

NPPTL COVID-19 Response: Beyond Shelf Life/Stockpiled Respirator Assessment

Manufacturer: Safe Life Corporation

Model Tested: A450 (LOT # 090824)

Date Tested: May 14, 2020

Report Prepared: May 14, 2020

These findings pertain to the Safe Life Corporation, A450 (LOT # 090824) submitted for testing, and may not be applicable to other stockpile facilities and/or under different environmental storage conditions. The maximum and minimum filter efficiency was 98.41% and 70.30%, respectively. Eleven respirators measured more than 95% efficiency. Nine respirators measured less than 95% efficiency. There was no designated expiration date for these models by the previously held NIOSH approval holder.

NIOSH regulation sets the minimum quality and performance requirements for the approval of respirators (42 CFR 84). **NIOSH does not have requirements for shelf life or storage conditions for particulate-only APRs.** The approval holder (i.e. the entity that is granted the approval from NIOSH) is responsible for understanding how their products' design or performance may be affected by various use or storage conditions and must provide instruction for establishing the proper use, storage, and maintenance procedures for their approved products, which may include designating a shelf life. FFR or particulate filter packaging (such as the box) often includes NIOSH-approved user instructions, label information, and recommendations on shelf life. Additionally, some approval holders also disseminate recommendations related to storage and shelf life through resources such as user and web notices. The respirators tested in this study were generally not designed for long-term storage.

Based on research conducted by NIOSH and this limited testing, NIOSH does not have enough information to definitively know the level of protection that may be provided by respirators that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the approval holder's designated shelf life. Users of respirators that have exceeded the designated shelf life should be forewarned to avoid a false sense of confidence; these devices may not provide the same level of protection as those that have not exceeded the designated shelf life. We recommend contacting the approval holder(s) of the respirators in the stockpile with specific questions regarding the use of product beyond the manufacturer- designated shelf life.

The results provided in this letter are specific to the subset of NIOSH-approved N95s, past their designated shelf life, that were provided to NPPTL for evaluation.

These results will be added to the CDC guidance for [Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life](#).

