Final
Review report for the active substance Cerevisane

Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on
13 February 2015
in view of the approval of cerevisane as active substance in accordance with
Regulation (EC) No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance
cerevisane, made in the context of the work provided for in Articles 7 to 13 of Regulation (EC)
No 1107/2009 concerning the placing of plant protection products on the market and repealing
Council Directives 79/117/EEC and 91/414/EEC, with a view to the possible approval of this
substance for the use in plant protection products.

In accordance with the provisions of Article 7 of that Regulation, the authorities of France
received on 5 March 2012 an application from Agro-Levures et Dérivés SAS, hereafter referred
to as the applicant, for the approval of the active substance cerevisane for use in plant protection
products. The authorities of France indicated to the Commission on 14 May 2012 the results of
their examination of the completeness of the dossier satisfying the requirements of Article 8,
according to the provisions of Article 9 of the Regulation. Subsequently, and in accordance
with the requirements of Article 9(3), a dossier on cerevisane was distributed to the Member States,
the European Food Safety Authority (EFSA) and the Commission.

Thereupon, France as rapporteur Member State started the detailed examination of the dossier
provided by the applicant. According to the provisions of Article 11, the rapporteur Member
State shall prepare and submit it to the Commission and EFSA within twelve months a report
(the draft assessment report), assessing whether the active substance can be expected to meet the
criteria provided for in Article 4 of the Regulation.

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1 Does not necessarily represent the views of the Commission.
France submitted that draft assessment report to the Commission and EFSA on 22 February 2013.

On 5 March 2013, EFSA circulated the draft assessment report to Member States and the applicant and, in addition, organised a public consultation on it, in line with the provisions of Article 12(1) of the Regulation.

EFSA organised a consultation to review the draft assessment report and the comments received thereon (peer review) in accordance with the provisions of Article 12(2) and 12(3). In this framework, EFSA decided to request additional information from the applicant and to conduct specific consultations of experts from Member States and the rapporteur.

According to the provisions of Article 12(2) of the Regulation, EFSA sent to the Commission its conclusion on the risk assessment [Conclusion on the peer review of the pesticide risk assessment of the active substance cerevisane (cell walls of Sacharomyces cerevisiae strain LAS 117) (approved: 7 February 2014)]3. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 13 of that Regulation, the Commission produced a draft review report and a draft Regulation on cerevisane. The Commission referred the draft review report to the applicant for commenting on 8 December 2014 and on 11 December 2014 to the Standing Committee on Plants, Animals, Food and Feed, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 13 February 2015.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of EFSA, and the comments and clarifications submitted after the conclusion of EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of Commission Implementing Regulation (EU) 2015/5534 concerning the approval of cerevisane as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing cerevisane they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

This review report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011, submitted for the purpose of approval of the active substances, as well as the result of the evaluation of those data.

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In accordance with the provisions of Article 10 of Regulation (EU) No 188/2011, this review report will be made available to the public.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. **Overall conclusion in the context of Regulation (EC) No 1107/2009**

The overall conclusion from the evaluation is that it may be expected that plant protection products containing cerevisane will fulfil the safety requirements laid down in Article 4(1) – (3) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each cerevisane containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

Based on the toxicological profile of cerevisane, there is no need for establishing toxicological reference values.

*Saccharomyces cerevisiae*, the main constituent of cerevisane, is a ubiquitous yeast also used in food production where it is not at all (baking) or only partly (production of beer and wine) removed from the final product. It is considered safe for consumers having a presumption of safety status5. Possible residues from cerevisane are not expected to differ from those commonly occurring in normal diets.

In the absence of any hazardous potential for consumers, residue data for cerevisane are not required and the calculation of the potential exposure of consumers is not necessary. The review concludes that it is appropriate to include cerevisane in Annex IV to Regulation (EC) No 396/2005.

The review has identified several acceptable exposure scenarios for operators, workers and bystanders, which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

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The review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report.

Cerevisane does not meet any of the criteria listed in point 5 of Annex II to Regulation (EC) No 1107/2009. Cerevisane is made from cell walls of *Saccharomyces cerevisiae*. For this yeast, as all protein containing biological matrices, a sensitizing potential cannot fully be excluded. The review concluded based on evidence produced by the applicant that cerevisane is not a skin or eye sensitizer. However, no information was submitted in order to exclude possible sensitization by inhalation. Taking into account that these properties would not prevent from approving *Saccharomyces cerevisiae* as a low risk active substance, it was decided to take the same approach for the dried cell walls of the yeast and the review concludes that cerevisane shall be considered a low risk active substance in accordance with Article 22 of Regulation (EC) No 1107/2009.

4. **Identity and Physical/chemical properties**

The main identity of cerevisane is given in Appendix I.

At the time of evaluation no FAO specification was allocated.

The active substance shall have a minimum purity of 924 g/kg.

The review has established that for the active substance as specified by Agro-Levures et Dérivés in the application, there are no manufacturing impurities which are considered to be of toxicological, ecotoxicological and/or environmental concern.

5. **Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the evaluation process. These endpoints are listed in the conclusion of EFSA, and in section 3 of this report.

