

**PEST MANAGEMENT REGULATORY AGENCY**

**DATA REQUIREMENTS FOR**

**USE SITE CATEGORY (USC # 12): Stored Food and Feed - TGAI**

| <b>Data Code</b> | <b>Title</b>   | <b>Data required</b> | <b>Conditions</b>          | <b>Volume No and Pages</b> |
|------------------|--|----------------------|----------------------------|----------------------------|
| <b>0</b>         | <b>Index</b>   | <b>R</b>             |                            |                            |
| <b>1</b>         | <b>Label</b>   | <b>R</b>             |                            |                            |
| <b>2</b>         | <b>Chemistry requirements for the registration of a technical grade of active ingredient (TGAI) or an integrated system product.</b> |                      |                            |                            |
| 2.1              | Applicant's Name and Office Address  | R                    |                            |                            |
| 2.2              | Manufacturer's Name and Office Address and Manufacturing Plant's Name and Address  | R                    |                            |                            |
| 2.3              | Product Trade Name   | R                    |                            |                            |
| 2.3.1            | Other Names  | R                    |                            |                            |
| 2.4              | Common Name  | R                    |                            |                            |
| 2.5              | Chemical Name  | R                    |                            |                            |
| 2.6              | Chemical Abstracts Registry Number   | R                    |                            |                            |
| 2.7              | Structural Formula   | R                    |                            |                            |
| 2.8              | Molecular Formula  | R                    |                            |                            |
| 2.9              | Molecular Weight   | R                    |                            |                            |
| <b>2.11</b>      | <b>Manufacturing Methods for the TGAI</b>  |                      |                            |                            |
| 2.11.1           | Manufacturing Summary  | R                    |                            |                            |
| 2.11.2           | Description of Starting Materials  | R                    |                            |                            |
| 2.11.3           | Detailed Production Process Description  | R                    |                            |                            |
| 2.11.4           | Discussion of Formation of Impurities  | R                    |                            |                            |
| <b>2.12</b>      | <b>Specifications</b>  |                      |                            |                            |
| 2.12.1           | Establishing Certified Limits  | R                    |                            |                            |
| 2.12.2           | Control Product Specification Form   | R                    |                            |                            |
| <b>2.13</b>      | <b>Preliminary Analysis</b>  |                      |                            |                            |
| 2.13.1           | Methodology/Validation   | R                    |                            |                            |
| 2.13.2           | Confirmation of Identity   | R                    |                            |                            |
| 2.13.3           | Batch Data   | R                    |                            |                            |
| 2.13.4           | Impurities of Toxicological Concern  | CR                   | If applicable              |                            |
| <b>2.14</b>      | <b>Chemical and Physical Properties</b>  |                      |                            |                            |
| 2.14.1           | Colour   | R                    |                            |                            |
| 2.14.2           | Physical State   | R                    |                            |                            |
| 2.14.3           | Odour  | R                    |                            |                            |
| 2.14.4           | Melting Point / Melting Range  | R                    | Solid at room temperature  |                            |
| 2.14.5           | Boiling Point / Boiling Range  | R                    | Liquid at room temperature |                            |
| 2.14.6           | Density or Specific Gravity  | R                    |                            |                            |
| 2.14.7           | Water Solubility (mg/L)  | R                    | See 8.2.1                  |                            |
| 2.14.8           | Solvent Solubility (mg/L)  | R                    |                            |                            |
| 2.14.9           | Vapour Pressure  | R                    | See 8.2.1                  |                            |
| 2.14.10          | Dissociation Constant  | R                    | See 8.2.1                  |                            |
| 2.14.11          | Octanol/Water Partition Coefficient  | R                    | See 8.2.1                  |                            |

