*This single cover page is to be included; applicant is not to apply additional formatting to this document or insert new headers/footers, table of contents, extraneous information etc. Sample/guidance text for all data requirements is in red and is to be amended as appropriate.*

**Formulation / End-use Product**

Product Chemistry Evaluation

(based on OECD Dossier Numbering)

Identity, Physical and Chemical Properties, Analytical Methods, Confidential Information

Prepared by: Applicant

Reviewed/edited by: Primary chemistry reviewer, Regulatory Authority

Secondary chemistry reviewer, Regulatory Authority

Approved by: Approving manager, Regulatory Authority responsible for primary review

Approving manager, Regulatory Authority responsible for secondary review

*Placeholder page for Agency-specific administrative information*

* *PMRA will capture submission number, source code, registration number, submission history, label/hazard review, introduction, summary of findings, conclusion, chemical equivalence assessment as applicable (appended after CBI portion), peer review and signature blocks*
* *EPA will capture DP barcode, registration/file symbol number, product code, decision number, introduction, summary of findings, conclusions, chemical equivalence assessment as applicable (appended after CBI portion), peer review and signature blocks*

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# IIIA 1.0 IDENTITY OF THE FORMULATION / END-USE PRODUCT

## IIIA 1.1 Applicant

DACO 3.1.1 / OPPTS 830.1550

**In the United States of America**:
Company A (the proposed owner of the registration in the U.S.) including address

**In Canada**:
Company B (the proposed owner of the registration in Canada) including address

**Contacts:**

Global Name, address, telephone, e-mail, fax

USA As above

Canada As above

## IIIA 1.3 Trade name

DACO 3.1.3 / OPPTS 830.1550

Proposed trade name in each country

## IIIA 1.4.1 Contents of pure active ingredient (guarantee)

DACO 3.3 / OPPTS 830.1550

Product guarantee = active ingredient at … %

## IIIA 1.5 Type of formulation and code

DACO 3.5.4 / OPPTS 830.1550

If necessary, both CropLife International code and country-specific code

## IIIA 1.6 Function

Herbicide, fungicide, insecticide, antimicrobial …

#

# IIIA 2.0 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE FORMULATION / END-USE PRODUCT

| Annex IIIA pointTest or property | Guideline and method | Test material purity and specification | Study findings and applicant comments | Reviewer conclusions | Data accepted 1 | GLP Y/N | Reference |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **IIIA 2.1 Colour** | Visual assessment, DACO 3.5.1, OPPTS 830.6302 |  | The product is … |  |  |  | Applicant report #PMRA #MRID # |
| **IIIA 2.1 Physical state** | Visual assessment, DACO 3.5.2, OPPTS 830.6303 |  | The product is a … |  |  |  |  |
| **IIIA 2.1 Odour** | Olfactory assessment, DACO 3.5.3, OPPTS 830.6304 |  | The odour of the product is … |  |  |  |  |
| IIIA 2.2.1 Explosive properties | EC A.14, DACO 3.5.12, OPPTS 830.6316 |  | The product did not react explosively to thermal stress, mechanical stress or to friction, using … |  |  |  |  |
| IIIA 2.2.2 Oxidising and reducing properties / chemical incompatibility  | EC A.21, DACO 3.5.8, OPPTS 830.6314 |  | The product was determined (not) to be compatible with oxidizing agents, reducing agents, fire extinguishing agents and water, using the following tests: |  |  |  |  |
| IIIA 2.3.1 Flash point (liquids) / flame extension (pressurized products) | EC A.9, DACO 3.5.11,OPPTS 830.6315 |  | The flash point of the product was determined to be …°C, using …ORThe flame extension of the product was determined to be … cm, using … |  |  |  |  |
| IIIA 2.3.2 Flammability (solids) | EC A.10 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.3.3 Auto flammability | EC A.15 |  | Not required by PMRA or EPA  |  |  |  |  |
| IIIA 2.4.1 Free acidity / alkalinity | CIPAC MT 191 |  | Not required by PMRA or EPA  |  |  |  |  |
| IIIA 2.4.2 pH  | CIPAC MT 75.3, DACO 3.5.7, OPPTS 830.7000 |  | The pH of the product (in a 1% aqueous dilution) was determined to be … |  |  |  |  |
| IIIA 2.5.1 Kinematic viscosity  | OECD 114 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.5.2 Dynamic viscosity | CIPAC MT 192, DACO 3.5.9, OPPTS 830.7100 |  | The dynamic viscosity of the product was determined to be …, using … at temperatures … and shear rate xx s-1 |  |  |  |  |
| IIIA 2.5.3 Surface tension | EC A.5 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.6.1 Relative density / density  | EC A.3, OECD 109, DACO 3.5.6, OPPTS 830.7300 |  | The (relative) density of the product was determined to be …, using …  |  |  |  |  |
| IIIA 2.6.2 Bulk/tap density | CIPAC MT 186, DACO 3.5.6, OPPTS 830.7300 |  | If applicable (solids) |  |  |  |  |
