REGISTRATION REPORT

Part A

Risk Management

Product code: LBG-42FFM

Product name(s): LASVEGAS

Active Substance(s):

folpet, 300 g/L

potassium phosphonates , 670 g/L

(equivalent to 450 g/L phosphonic acid)

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: ADAMA France S.A.S.

Date: 03/01/2020

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PART A – Risk Management

The company ADAMA France S.A.S. has requested marketing authorisation in France for the product LASVEGAS (product code: LBG-42FFM), containing 300 g/L folpet and 670 g/L potassium phosphonates (equivalent to 450 g/L phosphonic acid) for use as a fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to LASVEGAS (LBG-42FFM) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of LASVEGAS (LBG-42FFM) have been made using endpoints agreed in the EU peer review(s) of both folpet and potassium phosphonates.

This document describes the specific conditions of use and labelling required for France for the registration of LASVEGAS (LBG-42FFM).

Appendix 1 of this document provides a copy of the French Decision.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

Appendix 3 of this document concerns letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of ADAMA France S.A.S.'s application to market LASVEGAS (LBG-42FFM) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Folpet

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as fungicide can be authorised. PART B In assessing applications to authorise plant protection products containing folpet for uses other than winter wheat Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on folpet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; —the dietary exposure of consumers in view of future revisions of Maximum Residue Levels;

— the protection of birds, mammals, aquatic and soil organisms. Conditions of authorisation should include risk mitigation measures. The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and earthworms. They shall ensure that the notifiers at whose request folpet has been included in this Annex provide such studies to the Commission within two years from the approval.
An EFSA conclusion is available (EFSA Scientific Report (2009) 297, 1-80). A Review Report is available (SANCO/10032/2006 – rev. 5; 11 July 2008).

Potassium phosphonates

Commission Implementing Regulation (EU) No 369/2013 of 22 April 2013 approving the active substance potassium phosphonates, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.
For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium phosphonates, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 March 2013, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the risk to birds and mammals, — the risk of eutrophication of surface water, if the substance is applied in regions or under conditions favouring a quick oxidation of the active substance in surface water. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the long-term risk to insectivorous birds. The applicant shall submit to the Commission, the Member States and the Authority that information by 30 September 2015.
An EFSA conclusion is available (EFSA Journal 2012;10 (12):2963). A Review Report is available (SANCO/10416/2013 rev 2).

1.3 Regulatory approach

The present application (2016-0042 / 2016-0055 / 2017-0895) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4th May 2017[2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and

[1] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

[2] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

eight hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, drift buffer zones may be reduced under some circumstances as explained in Appendix 3 of the above-mentioned French Order.

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[5] provides that:
- an authorisation granted for a "reference" crop applies also for "linked" crops, unless formally stated in the Decision
- the "reference" and "linked" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of LASVEGAS (LBG-42FFM), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary for folpet.

The applicant has provided a letter of access for potassium phosphonates active substance. This letter of access is available upon request.

[3] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

[4] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

[5] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

[6] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	LASVEGAS (LBG-42FFM)
Authorisation number	N/A: no marketing authorisation granted
Function	fungicide
Applicant	ADAMA France S.A.S.
Composition	300 g/L folpet 670 g/L potassium phosphonates
Formulation type (code)	Suspension concentrate (SC)
Packaging	N/A: not registered in France

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	Skin sensitisation, category 1 Eye irritation, category 2Carcinogenicity, category 2	
Environmental hazards	-	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H317	May cause an allergic skin reaction
	H319	Causes serious eye irritation
	H351	Suspected of causing cancer
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		Contains 1,2-benzisothiazol-3(2H)-one (CAS No. 2634-33-5)

See Part C for justifications of the classification and labelling proposals.

2.2.2 Other phrases in compliance with Regulation (EU) No 547/2011

N/A: no marketing authorisation granted.

