COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX

concerning the renewal of the authorisation of *Bacillus subtilis* DSM 15544 as a feed additive for chickens for fattening and repealing Regulation (EC) No 1444/2006 (holder of authorisation Asahi Calpis Wellness Co. Ltd., represented in the Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office)

(Text with EEA relevance)
COMMISSION IMPLEMENTING REGULATION (EU) .../

of XXX

concerning the renewal of the authorisation of *Bacillus subtilis* DSM 15544 as a feed additive for chickens for fattening and repealing Regulation (EC) No 1444/2006 (holder of authorisation Asahi Calpis Wellness Co. Ltd., represented in the Union by Asahi Calpis Wellness Co. Ltd Europe Representative Office)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.

(2) *Bacillus subtilis* C-3102 (DSM 15544) was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 1444/2006².

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens for fattening, requesting that additive to be classified in the additive category ‘zootechnical additives’. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 13 June 2018³ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.

(5) The assessment of *Bacillus subtilis* C-3102 (DSM 15544) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 1444/2006 should be repealed.

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¹ OJ L 268, 18.10.2003, p. 29.
³ EFSA Journal 2018;16(7):5340.
The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed, HAS ADOPTED THIS REGULATION:

Article 1
The authorisation of the additive specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is renewed subject to the conditions laid down in that Annex.

Article 2
Regulation (EC) No 1444/2006 is repealed.

Article 3
This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER
## ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CFU/kg of complete feedingstuff with a moisture content of 12%</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category of zootechnical additives. Functional group: gut flora stabilisers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| 4b1820 | Asahi Calpis Wellness Co. Ltd. represented by Asahi Calpis Wellness Co. Ltd Europe Representative Office | Bacillus subtilis C-3102 (DSM 15544) | *Additive composition:* Bacillus subtilis C-3102 (DSM 15544) with minimum of 1 \( \times 10^{10} \) CFU/g  
*Characterisation of the active substance:* Viable spores (CFU) of Bacillus subtilis C-3102 (DSM 15544)  
*Analytical method:* Enumeration: spread plate method using tryptone soya agar (EN 15784:2009)  
Identification: pulsed-field gel electrophoresis (PFGE). | Chickens for fattening | - | 5 \( \times 10^8 \) | - | 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.  
2. The use is permitted in feed containing one of the following authorised coccidiostats: monensin sodium, salinomycin sodium, seduramycin sodium, lasalocid sodium, maduramycin ammonium narasin, diclazuril.  
3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and [10 years from the date of entry into force of this Regulation To be completed by the Service responsible for the publication] |  | | |

1 Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
measures, the additive and premixtures shall be used with personal protective equipment, including eye and breathing protection.
COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX

concerning the renewal of the authorisation of lanthanum carbonate octahydrate as a feed additive for cats and repealing Regulation (EC) No 163/2008 (holder of authorisation Bayer HealthCare AG)

(Text with EEA relevance)
COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX

centre concerned the renewal of the authorisation of lanthanum carbonate octahydrate as a feed additive for cats and repealing Regulation (EC) No 163/2008 (holder of authorisation Bayer HealthCare AG)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.

(2) Lanthanum carbonate octahydrate was authorised for 10 years as a feed additive for cats by Commission Regulation (EC) No 163/2008².

(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of lanthanum carbonate octahydrate as a feed additive for cats, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 29 November 2018³ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.

(5) The assessment of lanthanum carbonate octahydrate shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

(6) As a consequence of the renewal of the authorisation of lanthanum carbonate octahydrate as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 163/2008 should be repealed.

¹ OJ L 268, 18.10.2003, p. 29.
³ EFSA Journal 2018;16(12):5542.
HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 163/2008 is repealed.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER
## ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4d1</td>
<td>Bayer HealthCare AG</td>
<td>Lanthanum carbonate octahydrate</td>
<td>Additive composition: Preparation of Lanthanum carbonate octahydrate At least 85% Lanthanum carbonate octahydrate as active substance. Characterisation of the active substance: Lanthanum carbonate octahydrate $\text{La}_2(\text{CO}_3)_3*8\text{H}_2\text{O}$ CAS number 6487-39-4 Analytical method: Inductively coupled plasma optical emission spectrometry (ICP-OES)</td>
<td>Cats</td>
<td>1 500</td>
<td>7 500</td>
<td>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the</td>
<td>[10 years from the date of entry into force of this Regulation To be completed by the Service responsible for the publication]</td>
</tr>
</tbody>
</table>

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1. Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
additive and premixtures shall be used with personal protective equipment, including breathing protection.

