

## **REGISTRATION REPORT**

### **Part A**

### **Risk Management**

**Product code: 1 31063 01**

**Product names: TAMROK J 240**

(Non professional, home and garden uses)

**Active Substance:**

**glyphosate, 240 g/L**

**COUNTRY: FRANCE**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(marketing authorisation)**

**Applicant: PHYTEUROP**

**Date: 2018/01/16**

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## PART A – Risk Management

The company PHYTEUROP has requested marketing authorisation in France for the product TAMROK J 240 (formulation code: 1 31063 01), containing 240 g/L glyphosate, for use as a herbicide for non professional garden uses.

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 TAMROK J 240 (1 31063 01) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of TAMROK J 240 (1 31063 01) have been made using endpoints agreed in the EU peer review of glyphosate.

This document describes the specific conditions of use and labelling required for France for the registration of TAMROK J 240.

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 is a copy of the letter(s) of Access.

## 1 DETAILS OF THE APPLICATION

### 1.1 Application background

The present registration report concerns the evaluation of PHYTEUROP's application to market TAMROK J 240 (1 31063 01) in France as a herbicide (product uses described under point 2.3) for non professional garden uses. 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

#### Glyphosate

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.

Commission Implementing Regulation (EU) 2016/1056 of 29 June 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance glyphosate

Commission Implementing Regulation (EU) 2016/1313 of 1 August 2016 amending Implementation Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glyphosate (Text with EEA relevance)

Specific provisions of Regulation (EU) No 540/2011 were as follows:

Only uses as herbicide may be authorised

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 glyphosate, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plant Health on 29 June 2001 shall be taken into account. In this overall assessment Member States:

- must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crop uses

Specific provisions of Regulation (EU) 2016/1056 of 29 June 2016 were as follows :

In the sixth column, ‘expiration of approval’, of entry 25 on glyphosate in Part A of the Annex to Implementing Regulation (EU) No 540/2011, the words ‘30 June 2016’ are replaced by the words ‘6 months from the date of receipt of the opinion of the Committee for Risk Assessment of the European Chemicals Agency by the Commission or 31 December 2017, whichever is the earlier’

Specific provisions of Regulation (EU) 2016/1313 of 1 August 2016 were as follows :

Only uses as herbicide may be authorised

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 glyphosate, and in particular Appendices I and II thereof, as amended in the Standing Committee on Plants, Animals, Food and Feed on 27 June 2016 shall be taken into account. In this overall assessment Member States

- must pay particular attention to the protection of the groundwater in vulnerable areas, in particular with respect to non-crop use
- must pay particular attention to risks from the use in specific areas referred to in Article 12(a) of Directive 2009/128/EC
- must pay particular attention to compliance of pre-harvest uses with good agricultural practices

Member States shall ensure that plant protection products containing glyphosate do not contain the co-formulant POE-tallowamine (CAS No 61791-26-2)

There is no definitive EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance.

A Review Report is available (6511/VI/99-final 21 January 2002) and an addendum to the Review report (Glyphosate SANTE/11051/2016 rev 0 11 July 2016)

### 1.3 Regulatory approach

The present applications (2013-1723) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)<sup>1</sup> 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”)<sup>2</sup> – 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<sup>3</sup> provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres;
- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 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.

<sup>1</sup> French Food Safety Agency, Afssa, before 1 July 2010

<sup>2</sup> 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

<sup>3</sup> 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>

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<sup>4</sup>, 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<sup>5</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014<sup>6</sup> 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<sup>7</sup> 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 TAMROK J 240 (1 31063 01), 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

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. A copy of the letter(s) of access is reproduced in Part A, Appendix 3.

