

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
SAN FRANCISCO, CALIFORNIA**



In the Matter of:)	
)	
Twin Med, LLC)	Docket No. FIFRA-09-2025-0033
)	
)	RESPONDENT TWIN MED, LLC'S
)	ANSWER TO COMPLAINT
Respondent.)	

Respondent Twin Med, LLC, (“Respondent”) answers USEPA’s (“EPA”) Complaint as follows:

GENERAL DENIAL

Except as expressly admitted or qualified, Defendants deny each and every allegation of Plaintiffs’ Complaint, in whole and in part.

SPECIFIC DENIALS

Pursuant to 40 C.F.R. § 22.15, Respondent, by and through its undersigned counsel, files this Answer and responds to the specific allegations in the numbered Paragraphs in EPA’s Complaint and states:

- When Respondent says that something “speaks for itself,” it does not admit that the referenced material exists, is accurate, or is placed in the proper context.
- Respondent is not obligated to respond to the headings of the Complaint. The headings are reproduced for ease of reference. Inclusion of the headings does not constitute an admission of the Complaint’s allegations or characterizations. Respondent denies all titles and subheadings in the Complaint
- Anything not expressly admitted by Respondent is denied.

I. “PRELIMINARY STATEMENT”

The “Preliminary Statement” section states legal conclusions to which no response is required.

II. “APPLICABLE STATUTORY AND REGULATORY SECTIONS”

1-12. The allegations contained in Paragraphs 1 through 12 of the Complaint are legal conclusions to which no response is required or refer to statutes and regulations that speak for themselves. To the extent a response is required, Respondent otherwise denies the allegations contained in Paragraphs 1 through 12 of the Complaint.

III. “ALLEGATIONS”

13. Respondent repeats and restates its answers, denials, and defenses to Paragraphs 1 through 12 and incorporates each by reference as if fully set forth herein.

14. Respondent admits the allegations contained in Paragraph 14 of the Complaint.

15. Respondent admits the allegations contained in Paragraph 15 of the Complaint.

16. Respondent admits the allegations contained in Paragraph 16 of the Complaint.

17. Respondent admits the allegations contained in Paragraph 17 of the Complaint.

18. Respondent admits the allegations contained in Paragraph 18 of the Complaint.

19. Paragraph 19 of the Complaint contains legal conclusions to which no response is required.

20. Paragraph 20 of the Complaint contains legal conclusions to which no response is required.

21. Respondent can neither confirm nor deny the allegations contained in Paragraph 21 of the complaint, which are uniquely within EPA's knowledge.

22. Paragraph 22 of the Complaint (misnumbered in Complaint as Paragraph 23) contains legal conclusions to which no response is required. To the extent a response is required, Respondent admits to the allegations to the extent that it sold WynnMed Disinfectant Wipes for a limited period after August 17, 2021. Respondent notes that the alleged violations occurred during the public health crisis of the COVID-19 pandemic. The alleged violations arose out of a desire to prevent imminent harm to the public health, rather than to develop a competitive advantage. Respondent only took actions it believed to be consistent with FIFRA's ultimate goals of protecting the public health and the environment. Moreover, Respondent's alleged violations involved a chemical with low acute toxicity, Respondent's violations did not result in harm to the public health or environment, Respondent has never previously violated FIFRA, Respondent immediately corrected the alleged violations, and Respondent worked with EPA throughout the inspection

process to mitigate any potential impacts. Respondent's alleged violations ultimately were, at most, the result of negligence while Respondent attempted to respond to a global health crisis by providing a safe, effective product to consumers who were scared and looking for answers. Respondent thus contends that no civil penalty amount is appropriate, and if a penalty award is appropriate, Respondent contends that the proposed penalty amount is excessive and unwarranted given the above described circumstances.

23. Paragraph 23 of the Complaint (misnumbered in Complaint as Paragraph 23) contains legal conclusions to which no response is required. To the extent that a response is required, Respondent notes that the alleged violations occurred during the public health crisis of the COVID-19 pandemic. The alleged violations arose out of a desire to prevent imminent harm to the public health, rather than to develop a competitive advantage. Respondent only took actions it believed to be consistent with FIFRA's ultimate goals of protecting the public health and the environment. Moreover, Respondent's alleged violations involved a chemical with low acute toxicity, Respondent's violations did not result in harm to the public health or environment, Respondent has never previously violated FIFRA, Respondent immediately corrected the alleged violations, and Respondent worked with EPA throughout the inspection process to mitigate any potential impacts. Respondent's alleged violations ultimately were, at most, the result of negligence while Respondent attempted to respond to a global health crisis by providing a safe, effective product to consumers who were scared and looking for answers. Respondent thus contends that no civil penalty amount is appropriate, and if a penalty award is appropriate, Respondent contends that the proposed penalty amount is excessive and unwarranted given the above described circumstances.

