Health Canada Santé Canada

# Evaluation Report for Category B, Subcategory 1.1 Application

**Application Number:** 2021-2486
**Application:** Changes to TGAI Product Chemistry – New Source (site) Same Registrant
**Product:** Forum Technical (Dimethomorph)
**Registration Number:** 24545
**Active ingredient (a.i.):** Dimethomorph
**PMRA Document Number: 3408889**

## Purpose of Application

The purpose of this submission is to add a new manufacturing site to Forum Technical (Dimethomorph).

## Chemistry Assessment

| | |
|---|---|
| Common Name: | Dimethomorph |
| IUPAC* Chemical Name: | (2*EZ*)-3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-(morpholin-4-yl)propenone |
| CAS† Chemical Name: | 4-[3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)-1-oxo-2-propen-1-yl]morpholine |

* International Union of Pure and Applied Chemistry
† Chemical Abstracts Service

Forum Technical (Dimethomorph) has the following properties:

| Property | Result |
|---|---|
| Colour and physical state | Colourless to grey solid |
| Nominal concentration | 98% |
| Odour | Odourless |
| Density | 1.318 g/mL |
| Vapour pressure | $9.7 \times 10^{-7}$ Pa for *E*-isomer<br>$1.0 \times 10^{-6}$ Pa for *Z*-isomer |
| pH | Not applicable as the active is almost insoluble in water |



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| Property | Result |
|---|---|
| Solubility in water | pH Solubility (mg/L)<br>4 81.1<br>7 49.2<br>9 41.8 |
| n-Octanol/water partition coefficient | Log $K_{ow}$ = 2.63 for *E*-isomer<br>Log $K_{ow}$ = 2.73 for *Z*-isomer |

The required chemistry data for Forum Technical (Dimethomorph) have been provided, reviewed, and found to be acceptable.

**Health, Environmental and Value Assessments**

Health, environmental and value assessments were not required for this application.

**Conclusion**

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information sufficient to support addition of the manufacturing site to Forum Technical (Dimethomorph).

## References


| PMRA Document Number | References |
|---|---|
| 3236643 | 2020, Description of the Manufacturing Process of Dimethomorph / BAS 550 F [Privacy removed], DACO: 2.11,2.11.1,2.11.2,2.11.3,2.11.4 CBI |
| 3236644 | 2020, Dimethomorph TGAI- Description of the Manufacturing Process, DACO: 2.11.1,2.11.3 CBI |
| 3236645 | 2017, Determination of Active Content of Dimethomorph- Method Validation, DACO: 2.13.1 CBI |
| 3236646 | 2020, Determination of Active Content and Impurity Profile of Dimethomorph (Including Amendment No. 1), DACO: 2.13.2,2.13.3,2.13.4 CBI |
| 3290540 | 2021, 5 Batch Analysis of [CBI Removed] in Dimethomorph Technical, DACO: 2.13.4 CBI |
| 3394464 | 2022, DACO 2 BASF Response to PMRA Request for Clarification Regarding Submission No 2021-2486, DACO: 2.0 CBI |



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