## 2 DETAILS OF THE AUTHORISATION

### 2.1 Product identity

<b>Product name (code)</b>	TAMROK J 240 (1 31063 01)
<b>Authorisation number</b>	N/A : authorization not granted in France
<b>Function</b>	Herbicide
<b>Applicant</b>	PHYTEUROP
<b>Composition</b>	240 g/L glyphosate (under isopropylamin (IPA) salts form : 324 g/L)

<sup>4</sup> 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

<sup>5</sup> 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

<sup>6</sup> <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

<sup>7</sup> SANCO document “guidance document: - Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

<b>Formulation type (code)</b>	Soluble concentrate (SL)
<b>Packaging</b>	none. The proposed packaging are unable to ensure a minimum exposure of the non professional uses. Refer to RR section 1 for claimed packaging.

The preparation does not contains POE-tallowamine (n° CAS 61791-26-2).

## 2.2 Classification and labelling

### 2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

<b>Physical hazards</b>	No classification	
<b>Health hazards</b>	No classification	
<b>Environmental hazards</b>	No classification	
<b>Hazard pictograms</b>	-	
<b>Signal word</b>	-	
<b>Hazard statements</b>	-	-
<b>Precautionary statements –</b>	<i>For the P phrases, refer to the extant legislation</i>	
<b>Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)</b>		

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

In the previous glyphosate public joint assessments related to human health (European commission, FAO/ OMS (Joint Meeting on Pesticides Residues)), it has been found that the observed effects in genotoxicity and cancerogenicity studies do not lead to consider the active substance as cancerogenic and to propose a classification. The detailed scientific data led the IARC to propose a classification as probably carcinogenic to humans (Group 2A). EFSA has finalized the re- assessment of glyphosate in the context of the renewal of its approval (EFSA 2015), the findings from IARC regarding the potential carcinogenicity of glyphosate have been taking into account during the European peer review assessment process.

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

The authorisation of the product is linked for non professional uses only to the following conditions:

N/A: authorization not granted in France

### 2.2.4 Other phrases linked to the preparation

N/A: authorization not granted in France

## 2.3 Product uses

**Please note:** The GAP Table below reports the intended uses proposed by the applicant,  
When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

**PPP (product name/code)** **TAMROK J 240 (1 31063 01)**  
**active substance 1** **glyphosate**

**Formulation type:** **Soluble Concentrate (SL)**  
**Conc. of as 1:** **240 g/L**

**Applicant:** **PHYTEUROP**  
**Zone(s):** **southern EU**

**professional use** ☐  
**non professional use** ☒

**Verified by MS:** yes

Crop and/ or situation  (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)  (l)	Remarks:  (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g a.s./hL min max	water L/ha min max	g a.s./ha min max		
Weeding in cultivated area	South	13106301	F	Easy to control	SL	240 g/L	Downward spraying	-	1 (full treatment) or 3 (per spot)	-	-	1000	1800	F (except vegetables crops: 30)	Local treatment only on target plant <b>Not Acceptable</b> risk of crop commodities contamination on post-plant and the packagings are unable to ensure a minimum exposure of the non professional users.
				Hard to control	SL	240 g/L	Downward spraying	-	1 (full treatment) or 3 (per spot)	-	-	1000	2520	F (except vegetables crops: 30)	
Weeding after harvest and before the following sowing in cultivated area	South	13106301	F	Easy to control	SL	240 g/L	Downward spraying	-	1 (full treatment) or 3 (per spot)	-	-	1000	1800	F (except vegetables crops: 30)-	<b>Not Acceptable</b> The packagings are unable to ensure a minimum exposure of the non professional users.
				Hard to control	SL	240 g/L	Downward spraying	-	1 (full treatment) or 3 (per spot)	-	-	1000	2520	F (except vegetables)	<b>Not Acceptable</b> The packagings are unable to