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|------------------|--|----------------------|---|----------------------------|
| 2.14.12          | UV/Visible Absorption Spectra                  | R                    | See 8.2.1   |                            |
| 2.14.13          | Stability (Temperature, Metals)                | R                    |   |                            |
| 2.14.14          | Storage Stability Data                         | CR                   | Required for integrated system products   |                            |
| 2.15             | Sample(s) of Analytical Standards and ROC      | R                    |   |                            |
| 2.16             | Other Studies/Data/Reports                     | CR                   | If available  |                            |
| <b>4</b>         | <b>Toxicology</b>                              |                      |   |                            |
| 4.1              | Summaries                                      | R                    |   |                            |
| <b>4.2</b>       | <b>Acute Studies — TGAI</b>                    |                      |   |                            |
| 4.2.1            | Acute Oral                                     | R                    |   |                            |
| 4.2.2            | Acute Dermal                                   | R                    |   |                            |
| 4.2.3            | Acute Inhalation                               | R                    |   |                            |
| 4.2.4            | Primary Eye Irritation                         | R                    |   |                            |
| 4.2.5            | Primary Dermal Irritation                      | R                    |   |                            |
| 4.2.6            | Dermal Sensitization                           | R                    |   |                            |
| 4.2.7            | Potentiation/Interaction                       | CR                   | If available  |                            |
| 4.2.8            | Antidote                                       | CR                   | If available  |                            |
| 4.2.9            | Other Acute Studies                            | CR                   | If available  |                            |
| <b>4.3</b>       | <b>Short-term Studies — TGAI</b>               |                      |   |                            |
| 4.3.1            | Short-term Oral (90-day rodent)                | R                    |   |                            |
| 4.3.2            | Short-term Oral (90-day and/or 12-month dog)   | R                    |   |                            |
| 4.3.3            | Short-term Oral (28-day)                       | CR                   | If available  |                            |
| 4.3.4            | Short-term Dermal (90-day)                     | CR                   | If available  |                            |
| 4.3.5            | Short-term Dermal (21/28-day)                  | R                    |   |                            |
| 4.3.6            | Short-term Inhalation (90-day)                 | CR                   | Required if there is the likelihood of significant repeated inhalation exposure to the product as a gas, vapor or aerosol |                            |
| 4.3.7            | Short-term Inhalation (21/28-day)              | CR                   | If available  |                            |
| 4.3.8            | Other Short-term Studies                       | CR                   | If available  |                            |
| <b>4.4</b>       | <b>Long-term Studies — TGAI</b>                |                      |   |                            |
| 4.4.1            | Chronic (rodent)                               | R                    | 4.4.1 and 4.4.2 could be submitted as a combined study under 4.4.4  |                            |
| 4.4.2            | Oncogenicity (rodent species 1)                | R                    | 4.4.1 and 4.4.2 could be submitted as a combined study under 4.4.4  |                            |
| 4.4.3            | Oncogenicity (rodent species 2)                | R                    |   |                            |
| 4.4.4            | Combined Chronic/Oncogenicity (rodent)         | CR                   | 4.4.1 and 4.4.2 could be submitted as a combined study under 4.4.4  |                            |
| 4.4.5            | Other Long-term Studies                        | CR                   | If available  |                            |
| <b>4.5</b>       | <b>Special Studies — TGAI</b>                  |                      |   |                            |
| 4.5.1            | Multigeneration Reproduction (rodent)          | R                    |   |                            |
| 4.5.2            | Prenatal Developmental Toxicity (rodent)       | R                    |   |                            |
| 4.5.3            | Prenatal Developmental Toxicity (non-rodent)   | R                    |   |                            |
| 4.5.4            | Genotoxicity: Bacterial Reverse Mutation Assay | R                    |   |                            |