3. In the directions for use of the additive, the following shall be indicated:

- for adult cats;
- recommended dose of inclusion in moist feed with 20-25% dry matter content: 375 to 1500mg/kg;
- avoid simultaneous use of feeds with high level of phosphorus.”,
COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

classifying the authorisation of a preparation of *Bacillus licheniformis* DSM 28710 as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying (holder of authorisation HuvePharma NV)

(Text with EEA relevance)
COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

concerning the authorisation of a preparation of Bacillus licheniformis DSM 28710 as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying (holder of authorisation HuvePharma NV)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of Bacillus licheniformis DSM 28710. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.

(3) That application concerns the authorisation of a preparation of Bacillus licheniformis DSM 28710 as a feed additive for turkeys for fattening, turkeys reared for breeding and minor poultry species for fattening and reared for laying, to be classified in the additive category ‘zootechnical additives’.

(4) The preparation of Bacillus licheniformis DSM 28710, belonging to the additive category of ‘zootechnical additives’, was authorised for ten years as a feed additive for chickens for fattening and chickens reared for laying by Commission Implementing Regulation (EU) 2017/1904².

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 28 November 2018¹ that, under the proposed conditions of use, the preparation of Bacillus licheniformis DSM 28710 does not have an adverse effect on animal health or the environment. It also concluded that the additive is considered as a potential respiratory sensitisier and that no conclusion could be drawn on skin or eyes sensitisation or irritation by the additive. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the additive has a potential to be efficacious in feed to gain ratio in turkeys for fattening at the recommended dose and that this conclusion can be extended to turkeys reared for

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¹ OJ L 268, 18.10.2003, p. 29.
breeding and to minor poultry species for fattening and those reared for laying. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the preparation of *Bacillus licheniformis* DSM 28710 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed.

HAS ADOPTED THIS REGULATION:

**Article 1**

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

**Article 2**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*
*The President*
*Jean-Claude JUNCKER*
## ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Minimum content CFU/kg of complete feedingstuff with a moisture content of 12%</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
</table>
| 4b1828                               | HuvePharma NV                       | **Bacillus licheniformis DSM 28710** | **Additive composition**  
Preparation of *Bacillus licheniformis* DSM 28710 containing a minimum of 3.2 x 10⁹ CFU/g of additive  
Solid form  
**Characterisation of the active substance**  
Viable spores of *Bacillus licheniformis* DSM 28710  
**Analytical method**¹  
For the enumeration of *Bacillus licheniformis* DSM 28710 in additive, premixture and feedingstuffs:  
- Spread plate method EN 15784  
For the identification of *Bacillus licheniformis* DSM 28710:  
- Pulsed Field Gel Electrophoresis (PFGE) | Turkeys for fattening  
Turkeys reared for breeding  
Minor poultry species for fattening or reared for laying | - | 1.6 x 10⁹ | - | 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.  
2. The use is permitted in feed for turkeys containing the following authorised coccidiostats: diclazuril, halofuginone, robenidine, lasalocid, maduramicin, or monensin.  
3. The use is permitted in feed for minor poultry species for fattening or reared for laying containing the following authorised coccidiostats: diclazuril or lasalocid.  
4. For users of the additive and premixtures, feed business operators shall establish operational procedures and appropriate organisational measures to address hazards by inhalation, dermal contact or eyes contact. Where the dermal, inhalator or eyes exposure cannot be eliminated or reduced to a |

¹ Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
minimum by such procedures and measures, the additive and premixtures shall be used with appropriate personal protective equipment.
COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX

cconcerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by *Trichoderma reesei* (BCCM/MUCL 49755) as a feed additive for chickens for fattening and weaned piglets (holder of authorisation Berg and Schmidt GmbH Co. KG)

(Text with EEA relevance)
COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX

concerning the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (BCCM/MUCL 49755) as a feed additive for chickens for fattening and weaned piglets (holder of authorisation Berg and Schmidt GmbH Co. KG)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (BCCM/MUCL 49755). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (BCCM/MUCL 49755) as a feed additive for chickens for fattening and weaned piglets to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 25 January 2017² and 2 October 2018³ that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (BCCM/MUCL 49755) does not have an adverse effect on animal health, consumer safety or the environment. It was also concluded that the additive may have a skin and respiratory sensitisation potential. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that the additive is considered efficacious in improving final body weight and feed to gain ratio in chickens for fattening and weaned piglets. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

¹ OJ L 268, 18.10.2003, p. 29.
² EFSA Journal 2017;15(2):4707
³ EFSA Journal 2018;16(10):5457.
The assessment of the preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by Trichoderma reesei (BCCM/MUCL 49755) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER
**EN**

**ANNEX**

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Units of activity/kg of complete feedingstuff with a moisture content of 12%</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4a26</td>
<td>Berg and Schmidt GmbH Co. KG</td>
<td>Endo-1,4-beta-xylanase (EC 3.2.1.8)</td>
<td><strong>Additive composition</strong> Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <em>Trichoderma reesei</em> (BCCM/MUCL 49755) with a minimum activity of 15 000 EPU/g Solid form</td>
<td>Chickens for fattening  Weaned piglets</td>
<td>-</td>
<td>1 500 EPU</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

**Category of zootechnical additives. Functional group: digestibility enhancers.**

1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.
2. For use in weaned piglets up to approximately 35kg body weight.
3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment.