Applicant: PHYTEUROP

Evaluator: FRANCE  
Date: 2018/01/16

Crop and/ or situation  (a)	Zone	Product code	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)  (l)	Remarks:  (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g a.s./hL min max	water L/ha min max	g a.s./ha min max		
														<b>crops: 30)-</b>	ensure a minimum exposure of the non professional users.
Orchards	South	13106301	F	Easy to control	SL	240 g/L	Downward spraying	BBCH 00-85 BBCH 89-97	1 (full treatment) or 3 (per spot)	-	-	1000	1800	21 except kiwis 90 olives 7 <b>pome fruits 28</b>	<b>Not Acceptable</b> The packagings are unable to ensure a minimum exposure of the non professional users.
				Hard to control	SL	240 g/L	Downward spraying	BBCH 00-85 BBCH 89-97	1 (full treatment) or 3 (per spot)	-	-	1000	2520	21 except kiwis 90 et olives 7 <b>pome fruits 28</b>	<b>Not Acceptable</b> The packaging are unable to ensure a minimum exposure of the non professional users.
Grapevine	South	13106301	F	Easy to control	SL	240 g/L	Downward spraying	BBCH 00-85 BBCH 89-97	1 (full treatment) or 3 (per spot)	-	-	1000	1800	<b>21</b>	<b>Not Acceptable</b> The packagings are unable to ensure a minimum exposure of the non professional users.
				Hard to control	SL	240 g/L	Downward spraying	BBCH 00-85 BBCH 89-97	1 (full treatment) or 3 (per spot)	-	-	1000	2520	<b>21</b>	<b>Not Acceptable</b> The packagings are unable to ensure a minimum exposure of the non professional users.



- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
  - (f) All abbreviations used must be explained
  - (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at 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
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) 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

TAMROK J 240 (1 31063 01) is a soluble concentrate (SL) formulation. All studies have been performed in accordance with the current requirements. The appearance of the formulation is an amber-brown liquid. It is not explosive and has no oxidising properties. It has a self-ignition temperature > 463 °C. In aqueous solution (1 %), its pH is 4.70 at 22 °C. Ambient shelf life study should be required in post authorization.

##### 3.1.2 Methods of analysis

###### 3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substance and relevant impurities (formaldehyde and N-nitrosoglyphosate) in the formulation are available and validated.

As these relevant impurities (formaldehyde and N-nitrosoglyphosate) are by-products of the manufacturing process for glyphosate and as such cannot be formed in unacceptable concentrations by storage of the formulation, an analytical method for their determination in the formulation is not necessary.

###### 3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report/this dossier and validated for the determination of residues of glyphosate in plants (high-water-, high-acid- and dry-content matrices), soil, water (drinking) and air.

To update the dossier :

- An analytical method (and a confirmatory method if necessary) and its ILV are required for the determination of glyphosate residues in foodstuffs of animal origin.
- A fully validated analytical method is required for the determination of glyphosate residues in surface water.

The active substance is neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

##### 3.1.3 Mammalian Toxicology

###### 3.1.3.1 Acute Toxicity

TAMROK J 240 (1 31063 01), containing 240 g/L glyphosate has a low acute oral, dermal and inhalational toxicity. It is not irritating to the rabbit skin and eye and it is not a skin sensitiser.

###### 3.1.3.2 Operator Exposure

###### Exposure assessment

The acceptable daily intake (ADI) of glyphosate in the context of its evaluation for approbation is 0.3 mg/kg bodyweight/day. This is based on the no observed adverse effect level (NOAEL) in a 2-years oral rat toxicity study and a 100-fold assessment factor.

###### Dermal absorption

Determined from *in vivo* studies on rhesus monkeys and *in vitro* studies on human skin which are performed on a similar formulation, the dermal absorption values proposed for glyphosate in the preparation TAMROK J 240 (1 31063 01) are 3 % for the non diluted formulation and 3 % for the diluted formulation.

###### Operator exposure

The acceptable operator exposure level (AOEL) of glyphosate, in the context of its evaluation for approbation, is 0.2 mg/kg bw/d. This is based on the no observed adverse effect level in an oral rabbit teratogenesis study and a 1200-fold assessment factor (corrected by the oral absorption value of 30 %).

