



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

Office of
Chief Counsel

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***Hazardous Materials Safety
Law Division***

NOTICE OF PROBABLE VIOLATION

PHMSA Case No: 23-0005-PM-EA

Date Issued: June 2, 2023

Respondent: Zacros America, Inc.
220 Lake Drive
Newark, Delaware 19702
ATTN: Mr. Richard Broo, President

No. of Alleged Violations: 1

Total Proposed Assessment: \$8,400 (includes \$2,100 reduction for corrective actions)

The Office of Chief Counsel of the Pipeline and Hazardous Materials Safety Administration (PHMSA) alleges that you have violated certain provisions of the Federal hazardous materials transportation law, 49 U.S.C. § 5101 *et seq.*, and/or the Hazardous Materials Regulations (HMR), 49 CFR Parts 171-180. PHMSA sets forth the specific allegations in Addendum A to this Notice.

What are the maximum and minimum civil penalties that PHMSA can assess? Federal law sets a maximum civil penalty of \$81,993 (or \$191,316 if the violation results in death, serious illness or severe injury, or substantial destruction of property), and a minimum civil penalty of \$493 if the violation concerns training, for each violation of the Federal hazardous materials transportation law or the HMR. Each day of a continuing violation by a shipper or transporter of hazardous materials constitutes a separate violation for which the maximum penalty may be imposed (49 U.S.C. § 5123(a)).

What factors does PHMSA consider when proposing and assessing a civil penalty? Federal law requires PHMSA to consider certain factors when proposing and assessing a civil penalty for a violation of Federal hazardous materials transportation law or the HMR. Please refer to Addendum B to this Notice for more information concerning these factors, which include corrective actions you take to attain and ensure compliance with the HMR.

How do I respond? You may respond to this Notice in any of three ways:

- (1) By paying the proposed assessment (49 CFR § 107.313(a)(1));
- (2) By sending an informal response, which can include a request for an informal conference (49 CFR § 107.313(a)(2)); or
- (3) By requesting a formal hearing (49 CFR § 107.313(a)(3)).

Details on these three options are provided in Addendum B to this Notice and also online at: (<https://www.phmsa.dot.gov/hazmat/field-operations/nopvresponses>). PHMSA explains its procedures for assessing civil penalties and imposing compliance orders in 49 CFR §§ 107.307 - 107.331.

When is my response due? You must respond within thirty (30) days from the date that you receive the Notice (49 CFR § 107.313(a)). I may extend the 30-day period for your response if you ask for an extension, and show good cause, within the original 30-day period (49 CFR § 107.313(c)). A response received out of time will not be considered. To assure timely receipt, **PHMSA strongly encourages you to submit your response by e-mail, fax, or express mail.**

What happens if I fail to respond? You waive your right to contest the allegations made in Addendum A to this Notice if you fail to respond within thirty (30) days of receiving it (or by the end of any extension). In that event, the Chief Counsel may find that you committed the violation(s) alleged in this Notice and assess an appropriate civil penalty.

What happens if PHMSA issues an Order assessing a civil penalty, and I fail to pay? If you fail to pay a civil penalty assessed by an Order, on the 91st day after the date of the Order you will be prohibited from conducting hazardous materials operations, in accordance with 49 CFR Part 109, Subpart E. If PHMSA issues a cease operations order and you continue to conduct hazardous materials operations, you may be subject to additional penalties, including criminal prosecution pursuant to 49 U.S.C. 5124. The prohibition shall continue until payment of the penalty has been made in full, or until PHMSA approves an acceptable payment plan.

The Case Exhibits have been supplied to you in electronic format. If this creates an undue hardship for you, please contact me.

ARIS D
GENERETTE
Digitally signed by
ARIS D GENERETTE
Date: 2023.06.02
22:43:11 -04'00'
Aris Generette, Attorney

Enclosures: Addendum A
Addendum B
Addendum C

ELECTRONIC SERVICE

ADDENDUM A

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PHMSA Case No. 23-0005-PM-EA
(Zacros America, Inc.)

GENERAL ALLEGATIONS

General Factual Allegations/Averments

1. On October 11, 13, and 20, 2022, PHMSA's Investigator conducted an inspection at the Newark, Delaware facility of Zacros America, Inc. (Zacros).
2. Mr. Donald McMillan, Packaging Engineer, was present for the inspection and signed the exit briefing.
3. Respondent manufactures and conducts testing on UN packaging.
4. As a manufacturer of UN standard packaging, Respondent is a regulated entity subject to the HMR and to the jurisdiction of the Secretary of Transportation, PHMSA's Associate Administrator for Hazardous Materials Safety, and PHMSA's Office of the Chief Counsel (49 U.S.C. § 5103(b) and 49 CFR § 107.301).