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1 One Endopentosanase Unit (EPU) corresponds to the amount of enzyme which liberates 0.0083 μmol of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 4.7 and 50°C

2 Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
including skin, eyes and breathing protection.
COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a preparation of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/NCIMB 40788 as a feed additive for all animal species

(Text with EEA relevance)
COMMISSION IMPLEMENTING REGULATION (EU) .../...
of XXX

concerning the authorisation of a preparation of Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788 as a feed additive for all animal species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788 as a feed additive for all animal species to be classified in the additive category ‘technological additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 2 October 2018² that, under the proposed conditions of use, the preparation of Lactobacillus hilgardii CNCM I-4785 and Lactobacillus buchneri CNCM I-4323/NCIMB 40788 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive is considered a potential respiratory sensitiser and that no conclusion could be drawn on skin or eyes sensitisation or irritation by the additive. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the preparation concerned has the potential to improve the production of silage from easy and moderately difficult to ensile forage materials. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

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¹ OJ L 268, 18.10.2003, p. 29.
² EFSA Journal 2018; 16(10):5455.
The assessment of the preparation of *Lactobacillus hilgardii* CNCM I-4785 and *Lactobacillus buchneri* CNCM I-4323/NCIMB 40788 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed, HAS ADOPTED THIS REGULATION:

**Article 1**

The preparation specified in the Annex, belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

**Article 2**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,


*For the Commission*

*The President*

*Jean-Claude JUNCKER*
EN

ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1k20757</td>
<td><em>Lactobacillus hilgardii</em> CNCM I-4785 and <em>Lactobacillus buchneri</em> CNCM I-4323/NCIMB 40788</td>
<td>Additive composition: Preparation of <em>Lactobacillus hilgardii</em> CNCM I-4785 and <em>Lactobacillus buchneri</em> CNCM I-4323/NCIMB 40788 containing a minimum of $1.5 \times 10^{11}$ CFU/g additive (ratio of 1:1). Characterisation of the active substance: Viable cells of <em>Lactobacillus hilgardii</em> CNCM I-4785 and <em>Lactobacillus buchneri</em> CNCM I-4323/NCIMB 40788. Analytical method: Enumeration in the feed additive and premixtures: spread plate method on MRS agar: EN 15787. Identification of the feed additive: Pulsed Field Gel Electrophoresis (PFGE).</td>
<td>All animal species</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other microorganisms as silage additives: $3 \times 10^8$ CFU/kg (<em>L. hilgardii</em> CNCM I-4785 and <em>L. buchneri</em> CNCM I-4323/NCIMB 40788 in ratio of 1:1) of easy and moderately difficult to ensile fresh material². 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from the use of the additive and premixtures.</td>
<td>[to be completed by the Service responsible for the publication: insert precise date]</td>
</tr>
</tbody>
</table>

¹ Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

<table>
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<tr>
<th>Identification number of the additive</th>
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<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technological additives: silage additives</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>CFU of additive/kg of fresh material</td>
<td></td>
<td>from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.</td>
<td></td>
</tr>
</tbody>
</table>
COMMISSION IMPLEMENTING REGULATION (EU) …/... of XXX

concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for all pigs other than weaned piglets and sows and all minor porcine species (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)

(Text with EEA relevance)
COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX

concerning the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for all pigs other than weaned piglets and sows and all minor porcine species (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition1, and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of the preparation of Saccharomyces cerevisiae CNCM I-1079 as a feed additive for all pigs other than weaned piglets and sows and all minor porcine species to be classified in the additive category 'zootechnical additives'.

(4) That preparation was already authorised as a zootechnical additive for ten years by Commission Implementing Regulation (EU) 2018/3472 for use with weaned piglets and sows, and by Commission Implementing Regulation (EU) 2017/19053 for use with chickens for fattening and minor poultry species for fattening.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 28 November 20184 that, under the proposed conditions of use, the preparation of Saccharomyces cerevisiae CNCM I-1079 does not have an adverse effect on animal health, human health or the environment. It also concluded that the additive has the

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potential to be efficacious in all pigs. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed.