The new acceptable operator exposure level (AOEL) of glyphosate, proposed by Efsa (2015), is 0.1 mg/kg bw/d. This is based on the no observed adverse effect level in an oral rabbit teratogenesis study and a 500 fold assessment

factor.

Estimate of operator exposure to glyphosate according UKPOEM model (home garden – manual spreading) revealed that the risk is considered as acceptable on home garden without personal protective equipment.

**NB:** the notifier has provided a risk assessment with the UPJ model, estimate of operator exposure to glyphosate according UPJ French model (manual spreading) revealed that the risk is considered as acceptable on home garden without personal protective equipment.

The proposed packaging are unable to ensure a minimum exposure of the non professional users.

### **3.1.3.3 Bystander Exposure**

Bystander exposure is considered to be negligible for preparations used on home garden.

### **3.1.3.4 Worker Exposure**

TAMROK J 240 (1 31063 01) is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered to be negligible and is thus not calculated.

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

## **3.1.4 Residues and Consumer Exposure**

### **3.1.4.1 Residues**

#### **Selection of critical uses and justification**

The GAPs with respect to consumer intake and risk assessment for the preparation 1 31063 01 are presented in table 2.3.

#### **Overall conclusion**

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for glyphosate as laid down in Reg. (EU) 396/2005.

The chronic and the short-term intakes of glyphosate 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 uses except on for herbicide selection treatment on grass. Moreover, regarding residue data available, a PHI of 28 d (instead PHI 26) on pome fruits, and a PHI of 21 d on grape (instead PHI 3), are proposed.

As far as consumer health protection is concerned, France, zRMS agrees with the authorization of the intended uses except on cultivated areas on post-plant is restricted where contamination of commodities crops cannot avoid.

#### **Data gaps**

Data gaps should be listed in the summary to give an overview (especially for cMS).

#### **Noticed data gaps are:**

Cultivated areas: not acceptable because of possibilities of contamination of commodities crops

Grape: 3d not supported

Pome fruits: 21d not supported

#### **Post- registration demands:**

- Confirmatory southern residue trials on citrus, tree nuts, plum and grapevine
- Confirmatory northern residue trials on grapevine

#### **Mitigation measures**

Additionally in the framework of this dossier it is proposed to add a mitigation measure for intended uses in all orchards and grapevines. Indeed, considering that commodities can be present during treatment, the following mitigation measure is proposed to avoid any fruits contamination: “Use application material or agricultural practices

to avoid fruits contact with active substance or with soil treated with active substance”.

### Summary of the evaluation

The product 1 31063 01 (TAMROCK J 240) is composed of glyphosate (isopropylamine salt)

### Summary for glyphosate

Use- No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
	<b>Orchards treatments</b> * Nuts	Yes	Yes additionnal SEU residue trials requested	Yes	Yes	Yes with mitigation measures	No	No
	<b>Orchards treatments</b> * Citrus fruits	Yes	Yes additionnal SEU residue trials requested	Yes	Yes	Yes with mitigation measures	No	
	<b>Orchards treatments</b> * Pome fruits	Yes	Yes	No 28d proposed	Yes	Yes with mitigation measures	No	
	<b>Orchards treatments</b> * Stone fruits peach/apricot cherry	Yes	Yes additionnal SEU residue trials requested	Yes	Yes	Yes with mitigation measures	No	
	<b>Orchards treatments</b> * Olives	Yes	Yes	Yes	Yes	Yes with mitigation measures	No	
	<b>Orchards treatments</b> * Kiwi	Yes	Yes	Yes	Yes	Yes with mitigation measures	No	
	<b>Vineyards treatment</b> *grape	Yes	Yes additionnal SEU and NEU residue trials requested	Yes	Yes	Yes with mitigation measures	No	
	<b>Cultivated areas</b>	Yes	Yes	Yes	Yes	No	No	
	<b>INTERCROP treatment</b>	Yes	Yes	Yes	Yes	Yes	No	

**Additionally in the framework of this dossier it is proposed to add a mitigation measure for intended uses in all orchards and grapevines.** Indeed, considering that commodities can be present during treatment, the following mitigation measure is proposed to avoid any fruits contamination: “Use application material or agricultural practices to avoid fruits contact with active substance or with soil treated with active substance”.

