|  |  |  |  |
| --- | --- | --- | --- |
| **Assessment summary table – GHS hazard classification for health and environment** (v20240606)  **Approach ii. – Use of existing classifications of the active ingredient and co-formulants**  **Approach iii. – Classification based on physico-chemical and (eco-)toxicological data**   1. **Identification of the pesticide product and its components** | | | |
| **Product name & formulation type:** |  | **Name** | **Concentration** (g/kg or g/L) |
| **Active ingredient(s):** | 1. |  |
| 2. |  |
| **Co-formulants:** | 1. |  |
| **Applicant:** | 2. |  |
| 3. |  |
| **Registration file number:** | 4. |  |
| **Reference country or database(s) of existing classifications:** | 5. |  |
| 6. |  |
| *[add more, if needed]* |  |
| **Name of the assessor:** | **Date of the assessment:** | | |

**Copy-paste** one set of green tables per substance

**✂ ……..**

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| **Assessment summary table – GHS hazard classification for health and environment**  **Approach ii. – Use of existing classifications of the active ingredient and co-formulants**  **Approach iii. – Classification based on physical and (eco-)toxicological data**   1. **Classification of active ingredient(s)and co-formulant(s) in the product**   One (1) table per substance | |
| **Substance name:** | **Substance ID number:** |
| **Substance concentration in product/mixture:** | |

| **2A. Health classification** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Hazard class** | **Information from application/SDS[[1]](#footnote-1)** *(if available)* | | **Information from reference source** | | **Retained substance classification and its justification[[2]](#footnote-2)** |
| **Substance classification** | **Test result or converted point estimate used for classification** | **Substance classification** | **Source** |
| **Acute toxicity – *Oral*** |  |  |  |  |  |
| **Acute toxicity – *Dermal*** |  |  |  |  |  |
| **Acute toxicity – *Inhalation*** |  |  |  |  |  |
| **Skin corrosion/irritation** |  |  |  |  |  |
| **Serious eye damage/eye irritation** |  |  |  |  |  |
| **Respiratory or skin sensitization** |  |  |  |  |  |
| **Germ cell mutagenicity** |  |  |  |  |  |
| **Carcinogenicity** |  |  |  |  |  |
| **Reproductive toxicity** |  |  |  |  |  |
| **Specific target organ toxicity (STOT) – Single exposure** |  |  |  |  |  |
| **Specific target organ toxicity (STOT) – Repeated exposure** |  |  |  |  |  |
| **Aspiration hazard** |  |  |  |  |  |

| **2B. Environment classification** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Hazard class** | **Information from application/SDS[[3]](#footnote-3)** *(if available)* | | **Information from reference source** | | **Retained substance classification and its justification[[4]](#footnote-4)** |
| **Substance classification** | **Test result or converted point estimate used for classification** | **Substance classification** | **Source** |
| **Aquatic – acute toxicity** |  |  |  |  |  |
| * *Fish* |  |  |  |  |
| * *Aquatic invertebrates* |  |  |  |  |
| * *Algae* |  |  |  |  |
| **Aquatic – chronic toxicity** |  |  |  |  |  |
| * *Fish* |  |  |  |  |
| * *Aquatic invertebrates* |  |  |  |  |
| * *Algae* |  |  |  |  |
| * *Rapid degradability* | ⬜ Yes ⬜ No |  |  |  |
| * *Bioaccumulation* | ⬜ Yes ⬜ No |  |  |  |
| **Hazardous to ozone layer** |  |  |  |  |  |