2.2.3 Other phrases linked to the preparation

N/A: no marketing authorisation granted.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

GAP rev. 1, date: 2020-01-03

PPP (product name/code):	LASVEGAS (LBG-42FFM)	Formulation type:	**SC** [a, b]
Active substance 1:	folpet	Conc. of as 1:	**300 g/L** [c]
Active substance 2:	potassium phosphonates	Conc. of as 2:	**670 g/L** [c]
Applicant:	**ADAMA France S.A.S.**	Professional use:	☒
Zone(s):	southern [d]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Grapes (table grapes and wine grapes)	F	Dead arm *Cryptosporella viticola*	Foliar spray	BBCH 10 – 13	a) 1 b) 6	12-14	a) 1.75 (0.35 L/hL)** b) 21.75	a) 525 + 787.5 a) 6525 + 9787.5	100 / 500 (Spray volume, until the run off point)	28 (wine grapes) F (BBCH 69) (table grapes)	**Not acceptable** Risk for operator, worker, resident, bystander, MRL (wine grapes)
2	FR	Grapes (table grapes and wine grapes)	F	Downy Mildew *Plasmopara viticola*	Foliar spray	Wine grapes: BBCH 14-85	a) 5 b) 6	12-14	a) 4 b) 21.75	a) 1200 + 1800 a) 6525 + 9787.5	150 / 500	28 (wine grapes)	**Not acceptable** Risk for operator, worker, resident, bystander, MRL (wine grapes)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
				Black-rot *Guignardia bidwellii* Rotbrenner*Pseudopeziza tracheiphila*		Table grapes: BBCH 14-69						F (BBCH 69) (table grapes)	

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/L
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

LASVEGAS (LBG-42FFM) is a grey/green viscous water based liquid formulation (suspension concentrate). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product has a flash point of 120°C. It has a self-ignition temperature of 285 °C. In aqueous solution (1%), it has a pH value of 4.86 at ambient temperature. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE/PA packaging. Since the product is a water based formulation, results are extrapolable to HDPE packaging. Its technical characteristics are acceptable for an SC formulation. The product should be shaken prior using. The product must be stored at a temperature below 40°C.

3.1.2 Methods of analysis

Analytical methods for the determination of the active substances and the relevant impurities (perchloromethylmercaptan and carbon tetrachloride from technical folpet) in the formulation are available and validated.

Analytical methods are available in the Draft Assessment Report and this dossier and validated for the determination of residues of folpet and potassium phosphonates residues in plants (acidic crops), soil, water (surface and drinking) and air. Considering the intended uses (grapes), analytical methods for the determination of residues in foodstuffs of animal origin are not necessary.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="4">Active Substance: potassium phosphonates</td></tr>
<tr><td>ADI</td><td colspan="2">2.25 mg kg bw/d</td><td rowspan="4">EU/ (2013)</td></tr>
<tr><td>ARfD</td><td colspan="2">Not applicable</td></tr>
<tr><td>AOEL</td><td colspan="2">5 mg/kg bw/d</td></tr>
<tr><td>AAOEL</td><td colspan="2">Not applicable</td></tr>
<tr><td rowspan="4">Dermal absorption</td><td colspan="3">Based on an in vitro human study performed on formulation:</td></tr>
<tr><td></td><td>Concentrate (tested)
450 g/L</td><td>Diluted formulation (tested)
0.21 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.1</td><td>7</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
670 g/L</td><td>Spray dilution
(used in formulation)
1.575 g/L</td></tr>
<tr><td></td><td>Dermal absorption endpoints %</td><td>0.1</td><td>7</td></tr>
<tr><td>Oral absorption</td><td colspan="2">60%</td><td>EFSA (2012)</td></tr>
</table>

Active Substance: **folpet**			
ADI	0.1 mg kg bw/d		EU (2007)
ARfD	0.2 mg/kg bw		
AOEL	0.1 mg/kg bw/d		
AAOEL	None		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 300 g/L	Spray dilution (used in formulation) 1.05 g/L
	Dermal absorption endpoints %	**25%**	**75%**
Oral absorption	> **80%**		**EFSA (2009)**

3.1.3.1 Acute Toxicity

LASVEGAS (LBG-42FFM) containing 300 g/L folpet and 670 g/L potassium phosphonates (equivalent to 450 g/L phosphonic acid) has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin, is irritating to the rabbit eye and is a skin sensitiser.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[7]	Equipment *Application method*	Maximum application rate kg as /ha	Minimum volume water (L/ha)
Grape	F	Vehicle mounted */Upward spraying*	4L LASVEGAS (LBG-42FFM) /ha Folpet : 1,2 kg/ha Potassium Phosphonate: 2,68 kg/ha	150

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[8]:

Crop	Equipment	PPE and/or working coverall	% AOEL Folpet	% AOEL Potassium Phosphonate
Grape	Vehicle mounted *Upward spraying (drift reduction technology)*	Working coverall and gloves during mixing/loading and application	**198**	0.96
		Working coverall and gloves during mixing/loading and application and closed cab	23%	-

[7] Open field or glasshouse
[8] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

According to the model calculations, it can be concluded that the risk for the operator using LASVEGAS (LBG-42FFM) is acceptable with a working coverall and gloves during mixing/loading and application **for an application with a vehicle mounted with closed cab.**

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[9].