Moreover, regarding residue data available, a PHI of 28 d on pome fruits is proposed (instead PHI 21), a PHI of 21 d on grape, and additional residue trials are required at post-authorization level on citrus, stone fruits, treenuts and grape.

The effects of processing on the nature of glyphosate 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.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

#### Summary for 1 31063 01 (TAMROCK J 240)

Crop	PHI for Product code 1 31063 01 (TAMROCK J 240) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for Product code proposed by zRMS	zRMS Comments (if different PHI proposed)
		glyphosate		
<b>Orchards treatments</b> citrus Treenuts	21	Yes		additionnal SEU residue trials requested on citrus and nuts mitigation measures proposed
<b>Orchards treatments</b> Pome fruit	21	No	28	mitigation measures proposed
<b>Orchards treatments</b> Stone fruits	21	Yes		additionnal SEU residue trials requested on plum mitigation measures proposed
<b>Orchards treatments</b> Olive	7	Yes		mitigation measures proposed
<b>Orchards treatments</b> kiwi	90	Yes		mitigation measures proposed
<b>Vineyards treatment</b> grape	3	No	21	mitigation measures proposed
<b>Cultivated areas</b>	F Vegetable crops: 30	Yes		risk of crop commodities contamination on post-plant
<b>INTERCROP treatment</b>	F Vegetable crops: 30	Yes		

NR: not relevant

\* Purpose of withholding period to be specified

\*\* F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

#### Waiting periods before planting succeeding crops

Not necessary.

#### 3.1.5 Environmental fate and behaviour

According to the conditions of use described in the dossier provided for non professional uses, it is considered that exposition of environment and non-target organisms is covered by the risk assessments performed for the professional uses presented in BUGGY GREENLINE (1 31063 01) the same preparation intended for professional uses. The risk for groundwater contamination and for non-target organisms is considered acceptable subject to the application of mitigation measures defined for uses already assessed.

#### 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 review for active substance and its 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.

The conclusions of the risk assessment of the preparation BUGGY GREENLINE (1 31063 01) (same preparation intended for professional uses) are considered relevant for the uses intended for TAMROK J 240 (1 31063 01). Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms are acceptable for the intended uses.

The mitigation measures to protect aquatic organisms and terrestrial plants are adapted for a non professional use as follows:

Do not discharge into the sink, gutter or any other water hole the non-used container leftovers and the sprayer washing water.

To protect aquatic organisms do not apply at least 5 meters away from any surface water bodies (well, pond, stream, river...).

Avoid spray drift and runoff to nearby plants.

### 3.1.7 Efficacy

This is a request for the new preparation TAMROCK J 240 (1 31063 01) for general weeding only in France. It is based on 240 g a.i./ha of glyphosate under isopropylamin (IPA) salts form. This active substance is formulated under a Concentrate Suspension (SC). France is zRMS and the only cMS of this dossier.

The product complies with the Uniform Principles.

Considering the data submitted:

- ✓ the efficacy of TAMROCK J 240 (1 31063 01) is considered as satisfying on the claimed uses.
- ✓ the preparation TAMROCK J 240 (1 31063 01) cannot be considered as a selective product. Considering the foliar mode of penetration of glyphosate, the preparation should not be directed on the green parts of plants.
- ✓ Considering all the cases of resistance to glyphosate in the world, France considers that the applicant should put a resistance monitoring for its active substance glyphosate. This monitoring should allow to study the possible occurrence or development of resistance on weeds and more especially on:
  - Ray grass (*Lolium multiflorum* Lam., *Lolium perenne* L. et *Lolium rigidum* Gaud.),
  - *Conyza* sp.,
  - Common ragweed (*Ambrosia artemisiifolia* L.).