| IIIA 2.7.1 Stability after storage for 14 days at 54°C | CIPAC MT 463, DACO 3.5.10, OPPTS 830.6317 |  | The product was stored at a temperature of 54°C for a period of 14 days in … The following results were obtained after completion of accelerated storage:Active content …(Note: this study is one of two options to address this data requirement; see also IIIA 2.7.5) |  |  |  |  |
| IIIA 2.7.2 Stability after storage for other periods and/or temperatures |  |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.7.3 Minimum content after heat stability testing |  |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.7.4 Effect of low temperature on stability | CIPAC MT 39 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.7.5 Shelf life (stability) following storage at ambient temperature for at least one year  | GIFAP Monograph No 17, DACO 3.5.10, OPPTS 830.6317 |  | The product was stored at a temperature of …°C for a period of … in … The following results were obtained after completion of ambient storage:Active content …(Note: this study is one of two options to address this data requirement; see also IIIA 2.7.1) |  |  |  |  |
| IIIA 2.7.6 Shelf life in months |  |  | Not required by PMRA or EPA  |  |  |  |  |
| IIIA 2.8.1 Wettability | CIPAC MT 53.3 |  | Not required by PMRA or EPA  |  |  |  |  |
| IIIA 2.8.2 Persistent foaming | CIPAC MT 47 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.3.1 Suspensibility | CIPAC MT 184 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.3.2 Dispersibility (WG) or Spontaneity of dispersion (SC) | CIPAC MT 174, CIPAC MT 160 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.4 Dilution stability | CIPAC MT 179, CIPAC MT 41 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.5.1 Dry sieve test | CIPAC MT 59 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.5.2 Wet sieve test | CIPAC MT 185 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.6.1 Size distribution of particles | OECD 110 or CIPAC MT 187 (WP), OPPTS 830.7520 |  | Not required by PMRA *except in the case of nanomaterials – see new data requirement at bottom of table*Required by EPA. For nanomaterials, please contact appropriate product manager.  |  |  |  |  |
| IIIA 2.8.6.2 Nominal size range of granules | CIPAC 170 (WG) |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.6.3 Dust content | CIPAC MT 171 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.6.4 Particle size of dust | OECD 110 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.6.5 Friability and attrition characteristics of granules | CIPAC MT 178 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.7.1 Emulsifiability | CIPAC MT 36 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.7.2 Emulsion stability | CIPAC MT 20  |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.7.3 Re‑emulsifiability | CIPAC MT 36 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.7.4 Stability of dilute emulsions | CIPAC MT 20  |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.7.5 Stability of emulsions |  |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.8.1 Flowability | CIPAC MT 172 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.8.2 Pourability | CIPAC MT 148.1 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.8.8.3 Dustability following accelerated storage | CIPAC MT 34 |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.9.1 Physical compatibility of tank mixes | ASTM method E1518-93 static test  |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.9.2 Chemical compatibility of tank mixes |  |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.10.1 Distribution (seed treatment) |  |  | Not required by PMRA or EPA |  |  |  |  |
| IIIA 2.10.2 Adhesion (seed treatment) |  |  | Not required by PMRA or EPA |  |  |  |  |
| **IIIA 2.11 Miscibility** | DACO 3.5.13, OPPTS 830.6319 |  | Applicant to provide data, or a waiver if not applicable |  |  |  |  |
| **IIIA 2.12 Dielectric breakdown voltage** | DACO 3.5.15, OPPTS 860.6321 |  | Applicant to provide data, or a waiver if not applicable |  |  |  |  |
| **IIIA 2.13 Corrosion characteristics** | DACO 3.5.14, OPPTS 860.6320 |  | Corrosion characteristics were examined concurrently with the accelerated / ambient storage stability test. After storage for … in … at a temperature of …°C, the product did (not) have any adverse effects on its commercial packaging. |  |  |  |  |
| **IIIA 2.14 Container material** | DACO 3.5.5 |  |  |  |  |  |  |
| **IIIA 2.15 Other special studies****PMRA: Nanomaterial characteristics** | DACO 3.5.16 |  | Required by PMRA if the formulated product contains a nanomaterial |  |  |  |  |
| 1 A = acceptable, N = not acceptable, NR = not required, NA = not applicable, G = data gap, U = requires upgrading, W = waived |

