

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

Manufacturer: Safe Life Corporation

Model Tested: A430 (LOT # 091110)

Date Tested: May 13, 2020

Report Prepared: May 14, 2020

These findings pertain to the Safe Life Corporation, A430 (LOT # 091110) 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 95.53% and 84.80%, respectively. One respirator measured more than 95% efficiency. Nineteen 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

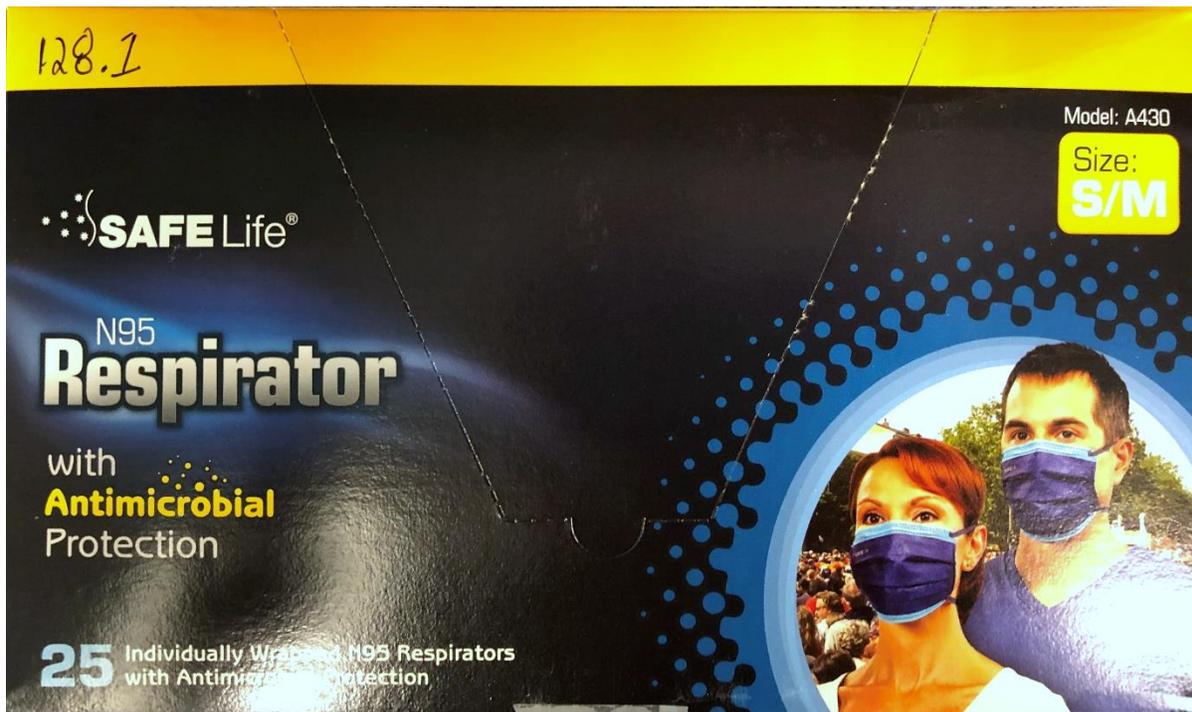
Item Tested: A430 (LOT # 091110)

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	9.7	5.64	6.40	93.60
2	85	11.8	4.14	4.47	95.53
3	85	9.6	11.2	12.3	87.70
4	85	12.1	12.7	12.9	87.10
5	85	10.7	10.8	11.0	89.00
6	85	10.0	12.8	15.2	84.80
7	85	11.8	8.15	8.15	91.85
8	85	9.3	10.4	12.2	87.80
9	85	14.0	8.04	8.04	91.96
10	85	11.4	7.01	7.12	92.88
11	85	12.2	5.84	5.99	94.01
12	85	8.4	14.1	14.4	85.60
13	85	9.2	7.65	7.79	92.21
14	85	11.2	6.54	6.83	93.17
15	85	8.4	12.3	14.6	85.40
16	85	8.3	12.5	15.1	84.90
17	85	10.6	4.85	5.35	94.65
18	85	9.4	11.3	13.3	86.70
19	85	10.8	4.83	5.57	94.43
20	85	10.6	4.99	5.58	94.42
Minimum Filter Efficiency: 84.80			Maximum Filter Efficiency: 95.53		