HAS ADOPTED THIS REGULATION:

*Article 1*

The preparation specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’, is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union.*

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*

*The President*

*Jean-Claude JUNCKER*
### Category of zootechnical additives. Functional group: gut flora stabilisers.

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4d1703</td>
<td>Danstar Ferment AG represented by Lallemand SAS</td>
<td>Saccharomyces cerevisiae CNCM I-1079</td>
<td>Additive composition: Preparation of <em>Saccharomyces cerevisiae</em> CNCM I-1079 containing a minimum of: - $1 \times 10^{10}$ CFU/g of additive (coated form); - $2 \times 10^{10}$ CFU/g of additive (not-coated form);</td>
<td>All pigs other than sows and weaned piglets</td>
<td>-</td>
<td>$1 \times 10^9$</td>
<td>CFU/kg of complete feedingstuff with a moisture content of 12%</td>
<td>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal</td>
<td>[10 years from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication]</td>
</tr>
</tbody>
</table>

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1. Details of the analytical methods are available at the following address of the Reference Laboratory: [https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports](https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports)
| protective equipment, including breathing protection. |
COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of riboflavin produced by Ashbya gossypii (DSM 23096), riboflavin produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) and riboflavin 5´-phosphate sodium salt produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) (sources of vitamin B2) as feed additives for all animal species.

(Text with EEA relevance)
COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of riboflavin produced by Ashbya gossypii (DSM 23096), riboflavin produced by Bacillus subtilis (DSM 17339 and DSM 23984) and riboflavin 5'-phosphate sodium salt produced by Bacillus subtilis (DSM 17339 and DSM 23984) (sources of vitamin B₂) as feed additives for all animal species

(Text with EEA relevance)
COMMISSION IMPLEMENTING REGULATION (EU) …/…

of XXX

concerning the authorisation of riboflavin produced by Ashbya gossypii (DSM 23096), riboflavin produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) (sources of vitamin B_2) as feed additives for all animal species.

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹, and in particular Article 9(2) thereof,

Whereas:


(2) Riboflavin produced by Ashbya gossypii (DSM 23096), riboflavin produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) were authorised as sources of vitamin B_2 without a time limit as feed additives for all animal species in accordance with Directive 70/524/EEC. Those additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, two applications were submitted for the re-evaluation of riboflavin produced by Ashbya gossypii (DSM 23096), riboflavin produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) and riboflavin 5'-phosphate sodium salt produced by Bacillus subtilis (DSM 17339 and/or DSM 23984) for all animal species, requesting those additives to be classified in the additive category "nutritional additives". One application concerns riboflavin produced by Ashbya gossypii (DSM 23096) and the other application concerns riboflavin and riboflavin 5'-phosphate ester monosodium salt, both produced by Bacillus subtilis (DSM 17339 and/or DSM 23984). Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) In accordance with Article 7 of Regulation (EC) No 1831/2003, one of the two applications also requested the authorisation of riboflavin produced by Bacillus subtilis.

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¹ OJ L 268, 18.10.2003, p. 29.
(DSM 17339 and/or DSM 23984) and riboflavin 5’-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) as feed additives for all animal species for use in water for drinking. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003 for the use in water for drinking.

(5) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 3 December 2015\(^3\) and 13 June 2018\(^4\) that, under the proposed conditions of use, riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5’-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) do not have adverse effects on animal health, consumer safety or the environment. It also concluded that the additives containing riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5’-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) are not irritant to skin and eyes. In the absence of data, cannot conclude on skin sensitisation. Riboflavin is a recognised as photosensitiser, which may elicit skin and eye photoallergic reactions. Workers might be exposed to a respirable dust when handling riboflavin and riboflavin 5’-phosphate sodium salt; in the absence of data on inhalation toxicity, the Authority cannot conclude on a possible risk by inhalation. Therefore, the Commission consider that appropriate protective measures should be taken to prevent effects on human health, in particular as regards the users of the additive. The Authority further concluded that riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5’-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) are effective sources of vitamin B\(_2\) in covering the animal’s nutritional requirements. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the reports on the method of analysis of in feed and, where applicable, in water, submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of riboflavin produced by *Ashbya gossypii* (DSM 23096), riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5’-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied for the use in feed and for riboflavin produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) and riboflavin 5’-phosphate sodium salt produced by *Bacillus subtilis* (DSM 17339 and/or DSM 23984) also for the use in water for drinking. Accordingly, the use of those additives should be authorised as specified in the Annex to this Regulation.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation for the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

\(^3\) EFSA Journal 2016;14(1):4349.
\(^4\) EFSA Journal 2018;16(7):5337.
HAS ADOPTED THIS REGULATION:

Article 1
Authorisation

The substances specified in the Annex, belonging to the additive category ‘nutritional additives’ and to the functional group ‘vitamins, pro-vitamins and chemically well-defined substances having similar effect’, are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2
Transitional Measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until [6 months from the date of entry into force of this Regulation - Date to be inserted by the Service responsible for the publication].