IV. "PROPOSED CIVIL PENALTY"

The statutes and regulations referenced in the "Proposed Civil Penalty" section speak for themselves. To the extent a response is required, Respondent denies the allegations in the "Proposed Civil Penalty" section. Respondent also denies that EPA is entitled to the penalty requested in the "Proposed Civil Penalty" section.

V. "NOTICE OF OPPORTUNITY TO REQUEST HEARING"

This section contains legal conclusions to which no response is required.

VI. “INFORMAL SETTLEMENT CONFERENCE”

This section contains instructions for requesting a settlement conference to which no response is required.

VII. “ALTERNATIVE DISPUTE RESOLUTION”

This section contains instructions for dispute resolution to which no response is required.

VIII. “CONSENT AGREEMENT AND FINAL ORDER”

This section contains legal conclusions to which no response is required.

ADDITIONAL DEFENSES

By asserting the matters set forth below, Respondent does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters.

FIRST ADDITIONAL DEFENSE

The Complaint fails to state a claim upon which relief can be granted, or upon which relief can be granted against Respondent.

SECOND ADDITIONAL DEFENSE

The alleged violations were caused by the acts or omissions of third-persons or entities over which Respondent had limited or no control.

THIRD ADDITIONAL DEFENSE

The proposed civil penalty is unnecessary and unwarranted given the alleged violations occurred during the unprecedented public health crisis caused by the COVID-19 pandemic. During the violation period, demand for effective surface disinfectants and germicides surged dramatically, leading to severe shortages of approved sanitizing products. Respondent’s alleged violations, to the extent that they occurred, arose out of a desire to prevent imminent harm to the public. Any distributions of unregistered products were not made for any competitive advantage; but rather to address a public health emergency where time lost meant public lives at risk. Respondent should not be subject to a severe and burdensome civil penalty for alleged actions that are ultimately consistent with FIFRA’s overall goal of protecting the public health. Moreover, as

detailed in Respondent's communications with EPA, the case-specific factors under the ERP do not support the application of such a significant penalty. For example, the primary active ingredient involved in the alleged violations was isopropyl alcohol, a common solvent with low acute toxicity. As such, the alleged violations did not result in any harm to human health or the environment. Moreover, Respondent has no prior FIFRA violations, ceased and corrected the violations immediately after discovery, and worked with EPA to rectify the violations. Respondent never sought to intentionally violate the law or take advantage of the fear and uncertainty caused by the COVID-19 Pandemic. Instead, it sought to provide a quality, safe product to consumers who were scared and looking to established companies for answers. Respondent should not be penalized so excessively for actions it ultimately took to support the public health and welfare.

FOURTH ADDITIONAL DEFENSE

Respondent reserves the right to amend this Answer to add additional defenses if they become apparent from further discovery.

FIFTH ADDITIONAL DEFENSE

EPA seeks an excessive fine in violation of the Eighth Amendment of the U.S. Constitution.

SIXTH ADDITIONAL DEFENSE

This Court does not have the authority to impose civil penalties as the EPA is not vested with the judicial power of the United States. This proceeding therefore violates Article III of the U.S. Constitution.

SEVENTH ADDITIONAL DEFENSE

The Administrative Law Judge presiding over this proceeding was not properly appointed under the Appointments Clause of the U.S. Constitution.

EIGHTH ADDITIONAL DEFENSE

The Environmental Appeals Board members to which an Order in this proceeding would be appealed were not properly appointed under the Appointments Clause of the U.S. Constitution.

NINTH ADDITIONAL DEFENSE

This proceeding violates Respondent's due process rights under the Fifth Amendment of the U.S. Constitution.

TENTH ADDITIONAL DEFENSE

This proceeding violates Respondent's right to a jury trial under the Seventh Amendment of the U.S. Constitution.

WHEREFORE, Respondent, Twin Med, LLC, requests the entry of an Order:

- A. Dismissing this case;
- B. Awarding to it costs and expenses, including attorney's fees; and
- C. Granting it such other and further relief as may be justified.

Dated: February 17, 2025

Respectfully submitted,

/s/ Scott Watson

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Attorneys for Respondent

CERTIFICATE OF SERVICE

I, Scott Watson, hereby certify that on February 17, 2025, the foregoing document has been filed with the Regional Hearing Clerk, and that a true and correct copy was served by email on counsel for the USEPA: David Kim at kim.david@epa.com and on the Regional Hearing Clerk Tu Ponly at tu.ponly@epa.gov.

Respectfully submitted,

/s/ Scott Watson

Scott Watson