

AICIS Executive Director’s decisions on requests for variation of the draft evaluation report (ER1) for Ethanol, 2-[2-(2-methoxyethoxy)ethoxy]-, 1,1',1''-triester with boric acid (H3BO3)

BASF Australia Pty Ltd

Request 1

**Page 8, Recommendations to regulatory bodies**

*"The following precautionary statement is also recommended:*

*• P263: Avoid contact during pregnancy/while nursing (ND)"*

**Suggested change:**

*“We would like to remove the P263 statement from Page 8 of the draft report.”*

**Reason:**

The precautionary statement P263 is only applicable for the hazard statement H362. Under GHS Revision 7, there is no requirement to list the P263 statement under the hazard statement H361. Therefore, we don't believe there is any justification for using P263 for the hazard statement H361d.

Decision 1

Variation approved.

AICIS response 1

The Executive Director is satisfied that the report, varied as requested, would be correct. The justification for variation is consistent with the absence of this precautionary statement for ‘Toxic to Reproduction’ in Appendix D - Application of Label Elements in‘Labelling of workplace hazardous chemicals - Code of practice’ (Safe Work Australia 2018). The text will be deleted in the report as requested.

Request 2

**Page 8, Recommendations to regulatory bodies**

*“Based on the assessment findings, a hazard classification is recommended to Safe Work Australia as below:*

* *Toxic to Reproduction (Category 2): H361D - Suspected of damaging the unborn child (ND).”*

**Suggested change:**

*”The hazard statement H361D on Page 8 should be renamed as H361d as per the reference on Page 25 of the draft report.)”*

**Reason:**

By convention, H361D should be reworded as H361d. This is accepted internationally.

Decision 2

Variation approved.

AICIS response 2

The Executive Director is satisfied that the report, varied as requested, would be correct. This is a typographical error and the upper case ‘H361D’ will be replaced with a lower case ‘H361d’ in the amended report.

Clariant Australia Pty Ltd

Request 1

**Page 8, Recommendations to regulatory bodies**

*"The following precautionary statement is also recommended:*

*• P263: Avoid contact during pregnancy/while nursing (ND)"*

**Suggested change:**

*“Clariant proposes the precautionary statement P263 is omitted.”*

**Reason:**

The precautionary statement P263 suggested by AICIS is not mandatory. This can be seen by the table taken from Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging (CLP) of substances and mixtures - Table 3.7.3 - Label elements for reproductive toxicity.

According to the GHS, P263 only applies in case of H362 but not with H361.
There is no information indicating the P263 Phrase. The classification for effects on or via lactation is independent of consideration of the reproductive toxicity and should be treated separately.

In Europe, Clariant does not include the P263 phrase on its Safety Data Sheets and labels for brake fluids containing the notified chemical.

Decision 1

Variation approved.

AICIS response 1

The Executive Director is satisfied that the report, varied as requested, would be correct. The justification for variation is consistent with the absence of this precautionary statement for ‘Toxic to Reproduction’ in Appendix D - Application of Label Elements in‘Labelling of workplace hazardous chemicals - Code of practice’ (Safe Work Australia 2018). The text will be deleted in the report as requested.

Request 2

**Page 8, Recommendations to regulatory bodies**

*“Based on the assessment findings, a hazard classification is recommended to Safe Work Australia as below:*

* *Toxic to Reproduction (Category 2): H361D - Suspected of damaging the unborn child (ND).”*

**Suggested change:**

*"In order to maintain a globally harmonized approach for Classification & Labelling, Clariant recommends adoption of the Classification & Labelling below:*

* *Toxic to Reproduction (Category 2): H361d - Suspected of damaging the unborn child (ND)”*

**Reason:**

None provided.

Decision 2

Variation approved.

AICIS response 2

The Executive Director is satisfied that the report, varied as requested, would be correct. This is a typographical error and the upper case ‘H361D’ will be replaced with a lower case ‘H361d’ in the amended evaluation report.

Request 3

**Page 8, Recommendations to regulatory bodies**

*"The following precautionary statement is also recommended:*

*• P263: Avoid contact during pregnancy/while nursing (ND)"*

**Suggested change:**

*“The following precautionary statements are recommended:*

*P201: Obtain special instructions before use.*

*P202: Do not handle until all safety precautions have been read and understood.*

*P280: Wear protective gloves/protective clothing/eye protection/face protection.*

*Response:*

*P308 + P313: IF exposed or concerned: Get medical advice/attention.*

*Storage:*

*P405: Store locked up.*

*Disposal:*

*P501: Dispose of contents/container in accordance with local/regional/national/ international regulations.*

**Reason:**

In order to maintain a globally harmonized approach for Classification & Labelling, Clariant recommends inclusion of the precautionary statements for prevention, response, storage and disposal.

Decision 3

Variation partly approved.