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation or cutting, sorting, bundling, carrying or hand harvesting or maintenance activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 47% of the AOEL of potassium phosphonates and **to 11262% of the AOEL of folpel with PPE.**

It is concluded that there is unacceptable risk anticipated for the worker.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.3.5 Resident Exposure

Residential exposure was assessed according to EFSA model. An unacceptable risk was determined for residents (adult and child) when drift reduction technology and mitigation measures such as a buffer zone of 10 meters and anti-drift nozzles are taken to reduce the resident exposure:

Model (AOEM) - All pathways (mean)	**% AOEL Folpet**	**% AOEL Potassium Phosphonate**
Resident (children)	**653%**	2.8%
Resident (adults)	**361%**	1.5%

3.1.3.6 Relevance of metabolites

Not relevant

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 20 mg/kg on wine grapes and 6 mg/kg on table grapes for folpet is not expected in NEU and SEU. An exceedance of the current MRL of 100 mg/kg on grapes for fosetyl as laid down in Reg. (EU) n°396/2005 is not expected in the southern zone of Europe. However, although, MRL application for potassium phosphonates (fosetyl) is already under evaluation in Europe, pending the conclusions of this assessment and the publication of the new MRL in an European Regulation,

[9] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

according to the NEU data set, the use of LASVEGAS (LBG-42FFM) could lead to an MRL exceedance of fosetyl on wine grapes.

The chronic and the short-term intakes of folpet and phosphonic acid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, zRMS agrees with the authorization of the intended use on wine and table grapes in Southern Europe and on table grapes only in France.

Summary for potassium phosphonates

Use-No.*	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance Reg SANTE/11196/2018**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**	**Comments**
1	Wine Grapes	Yes	Yes	Yes	Yes	**No in NEU** Yes in SEU	No	Not relevant	Pending the vote for new MRL for fosetyl on grapes, this intended use leads to an MRL exceedance in the NEU
1bis	Table Grapes					Yes	No	Not relevant	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of potassium phosphonates residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were not considered for risk assessment.

Since grapes are perennial crops and are not fed to livestock, there is no need to investigate residue levels in succeeding crops and in commodities of animal origin.

Summary for folpet

Use-No.*	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance Reg 2018/832**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**	**Comments**
1	Table	Yes	Yes	Yes	Yes	**Yes**	No	No	

Use-No.*	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance Reg 2018/832**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**	**Comments**
	Grapes								
1 bis	Wine grapes	Yes	Yes	Yes	Yes	**Yes**		No	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

The effects of processing on the nature of folpet residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were considered for risk assessment.

Since grapes are perennial crops and are not fed to livestock, there is no need to investigate residue levels in succeeding crops and in commodities of animal origin.

Summary for LASVEGAS (LBG-42FFM)

Crop	**PHI for LASVEGAS (LBG-42FFM) proposed by applicant**	**PHI/ Withholding period* sufficiently supported for**		**PHI for LASVEGAS (LBG-42FFM) proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
		Potassium phosphonates	**Folpet**		
Table Grapes	BBCH 10-13 & 14-69 PHI type F	Yes	Yes	F (BBCH 69)	
Wine grapes	BBCH 10-13 & 14-85 PHI: 28 days	Yes (SEU) **No (NEU)**	Yes	None	MRL exceedance in NEU

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substances and their metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of phosphonic acid equivalents (from potassium phosphonates), folpet and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC_{SOIL} and PEC_{SW} derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PEC_{GW} for active substances and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[10] and in Directive 98/83/CE[11]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses. Risk mitigations are required for aquatic organisms.