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| 4.5.5            | Genotoxicity: In vitro Mammalian Cell Assay   | R                    |   |                            |
| 4.5.6            | Genotoxicity: In vitro Mammalian Clastogenicity   | CR                   | Required if not addressed in study submitted for 4.5.5  |                            |
| 4.5.7            | Genotoxicity: In vivo Cytogenetics  | R                    |   |                            |
| 4.5.8            | Other Genotoxicity Studies  | CR                   | If available  |                            |
| 4.5.9            | Metabolism/Toxicokinetics in Mammals (laboratory animals)   | R                    |   |                            |
| 4.5.10           | Acute Delayed Neurotoxicity (hen)   | CR                   | Required if the test substance is an organophosphorus substance or is structurally related to other substances that may cause delayed neurotoxicity   |                            |
| 4.5.11           | 28-day Delayed Neurotoxicity (hen)  | CR                   | Required if results of acute delayed neurotoxicity study indicates effects, or if other available data indicate the potential for this type of delayed neurotoxicity  |                            |
| 4.5.12           | Acute Neurotoxicity (rat)   | CR                   | Required if there is neurotoxic potential   |                            |
| 4.5.13           | 90-day Neurotoxicity (rat)  | CR                   | Required if there is neurotoxic potential   |                            |
| 4.5.14           | Developmental Neurotoxicity   | CR                   | Required if neurological effects are observed in other studies<br>Should be considered if test substance:<br>i) causes neuropathology or neurotoxicity in adults;<br>ii) is hormonally active <i>in vivo</i> ; or<br>iii) causes other types of nervous system involvement at a developmental stage |                            |
| 4.8              | Other Studies/Data/Reports  | CR                   | If available  |                            |
| <b>6</b>         | <b>Metabolism/Toxicokinetics Studies (TGAI or EP)</b>   |                      |   |                            |
| 6.1              | Summaries   | R                    |   |                            |
| 6.2              | Livestock   | R                    | If fed  |                            |
| 6.3              | Plant   | R                    |   |                            |
| 6.4              | Other Studies/Data/Reports  | CR                   | If available  |                            |
| <b>8</b>         | <b>Environmental Chemistry and Fate</b>   |                      |   |                            |
| 8.1              | Summaries   | R                    |   |                            |
| <b>8.2</b>       | <b>Laboratory Studies</b>   |                      |   |                            |
| 8.2.1            | Summary of Physicochemical Properties to include: Solubility in Water, Vapour Pressure, Dissociation Constant, Octanol/Water Partition Coefficient, UV-Visible Absorption Spectra (See Part 2 - TGAI) | R                    | Data submitted under 2.14.7; 2.14.9; 2.14.10; 2.14.11; and 2.14.12  |                            |
| <b>8.2.2</b>     | <b>Analytical Methodology (parent compound and transformation products)</b>   |                      |   |                            |

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| 8.2.2.1          | Soil   | CR                   | If there is a potential for soil exposure   |                            |
| 8.2.2.2          | Sediment   | CR                   | If there is a potential for aquatic exposure  |                            |
| 8.2.2.3          | Water  | CR                   | See 8.2.2.2   |                            |
| 8.2.2.4          | Biota  | CR                   | If there is a potential for exposure  |                            |
| <b>8.2.3</b>     | <b>Laboratory Studies of Transformation</b>                |                      |   |                            |
| 8.2.3.1          | Summary  | R                    |   |                            |
| 8.2.3.2          | Hydrolysis   | R                    |   |                            |
| <b>8.2.3.3</b>   | <b>Phototransformation</b>                                 |                      |   |                            |
| 8.2.3.3.3        | Air  | CR                   | If volatilization is indicated by vapour pressure or Henry's Law Constant                                   |                            |
| <b>8.2.3.4</b>   | <b>Biotransformation in Soil</b>                           |                      |   |                            |
| 8.2.3.4.2        | Aerobic Soil 20°-30°C                                      | CR                   | If there is a potential for soil exposure   |                            |
| <b>8.2.3.5</b>   | <b>Biotransformation in Aquatic Systems</b>                |                      |   |                            |
| 8.2.3.5.2        | Aerobic Water 20°-30°C                                     | CR                   | If there is a potential for aquatic exposure.   |                            |
| <b>8.2.4</b>     | <b>Laboratory Studies of Mobility</b>                      |                      |   |                            |
| 8.2.4.1          | Summary  | CR                   | If there is a potential for soil exposure   |                            |
| 8.2.4.2          | Adsorption/Desorption                                      | CR                   | One of 8.2.4.2; 8.2.4.3.1; 8.2.4.3.2; or 8.2.4.4 is required (R), if there is a potential for soil exposure |                            |
| <b>8.2.4.3</b>   | <b>Soil Column Leaching</b>                                |                      |   |                            |
| 8.2.4.3.1        | Unaged Soil  | CR                   | See 8.2.4.2   |                            |
| 8.2.4.3.2        | Aged Soil  | CR                   | See 8.2.4.2   |                            |
| 8.2.4.4          | Soil TLC Leaching  | CR                   | See 8.2.4.2   |                            |
| 8.2.4.5          | Volatilization   | CR                   | If volatilization is indicated by vapour pressure or Henry's Law Constant                                   |                            |
| <b>8.4</b>       | <b>Storage, Disposal and Decontamination (TGAI and EP)</b> |                      |   |                            |
| 8.4.1            | Summary  | R                    |   |                            |
| <b>8.5</b>       | <b>Other Environmental Fate Studies (TGAI and EP)</b>      |                      |   |                            |
| 8.5.1            | Summary  | CR                   | Based on concerns arising from results of other studies   |                            |
| 8.6              | Other Studies/Data/Reports                                 | CR                   | If available  |                            |
| <b>9</b>         | <b>Environmental Toxicology</b>                            |                      |   |                            |
| 9.1              | Summary  | CR                   |   |                            |
| <b>9.2</b>       | <b>Non-Target Terrestrial Invertebrates</b>                |                      |   |                            |
| 9.2.1            | Summaries  | CR                   |   |                            |
| 9.2.5            | Predators  | CR                   | If there is a potential for exposure  |                            |
| 9.2.6            | Parasites  | CR                   | See 9.2.5   |                            |
| <b>9.3</b>       | <b>Non-Target Freshwater Invertebrates</b>                 |                      |   |                            |