AICIS response 3

The Executive Director is not satisfied that the report, varied as requested, would be correct. With the exception of ‘P280: Wear protective gloves/protective clothing/eye protection/face protection’, all of the precautionary statements listed in “Suggested change’ are recommended in the ‘Labelling of workplace hazardous chemicals - Code of practice’ (Safe Work Australia, 2018).

AICIS queried the inclusion of P280 as both the Regulation (EC) No 1272/2008 on CLP Parliament referenced by Clariant (Request 1) and the ‘Labelling of workplace hazardous chemicals - Code of practice’ (Safe Work Australia, 2018) recommend the use of ‘P281: Use personal protective equipment as required’. The Code of practice is aligned to the third revised edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS, United Nations, 2009).

In response, Clariant stated that the European CLP regulations were revised on 4 October 2019 resulting in the replacement of P281 by P280 for use in Europe. AICIS notes this is consistent with the replacement made in the GHS Revision 7 (United Nations, 2017). In Australia, the two-year transitional period from GHS Revision 3 to GHS Revision 7, that was due to start on 1 July 2020, has been delayed due to the impact of COVID-19. To ensure that any importers that had already begun work on implementing GHS Revision 7 are not disadvantaged, state and territory governments have allowed businesses to start classifying and labelling chemicals in accordance with GHS Revision 7 from 1 July 2020.

The Executive Director has decided to amend the text as suggested to recommend the use of either P280 or P281 until the end of the transition to GHS Revision 7 on 1 January 2023. After this date, P280 alone is to be used.

The revised section will be included under ‘Hazard communication, Labels’ on page 9:

*“The following precautionary statements are recommended:*

*Prevention:*

*P201: Obtain special instructions before use.*

*P202: Do not handle until all safety precautions have been read and understood.*

*P281: Use personal protective equipment as required OR P280: Wear protective gloves/ protective clothing/eye protection/face protection\**

*Response:*

*P308 + P313: IF exposed or concerned: Get medical advice/attention.*

*Storage:*

*P405: Store locked up.*

*Disposal:*

*P501: Dispose of contents/container in accordance with relevant Commonwealth, state, territory and local government legislation.”*

*\* Either P281 or P280 can be used until 1 January 2023. After this date, when Australia has transitioned to the seventh revised edition of the GHS (United Nations, 2017), P280 alone is to be used.*

HSY Autoparts Pty Ltd

Request 1

**Page 8, Recommendations to regulatory bodies**

*"The following precautionary statement is also recommended:*

*• P263: Avoid contact during pregnancy/while nursing (ND)"*

**Suggested change:**

“*Remove the P263 statement from Page 8 of the draft report.*”

**Reason:**

The precautionary statement P263 is only applicable for the hazard statement H362. Under the GHS, there is no requirement to list the P263 statement under the hazard statement H361

Decision 1

Variation approved.

AICIS response 1

The Executive Director is satisfied that the report, varied as requested, would be correct. The justification for variation is consistent with the absence of this precautionary statement for ‘Toxic to Reproduction’ in Appendix D - Application of Label Elements in ‘Labelling of workplace hazardous chemicals - Code of practice’ (Safe Work Australia 2018). The text will be deleted in the report as suggested.

Request 2

**Page 8, Recommendations to regulatory bodies**

*“Based on the assessment findings, a hazard classification is recommended to Safe Work Australia as below:*

* *Toxic to Reproduction (Category 2): H361D - Suspected of damaging the unborn child (ND).”*

**Suggested change:**

“*The hazard statement H361D on Page 8 should be renamed as H361d.*”

**Reason:**

H361D should be expressed as H361d as this is the GHS convention.

Decision 2

Variation approved.

AICIS response 2

The Executive Director is satisfied that the report, varied as requested, would be correct. This is a typographical error and the upper case ‘H361D’ will be replaced with a lower case ‘H361d’ in the amended report

Request 3

**Page 8, Recommendations to regulatory bodies**

*“Based on the assessment findings, a hazard classification is recommended to Safe Work Australia as below:”*

**Suggested change:**

*“Add the other listed precautionary statements:*

*Prevention:*

*P201: Obtain special instructions before use.*

*P202: Do not handle until all safety precautions have been read and understood.*

*P281: Use personal protective equipment as required.*

*Response:*

*P308 + P313: IF exposed or concerned: Get medical advice/attention.*

*Storage:*

*P405: Store locked up.*

*Disposal:*

*P501: Dispose of contents/container in accordance with local/regional/national/ international regulations.”*

**Reason:**

The Safe Work Australia Labelling code of practice recommends that these precautionary statements be included for chemicals which are classified as ‘Toxic to Reproduction (Category 2): H361d - Suspected of damaging the unborn child’.

Decision 3

Variation approved.