3.1.6.1 Efficacy

Considering the data provided:

- LASVEGAS (LBG-42FFM) efficacy is considered as satisfactory for all intended uses.
- LASVEGAS (LBG-42FFM) risk of phytotoxicity is considered as acceptable.
- The risks of negative impact on yield, quality, wine making process, propagation and adjacent crops are considered as acceptable.
- The risk of resistance development to folpet and potassium phosphonates does not require a monitoring for the claimed uses.

[10] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

[11] Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision. **For potassium phosphonates, the use of product could lead to an MRL exceedance on wine grapes. For folpel, an unacceptable risk is anticipated for the operator (tractor without cabin), worker, and resident, bystander (adult and child).**

3.3 Substances of concern for national monitoring

No information stated.

3.4 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

3.4.1 Post-authorisation monitoring

N/A: Not registered in France.

3.4.2 Post-authorisation data requirements

N/A: Not registered in France.

3.4.3 Label amendments

N/A: Not registered in France.

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique ***LASVEGAS***

de la société *ADAMA FRANCE SAS*

enregistrées sous les *n°2016-0042, 2016-0055, 2017-0894 et 2017-0895*

Vu les conclusions de l'évaluation de l'Anses du 4 octobre 2019,

Considérant que l'estimation de l'exposition, liée à l'utilisation du produit, pour les usages revendiqués, est supérieure au niveau acceptable d'exposition au folpel pour les travailleurs, les opérateurs avec un tracteur sans cabine, les résidents et les personnes présentes,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

LASVEGAS
AMM n°-

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Informations générales sur le produit	
Noms du produit	LASVEGAS SYNCITY VINERGY
Type de produit	Produit de référence
Titulaire	ADAMA FRANCE SAS 33 rue de Verdun 92156 SURESNES France
Formulation	Suspension concentrée (SC)
Contenant	300 g/L - folpel 670 g/L - phosphonates de potassium
Numéro d'intrant	009-2016.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 03 JAN. 2020

Caroline SEMAILLE
Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

LASVEGAS
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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703206 Vigne*Trt Part. Aer.* Black rot	4 L/ha	5/an	F (BBCH 69)
	Motivation du refus : L'usage sur raisin de table est refusé en raison d'un risque d'effet nocif pour les opérateurs avec tracteur sans cabine, les résidents, les personnes présentes et les travailleurs. L'usage à 4 applications est refusé au même motif.		
	4 L/ha	5/an	28
	Motivation du refus : L'usage sur raisin de cuve est refusé en raison d'un risque d'effet nocif pour les opérateurs avec tracteur sans cabine, les résidents, les personnes présentes et les travailleurs. L'usage sur raisin de cuve est également refusé en raison d'un risque de dépassement des limites maximales de résidus. L'usage à 4 applications est refusé aux mêmes motifs.		
12703202 Vigne*Trt Part. Aer.* Excoriose	1,75 L/ha	1/an	F (BBCH 13)
	Motivation du refus : L'usage sur raisin de table est refusé en raison d'un risque d'effet nocif pour les opérateurs avec tracteur sans cabine, les résidents, les personnes présentes et les travailleurs.		
	1,75 L/ha	1/an	28
	Motivation du refus : L'usage sur raisin de cuve est refusé en raison d'un risque d'effet nocif pour les opérateurs avec tracteur sans cabine, les résidents, les personnes présentes et les travailleurs. L'usage sur raisin de cuve est également refusé en raison d'un risque de dépassement des limites maximales de résidus.		