Evaluation of Stockpiled and Beyond Manufacturer-Designated Shelf Life N95s



Test: TEB-APR-STP-0059

Manufacturer: Safe Life Corporation

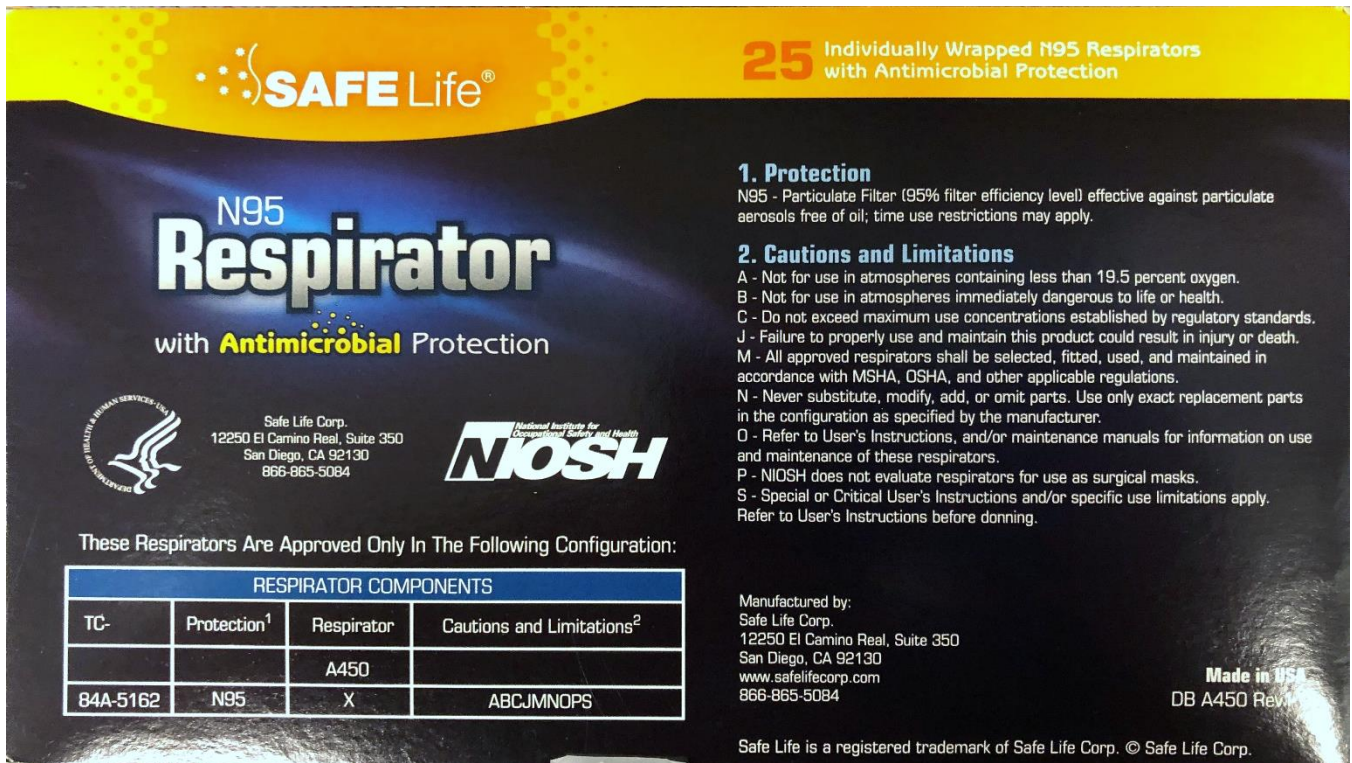
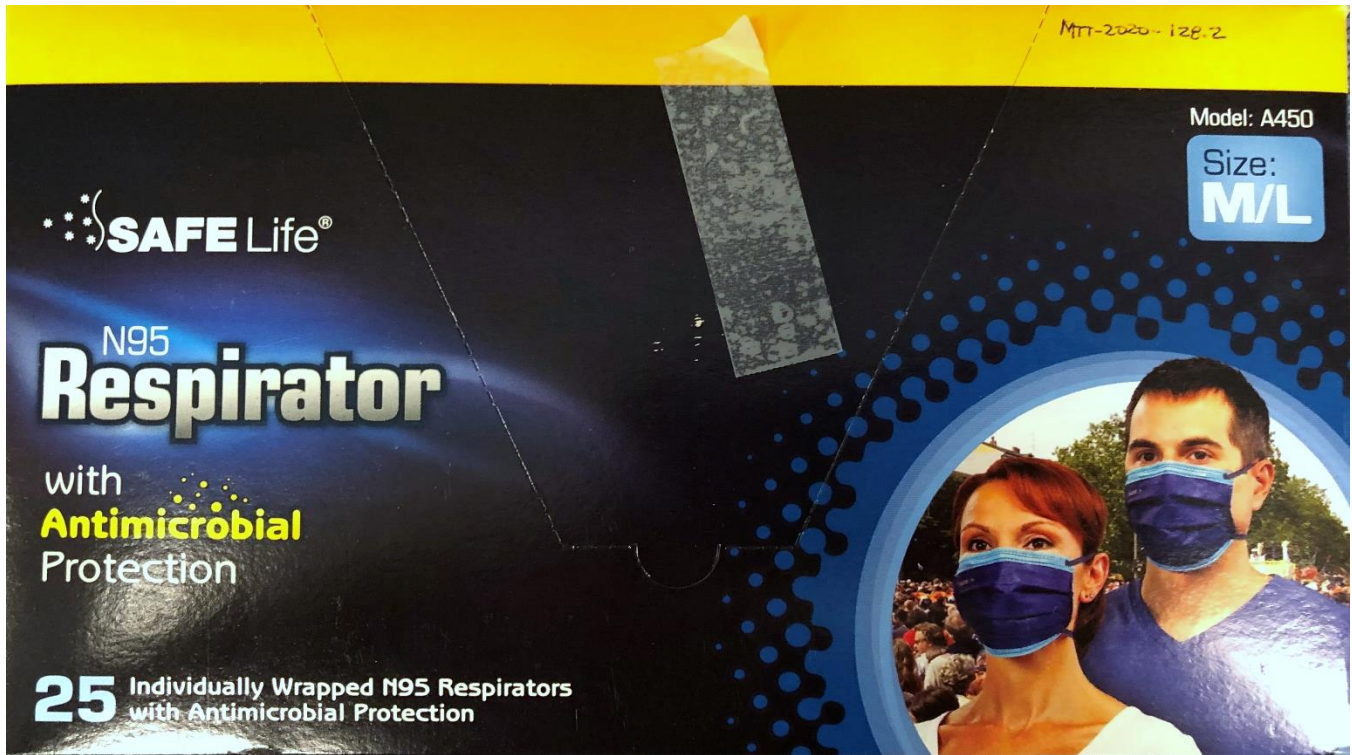
Item Tested: A450 (LOT # 090824)