**…….. ✂**

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| **Assessment summary table – GHS hazard classification for health and environment**  **Approach ii. – Use of existing classifications of the active ingredient and co-formulants**  **Approach iii. – Classification based on physico-chemical and (eco-)toxicological data**   1. **Classification the formulated product** |
| **Product name:** |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **3A. Health classification – Product** | | | | | | | | |
| **Hazard class** | **Proposed classification of the product from the application dossier** *(if available)* | **Product data from registration dossier or SDS** *(if available)* | **Classification based on substance data[[5]](#footnote-5)** | | | | | **Retained product classification and its justification[[6]](#footnote-6)** |
| **Substance name[[7]](#footnote-7)** | **LD50 or Converted acute toxicity point estimate[[8]](#footnote-8)** | **Concentration in the product** (%) | *Classification rules for the pesticide product* | **Calculated classification** |
| **Acute toxicity – *Oral*** |  |  | *1:* |  |  | *Calculate the ATEmix using the rules and formula of section 3.1.3.6 in the GHS.* | ATEmix =  Classifies as: |  |
| *2:* |  |  |
| *3:* |  |  |
| *…:* |  |  |
| **Acute toxicity – *Dermal*** |  |  | *1:* |  |  | ATEmix =  Classifies as: |  |
| *2:* |  |  |
| *3:* |  |  |
| *…:* |  |  |
| **Acute toxicity – *Inhalation*** |  |  | *1:* |  |  | ATEmix =  Classifies as: |  |
| *2:* |  |  |
| *3:* |  |  |
| *…:* |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **3A. Health classification – Product** | | | | | | | |
| **Hazard class** | **Proposed classification of the product from the application dossier** *(if available)* | **Product data from registration dossier or SDS** *(if available)* | **Classification based on substance data[[9]](#footnote-9)** | | | | **Retained product classification and its justification[[10]](#footnote-10)** |
| **Substances in category or sub category** | **Sum of concentrations of relevant substance(s) classified in each category** (%) | *Classification rules for the pesticide product* | **Calculated classification** |
| **Skin corrosion/ irritation** |  |  | 1: |  | *Determine the classification of the product using the rules and tables of section 3.2.3.3 of the GHS.* |  |  |
| 1A: |  |
| 1B: |  |
| 1C: |  |
| 2: |  |
| 3: |  |
| **Serious eye damage/ eye irritation** |  |  | 1: |  | *Determine the classification of the product using the rules and tables of section 3.3.3.3 of the GHS* |  |  |
| 2/2A: |  |
| 2B: |  |
| **Aspiration hazard** |  |  | 1: |  | *Determine the classification of the product using the rules and tables of section 3.10.3.3 of the GHS.* |  |  |
| 2: |  |

| **3A. Health classification – Product** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard class** | **Proposed classification of the product from the application dossier** *(if available)* | **Product data from registration dossier or SDS** *(if available)* | **Classification based on substance data[[11]](#footnote-11)** | | | | **Retained product classification and its justification[[12]](#footnote-12)** |
| **Substances in category or sub category** | **Concentrations of every substance classified in each category** (%)[[13]](#footnote-13) | *Classification rules for the pesticide product* | **Calculated classification** |
| **Respiratory or skin sensitization** |  |  | 1: |  | *Determine the classification of the product using the rules and tables of section 3.4.3.3 of the GHS.* |  |  |
| 1A: |  |
| 1B: |  |
| **Germ cell mutagenicity** |  |  | 1A: |  | *Determine the classification of the product using the rules and tables of section 3.5.3.3 of the GHS.* |  |  |
| 1B: |  |
| 2: |  |
| **Carcinogenicity** |  |  | 1: |  | *Determine the classification of the product using the rules and tables of section 3.6.3.3 of the GHS.* |  |  |
| 1A: |  |
| 1B: |  |
| 2: |  |
| **Reproductive toxicity** |  |  | 1A: |  | *Determine the classification of the product using the rules and tables of section 3.7.3.3 of the GHS.* |  |  |
| 1B: |  |
| 2: |  |
| Effects via lactation: |  |
| **Specific target organ toxicity (STOT) – Single exposure** |  |  | 1: |  | *Determine the classification of the product using the rules and tables of section 3.8.3.4 of the GHS.* |  |  |
| 2: |  |
| 3: |  |
| **Specific target organ toxicity (STOT) – Repeated exposure** |  |  | 1: |  | *Determine the classification of the product using the rules and tables of section 3.9.3.4 of the GHS.* |  |  |
| 2: |  |

| **3B. Environment classification – Product**  **i. Classification of pesticide products when toxicity data are available for all substances in the formulation (mixture)[[14]](#footnote-14)** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard class** | **Proposed classification of the product from the application dossier** *(if available)* | **Product data from registration dossier or SDS** *(if available)* | **Classification based on substance data[[15]](#footnote-15)** | | | | | **Retained product classification and its justification[[16]](#footnote-16)** |
| **Substance name[[17]](#footnote-17)** | **Toxicity endpoint** | **Concentration in the product** (%) | *Classification rules for the pesticide product* | **Calculated classification** |
| **Aquatic acute** |  |  |  | ***LC50 or EC50*** |  | *Calculate the* L(E)C50m *using the rules and formula of section 4.1.3.5.2 in the GHS.* | L(E)C50m =  Classifies as: |  |
| *1:* |  |  |
| *2:* |  |  |
| *3:* |  |  |
| *…:* |  |  |
| **Aquatic chronic** |  |  |  | ***NOEC*** |  | *Calculate the* EqNOECm *using the rules and formula of section 4.1.3.5.2 in the GHS.* | EqNOECm =  Classifies as: |  |
| *1:* |  |  |
| *2:* |  |  |
| *3:* |  |  |
| *…:* |  |  |