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SAFE Life®

25 Individually Wrapped N95 Respirators with Antimicrobial Protection

N95 Respirator
with **Antimicrobial Protection**

Safe Life Corp.
12250 El Camino Real, Suite 350
San Diego, CA 92130
866-865-5084

NIOSH
National Institute for Occupational Safety and Health

These Respirators Are Approved Only In The Following Configuration:

RESPIRATOR COMPONENTS			
TC-	Protection ¹	Respirator	Cautions and Limitations ²
84A-5161	N95	A430	ABCJMNOPS

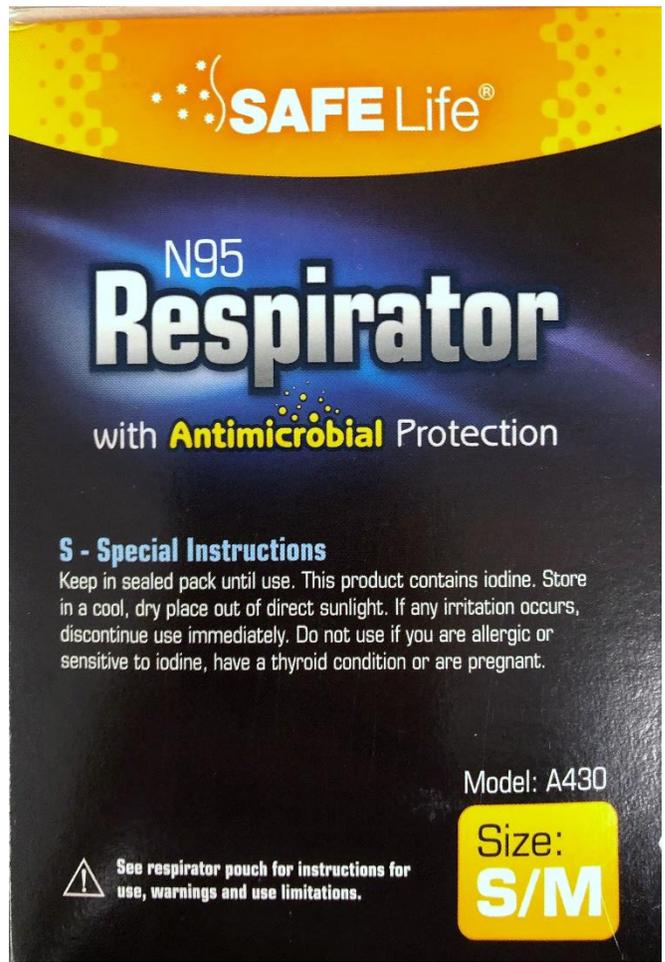
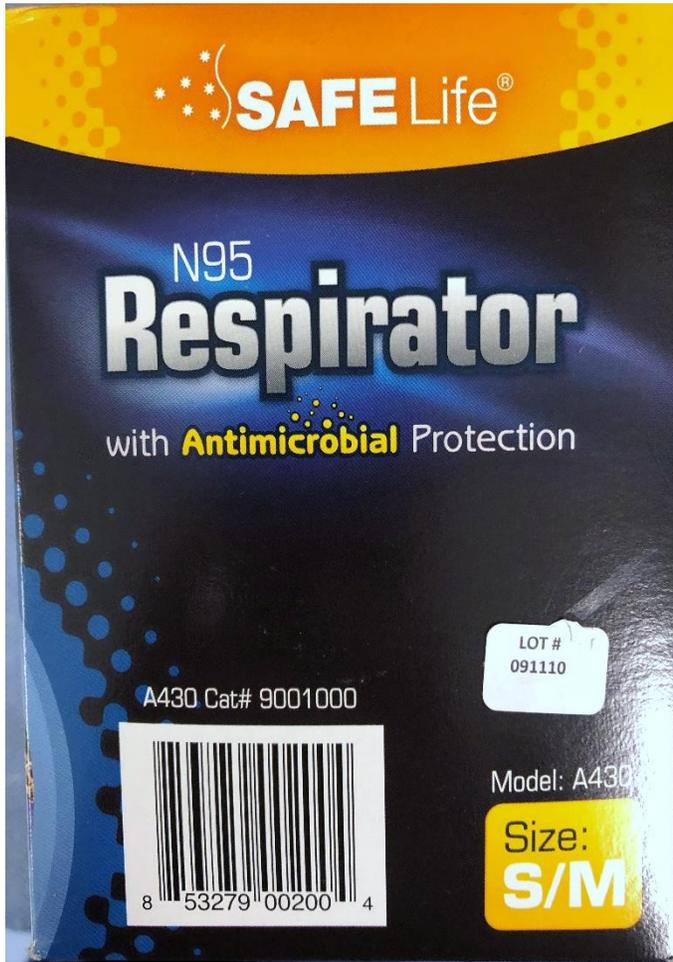
1. Protection
N95 - Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.