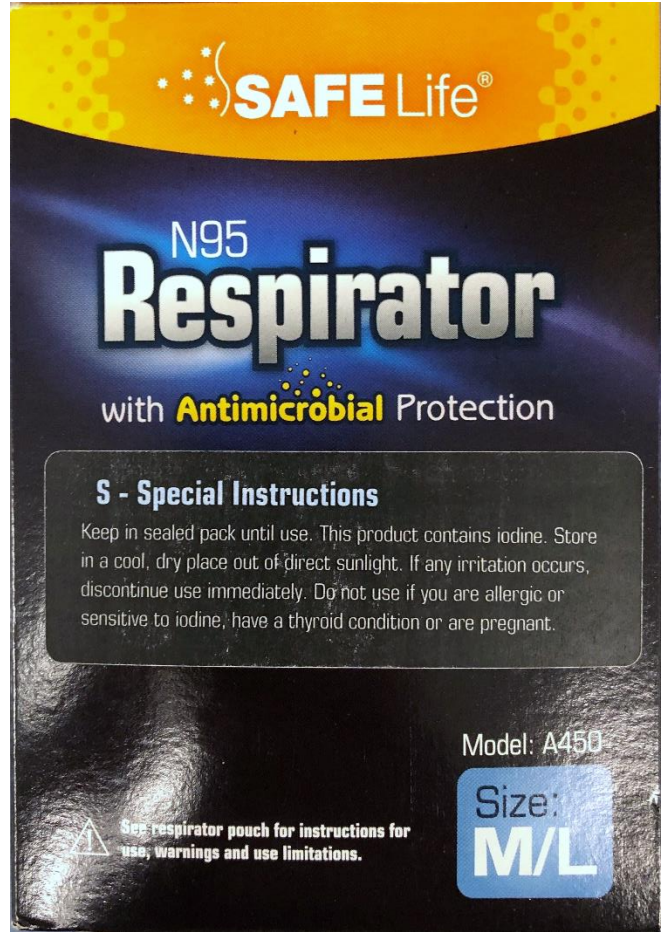
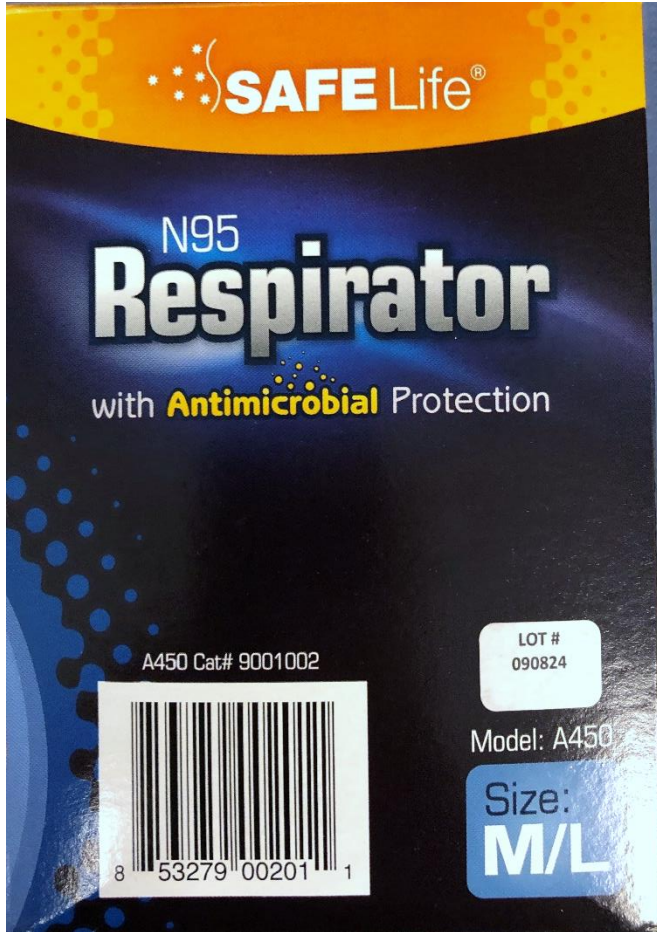
Expiration Date: None Provided

