DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	11/17/2025-11/21/2025
	FEI NUMBER 3003076465

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Furuyashiki Nobuyoshi, Deputy Plant Manager

FIRM NAME	STREET ADDRESS
Nissan Chemical Corporation	6903-1 Onoda
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sanyo-Onoda, Yamaguchi, 756-0093 Japan	Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

Stability studies do not support the labeled retest date.

Specifically,

Your firm does not perform microbial testing during stability studies to establish the risk of microbial contamination throughout the (b) (4) shelf life or retest date of (b) (4) API.

(b) (4) batches of (b) (4) API were released for the US market within the last three years since November 2022.

AMENDMENT 1

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Sara H Gabel, Investigator

X Sara H Gabel
Investigator
Signed By: 2003025353
Date Signed: 11-21-2025
15:13:36

DATE ISSUED
11/21/2025