# IIIA 5.0 ANALYTICAL METHODS AND VALIDATION

## IIIA 5.1 Analytical standards and samples

### IIIA 5.1.1 Samples of the preparation

OPPTS 830.1900

Submittal of sample not required by PMRA; required by EPA.

## IIIA 5.2 Methods for the analysis of the formulation

### IIIA 5.2.1 Methods for the determination of the active ingredient in the formulation

DACO 3.4.1 / OPPTS 830.1800

Reference: Author, year, title, company, report number, GLP Y/N

 PMRA #, MRID #

If multiple actives are present in the formulation, the method for each active must be capable of determining it in the presence of the other active(s) as well as the formulation components.

| **Table 5.2.1-1. Details of the analytical method used to determine the active ingredient in the formulated product** |
| --- |
| Method ID | Company A Method 1.1 |
| Sample preparation | 100 mg of technical product is dissolved in 10 mL of solvent… |
| Instrument | HPLC |
| Detector | MS-MS *OR* UV at … nm |
| Column  | Company B tradename, dimensions |
| Mobile phase (for LC) or oven temperature (for GC) |  |
| Quantitation | By external standard (lot #, purity) obtained from Commercial Source C *OR* synthesized/characterized by the applicant with supporting data |
| Retention time |  |
| Total run time |  |
| Chromatograms | Provided chromatograms for the sample, standard and formulation blank; no interferences were noted around the peaks of interest. |
| *footnotes as applicable; table to be tailored to suit method if needed (e.g. titration)* |

| **Table 5.2.1-2. Method validation data** |
| --- |
| Component Method Type / ID | Linearity (w %) / Correlation coefficient | Accuracy as recovery (%) | Precision as RSD (%) |
| Active HPLC-MS/MS / Method 1.1 |  |  |  |
| *footnotes as applicable – e.g. details of accuracy or precision determination* |

A validated analytical method was provided for determination of the active in the formulated end-use product and was assessed to be … as an enforcement analytical method.

### IIIA 5.2.2 + 3 + 4 + 5, 5.3 Methods capable of determining the presence of more than one active substance in the preparation / Applicability of existing CIPAC methods / Methods for the determination of impurities in the preparation / Methods for the determination of formulants or constituents of formulants in the preparation / Analytical methods for the determination of residues / Storage stability of working solutions in analytical method

Not required by PMRA or EPA

# CONFIDENTIAL BUSINESS INFORMATION (CBI)

## IIIA 1.2 Formulator (manufacturer) of formulation / end-use product

DACO 3.1.2 / OPPTS 830.1550

Formulator(s) of the product, including physical address of plant

## IIIA 1.4 Composition of the formulation / end-use product

### IIIA 1.4.1 + 2 + 3 Contents of technical active ingredient, pure active ingredient and formulants / Certified limits of each component / ISO common name / CAS number for active ingredient / Salt, ester, anion or cation of active substance