Manufacture Date: None Provided

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	16.9	17.6	21.5	78.50
2	85	12.4	3.09	3.29	96.71
3	85	13.7	2.73	2.74	97.26
4	85	8.2	1.55	1.98	98.02
5	85	12.5	22.5	23.3	76.70
6	85	14.9	22.0	22.0	78.00
7	85	7.2	24.5	25.4	74.60
8	85	12.6	18.2	19.7	80.30
9	85	9.1	4.12	4.77	95.23
10	85	11.0	2.21	2.79	97.21
11	85	13.1	3.12	3.22	96.78
12	85	13.0	10.6	10.6	89.40
13	85	12.1	28.5	28.5	71.50
14	85	12.8	20.3	20.3	79.70
15	85	10.2	29.7	29.7	70.30
16	85	14.7	1.53	1.59	98.41
17	85	11.6	2.35	2.84	97.16
18	85	9.0	1.94	2.27	97.73
19	85	9.6	1.53	1.70	98.30
20	85	9.5	1.79	2.22	97.78
Minimum Filter Efficiency: 70.30			Maximum Filter Efficiency: 98.41		

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128.2

Model: A450

Size: **M/L**

Quantity: **1**
Single Use Only
(Disposable)

SAFE Life®

N95 Respirator
with **Antimicrobial** Protection

Donning and Fitting

- Pre-shape the nose clip at the top center of the respirator as it will rest over the bridge of the nose.
- Hold the respirator in one hand with straps dangling beneath and the inside of the respirator facing upward.
- Hold the respirator against the face, pull the top head strap over the head and position it above the ears. Pull the lower head strap over the head and position it around the neck below the ears.
- Hold the nose clip while pulling down on the bottom of the respirator to open the pleats and position the bottom of the respirator just beneath the chin. Press nose clip to form along the nose on both sides until a good seal is established.
- FIT CHECK:** Place both hands on the edges of the respirator, being careful not to disturb the position of the respirator. Exhale sharply to detect any leakage. If you detect air leaks, re-position or replace the mask as needed to achieve a satisfactory seal.

Removal of Respirator
After use, microorganisms may be present on the exterior surface of any mask or respirator. Remove the used protective device carefully, avoiding self-contamination, and immediately sanitize hands. Disinfect surfaces in the immediate area where droplets of microorganisms may have fallen.

Important
If you cannot achieve a satisfactory fit, do not enter the contaminated area. Failure to follow all instructions and limitations can seriously reduce the effectiveness of any respirator and could lead to illness, injury or disease. Respirators cannot completely eliminate the risk of contracting disease or infection.

FW A450 Rev1.0
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HEAD STRAPS

LOT #
090824

Use Information

- Failure to follow all instructions and limitations can seriously reduce the effectiveness of this respirator and could lead to illness, injury or death.
- Before occupational use, the wearer must be trained by the employer in the correct use of the respirator in accordance with applicable safety and health standards.
- OSHA standards including 29CFR 1910.134(e) (5) and CSA standard Z94.4-83 require that the wearer be fit-tested either qualitatively or quantitatively.
- Discard the respirator and replace with a new one if:
 - excessive clogging of the respirator causes breathing difficulty
 - the respirator becomes damaged.

Use Limitations

- Do not use the respirator or enter or stay in a contaminated area under the following circumstances:
 - atmosphere contains less than 19.5% oxygen
 - if you smell or taste a contaminant
 - for protection against gases or vapors
 - contaminants or their concentrations are unknown or immediately dangerous to life or health
 - concentrations of contaminants exceed maximum use

5. Discard the respirator and replace with a new one after every use.

6. Leave the contaminated area if dizziness, irritation or other distress occurs.

concentrations in applicable OSHA standards or applicable government regulations or 10 times the PEL (Permissible Exposure Limit), whichever is lower

- for sandblasting, paint-spray operations, asbestos exposure.
- Do not alter, abuse or misuse the respirator.
- Do not use the respirator with obstructive facial hair such as beards or with other conditions that may prevent a good seal between the face and the seating surface of the respirator.

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