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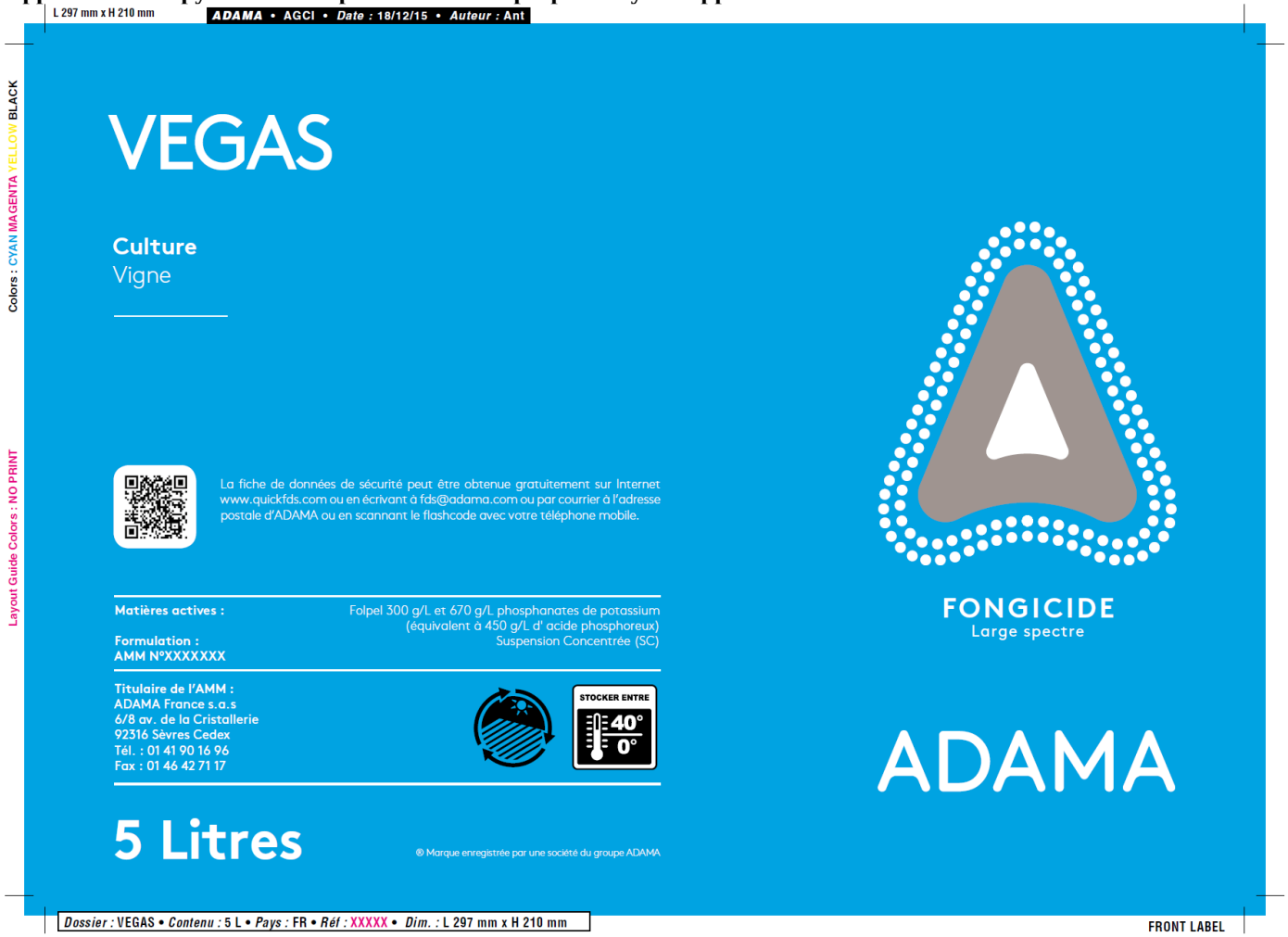
Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703203 Vigne*Trt Part. Aer.* Mildiou(s)	4 L/ha	5/an	F (BBCH 69)
	Motivation du refus : L'usage sur raisin de table est refusé en raison d'un risque d'effet nocif pour les opérateurs avec tracteur sans cabine, les résidents, les personnes présentes et les travailleurs. L'usage à 4 applications est refusé au même motif.		
	4 L/ha	5/an	28
	Motivation du refus : L'usage sur raisin de cuve est refusé en raison d'un risque d'effet nocif pour les opérateurs avec tracteur sans cabine, les résidents, les personnes présentes et les travailleurs. L'usage sur raisin de cuve est également refusé en raison d'un risque de dépassement des limites maximales de résidus. L'usage à 4 applications est refusé aux mêmes motifs.		
12703207 Vigne*Trt Part. Aer.* Rougeot parasitaire	4 L/ha	5/an	F (BBCH 69)
	Motivation du refus : L'usage sur raisin de table est refusé en raison d'un risque d'effet nocif pour les opérateurs avec tracteur sans cabine, les résidents, les personnes présentes et les travailleurs. L'usage à 4 applications est refusé au même motif.		
	4 L/ha	5/an	28
	Motivation du refus : L'usage sur raisin de cuve est refusé en raison d'un risque d'effet nocif pour les opérateurs avec tracteur sans cabine, les résidents, les personnes présentes et les travailleurs. L'usage sur raisin de cuve est également refusé en raison d'un risque de dépassement des limites maximales de résidus. L'usage à 4 applications est refusé aux mêmes motifs.		