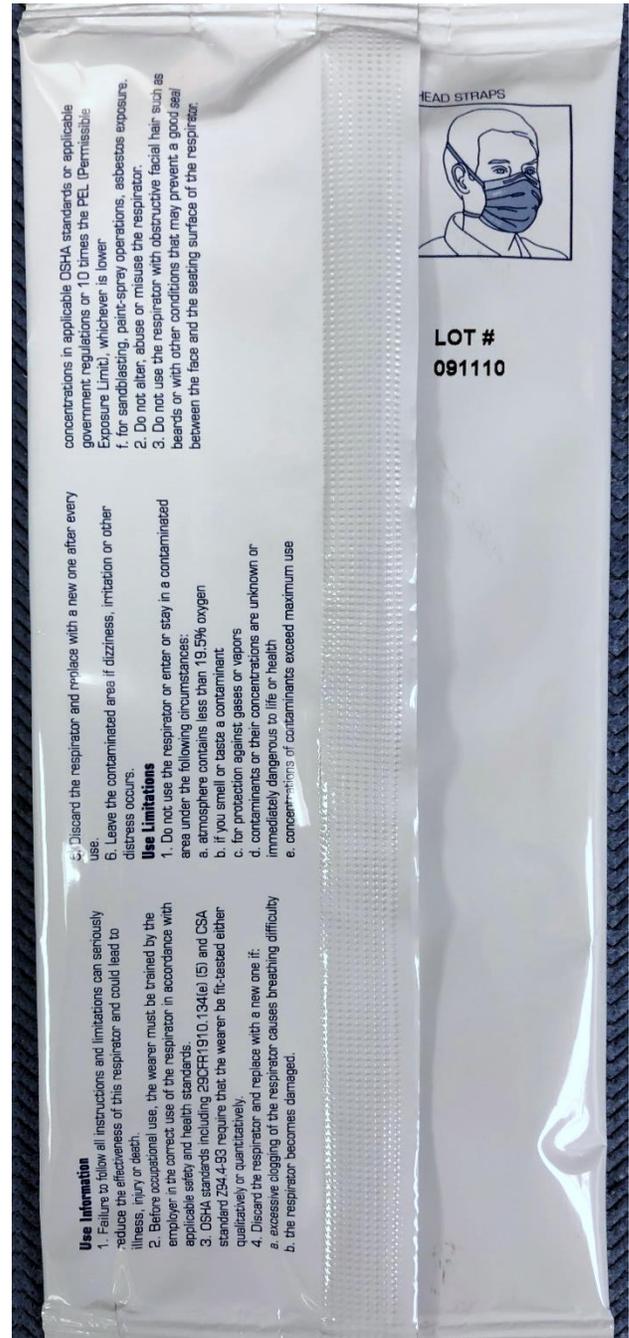
2. Cautions and Limitations
 A - Not for use in atmospheres containing less than 19.5 percent oxygen.
 B - Not for use in atmospheres immediately dangerous to life or health.
 C - Do not exceed maximum use concentrations established by regulatory standards.
 J - Failure to properly use and maintain this product could result in injury or death.
 M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
 N - Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
 O - Refer to User's Instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
 P - NIOSH does not evaluate respirators for use as surgical masks.
 S - Special or Critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

Manufactured by:
Safe Life Corp.
12250 El Camino Real, Suite 350
San Diego, CA 92130
www.safelifecorp.com
866-865-5084

Made in USA
DB A430 Rev1.1

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