SPECIFIC ALLEGATIONS

Probable Violation No. 1

Failing to ensure that packaging is capable of meeting required tests, in violation of 49 C.F.R. §§178.601(b) and 178.601(e).

Factual Allegations/Averments

1. Respondent manufactures a package marked as UN4G/Y32/S/**/USA/M6270.
2. During the inspection, PHMSA's investigator reviewed Respondent's test report for the aforementioned packaging, dated October 23, 2020.
3. Respondent's purchase order 4501334009 reflects the June 30, 2022 sale of the aforementioned package type to ThermoFisher Scientific.
4. On two separate occasions, PHMSA's investigator observed Respondent's filling of the aforementioned package, and placement into a freezer for conditioning.
5. PHMSA's investigator observed Respondent's preparation and subsequent drop testing.
6. Respondent dopped four of five samples, with the package failing on both "flat on long side" and "flat on short side" orientations.

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7. On two separate occasions, PHMSA's investigator observed the aforementioned packaging spill its contents during the drop testing.

8. It is the responsibility of the packaging manufacturer to assure that each package is capable of passing the prescribed tests.

9. Respondent failed to ensure that packaging was capable of meeting required tests, in violation of the HMR.

- Please see Inspection/Investigation Report Number 22303006 at pages 3-4 and the exhibits that accompany this report, which are incorporated herein.

FACTS ALREADY CONSIDERED (UNDER 49 CFR § 107.331) IN SETTING PROPOSED PENALTIES

Prior Violations:

When setting a civil penalty, PHMSA will review the respondent's compliance history and determine if there are any finally-adjudicated violations of the HMR initiated within the previous six years. Only cases or tickets that have been finally-adjudicated will be considered (i.e., the ticket has been paid, a final order has been issued, or all appeal remedies have been exhausted or expired). PHMSA will include prior violations that were initiated within six years of the present case; a case or ticket will be considered to have been initiated on the date of the exit briefing for both the prior case and the present case. If multiple cases are combined into a single Notice of Probable Violation or ticket, the oldest exit briefing will be used to determine the six-year period. If a situation arises where no exit briefing is issued, the date of the Notice of Probable Violation or Ticket will be used to determine the six-year period. PHMSA may consider prior violations of the Hazardous Materials Regulations from other DOT Operating Administrations.

The general standards for increasing a baseline proposed penalty on the basis of prior violations are as follows (49 CFR Part 107, Subpart D, Appendix A):

1. For each prior civil or criminal enforcement case—25 percent increase over the pre-mitigation recommended baseline penalty.
2. For each prior ticket—10 percent increase over the pre-mitigation recommended baseline penalty.

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3. If a respondent is cited for operating under an expired special permit and previously operated under an expired special permit (as determined in a finally-adjudicated civil, criminal, or administrative enforcement case or a ticket), PHMSA will increase the civil penalty 100 percent.
4. If a respondent is cited for the exact same violation that it has been previously cited for within the six-year period (in a finally-adjudicated civil, criminal, or administrative enforcement case or a ticket), PHMSA will increase the baseline for that violation by 100 percent. This increase will apply only when the present violation is identical to the previous violation and applies only to the specific violation that has recurred.
5. A baseline proposed penalty (both for each individual violation and the combined total) will not be increased more than 100 percent on the basis of prior violations.

PHMSA's records do not contain any prior violations by Respondent and PHMSA did not consider any prior violations in determining the proposed assessment for the violation in this Notice.

Penalty Increases for Multiple Counts:

PHMSA generally will treat multiple occurrences that violate a single regulatory provision as separate violations and assess the applicable baseline penalty for each distinct occurrence of the violation. PHMSA will generally consider multiple shipments or, in the case of package testers, multiple package designs, to be multiple occurrences; and each shipment or package design may constitute a separate violation.

PHMSA, however, will exercise its discretion in each case to determine the appropriateness of combining into a single violation what could otherwise be alleged as separate violations and applying a single penalty for multiple counts or days of a violation, increased by 25 percent for each additional instance, as directed by 49 U.S.C. 5123(c). For example, PHMSA may treat a single shipment containing three items or packages that violate the same regulatory provision as a single violation and apply a single baseline penalty with a 50 percent increase for the two additional items or packages; and PHMSA may treat minor variations in a package design for a package tester as a single violation and apply a single baseline penalty with a 25 percent increase for each additional variation in design.