Any new data that may modify the risk must be communicated to the competent authorities.

Uses according to the new catalog published in 2012 February	Nb of appl.	Application rates	Comments	French opinion – section 7
<b>General weeding * cultivated crops</b>	1	7,5 mL/10m <sup>2</sup> (weeds easy to weed) 10,5 mL/10m <sup>2</sup> (weeds hard to weed)	/	Favorable
<b>General weeding * before sowing</b>	1	7,5 mL/10m <sup>2</sup> (weeds easy to weed) 10,5 mL/10m <sup>2</sup> (weeds hard to weed)		Favorable
<b>Orchard * weeding</b>	1	7,5 mL/10m <sup>2</sup> (weeds easy to weed) 10,5 mL/10m <sup>2</sup> (weeds hard to weed)		Favorable
<b>Grapevine*weeding</b>	1	7,5 mL/10m <sup>2</sup> (weeds easy to weed) 10,5 mL/10m <sup>2</sup> (weeds hard to weed)		Favorable

### 3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted, as packaging cannot allow a minimal exposure of non-professional users. A copy of the decision issued can be found in Appendix 1 – Copy of the product Decision.

### **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: authorization not granted in France

#### **3.4.2 Post-authorisation data requirements**

N/A: authorization not granted in France

#### **3.4.3 Label amendments (see label in Appendix 2):**

N/A: authorization not granted in France

## Appendix 1 – Copy of the French Decision



### 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 réglementaire,*

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **TAMROK J 240***

*de la société PHYTEUROP*

*enregistrée sous le n°2013-1723*

*Vu les conclusions de l'évaluation de l'Anses du 14 décembre 2017,*

*Vu l'arrêté du 30 décembre 2010 relatif aux conditions d'emballage des produits phytopharmaceutiques pouvant être employés par des utilisateurs non professionnels,*

*Considérant que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel, conformément à l'article 1 de l'arrêté du 30 décembre 2010,*

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





Informations générales sur le produit		
Nom du produit	TAMROK J 240	
Type de produit	Deuxième gamme	
Titulaire	PHYTEUROP 55, rue Raspail CS 80105 92594 Levallois-Perret Cedex FRANCE	
Formulation	Concentré soluble (SL)	
Contenant	324 g/L - glyphosate sel d'isopropylamine (équivalent à 240 g/L de glyphosate acide)	
Produit de référence	Nom commercial	BUGGY GREENLINE
	N° AMM	2160960
Numéro d'intrant	9898-2013.01	
Numéro d'AMM	-	
Fonction	Herbicide	
Gamme d'usages	Amateur / emploi autorisé dans les jardins	

A Maisons-Alfort, le

16 JAN. 2018

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

TAMROK J 240  
AMM n°-

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## ANNEXE I : Conditions de mise sur le marché demandées

Classification du produit
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Sans classement.
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Pour les phrases P se référer à la réglementation en vigueur
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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>00201024</b> Cultures fruitières*Désherbage*Cult. Installées	10,5 mL/10 m <sup>2</sup>	1 en plein 3 par tache	-
	<b>Motivation du refus :</b> L'usage sur flore difficile est refusé au motif que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.		
	7,5 mL/10 m <sup>2</sup>	1 en plein 3 par tache	-
<b>11015924</b> Traitements généraux*Désherbage*Avt Mise Cult.	<b>Motivation du refus :</b> L'usage sur flore facile est refusé au motif que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.		
	7,5 mL/10 m <sup>2</sup>	1 en plein 3 par tache	-
	<b>Motivation du refus :</b> L'usage sur flore facile est refusé au motif que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.		
	10,5 mL/10 m <sup>2</sup>	1 en plein 3 par tache	-
	<b>Motivation du refus :</b> L'usage sur flore difficile est refusé au motif que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.		