DACO 3.3 + 3.3.1 / OPPTS 830.1550

Reference: Specification form dated …

 PMRA #, MRID #

| **Table 1.4-1. Specifications of formulation / end-use product.** |
| --- |
| Component | CAS No. (PMRA formulant list no. in parentheses) | Purpose | % nominal weight (certified limits) |
| Active – tradename, ISO-approved common and chemical name, purity in registered technical product  |  |  | % wt of technical product |
| Guarantee: active ingredient | % wt of pure active (limits) |
| Formulant (inert) – trade name, and primary component if supplied by applicant[PMRA NACT code in parentheses] | for single chemical formulant, or for primary component in mixture if available |  | % wt of formulant (limits) |
|  |  |  |  |
|  |  |  |  |
| Total |  |
| *Footnotes as applicable, e.g. impurities of concern in formulants and non-standard certified limits* |

### IIIA 1.4.4 Details of components, other than active ingredient, in the formulation

DACO 3.2.1 / OPPTS 830.1600

Reference: Author, year, title, company, report number, GLP Y/N

 PMRA #, MRID #

Specifications and MSDSs were provided for each formulant [i.e. are not necessary to include here]. Trade name and function are included in Table 1.4-1. Chemical names are confidential to the formulant manufacturers and are captured, along with detailed composition for each proprietary formulant mixture, in the PMRA formulants database. All necessary formulant information has been provided.

## IIIA 1.4.5 Formulation process

### IIIA 1.4.5.1 Description of formulation process

DACO 3.2.2 / OPPTS 830.1650

Reference: Author, year, title, company, report number, GLP Y/N

 PMRA #, MRID #

### IIIA 1.4.5.2 Potential for the formation of impurities including those of toxicological concern

DACO 3.2.3 + 3.4.2 / OPPTS 830.1670

Based on the formulation process which is a simple blending at ambient temperature and pressure, new impurities are (not) expected to be formed …

THIRD-PARTY CBI, TO BE FILLED OUT BY REGULATORY AGENCY: Impurities of human health or environmental concern are not expected to be present in the end-use product (PMRA would use specific standard text here) *OR* The following impurities of concern are expected to be carried through to the end-use product from its components. Formulant information is proprietary to the formulant manufacturers and is not to be disclosed to the applicant.

|  |
| --- |
| **Table 1.4-2. Impurities of concern in the formulation / end-use product.** |
| Impurity | Cause for concern | Source of impurity and level in source | Maximum level in product |
| e.g. Hexachlorobenzene | TSMP Track 1 substance [PMRA] | 10 ppm in TGAI | 1 ppm |
| e.g. Arsenic | Toxic heavy metal | 30-50 ppm in Formulant Mixture A | 1 ppm |

### IIIA 5.2.4 + 5 Analytical methods for the determination of impurities which are of toxicological, ecotoxicological or environmental concern in the formulation / Analytical methods for the determination of formulants or constituents of formulants in the product

Not required by PMRA or EPA, except in certain scenarios such as the following:

* essential oils where the applicant may choose to analyse an impurity (e.g. methyl eugenol) in the end-use product rather than the technical product
* end-use products (e.g. dimethylamine formulations of 2,4-D) where the impurity of concern (N-nitrosodimethylamine) is introduced/increased during the formulation process
* active ingredients that degrade upon storage to more toxic substances

# REFERENCES RELIED ON

| Annex No.,OECD Data Requirement No. | Author(s) | Year | TitleSourceCompany Report No.GLP or GEP Status (where relevant)Published or not | DataProtectionClaimed(Y/N) | Owner |
| --- | --- | --- | --- | --- | --- |
| IIIA, 1.4 | Smith, A.B. | 2013 | Formulation: manufacturing processCompany ACompany A Report No. 1GLP: NoPublished: No | Y | Company A  |
| IIIA, 1.9 | Jones, C.D. | 2014 | Technical grade: Identity, composition, and certified limitsCompany BCompany B Report No. 1GLP: NoPublished: No | Y | Company A |

PMRA and EPA will generate their respective reference lists electronically.