AICIS response 3

The Executive Director is satisfied that the report, varied as requested, would be correct. The precautionary statements listed in ‘Suggested change’ are recommended in the ‘Labelling of workplace hazardous chemicals - Code of practice’ (Safe Work Australia 2018). Statement P510 will be amended to reflect Australian requirements. The revised section will be included under ‘Hazard communication, Labels’ on page 9:

*“The following precautionary statements are recommended:*

*Prevention:*

*P201: Obtain special instructions before use.*

*P202: Do not handle until all safety precautions have been read and understood.*

*P281: Use personal protective equipment as required.*

*Response:*

*P308 + P313: IF exposed or concerned: Get medical advice/attention.*

*Storage:*

*P405: Store locked up.*

*Disposal:*

*P501: Dispose of contents/container in accordance with relevant Commonwealth, state, territory and local government legislation.”*

Request 4

**Page 8, Recommendations to regulatory bodies**

*"The following precautionary statement is also recommended:*

**Suggested change:**

*“Include the general precautionary statement P101: If medical advice is needed, have product container or label at hand”*

**Reason:**

This statement, P101: If medical advice is needed, have product container or label at hand, should be included since this statement is applicable as appropriate for consumer products.

Decision 4

Variation approved.

AICIS response 4

The Executive Director is satisfied that the report, varied as requested, would be correct. However, AICIS notes the recommendation regarding the use of general precautionary statements in the ‘Labelling of workplace hazardous chemicals - Code of practice’ (Safe Work Australia 2018):

‘General precautionary statements are not aligned with any particular hazard category and, according to the GHS principles, these statements are required for consumer products only. Manufacturers of hazardous chemicals may choose to include these on workplace labels, particularly where it is foreseeable that the chemical may be used in a non-workplace situation.’

A concluding paragraph will be included under ‘Hazard communication, Labels’ on page 9:

*“The following precautionary statements are recommended:*

*Prevention:*

*P201: Obtain special instructions before use.*

*P202: Do not handle until all safety precautions have been read and understood.*

*P281: Use personal protective equipment as required.*

*Response:*

*P308 + P313: IF exposed or concerned: Get medical advice/attention.*

*Storage:*

*P405: Store locked up.*

*Disposal:*

*P501: Dispose of contents/container in accordance with relevant Commonwealth, state, territory and local government legislation.”*

*Only the specific precautionary statements that apply to the hazard classification have been included. According to the GHS principles, a general precautionary statement that may apply in this case is ‘P101 - If medical advice is needed, have product container or label at hand’. Although general statements are required for consumer products only, the importers of the notified chemical may choose to include this on workplace labels, particularly where it is likely that the chemical may be available for consumer use.*

Consolidated variations

**Recommendations to regulatory bodies**

The chemical is not currently listed in Safe Work Australia’s Hazardous Chemical Information System (HCIS).

Based on the assessment findings, a hazard classification is recommended to Safe Work Australia as below:

* Toxic to Reproduction (Category 2): H361d – Suspected of damaging the unborn child (**ND**)

**Advice to industry**

**Hazard communication**

Labels

Importers should update their labels to reflect the updated hazard information in this assessment. Importers should also review their labels for compliance with ‘Labelling of workplace hazardous chemicals – Code of practice’ (Safe Work Australia, 2018a). At the time of this assessment, labelling to include the environmental hazard classification, under the GHS, is not mandated in Australia. It carries no legal status, but importers could include it in the labels as best practice.

The following information should be used for products/mixtures containing the chemical, if applicable, based on the concentration of the chemical:

* Concentration ≥ 3%: Suspected of damaging the unborn child (**ND**)

The following precautionary statements are recommended (**ND**):

Prevention:

* P201: Obtain special instructions before use.
* P202: Do not handle until all safety precautions have been read and understood.
* P281: Use personal protective equipment as required OR P280: Wear protective gloves/ protective clothing/eye protection/face protection.\*

Response:

* P308 + P313: IF exposed or concerned: Get medical advice/attention.

Storage:

* P405: Store locked up.

Disposal:

* P501: Dispose of contents/container in accordance with relevant Commonwealth, state, territory and local government legislation.

\* Either P281 or P280 can be used until 1 January 2023. After this date, when Australia has transitioned to the seventh revised edition of the GHS (United Nations, 2017), P280 alone is to be used.

Only the specific precautionary statements that apply to the hazard classification have been included.  According to the GHS principles, a general precautionary statement that may apply in this case is ‘P101 - If medical advice is needed, have product container or label at hand’.  Although general statements are required for consumer products only, the importers of the notified chemical may choose to include this on workplace labels, particularly where it is likely that the chemical may be available for consumer use.

References

Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Official Journal of the European Union 2008. Accessed at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32008R1272>

Safe Work Australia (2018) Labelling of workplace hazardous chemicals - Code of practice. Australian Government. Safe Work Australia. Accessed at: <https://www.safeworkaustralia.gov.au/system/files/documents/1909/model-cop-labelling-of-workplace-hazardous-chemicals.pdf>

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE). Accessed at: <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>

United Nations (2017) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 7th revised edition. United Nations Economic Commission for Europe (UN/ECE). Accessed at: <https://www.unece.org/trans/danger/publi/ghs/ghs_rev07/07files_e.html>