When aggravating circumstances exist for a particular violation, PHMSA may handle multiple instances of a single regulatory violation separately, each meriting a separate baseline or increase the civil penalty by 25 percent for each additional instance. Aggravating factors may include increased safety risks, continued violation after receiving notice, or separate and distinct acts. For example, if the multiple occurrences each require their own distinct action, then PHMSA may count each violation separately (e.g., failure to obtain approvals for separate fireworks devices) (49 CFR Part 107, Subpart D, Appendix A).]

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Corrective Action:

An important purpose of PHMSA's enforcement program is to bring the regulated community into compliance with the HMR, and to promote ongoing efforts by that community to maintain compliance. In determining the final penalty assessment, PHMSA considers documented evidence of actions taken by a Respondent to correct violations and ensure that they do not recur (49 CFR § 107.331(g)).

- Violation No.1: Respondent contacted customers to remove packagings from the market and identified the root cause of the failure. Respondent implemented new procedures and performed additional testing. Additionally, Respondent updated its production documentation for quality control. Based on this information, the proposed penalty has been reduced by 20%.

For possible mitigation of the proposed penalty amount, Respondent may provide information, such as any updated test reports and current information about the packaging, retesting, etc.

Financial Status

Under 49 CFR §107.331 (e) and (f), the proposed penalty may be reduced if Respondent demonstrates that it is unable to pay that penalty, or if payment of the proposed penalty would affect Respondent's ability to continue in business. Respondent's poor financial condition may be a basis for reducing the proposed penalty; a healthy financial condition is *not* a basis for increasing the penalty.

PHMSA has no information that indicates that Respondent is unable to pay the proposed penalty or that payment of the proposed penalty will affect Respondent's ability to continue in business. If Respondent wishes its financial condition to be considered in assessing a penalty for the violation(s) alleged in this Notice, it must provide current financial information (i.e., copies of Respondent's three most current Federal tax returns, an income statement, and a current balance sheet preferably certified).

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TOTAL CIVIL PENALTY PROPOSED

Probable Violation	Baseline Penalty	Corrective Action	Proposed Penalty
1	\$10,500	\$2,100	\$8,400
Total	\$10,500	\$2,100	\$8,400

ADDENDUM B

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**DEPARTMENT OF TRANSPORTATION
PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION**

How do I respond to this Notice of Probable Violation (Notice)?

You may respond to this Notice in any of three ways:

- (1) Pay the proposed assessment (49 C.F.R. § 107.315);
- (2) Send an informal response, which can include a request for an informal conference (§ 107.317); or
- (3) Request a formal hearing (§ 107.319).

How do I pay the proposed assessment?

You pay the proposed assessment by:

- (1) Sending a wire transfer, through the Federal Reserve Communications System (Fedwire), to the U.S. Treasury account (49 C.F.R. § 89.21(b)(3)). Addendum C contains the instructions for sending wire transfers. Questions concerning wire transfers should be directed to: DOT/PHMSA/MMAC, AMK-325/HQ-RM 181 6500 S MacArthur Blvd., Oklahoma City, OK 73169 (Telephone No. (405) 954-9309).

Or

- (2) Sending a certified check or money order if the penalty amount is \$10,000 or less. The certified check or money order must be payable to the "U.S. Department of Transportation" and must be mailed to: DOT/PHMSA/MMAC, AMK-325/HQ-RM 181 6500 S MacArthur Blvd., Oklahoma City, OK 73169 (Telephone No. (405) 954-9309).

Or

- (3) Using a credit card via the Internet. To pay electronically with a credit card, visit the following website address and follow the instructions:

<https://www.pay.gov/public/form/start/1078346>

Where do I send my response?

You must address your informal response or formal hearing request to the attorney who issued the Notice at the following address:

Pipeline and Hazardous Materials Safety Administration
Office of the Chief Counsel (PHC-10)
Room E26-105
U.S. Department of Transportation
1200 New Jersey Avenue S.E.
Washington, D.C. 20590

When is my response due? (§ 107.313)

You must respond to the Notice within thirty (30) days of the date you receive it. The attorney who issued the Notice may extend the 30-day period for your response if you ask for an extension, and show good cause, within the original 30-day period.

