

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

Manufacturer: Safe Life Corporation

Model Tested: B130 N95 Respirator & Surgical Mask (LOT # 356628)

Date Tested: April 25, 2020

Report Prepared: April 27, 2020

These findings pertain to the Safe Life Corporation, model B130 N95 Respirator and Surgical Mask submitted for testing, and may not be applicable to other stockpile facilities and/or under different environmental storage conditions. No failures for filtration performance were observed—i.e., the performance data suggests that these units would be protective so long as a proper fit is achieved. The maximum and minimum filter efficiency was 99.47% and 98.97%, respectively. All twenty respirators measured more than 95% efficiency. The designated expiration date for these models by the previously held NIOSH approval holder is 10/2022.

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

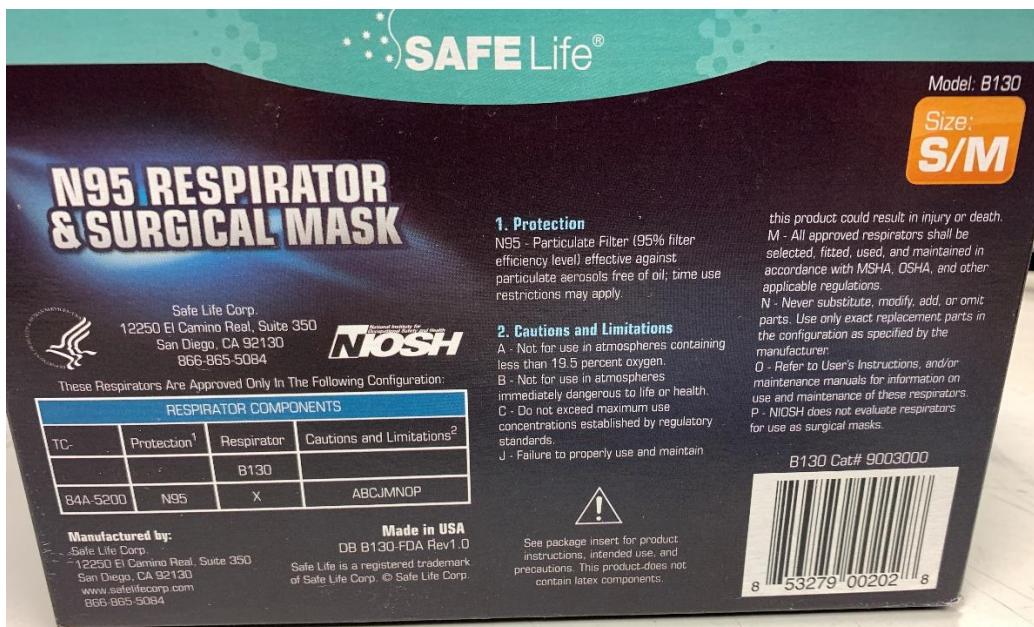
Item Tested: B130 N95 RESPIRATOR & SURGICAL MASK (LOT # 356628)

Expiration Date: 10/2022

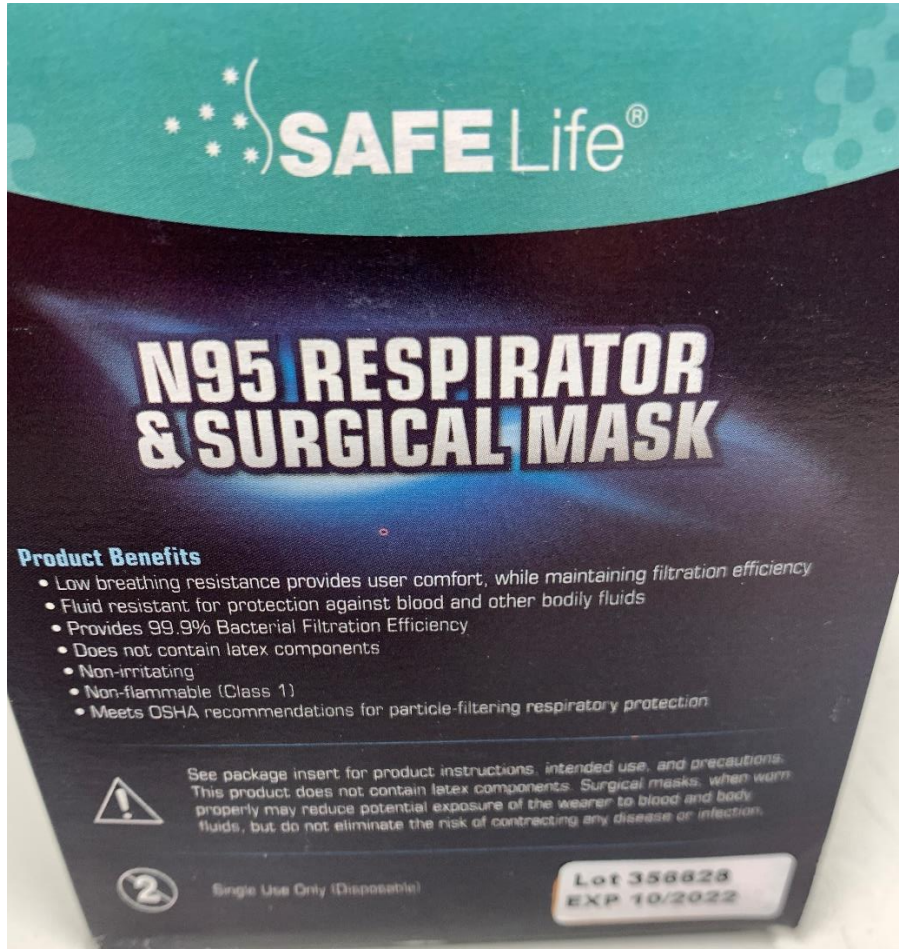
Manufacture Date: None Provided

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	14.1	0.53	0.53	99.47
2	85	11.7	0.71	0.71	99.29
3	85	15.5	1.03	1.03	98.97
4	85	15.0	0.77	0.77	99.23
5	85	16.7	.069	0.69	99.31
6	85	14.5	0.66	0.66	99.34
7	85	15.7	0.68	0.68	99.32
8	85	16.0	0.63	0.63	99.37
9	85	13.5	0.76	0.76	99.24
10	85	14.5	0.65	0.65	99.35
11	85	15.5	0.70	0.70	99.30
12	85	15.8	0.59	0.59	99.41
13	85	15.5	0.72	0.72	99.28
14	85	15.4	0.63	0.63	99.37
15	85	12.3	0.67	0.67	99.33
16	85	16.1	0.55	0.55	99.45
17	85	11.5	0.62	0.62	99.38
18	85	13.7	0.81	0.81	99.19
19	85	16.5	0.57	0.57	99.43
20	85	15.6	0.65	0.65	99.35
Minimum Filter Efficiency: 98.97			Maximum Filter Efficiency: 99.47		

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