharmacopoeia monograph (01/2008:20814) for the determination of *total polyphenols* in *pine tincture* and *ginkgo tincture*; iii) the methods of high performance thin-layer chromatography (HPTLC) for the determination of *total phenolic acids* and *total flavonoids* in *pine tincture* and *ginkgo tincture*, respectively; iv) the method of high performance liquid chromatography with spectrophotometric detection (HPLC-UV) based on the European Pharmacopoeia monograph (01/2011:1828) for the determination of *total flavone glycosides* in *ginkgo tincture*; v) the HPLC-UV methods of US Pharmacopoeia monograph 35-NF30 (powdered ginkgo extract) and of European Pharmacopoeia monograph (04/2008:1827) for

the determination of *total flavone glycosides* in *ginkgo extract*; vi) the spectrophotometric method of the European Pharmacopoeia monograph (01/2008:20814) for the determination of *tannins* in *juniper tincture*.

Recommended text for the register entry (analytical method)

For the determination of the phytochemical marker *pin-2(3)-ene* in the *feed additive (juniper oil)*:

- gas chromatography coupled with flame ionisation detection (GC-FID) (ISO 8897)

For the determination of the phytochemical marker *cis-thujopsene* in the *feed additive (cedarwood Texas oil)*:

- gas chromatography coupled with flame ionisation detection (GC-FID) (ISO 4725)

For the determination of the phytochemical markers *pin-2(3)-ene* and *pin-2(10)-ene* in the *feed additive (pine oil white)*:

- gas chromatography coupled with flame ionisation detection (GC-FID) (ISO 11020)

For the characterisation of the *feed additive (pine tincture)*:

- spectrophotometry for the determination of *total polyphenols* and
- high performance thin-layer chromatography (HPTLC) for the determination of *total phenolic acids*

For the characterisation of the *feed additive (ginkgo tincture)*:

- spectrophotometry for the determination of *total polyphenols*; and
- high performance thin-layer chromatography (HPTLC) for the determination of *total flavonoids*

For the determination of the phytochemical marker *total flavone glycosides* in the *feed additive (ginkgo tincture)*:

- high performance liquid chromatography with spectrophotometric detection (HPLC-UV)

For the determination of the phytochemical marker *total flavone glycosides* in the *feed additive (ginkgo extract)*:

- high performance liquid chromatography with spectrophotometric detection (HPLC-UV) (US Pharmacopoeia 35-NF30 or Ph. Eur. 04/2008:1827)

For the determination of the phytochemical marker *tannins* in the *feed additive (juniper tincture)*:

- spectrophotometry (Ph. Eur. 01/2008:20814)

5. DOCUMENTATION AND SAMPLES PROVIDED TO EURL

In accordance with the requirements of Regulation (EC) No 1831/2003, reference samples of botanically defined flavourings group BDG 18 – Coniferales, Ginkgoales have been sent to the European Union Reference Laboratory for Feed Additives. The dossier has been made available to the EURL by EFSA.

6. REFERENCES

- [1] *Application, Reference SANCO/D/2: FORW. APPL. 00196(10279)/1831/-2010
- [2] *Supplementary information – Partial withdrawal of applications – Ares(2019)1299322
- [3] *Supplementary information – Partial withdrawal of an application – Ares(2021)4247025
- [4] *Technical dossier, 2.1.3. Qualitative and quantitative composition of the additive
- [5] *Supplementary information – SIn_reply_juniper_berry_oil
- [6] *Supplementary information – 2021-10-19-SIn_reply_Cedarwood_texas_oil
- [7] *Supplementary information – 2020-11-10-Pine-oil-white-SIn-reply
- [8] *Supplementary information – Section II_Identity (pine tincture)
- [9] *Supplementary information – Section II_Identity (ginkgo tincture)
- [10] *Supplementary information – 2021-03-03 SIn reply Ginkgo tincture Final
- [11] *Supplementary information – 2023-01-04_EURL_appendix_ginkgo_extract
- [12] *Supplementary information – 2023-01-31 Juniper_tincture_SIn_reply
- [13] *Technical dossier, 2.5.1. Proposed mode of use in animal nutrition
- [14] *Supplementary information – 2021-02-02_EURL_appendix_juniper_berry_oil
- [15] ISO 8897:2010 – Oil of juniper berry (*Juniperus communis* L.)
- [16] *Supplementary information – 2021_10_19_EURL_appendix_cedarwood_Texas_oil
- [17] ISO 4725:2004 – Oil of cedarwood, Texas (*Juniperus mexicana* Schiede)
- [18] *Supplementary information – 2020-11-10-EURL_appendix_pine_oil_white
- [19] ISO 11020:1998 – Oil of turpentine, Iberian type (*Pinus pinaster* Sol.)
- [20] *Supplementary information – Annex_II_3_Methods of analysis (pine tincture)
- [21] *Supplementary information – European Pharmacopoeia monograph, 01/2008:20814
- [22] *Supplementary information – Annex_II_4_Results of analysis (pine tincture)

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- [23] *Supplementary information – Annex_II_3_Methods of analysis (ginkgo tincture)
- [24] *Supplementary information – Annex_II_4_Results of analysis (ginkgo tincture)
- [25] *Supplementary information – Annex Ia, SOP Greencoat Ginkgo Flavone Glycosides 2019-1
- [26] *Supplementary information – European Pharmacopoeia monograph, 01/2011:1828
- [27] *Supplementary information – Annex I Flavone Glycosides Ginkgo
- [28] *Supplementary information – US Pharmacopoeia monograph 35-NF30, powdered ginkgo extract
- [29] *Supplementary information – European Pharmacopoeia monograph, 04/2008:1827
- [30] *Supplementary information – 2023-01-04_EURL_appendix_juniper_tincture
- *Refers to Dossier no: FAD-2010-0320

7. RAPPORTEUR LABORATORY & NATIONAL REFERENCE LABORATORIES

The Rapporteur Laboratory for this evaluation is the European Union Reference Laboratory for Feed Additives, JRC, Geel, Belgium. This report is in accordance with the opinion of the consortium of National Reference Laboratories as referred to in Article 6(2) of Commission Regulation (EC) No 378/2005, as last amended by Regulation (EU) 2015/1761.

8. ACKNOWLEDGEMENTS

The following National Reference Laboratories contributed to this report:

- Centro di referenza nazionale per la sorveglianza ed il controllo degli alimenti per gli animali (CReAA), Torino (IT)
- Państwowy Instytut Weterynaryjny, Pulawy (PL)
- Instytut Zootechniki — Państwowy Instytut Badawczy, Krajowe Laboratorium Pasz, Lublin (PL)
- Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES), Wien (AT)
- Ústřední kontrolní a zkušební ústav zemědělský (ÚKZÚZ), Praha (CZ)
- Thüringer Landesanstalt für Landwirtschaft (TLL). Abteilung Untersuchungswesen. Jena (DE)