2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before [12 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

3. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before [24 months after the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] in accordance with the rules applicable before [the date of entry into force of this Regulation – Date to be inserted by the Service responsible for the publication] may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3
Entry into Force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States. Done at Brussels,

For the Commission
The President
Jean- Claude JUNCKER
### EN

#### ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
</tr>
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<tbody>
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</tbody>
</table>

- Category of nutritional additives. Functional group: Vitamins, provitamins and chemically well-defined substances having similar effect.

<table>
<thead>
<tr>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- mg of additive/kg of complete feedingstuff with a moisture content of 12%
| Additive composition | Characterisation of the active substance | Method of analysis | All animal species | - | - | - | 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves. |

| Riboflavin produced by Ashbya gossypii DSM 23096 | Riboflavin produced by Ashbya gossypii DSM 23096 | Riboflavin produced by Ashbya gossypii DSM 23096 | All animal species | - | - | - | |

| Characterisation of the active substance | | | | |

| Riboflavin | Riboflavin produced by Ashbya gossypii DSM 23096 | Riboflavin solid form produced by Ashbya gossypii DSM 23096 | Riboflavin solid form produced by Ashbya gossypii DSM 23096 |

| CAS number: 83-88-5 | Purity criteria: min. 80% of riboflavin | Purity criteria: min. 80% of riboflavin |

| Method of analysis | Method of analysis | Method of analysis |

| For the determination of Riboflavin in the feed additive: spectrophotometry at 444nm | For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1) | For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1) |

| For the determination of Riboflavin in feedingstuffs: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152) | For the determination of Riboflavin in feedingstuffs: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152) |

1 Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
<table>
<thead>
<tr>
<th>Ja825ii</th>
<th>&quot;Riboflavin&quot; or &quot;Vitamin B2&quot;</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Additive composition</strong></td>
<td>Riboflavin</td>
</tr>
</tbody>
</table>
| **Characterisation of the active substance** | Riboflavin  
\[C_{17}H_{20}N_{4}O_{6}\]  
CAS number: 83-88-5  
Riboflavin solid form produced by *Bacillus subtilis* DSM 17339 and/or DSM 23984  
Purity criteria: min. 96%, |
| **Method of analysis** |  
- For the determination of Riboflavin in the feed additive: spectrophotometry at 444nm (Ph.Eur.6.0, method 01/2008:0292)  
- For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1)  
- For the determination of Riboflavin in feedingstuffs and water: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152) |
| All animal species | - | - | - |
| 1. Riboflavin may be placed on the market and used as an additive consisting of a preparation.  
2. May be used in water for drinking.  
3. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.  
4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves. |

*Publications Office insert date 10 years from the date of entry into force of this Regulation*
<table>
<thead>
<tr>
<th>Additive composition</th>
<th>Riboflavin 5′-phosphate ester monosodium salt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characterisation of the active substance</td>
<td>Riboflavin 5′-phosphate sodium C_{17}H_{22}N_{4}O_{9}PNa</td>
</tr>
<tr>
<td>CAS number: 130-40-5</td>
<td></td>
</tr>
<tr>
<td>Riboflavin 5′-phosphate ester monosodium salt solid form produced after phosphorylation of riboflavin 98% produced by <em>Bacillus subtilis</em> DSM 17339 and/or DSM 23984.</td>
<td></td>
</tr>
<tr>
<td>Purity criteria: min. 65%</td>
<td></td>
</tr>
</tbody>
</table>

**Method of analysis**

For the determination of Riboflavin 5′-phosphate monosodium salt in feed additive: spectrophotometry method at 444nm (Ph.Eur.6.0, method 01/2008:0786)

For the determination of Riboflavin in premixtures: high-Performance Liquid Chromatography coupled to UV detector, HPLC-UV (VDLUFA Bd.III, 13.9.1)

For the determination of Riboflavin 5′-phosphate monosodium salt (as total Vitamin B₂) in feedingstuffs and water: high Performance Liquid Chromatography with Fluorescence detection, HPLC-FL (EN 14152)

| All animal species | - | - | - |

1. May be used in water for drinking.
2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.
3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.