What happens if I do not respond? (§ 107.313)

If you fail to respond to the Notice within thirty (30) days of receiving it (or by the end of any extension), you will waive your right to contest the allegations made in Addendum A to the Notice. In addition, the Chief Counsel will issue a default Order finding the facts as alleged in the Notice and assessing the civil penalty as outlined within that notice.

May I propose a compromise offer? (§ 107.327)

Yes. At any time before an order is issued and referred to the Attorney General for collection, you may propose to compromise a civil penalty case by submitting a specific compromise offer amount to the attorney handling the case (§ 107.327). The Chief Counsel may also propose a compromise.

If a compromise is agreeable to all parties, the attorney handling the case will forward a compromise agreement to you for signature. This document will outline the terms of the joint agreement and you must return a signed original to the attorney handling the case within 30 days. After this agreement has been returned it will be signed by the assigned attorney and presented to the Chief Counsel with a request that the Chief Counsel adopt the terms of that agreement by issuing a Compromise Order (49 C.F.R. § 107.327(a)(1)). The terms of the agreement constitute an offer of compromise until accepted by the Chief Counsel. When you agree to a compromise, you give up your right to appeal the order issued by the Chief Counsel.

What should I include in my informal response? (§107.317)

Your informal response must contain written explanations, information or arguments that respond to the allegation(s), the amount of the proposed civil penalty, or the terms of a proposed compliance order. Provide complete documentation of your explanations and arguments. No specific format is required for an informal response.

May I request an informal conference? (§ 107.317)

Yes. You may request an informal conference as part of your informal response. Please describe the issues you want to discuss during the conference. After receiving your request, the attorney handling the case will contact you to arrange the conference. Normally the conference will be held by telephone, and the attorney handling the case and the inspector who conducted the compliance inspection will participate in the conference.

What happens after I submit an informal response to the Notice?

We will hold an informal conference if you have asked for one. Based on the Notice, the evidence supporting the Notice, any written explanations, information and documentation that you provide, and matters presented at a conference, the Chief Counsel decides the case. The Chief Counsel may issue an order finding all or some of the violation(s) alleged in the Notice or may withdraw all or some of the alleged violation(s). If the Chief Counsel finds violation(s), the order will assess a civil penalty.

How do I appeal an order? (§ 107.325)

You may appeal an order to PHMSA's

Administrator. How do I request a formal hearing? (§ 107.319)

You must request a formal hearing within 30 days of the date that you receive the Notice. If you are granted an extension of time to respond to the Notice, you must submit a formal hearing request by the end of the extended time period. If you do not request a formal hearing within the specified time, you will waive your right to a formal hearing.

Your request for a formal administrative hearing must include the following:

- (1) The name and address of the respondent and any other person submitting the request;
- (2) A statement of which allegations of violations are not in dispute; and
- (3) A description of the issues that you will raise at the hearing. (The Administrative Law Judge will decide whether issues not raised in the request may be raised at the hearing.)

After receiving a request for a hearing that complies with these requirements, the Chief Counsel will request an Administrative Law Judge from the DOT Office of Hearings to preside over the hearing. Once an Administrative Law Judge is assigned, all further matters in the proceeding will be conducted by the Administrative Law Judge. Either you or PHMSA may appeal the decision of the Administrative Law Judge to PHMSA's Administrator.

How does PHMSA determine if I have committed a violation?

This is a civil penalty case and PHMSA uses the "knowingly" standard, which is defined in the Federal hazardous materials transportation law (See 49 U.S.C. 5123(a)(1)), in all civil penalty cases. The standard for a violation is similar to "negligence". After considering all the available information (including the additional information you provide in your response to the Notice), PHMSA must find either that (1) you had actual knowledge of the facts giving rise to the violation, or (2) you had imputed knowledge, of the facts giving rise to the violation, in that a reasonable person acting in the circumstances and exercising reasonable care would have that knowledge. PHMSA does not need to find that you actually knew about, or intended to violate, requirements in the Federal hazardous material transportation law or the HMR.

What factors does PHMSA consider when proposing and assessing a civil penalty? (§ 107.331)

PHMSA considers the following factors when proposing and assessing a civil penalty for a violation of the regulations:

- (1) The nature and circumstances of the violation(s);
- (2) The extent and gravity of the violation(s);
- (3) The degree of your culpability;
- (4) Your history, if any, of prior offenses;
- (5) Your ability to pay the penalty;
- (6) The effect of the penalty on your ability to continue in business;
- (7) The size of your business, and
- (8) Other matters as justice may require.

