

**Committee for Risk Assessment**  
**RAC**

Annex 2  
**Response to comments document (RCOM)**  
to the Opinion proposing harmonised classification and  
labelling at EU level of

**thiabendazole (ISO);**  
**2-(thiazol-4-yl)benzimidazole**

**EC Number: 205-725-8**

**CAS Number: 148-79-8**

CLH-O-0000001412-86-143/F

**Adopted**  
**15 March 2017**

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON THIABENDAZOLE (ISO); 2-(THIAZOL-4-YL)BENZIMIDAZOLE**

**COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION**

Comments provided during public consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the public consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the public consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties.

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**Substance name: thiabendazole (ISO); 2-(thiazol-4-yl)benzimidazole**

**EC number: 205-725-8**

**CAS number: 148-79-8**

**Dossier submitter: Spain**

**GENERAL COMMENTS**

| Date                                                                                                                                                                                                                                                            | Country | Organisation | Type of Organisation | Comment number |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------------|----------------------|----------------|
| 12.07.2016                                                                                                                                                                                                                                                      | France  |              | MemberState          | 1              |
| Comment received                                                                                                                                                                                                                                                |         |              |                      |                |
| We agree with the classification and the acute and chronic M factors proposed for Environmental hazards.<br>We agree with the Human Health classification proposal.<br><br>Please note that the CAS name of thiabendazole is 1H-Benzimidazole, 2-(4-thiazolyl)- |         |              |                      |                |
| Dossier Submitter's Response                                                                                                                                                                                                                                    |         |              |                      |                |
| Thank you for your comments.                                                                                                                                                                                                                                    |         |              |                      |                |
| RAC's response                                                                                                                                                                                                                                                  |         |              |                      |                |
| Noted.                                                                                                                                                                                                                                                          |         |              |                      |                |

| Date                                                                                                                                                                                                                                                                                                                                                                | Country | Organisation | Type of Organisation | Comment number |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------------|----------------------|----------------|
| 14.07.2016                                                                                                                                                                                                                                                                                                                                                          | Germany |              | MemberState          | 2              |
| Comment received                                                                                                                                                                                                                                                                                                                                                    |         |              |                      |                |
| The German CA supports the proposed environmental classification and labelling as Aquatic acute 1 (H400) and Aquatic chronic 1 (H410) and the acute M-factor = 1. However, concerning the chronic M-factor we suggest to consider all available chronic data, including the studies submitted within the framework of the approval process for biocidal substances. |         |              |                      |                |
| Dossier Submitter's Response                                                                                                                                                                                                                                                                                                                                        |         |              |                      |                |
| See below response to comment 4.                                                                                                                                                                                                                                                                                                                                    |         |              |                      |                |
| RAC's response                                                                                                                                                                                                                                                                                                                                                      |         |              |                      |                |
| Noted.                                                                                                                                                                                                                                                                                                                                                              |         |              |                      |                |

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON THIABENDAZOLE (ISO); 2-(THIAZOL-4-YL)BENZIMIDAZOLE**

**OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment**

| Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Country | Organisation | Type of Organisation | Comment number |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------------|----------------------|----------------|
| 14.07.2016                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Belgium |              | MemberState          | 3              |
| Comment received                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         |              |                      |                |
| <p>Based on the results of the aquatic toxicity test on the most sensitive species (Mysid shrimp with 96hEC50=0.34 mg/l, Daphnia magna with 21dNOEC=0.041mg/l, the fact that the substance is considered as not rapidly degradable it is justified to classify, following the classification criteria of the regulation 1272/2008, as Aquatic acute 1, H400, aquatic chronic 1, H410 . Furthermore, the substance shows low potential to bioaccumulate.</p> <p>In view of the proposed classification and toxicity band for acute toxicity between 1 mg/l and 0.1 mg/l, an M-factor for acute toxicity of 1 could be assigned and an M-factor for chronic toxicity of 1 (not rapidly degradable substance and NOEC between 0.1 mg/l and 0.01mg/l)</p> <p>In conclusion: we can agree with the proposed environmental classification by the Spanish competent authority.</p> |         |              |                      |                |
| Dossier Submitter's Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |              |                      |                |
| Thank you for your comments.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |         |              |                      |                |
| RAC's response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |         |              |                      |                |
| Noted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |         |              |                      |                |

| Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Country | Organisation | Type of Organisation | Comment number |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------------|----------------------|----------------|
| 14.07.2016                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Germany |              | MemberState          | 4              |
| Comment received                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         |              |                      |                |
| <p>Thiabendazole has been approved as biocidal substance for use in product-type 8 (wood preservatives) in 2010, with Spain as rapporteur. In the assessment report there is a chronic NOEC = 0.012 mg/L for fish available, which could suggest an M-Factor of 10. The corresponding study by Wilson, LeBlanc and Mastron (1982) is evaluated with reliability 2 and considered as acceptable by the rapporteur, despite certain deficiencies. Please consider this study and discuss the derivation of the chronic M-factor.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         |              |                      |                |
| Dossier Submitter's Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |         |              |                      |                |
| <p>This study was not taken into account for aquatic chronic harmonised classification of Thiabendazol because several deviations from OECD guideline No. 210 were identified and it was not carried out under GLP.</p> <p>Apart from this, the chronic toxicity value from <i>Daphnia magna</i> was considered more reliable since the study was validated according to OECD guideline No. 211.</p> <p>Despite this, the study mentioned in the comment is considered and its summary is reported below:</p> <p><b>Wilson, LeBlanc and Mastron (1982).</b><br/>Rainbow trout embryos and larvae were exposed through 30 days post "swim-up" to mean measured concentrations of Thiabendazole at 1.2, 2.8, 5.6, 12 and 29 microgram a.s/l under flow-through conditions. Mean measured concentrations did not verify the nominal values (measured concentrations averaged from 55 – 83 % of the nominal test concentrations). Effects on embryo viability, hatchability and larvae survival and growth</p> |         |              |                      |                |

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were the end points to estimate the NOEC, LOEC and MATC Viability of embryos exposed for 21 days to a mean measured concentration of 29 microgram a.s/l Thiabendazole was significantly reduced as compared to control and solvent control groups. No adverse effects on embryo viability, hatchability or survival and growth of larvae from exposure to mean measured concentrations less than or equal to 12 ug/l Thiabendazole were observed. Therefore, the NOEC of Thiabendazole for rainbow trout embryos and larvae was estimated to be 0.012 mg a.i./L, and the LOEC, based on viability of embryos, was higher than 0.012 mg a.i./L. The MATC was higher than 0.012 mg a.i./L and smaller than 0.029 mg a.i./L (geometric mean 0.019 mg a.i./L).

Several deviations from OECD guideline No. 210 were identified. However, the endpoint derived for embryos is deemed an accurate estimate of long term toxicity of Thiabendazole to fish.

**The NOEC is 0.012 mg a.s./l.**

Taking into account this endpoint, the aquatic chronic classification of Thiabendazole and the M-factor would not be modified:

**Aquatic Chronic 1** with M factor of **1**; CLP criteria for NOEC chronic values below or equal to 0.1 mg/l (NOEC = 0.012 mg/l), plus the fact that this substance is not rapidly degradable.

Justification for M-factor:

According to Table 4.1.3 from Commission Regulation (EU) No 487/2013 of 8 May 2013 for not rapidly degradable substances with NOEC value between 0.01 mg/l and 0.1 mg/l the M-factor is 1 (0.01 < NOEC ≤ 0.1 mg/l).

RAC's response

The study was taken into consideration, although it would not change the proposed classification and M-factor.

**OTHER HAZARDS AND ENDPOINTS – Physical Hazards**

| Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Country | Organisation | Type of Organisation | Comment number |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|--------------|----------------------|----------------|
| 12.07.2016                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | France  |              | MemberState          | 5              |
| Comment received                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |         |              |                      |                |
| <p>p16:<br/>According to the final addendum of the RAR of the active substance (june 2014), no reference is reported for flash point.</p> <p>According to the final addendum of the RAR of the active substance (june 2014), the reference for flammability test is Meeus 1997 and not Jackson 2003.</p> <p>No data have been reported for the self-ignition temperature. Nevertheless, according to final addendum of the RAR of the active substance (june 2014), the active substance thiabendazole is not auto flammable at ambient temperature (Welberry 1998).</p> |         |              |                      |                |
| Dossier Submitter's Response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |         |              |                      |                |
| We agree with the correction.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |         |              |                      |                |
| RAC's response                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |         |              |                      |                |
| Noted.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |         |              |                      |                |