TAMROK J 240  
AMM n° -

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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
<b>11015932</b> Traitements généraux*Désherbage*Cult. Installées (1)	10,5 mL/10 m <sup>2</sup>	1 en plein 3 par tache	-
	<b>Motivation du refus :</b> L'usage sur flore difficile est refusé au motif que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel et en raison d'un risque de dépassement des limites maximales de résidus.		
	7,5 mL/10 m <sup>2</sup>	1 en plein 3 par tache	-
<b>12705902</b> Vigne*Désherbage*Cult. Installées	<b>Motivation du refus :</b> L'usage sur flore facile est refusé au motif que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel et en raison d'un risque de dépassement des limites maximales de résidus.		
	7,5 mL/10 m <sup>2</sup>	1 en plein 3 par tache	-
	<b>Motivation du refus :</b> L'usage sur flore facile est refusé au motif que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.		
	10,5 mL/10 m <sup>2</sup>	1 en plein 3 par tache	-
	<b>Motivation du refus :</b> L'usage sur flore difficile est refusé au motif que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel.		

TAMROK J 240  
AMM n°-

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

Herbicide foliaire systémique non sélectif des zones cultivées			
Nom commercial : TAMROK J 240		N° d'AMM : XXXXXX (emploi autorisé dans les jardins)	
Détenteur de l'AMM : Phyteurop – 53 rue Raspail – 92594 LEVALLOIS-PERRET CEDEX		Type d'action : Herbicide (HRAC G)	
Formulation : 240 g/L (21,2%) de glyphosate acide équivalent à 324 g/L (28,7%) de sel d'isopropylamine		Composition :	
USAGES		Doses d'emploi (mL/10m²)	
Jardin d'amateur	- Désherbage en zones cultivées - Désherbage en zones cultivées après récolte - Désherbage avant mise en culture en zones cultivées - Arboriculture fruitière - vigne (cultures installées)	Flore facile (graminées annuelles)	7.5
		Flore difficile (dicotylédones annuelles et bisannuelles)	10.5
<p>Nombre maximum d'applications par an : 1 pour le traitement généralisé (en plein), 3 pour les traitements localisés (par tache).</p> <ul style="list-style-type: none"> <li>Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : <a href="http://ec.europa.eu/sanco_pesticides/public/index.cfm">http://ec.europa.eu/sanco_pesticides/public/index.cfm</a>.</li> <li>ZNT : 5 mètres. DAR : 5 jours sauf 7 jours sur céréales, 21 jours pour les cultures fruitières (sauf 90 jours pour le kiwi et 7 jours sur l'olive) et 30 jours pour les cultures potagères.</li> <li>Délai de rentrée : attendre le séchage complet de la zone traitée.</li> </ul> <p>TAMROK J 240 est une spécialité à base de glyphosate et d'adjuvants issus de la chimie du végétal. Cette spécialité est applicable après dilution dans l'eau. Désherbant systémique, TAMROK J 240 est absorbé par les parties vertes des végétaux. Il agit uniquement sur les plantes présentes touchées au moment du traitement.</p>			
Périodes et doses d'emploi			
<p>Traiter en période de végétation active au moyen d'un pulvérisateur adapté à la surface à désherber.</p> <p>TAMROK J 240 peut s'utiliser toute l'année : printemps – été pour les plantes herbacées, automne pour les ronces et plantes ligneuses.</p> <ul style="list-style-type: none"> <li>- sur annuelles : traiter par temps poussant au stade jeune des adventices.</li> <li>- sur vivaces : traiter par temps poussant sur adventices suffisamment développées (4 à 6 feuilles, 10 – 15 cm de haut).</li> </ul>			
Pour désherber 100 m²		TAMROK J240	Eau