| **3B. Environment classification – Product**  **ii. Classification of pesticide products when hazard classifications are available for all substances in the formulation (mixture)** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard class** | **Proposed classification of the product from the application dossier** *(if available)* | **Product data from registration dossier or SDS** *(if available)* | **Classification based on substance data[[18]](#footnote-18)** | | | | | **Retained product classification and its justification[[19]](#footnote-19)** |
| **Substance in Category** | **Sum of concentrations of relevant substance(s) classified in each category (%)** | **M factor** *(if applicable)* | *Classification rules for the pesticide product* | **Calculated classification** |
| **Aquatic acute** |  |  | 1: |  |  | *Determine the classification of the product using the rules and tables of section 4.1.3.5.5 of the GHS.* |  |  |
| 2: |  |  |
| 3: |  |  |
| **Aquatic chronic** |  |  | 1: |  |  | *Determine the classification of the product using the rules and tables of section 4.1.3.5.5 of the GHS.* |  |  |
| 2: |  |  |
| 3: |  |  |
| 4: |  |  |

1. SDS = Safety Data Sheet [↑](#footnote-ref-1)
2. Indicate which classification was retained and why this was done. If needed, contact the applicant for further explanations of their classification. [↑](#footnote-ref-2)
3. SDS = Safety Data Sheet [↑](#footnote-ref-3)
4. Indicate which classification was retained and why this was done. If needed, contact the applicant for further explanations of their classification. [↑](#footnote-ref-4)
5. Only relevant substances in the formulated product (pesticide active ingredient and relevant co-formulants) need to be included in the calculation of the Acute Toxicity Estimate (ATE) of the mixture. [↑](#footnote-ref-5)
6. Indicate which classification was retained and why this was done. If needed, contact the applicant for further explanations of their classification. [↑](#footnote-ref-6)
7. Enter relevant substances in this column; add lines for additional substances if required. [↑](#footnote-ref-7)
8. If available, LD50 values of the substances should be entered here. If no LD50 values are available, but the substance has been classified, the converted acute toxicity estimate of the respective acute toxicity category can be entered in the formula (see Table 3.1.2 in the GHS). [↑](#footnote-ref-8)
9. Only relevant substances in the formulated product (pesticide active ingredient and relevant co-formulants) need to be included in the calculation of the hazard class of the mixture. [↑](#footnote-ref-9)
10. Indicate which classification was retained and why this was done. If needed, contact the applicant for further explanations of their classification. [↑](#footnote-ref-10)
11. Only relevant substances in the formulated product (pesticide active ingredient and relevant co-formulants) need to be included in the calculation of the hazard class of the mixture. [↑](#footnote-ref-11)
12. Indicate which classification was retained and why this was done. If needed, contact the applicant for further explanations of their classification. [↑](#footnote-ref-12)
13. For the non-additive hazard classes, the formulated pesticide product (mixture) will be classified for a given hazard when at least one ingredient has been classified for that hazard, and is present at or above the appropriate concentration limit. [↑](#footnote-ref-13)
14. Either table 3B-I or Table 3B-ii is filled out, depending on whether toxicity data or hazard classifications are available for the substances in the product [↑](#footnote-ref-14)
15. Only relevant substances in the formulated product (pesticide active ingredient and relevant co-formulants) need to be included in the calculation of the toxicity of the mixture. [↑](#footnote-ref-15)
16. Indicate which classification was retained and why this was done. If needed, contact the applicant for further explanations of their classification. [↑](#footnote-ref-16)
17. Enter relevant substances in this column; add lines for additional substances if required. [↑](#footnote-ref-17)
18. Only relevant substances in the formulated product (pesticide active ingredient and relevant co-formulants) need to be included in the calculation of the hazard classification of the mixture. [↑](#footnote-ref-18)
19. Indicate which classification was retained and why this was done. If needed, contact the applicant for further explanations of their classification. [↑](#footnote-ref-19)