Appendix 2 – Copy of the draft product label as proposed by the applicant



MODE D'ACTION - PROPRIÉTÉS

VEGAS est un fongicide particulièrement intéressant et innovant du fait de son large spectre d'activité contre les maladies fongiques de la vigne. **VEGAS** associe deux substances actives, le folpel qui est un fongicide de contact à large spectre avec un mode d'action multi-site et le phosphanate de potassium (acide phosphoreux) qui a une activité systémique et agit comme un stimulateur des défenses naturelles des plantes. **VEGAS** appliqué en traitement préventif permet un excellent niveau de protection contre les champignons pathogènes du vignoble.
De plus, grâce à son mode d'action innovant **VEGAS** est un outil incontournable dans les programmes de traitement pour la gestion des résistances.

MODE D'EMPLOI :

Usages et doses homologués :

Libellé de l'usage	Cultures associées pour le produit	Cibles associées pour le produit	Dose	Nombre max d'application	DAR
Vigne*Trt.Part.Aer*Mildiou	Vigne	Mildiou	4,0 L/ha	5/an	28 (raisin de cuve)
Vigne*Trt.Part.Aer*Black-rot	Vigne	Black-rot	4,0 L/ha	5/an	28 (raisin de cuve)
Vigne*Trt.Part.Aer* Rougeot parasitaire	Vigne	Rougeot parasitaire	4,0 L/ha	5/an	28 (raisin de cuve)
Vigne*Trt.Part.Aer*Excoriose	Vigne	Excoriose	0,35 L/hl	1/an	28 (raisin de cuve)

ADAMA France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées dans le tableau ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres cultures et cibles telles que prévues par le catalogue des usages fixé par l'arrêté du 26 mars 2014.
Ainsi, l'attention de l'utilisateur est attirée sur les risques éventuels de non-conformité de cet élargissement permis par ce catalogue.

Les Limites Maximales de Résidus sont consultables à l'adresse suivante : http://ec.europa.eu/sanco_pesticides/public/index.cfm

Délai de rentrée des travailleurs sur la parcelle : 48 heures après traitement conformément à l'arrêté du 12 juin 2015 relatif à la mise sur le marché et à l'utilisation des produits visés à l'article L.253-1 du code rural.
Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur selon l'arrêté du 7 avril 2010 modifié par l'arrêté du 12 juin 2015.

Préparation de la bouillie

- Remplir la cuve du pulvérisateur à moitié d'eau et mettre l'agitateur en route.
- Verser lentement dans la cuve la quantité nécessaire de **VEGAS**
- Compléter le remplissage de la cuve.
- Agiter énergiquement la préparation pendant l'application.
- Attendre la pleine dissolution du produit avant d'incorporer les suivants.

Conditions de Traitement

VEGAS peut être utilisé à la cadence de 12-14 jours. En cas de forte pression mildiou ramener l'intervalle entre deux traitements à 10 jours. L'utilisation de **VEGAS** en traitement curatif après contamination de la vigne par le mildiou est formellement déconseillée.
Délai avant récolte :
- Raisin de cuve : DAR : 28 j.
- Raisin de table : dernière application au plus tard au stade BBCH 69, ne pas traiter après la floraison.

PRÉCAUTIONS GÉNÉRALES

Dans le cadre des Bonnes Pratiques Agricoles :

Equipements de protection individuels (EPI) :
Pour protéger l'opérateur, porter
Pendant le mélange/chargement :
- Gants en nitrile certifiés EN 374-3,
- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant,
- EPI partiel (blouse à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,

Pendant l'application :
- Combinaison de travail à capuche certifiée de catégorie III type 4,

- Gants en nitrile certifiés EN 374-3 à usage unique pendant l'application si application mécanique et dans le cas d'une intervention sur le matériel de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et stockés après utilisation à l'extérieur de la cabine.

Pendant le nettoyage du matériel de pulvérisation :
- Gants en nitrile certifiés EN 374-3,
- Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant,
- EPI partiel (blouse à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée,

Gestion du risque d'apparition de résistance : L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants. Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.