Flore facile (entretien courant)		75 mL	10 litres
Flore difficile (chardons, pissenlits, lierons, chiendent, ortie, ronces)		105 mL	10 litres
Mode d'emploi			
<p>Agiter en retournant 5 fois le bidon fermé. Verser la quantité nécessaire de TAMROK J 240 dans la cuve du pulvérisateur à demi remplie d'eau. Compléter le remplissage puis agiter. Ne préparer que la quantité de bouillie nécessaire.</p>			
<p><b>TAMROK J 240</b></p> <p><b>H413</b> Peut être nocif à long terme pour les organismes aquatiques.</p> <p>P260 Ne pas respirer les aérosols.</p> <p>P102 Tenir hors de portée des enfants.</p> <p>P270 Ne pas manger, boire ou fumer en manipulant ce produit.</p> <p>P271 Utiliser seulement en plein air ou dans un endroit bien ventilé.</p> <p>P273 Eviter le rejet dans l'environnement.</p> <p>P501 Eliminer le contenu/réceptacle dans une déchetterie ou par un organisme agréé.</p> <p>SP1 Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.]</p> <p>EUH401 Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.</p> <p>Distribué par : TRADI-AGRI (92)</p> <p><b>Bonnes Pratiques Phytosanitaires</b></p> <ul style="list-style-type: none"> <li>Porter des gants pendant les opérations de mélange, chargement et application de la bouillie.</li> <li>Utiliser seulement en plein air ou dans un endroit bien ventilé.</li> <li>Ne pas traiter sur un terrain risquant un entraînement vers un point d'eau : ruisseau, étang, mare, puits... en particulier si le terrain est en pente.</li> <li>Ne pas toucher le feuillage ou les parties vertes des plantes cultivées, ne pas appliquer sur gazon. En cas de contact avec le produit, couper les parties touchées.</li> <li>Traiter par temps calme et sans vent (&lt; 3 sur l'échelle de Beaufort), sur un feuillage sec.</li> <li>Ne pas utiliser dans les serres ou tunnels plastiques.</li> <li>Toujours conserver le produit dans son emballage d'origine. Le stocker à l'abri du gel et de la chaleur.</li> </ul> <p><b>Emballage</b></p> <ul style="list-style-type: none"> <li>Lors de la dernière utilisation, rincer trois fois à l'eau, verser dans le pulvérisateur le produit de rinçage puis pulvériser sur la zone traitée.</li> <li>Rincer trois fois le pulvérisateur après emploi et appliquez à nouveau sur la zone traitée. Ne jamais vider les fonds de bidon, de pulvérisateur ou les eaux de rinçage dans un égout, une cour, un fossé, près d'un point d'eau ou dans les sanitaires.</li> <li>Réemploi de l'emballage interdit : éliminer les emballages, avec ou sans reliquat de produit, dans une déchetterie.</li> </ul> <p><b>Premiers soins</b></p> <ul style="list-style-type: none"> <li>Enlever immédiatement les vêtements contaminés par le produit.</li> <li>Après inhalation : donner de l'air frais.</li> <li>Après contact avec la peau : laver immédiatement et abondamment à l'eau et au savon. Bien rincer.</li> <li>Après contact avec les yeux : rincer les yeux pendant plusieurs minutes, sous l'eau courante en écartant bien les paupières.</li> <li>Après ingestion : rincer la bouche à l'eau. Ne pas faire vomir.</li> </ul> <p>Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.</p> <p>La fiche de données de sécurité peut être obtenue gratuitement sur Internet à l'adresse <a href="http://www.quickfids.com">www.quickfids.com</a>.</p>			
*Marque déposée PHYTEUROP		<p>EMB : 49215 F</p> <p>Date de fabrication : voir sur l'emballage.</p> <p>Volume net : <b>1 L</b></p>	

### **Appendix 3 – Letter(s) of Access**

The letters of access have been removed for confidentiality reasons.