The nature and the timeliness of any corrective action you take to prevent future violations of a similar nature will be considered under item No. 8. However, you must submit documented evidence of that corrective action to the PHMSA attorney. If you have submitted documented evidence regarding any of these factors during PHMSA's investigation of the alleged violation(s), and that documentation is referenced in the Notice or accompanying Inspection/Investigation Report, you do not need to resubmit it.

Under the Small Business Regulatory Enforcement Fairness Act (SBREFA), PHMSA must consider the rights of small entities in enforcement actions. PHMSA's hazardous materials enforcement program has been designed to consider small businesses and the penalties that PHMSA proposes and assesses are generally considered appropriate for small businesses. PHMSA takes into consideration the size of the company when proposing and assessing a civil penalty.

However, special consideration may not be given to a small business if:

- (1) The small business has not corrected its violation(s) within a reasonable time;
- (2) The small business has committed one or more prior violations of the HMR;
- (3) The violations involve willful conduct;
- (4) The violations pose serious threats to health, safety or the environment; or
- (5) The small business has not made a good faith effort to comply with the law.

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. Our objective is to ensure a fair regulatory enforcement environment.

You have a right to contact the Small Business Administration's national Ombudsman at 1-888- REG-FAIR (1-888-734-3247) or <https://www.sba.gov/ombudsman> regarding the fairness of the compliance and enforcement activities by this agency.

The Pipeline and Hazardous Materials Safety Administration strictly forbids retaliatory acts by its employees. As such, you should feel confident that you will not be penalized for expressing your concerns about compliance and enforcement activities.

Where can I find more information on how PHMSA handles hazardous materials enforcement cases?

A more detailed discussion of these procedures is in 49 C.F.R. §§ 107.301 through 107.333. These procedures are also on the Office of the Chief Counsel's home page at <http://www.phmsa.dot.gov/org/office-of-chief-counsel>.

ADDENDUM C

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**INSTRUCTIONS FOR ELECTRONIC FUNDS TRANSFER TO
PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION,
U.S. DEPARTMENT OF TRANSPORTATION**

1. <u>RECEIVER'S ABA NO.</u> 021030004	2. <u>TYPE SUBTYPE</u> (provided by sending bank)
3. <u>SENDING BANK ARB NO.</u> (provided by sending bank)	4. <u>SENDING BANK REF NO.</u> (provided by sending bank)
5. <u>AMOUNT</u>	6. <u>SENDING BANK NAME</u> (provided by sending bank)
7. <u>RECEIVER NAME:</u> TREAS NYC	8. <u>PRODUCT CODE</u> (Normally CTR, or sending bank)
9. <u>BENEFICIAL (BNF)- AGENCY LOCATION CODE</u> BNF=/AC-69140001	10. <u>REASONS FOR PAYMENT</u> <i>Example: PHMSA Payment for Case #/Ticket</i>

INSTRUCTIONS: You, as sender of the wire transfer, must provide the sending bank with the information for Block (1), (5), (7), (9), and (10). The information provided in blocks (1), (7), and (9) are constant and remain the same for all wire transfers to the Pipeline and Hazardous Materials Safety Administration, Department of Transportation

Block #1 - RECEIVER ABA NO. - "021030004". Ensure the sending bank enters this nine digit identification number; it represents the routing symbol for the U.S. Treasury at the Federal Reserve Bank in New York.

Block #5 - AMOUNT - You as the sender provide the amount of the transfer. Please be sure the transfer amount is punctuated with commas and a decimal point. **EXAMPLE:** **\$10,000.00**

Block #7 - RECEIVER NAME- "TREAS NYC." Ensure the sending bank enters this abbreviation, which must be used for all wire transfer to the Treasury Department.

Block #9 - BENEFICIAL - AGENCY LOCATION CODE - "BNF=/AC-69140001" Ensure the sending bank enters this information. This is the Agency Location Code for Pipeline and Hazardous Materials Safety Administration, Department of Transportation

Block #10 - REASON FOR PAYMENT – "AC-Payment for PHMSA Case#" To ensure your wire transfer is credited properly, enter the case number/ticket number or Pipeline Assessment number."

Note: - A wire transfer must comply with the format and instructions or the Department cannot accept the wire transfer. You, as the sender, can assist this process by notifying, at the time you send the wire transfer, the General Accounting Division at (405) 954-9309.

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PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION,
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