

REGISTRATION REPORT

Part A

Risk Management

Product code: ABG-3206 (GA₃ 40% SG)

Product name: BERELEX 40SG

Active substance:

gibberellic acid, 400 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Label extension according to Art. 51

**Applicant: SUMITOMO CHEMICAL AGRO
EUROPE SAS**

Date: 17/06/2019

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PART A – Risk Management

The company SUMITOMO CHEMICAL AGRO EUROPE SAS has requested an extension¹ of the existing marketing authorisation in France for the product BERELEX 40SG (product code: ABG-3206 (GA₃ 40% SG); marketing authorisation n° 2140001), containing 400 g/kg gibberellic acid², for use as a plant growth regulator.

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 BERELEX 40SG (ABG-3206 (GA₃ 40% SG)) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of BERELEX 40SG (ABG-3206 (GA₃ 40% SG)) have been made using endpoints agreed in the EU peer review of gibberellic acid.

This document describes the specific conditions of use and labelling required for France for the registration of BERELEX 40SG (ABG-3206 (GA₃ 40% SG)).

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 SUMITOMO CHEMICAL AGRO EUROPE SAS's application to market BERELEX 40SG (ABG-3206 (GA₃ 40% SG)) in France as a plant growth regulator (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 label extension of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Gibberellic acid

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 plant growth regulator may be authorised.

PART B

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 gibberellic acid (SANCO/2613/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

Conditions of use shall include, where appropriate, risk mitigation measures.

An EFSA conclusion is available (EFSA Journal 2012;10(1):2507).

A Review Report is available (SANCO/2613/08 – rev. 3 updated 10 October 2014).

¹ Article 51 of Regulation (EC) No 1107/2009.

² Synonym: GA₃

1.3 Regulatory approach

The present application (2016-1566) 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”)³ – 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 4 May 2017⁴ 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 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 1107/2009⁵, 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 546/2011⁶, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁷ 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 extrapolation⁸ 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.

³ 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

⁴ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjutants 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/AGR1632554A/jo/texte>

⁵ 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

⁶ 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

⁷ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

⁸ SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of BERELEX 40SG (ABG-3206 (GA₃ 40% SG)), 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: the applicant is the owner of the active substance and/or PPP data.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	BERELEX 40SG (ABG-3206 (GA ₃ 40% SG)).
Authorisation number	2140001
Function	Plant growth regulator.
Applicant	SUMITOMO CHEMICAL AGRO EUROPE SAS.
Composition	400 g/kg gibberellic acid.
Formulation type (code)	Water-soluble granules (SG).
Packaging	Packaging not changed.

2.2 Classification and labelling

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

Classification not changed (unclassified).

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

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

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

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination via drains from farmyards and roads.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 metres to surface water bodies.

2.2.3 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁹ : refer to the Decision in Appendix 1 for the details.
Re-entry period ¹⁰ : Six hours.
Pre-harvest interval ¹¹ : Not necessary.
Other mitigation measures:
The other conditions of authorisation (dossier 2011-0007) are not changed.
The label must reflect the conditions of authorisation.

⁹ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

¹⁰ The legal basis for this is **Titre I Article 3** of the French Order of 4 May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹¹ According to the French Order of 4 May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses (minor uses article 51)

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 a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

PPP (product name/code) active substance 1		BERELEX 40SG/(ABG-3206 (GA ₃ 40% SG)) giberellic acid			Formulation type: Conc. of a.s. 1: professional use non-professional use		GAP rev. , date: 2019-06-17					
1	2	3	4	5	6	7	8	9	10	11	12	13
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
1	FR	Seed crops – vegetable seed production (lettuce)	F	Plant growth regulator	spraying	BBCH 30 to 50	a) 1 b) 2 (two at 25 gPF a.s./ha with eight-day interval)	a) 0.050 b) 0.050 a) 0.025 b) 0.050	a) 20 b) 20 a) 10 b) 20	100 - 400	not necessary	Acceptable
2	FR	Seed crops – vegetable seed production (pea)	F	Plant growth regulator	spraying	BBCH 30 to 50	a) 1 b) 1	a) 0.010 b) 0.010	a) 4 b) 4	100 - 400	not necessary	Acceptable
3	FR	Seed crops – vegetable seed production (cucumber)	F	Plant growth regulator	spraying	BBCH 30 to 50	a) 1 b) 6 (six at 25 g PF./ha)	a) 0.150 b) 0.150 a) 0.025 b) 0.150	a) 60 b) 60 a) 10 b) 60	100 - 400	not necessary	Acceptable

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 sucking 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

4 MANAGEMENT

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

4.1.1 Physical and chemical properties

The physico-chemical properties of the formulation have been evaluated, taken into account the in-use concentrations (from 0.00125 % to 0.018 %) considered acceptable during the previous evaluation of this formulation for marketing authorisation.

The in-use concentrations for the uses now requested for this extension of use (from 0.0025 % to 0.0625 %) are not covered by the previous assessment.

The physico-chemical properties provided in the dossier for extension of use have been evaluated and are considered acceptable.

4.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Covered by previous evaluation (2011-0007).

3.1.2.2 Analytical methods for residues

The analytical methods for the determination of the active substance residues in matrices (plants) submitted at European level and in the dossier of the preparation meet the regulatory requirements.