6. **Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing cerevisane**

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate.
7. **List of studies to be generated**

No further studies were identified which were at this stage considered necessary in relation to the approval of cerevisane under the current approval conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 11).

8. **Information on studies with claimed data protection**

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the sole data submitter has claimed data protection and which during the evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

9. **Updating of this review report**

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for cerevisane.
### APPENDIX I

#### Main identity

**CEREVISANE**

<table>
<thead>
<tr>
<th>Common name (ISO)</th>
<th>No ISO common name attributed; Name chosen by the applicant: Cerevisane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name (IUPAC)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Chemical name (CA)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>CIPAC No</td>
<td>980</td>
</tr>
<tr>
<td>CAS No</td>
<td>Not allocated</td>
</tr>
<tr>
<td>EC No (EINECS or ELINCS) ‡</td>
<td>Not allocated</td>
</tr>
<tr>
<td><strong>FAO SPECIFICATION</strong></td>
<td>Not available</td>
</tr>
<tr>
<td><strong>Minimum purity</strong></td>
<td>Minimum certified value for dried cell walls of <em>Saccharomyces cerevisiae</em> strain LAS117 in technical active substance: 924 g/kg</td>
</tr>
</tbody>
</table>

Specification of the major components of the active substance:

<table>
<thead>
<tr>
<th>Certified values rounded off by RMS</th>
</tr>
</thead>
</table>
| **Carbohydrates**  | Min 50.1 %  
Max 58.4 %  |
| **Mannans**  | Min 20.2 %  
Max 28.7 %  |
| **Glucans**  | Min 17.2 %  
Max 31.5 %  |
| **Crude Fat**  | Min 11.0 %  
Max 21.0 %  |
| **Crude proteins**  | Min 16.8 %  
Max 28.9 %  |

<table>
<thead>
<tr>
<th>Molecular formula</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular mass</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Structural formula</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
## APPENDIX II

List of uses supported by available data

**CEREOISAN**

<table>
<thead>
<tr>
<th>Crop and/or situation (a)</th>
<th>Product Name</th>
<th>F, G or I (b)</th>
<th>Pests or Group of pests controlled (c)</th>
<th>Formulation</th>
<th>Conc. of MPCA (d-f)</th>
<th>Method Kind (f-h)</th>
<th>Growth stage &amp; season (j)</th>
<th>Number min max (k)</th>
<th>Interval between applications (min)</th>
<th>Application rate per treatment kg /L, min max</th>
<th>water L/ha, min max</th>
<th>kg /ha (l)</th>
<th>PHI (days)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lettuce/ All Europe</td>
<td>ROMEO</td>
<td>G</td>
<td>Downy mildew</td>
<td>WP</td>
<td>1000*</td>
<td>Foliar spray</td>
<td>At any stage &amp; season. Preventive treatment Not in strong pressure</td>
<td>1 - 8</td>
<td>7 days</td>
<td>0.075 – 0.75</td>
<td>100-1000</td>
<td>0.75*</td>
<td>1</td>
<td>0.75 kg product/ha</td>
</tr>
<tr>
<td>Lettuce/ All Europe</td>
<td>ROMEO</td>
<td>F</td>
<td>Downy mildew</td>
<td>WP</td>
<td>1000*</td>
<td>Foliar spray</td>
<td>At any stage &amp; season. Preventive treatment Not in strong pressure</td>
<td>1 - 8</td>
<td>7 days</td>
<td>0.075 – 0.75</td>
<td>100-1000</td>
<td>0.75*</td>
<td>1</td>
<td>0.75 kg product/ha</td>
</tr>
<tr>
<td>Lettuce and other salads/ All Europe</td>
<td>ROMEO</td>
<td>G</td>
<td>Systemic Resistance Inducer (downy mildew, botrytis, rhizoctonia)</td>
<td>WP</td>
<td>1000*</td>
<td>Foliar spray</td>
<td>At any stage &amp; season. Preventive treatment Not in strong pressure</td>
<td>1 - 8</td>
<td>7 days</td>
<td>0.05-0.5</td>
<td>100-1000</td>
<td>0.5*</td>
<td>1</td>
<td>0.5 kg product/ha</td>
</tr>
<tr>
<td>Lettuce and other salads / All Europe</td>
<td>ROMEO</td>
<td>F</td>
<td>Systemic Resistance Inducer (downy mildew, botrytis, rhizoctonia)</td>
<td>WP</td>
<td>1000*</td>
<td>Foliar spray</td>
<td>At any stage &amp; season. Preventive treatment Not in strong pressure</td>
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<td>7 days</td>
<td>0.05-0.5</td>
<td>100-1000</td>
<td>0.5*</td>
<td>1</td>
<td>0.5 kg product/ha</td>
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* Concentrations and doses are expressed in technical active ingredient minimum purity 92.4%.

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure).
(b) Outdoor or field use (F), greenhouse 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).
(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 plant- type of equipment used must be indicated.
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavali-carb-isopropyl).
(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) Indicate the minimum and maximum number of applications possible under practical conditions of use.
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha).
(m) PHI - minimum pre-harvest interval.