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| 9.3.1            | Summary   | CR                   | If there is a potential for freshwater exposure  |                            |
| 9.3.2            | <i>Daphnia</i> sp. Acute  | CR                   | See 9.3.1  |                            |
| <b>9.4</b>       | <b>Non-Target Marine Invertebrates</b>  |                      |  |                            |
| 9.4.1            | Summary   | CR                   | If there is a potential for estuarine/marine exposure  |                            |
| 9.4.2            | Acute (Crustacean)  | CR                   | See 9.4.1  |                            |
| <b>9.5</b>       | <b>Fish</b>   |                      |  |                            |
| 9.5.1            | Summaries   | CR                   | If there is a potential for exposure   |                            |
| <b>9.5.2</b>     | <b>Acute Studies</b>  |                      |  |                            |
| 9.5.2.1          | Cold Water Fish (rainbow trout)   | CR                   | If there is a potential for freshwater exposure  |                            |
| 9.5.2.2          | Warm Water Fish (bluegill sunfish)  | CR                   | See 9.5.2.1  |                            |
| 9.5.2.4          | Marine/Estuarine Fish   | CR                   | If there is a potential for estuarine/marine exposure  |                            |
| <b>9.6</b>       | <b>Wild Birds</b>   |                      |  |                            |
| 9.6.1            | Summary   | CR                   | If there is a potential for exposure   |                            |
| 9.6.6            | Special Studies Related to the Intended Use-Pattern (TGAI and EP)                 | CR                   | Acute inhalation (LD <sub>50</sub> ) with bobwhite quail or mallard duck, if there is a potential for avian exposure |                            |
| <b>9.8</b>       | <b>Non-Target Plants</b>  |                      |  |                            |
| 9.8.1            | Summary   | CR                   |  |                            |
| 9.8.2            | Fresh Water Algae   | CR                   | If there is a potential for freshwater exposure  |                            |
| 9.8.3            | Marine Algae  | CR                   | If there is a potential for estuarine/marine exposure  |                            |
| 9.9              | Other Studies/Data/Reports  | CR                   | If available   |                            |
| <b>12.5</b>      | <b>Foreign Reviews</b>  |                      |  |                            |
| 12.5.2           | Foreign Reviews of Chemistry Requirements for TGAIs or Integrated System Products | CR                   |  |                            |
| 12.5.4           | Foreign Reviews of Toxicology   | CR                   |  |                            |
| 12.5.6           | Foreign Reviews of Metabolism / Toxicokinetics Studies                            | CR                   |  |                            |
| 12.5.8           | Foreign Reviews of Environmental Chemistry and Fate                               | CR                   |  |                            |
| 12.5.9           | Foreign Reviews of Environmental Toxicology                                       | CR                   |  |                            |
| <b>12.7</b>      | <b>Comprehensive Data Summaries</b>   | R                    |  |                            |

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