No MRL/residue definition in foodstuffs of animal origin is fixed. Therefore no analytical method is necessary for the determination of residues in these matrices.

4.1.3 Mammalian Toxicology

Covered by previous evaluation (2011-0007).

4.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Not necessary.

3.1.4.2 Consumer exposure

Not necessary.

4.1.5 Environmental fate and behaviour

Covered by previous evaluation (2011-0007).

4.1.6 Ecotoxicology

Covered by previous evaluation (2011-0007).

4.1.7 Efficacy

No data were submitted for minor uses article 51.

Supporting letter from seed producers and French national federation of seed producers were available to justify use of BERELEX 40SG (ABG-3206 (GA3 40% SG)) for claimed minor uses (article 51).

4.2 Conclusions arising from French assessment

Taking into account the above assessment, **an authorisation can be granted** as proposed in Appendix 1 – Copy of the product Decision.

4.3 Substances of concern for national monitoring

No information stated.

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

4.4.1 Post-authorisation monitoring

No further information is required.

4.4.2 Post-authorisation data requirements

Not necessary

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4.4.3 Label amendments

The draft label proposed by the applicant in Appendix 2 must be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label must reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision



Décision relative à une demande d'extension d'usages 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'extension d'usage majeur du produit phytopharmaceutique **BERELEX 40SG***

de la société SUMITOMO CHEMICAL AGRO EUROPE S.A.S
enregistrée sous le n°2016-1566

Vu les conclusions de l'évaluation de l'Anses du 20 mai 2019,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.



Informations générales sur le produit	
Nom du produit	BERELEX 40SG
Type de produit	Produit de référence
Titulaire	SUMITOMO CHEMICAL AGRO EUROPE S.A.S 10A rue de la Voie Lactée 69370 Saint Didier au Mont d'Or France
Formulation	Granulé soluble dans l'eau (SG)
Contenant	400 g/kg - acide gibbérellique
Numéro d'intrant	2110003
Numéro d'AMM	2140001
Fonction	Régulateur de croissance
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

La présente décision peut être retirée ou modifiée si des éléments le justifient.

A Maisons-Alfort le,

17 JUIN 2019

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)



ANNEXE I : Modalités d'autorisation du produit

Liste des nouveaux usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
12053814 Agrumes*Ttr Part.Aer.* Act. Nouaison	75 g/ha	2/an	entre les stades BBCH 67 et BBCH 71	F (BBCH 71)	5	-	-	-
12053813 Agrumes*Ttr Part.Aer.* Act. Qual. Fruits	50 g/ha	1/an	BBCH 81	F (BBCH 81)	5	-	-	-
16103802 Artichaut*Ttr Plants* Act. Floraison	12,5 g/hL	1/an	entre les stades BBCH 41 et BBCH 43	F (BBCH 43)	5	-	-	-
Dose maximale d'emploi : 20 L pour environ 400 pieds.								
12603811 Pommier*Ttr Part.Aer.* Act. Nouaison	37,5 g/ha	1/an	entre les stades BBCH 57 et BBCH 69	F (BBCH 69)	5	-	-	-
Uniquement sur poirier.								

BERELEX 40SG
AMM n°2140001

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Liste des nouveaux usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
	150 g/ha	1/an	entre les stades BBCH 30 et BBCH 50	Non applicable	5	-	-	-
Uniquement sur concombre. Fractionnement possible en 6 applications à la dose maximale de 25 g/ha. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.								
	50 g/ha	1/an	entre les stades BBCH 30 et BBCH 50	Non applicable	5	-	-	-
Uniquement sur laitue. Fractionnement possible en 2 applications à la dose maximale de 25 g/ha. Intervalle minimum entre les applications : 8 jours. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.								
10993800 Porte graine*Trit Part.Aer.* Act. Croiss. Florais.	10 g/ha	1/an	entre les stades BBCH 30 et BBCH 50	Non applicable	5	-	-	-
Uniquement sur pois potager. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.								

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage).
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

- **Pendant le mélange/chargement :**
 - Gants en nitrile certifiés EN 374-3 réutilisables,
 - Combinaison de travail tissée en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant,
 - EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.
- **Pendant l'application :**
 - Combinaison de travail cotte en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² avec traitement déperlant.

Si application avec tracteur sans cabine :

- Gants en nitrile certifiés EN 374-3 réutilisables pendant l'application et dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation.

Si application avec tracteur avec cabine :

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

Si application avec une lance ou un pulvérisateur à dos :

- Gants en nitrile certifiés EN 374-3 réutilisables pendant l'application.

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) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 heures



Protection de l'environnement (milieux, faune et flore)

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Protection de la faune

- SPE 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Pour les usages mineurs dont l'autorisation de mise sur le marché a été accordée dans le cadre de l'article 51 du règlement (CE) n°1107/2009, l'attention de l'utilisateur est attirée sur les risques éventuels de phytotoxicité

ou de manque d'efficacité.
Au regard des données à sa disposition, le titulaire de l'autorisation de mise sur le marché décline toute

Avant tout emploi du produit, il est recommandé à l'utilisateur de s'assurer de son efficacité ou de l'absence de risques éventuels de phytotoxicité sur la culture.

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

According to the applicant, “*Not mandatory according to Article 51 (5)*”.

Appendix 3 – Letter(s) of Access

Not applicable.