Conditions de stockage : Conserver le produit dans son emballage d'origine, dans un local réservé à cet usage, à l'abri de la chaleur et de l'humidité.

Emballages vides : Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides via une collecte organisée par les distributeurs partenaires de la filière Adivalor ou un autre service de collecte spécifique.
Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Nettoyage de l'équipement : Ne pas laisser de bouillie prête à l'emploi dans le pulvérisateur. Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur. Eviter toute contamination des mares, puisards, ruisseaux, eaux souterraines ou de distribution ou de tout autre point d'eau, par le produit, la bouillie de pulvérisation et les eaux de rinçage des équipements de traitement.

Premiers secours :
- **Inhalation :** Transporter la victime à l'air frais. En cas de respiration irrégulière ou d'absence de respiration, pratiquer la respiration artificielle. Consulter un médecin.
- **Contact avec la peau :** Rincer immédiatement au savon et à grande eau en retirant les chaussures et vêtements contaminés. Consulter un médecin si nécessaire.
- **Contact avec les yeux :** Rincer immédiatement et abondamment avec de l'eau. Après le rinçage initial, retirer les éventuelles lentilles de contact et continuer à rincer pendant au moins 15 minutes. Maintenir l'œil grand ouvert pendant le rinçage. Si les symptômes persistent, consulter un médecin.
- **Ingestion :** Rincer la bouche. Boire beaucoup d'eau. Si les symptômes persistent, consulter un médecin.

Mesures d'urgence : En cas d'urgence, contacter le centre antipoison le plus proche de votre domicile ou appeler le 15. Présentez aux secours la fiche de données de sécurité. Puis signalez vos symptomes au réseau Phyt'attitude : tél. 0 800 887 887 (numéro vert).

IMPORTANT
Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces... Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente du Ministère de l'Agriculture. Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

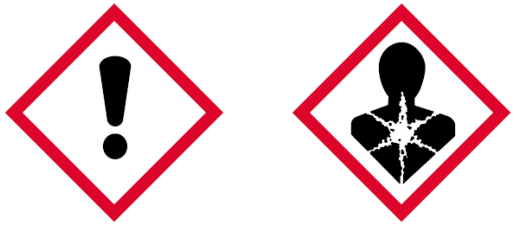
L 297 mm x H 210 mm

ADAMA • AGCI • *Date :* 18/12/15 • *Auteur :* Ant

Colors : MAGENTA YELLOW BLACK

Layout Guide Colors : NO PRINT

ATTENTION



VEGAS

AMM N°XXXXXXX
Suspension Concentrée (SC)
Contient Folpel 300 g/L et 670 g/L phosphonates de potassium (équivalent à 450 g/L d'acide phosphoreux)

H351	**Susceptible de provoquer le cancer.**
H317	**Peut provoquer une allergie cutanée.**
EUH401	**Respecter les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.**

Délai de rentrée des travailleurs sur la parcelle : 48 h après traitement

P102	Tenir hors de portée des enfants.
P201	Se procurer les instructions avant utilisation.
P280	Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/ du visage.
P302+352	EN CAS DE CONTACT AVEC LA PEAU : laver abondamment à l'eau et au savon.
P501	Eliminer le contenu/récipient dans un centre de collecte des déchets dangereux ou spéciaux.

SP1	Ne pas polluer l'eau avec le produit ou son emballage.
SPe3	Pour protéger les organismes aquatiques, respecter une zone non traitée comportant un dispositif végétalisé de 20 mètres par rapport aux points d'eau.

PRODUIT POUR LES PROFESSIONNELS : RESPECTER LES CONDITIONS D'EMPLOI.
Lire les instructions ci-jointes avant emploi.

Distribué par :
ADAMA France s.a.s
6/8 av. de la Cristallerie - 92316 Sèvres Cedex
Tél. : 01 41 90 16 96 - Fax : 01 46 42 71 17

N° de lot	VOIR EMBALLAGE
Date de fabrication	

0 000000 000000

Dossier : VEGAS • *Contenu :* 5 L • *Pays :* FR • *Réf :* XXXXX • *Dim. :* L 297 mm x H 210 mm

BACK LABEL

Appendix 3 – Letter(s) of Access

Letter(s) of access and, if necessary, an argumentation according to art. 62.4 of Reg (UE) No 1107/2009 have been submitted and are available under request.