

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

Manufacturer: Safe Life

Model Tested: B130 (LOT # 100923) and B150 (LOT # 100915)

Date Tested: April 11, 2020 (B150) and April 12, 2020 (B130)

Report Prepared: April 12, 2020

These findings pertain to the Safe Life B130 and B150 units from the facility in Kirtland AFB, New Mexico. They may not be applicable to other stockpile facilities and/or under different environmental storage conditions. No shelf life was designated for these models by the previously held NIOSH approval holder.

All tested samples passed the NIOSH filtration efficiency testing as indicated in the table below.

Based on the filtration results provided in this report, and under the circumstances regarding the shortage of NIOSH-approved respirators for the COVID-19 response, it is reasonable to assume that these products may perform as intended. NIOSH supports any requests the US Air Force makes to the FDA regarding the Safe Life B130 and Safe Life B150 inclusion in an FDA Emergency Use Authorization.

Based on prior research conducted by NIOSH and the limited testing results provided here, 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 time; 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.

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 air purifying respirators (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.

The results provided in this letter are specific to the subset of previously NIOSH-approved N95s 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 95s

Test: TEB-APR-STP-0059

Date Tested: April 11, 2020

Report Prepared: April 12, 2020

Manufacturer: Safe Life

Item Tested: B150 N95 RESPIRATOR & SURGICAL MASK LOT # 100915

Expiration Date: Not Provided **Manufacture Date:** Not Provided

Pictures have been added to the end of this report.

Respirator	Flow Rate Lpm	Initial Filter Resistance (mm H ₂ O)	Initial Penetration (%)	Maximum Penetration (%)	Filter Efficiency
1	85	22.4	0.742	0.742	99.26
2	85	21.0	1.02	1.02	98.98
3	85	16.7	0.472	0.472	99.53
4	85	20.6	0.788	0.833	99.17
5	85	19.1	0.733	0.733	99.27
6	85	18.5	0.770	0.770	99.23
7	85	19.3	0.746	0.746	99.25
8	85	18.6	0.765	0.765	99.23
9	85	18.8	0.647	0.647	99.35
10	85	18.4	0.853	0.853	99.15
11	85	21.4	0.868	0.868	99.13
12	85	18.1	1.17	1.17	98.83
13	85	19.5	0.828	0.828	99.17
14	85	20.4	1.08	1.08	98.92
15	85	19.8	0.765	0.765	99.23
16	85	19.5	0.872	0.872	99.13
17	85	23.7	0.871	0.871	99.13
18	85	21.8	0.935	0.954	99.05
19	85	21.2	0.954	0.954	99.05
20	85	17.5	0.762	0.762	99.24

Evaluation of Stockpiled and Beyond Manufacturer-Designated Shelf Life 95s

Test: TEB-APR-STP-0059

Date Tested: April 12, 2020

Report Prepared: April 12, 2020

Manufacturer: Safe Life

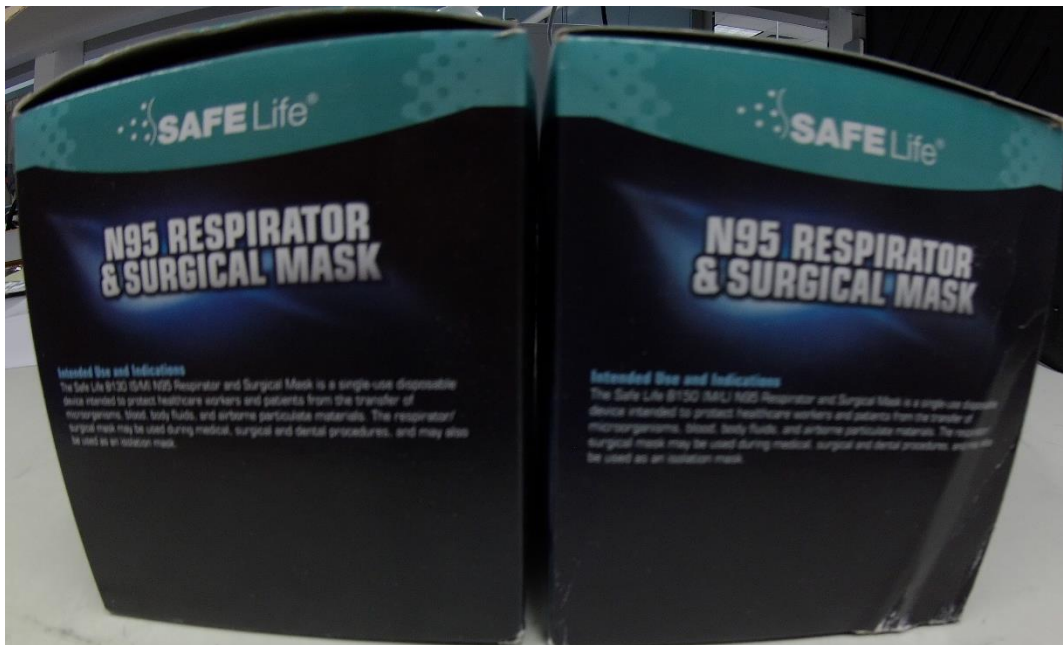
Item Tested: B130 N95 RESPIRATOR & SURGICAL MASK LOT # 100923

Expiration Date: Not Provided **Manufacture Date:** Not Provided

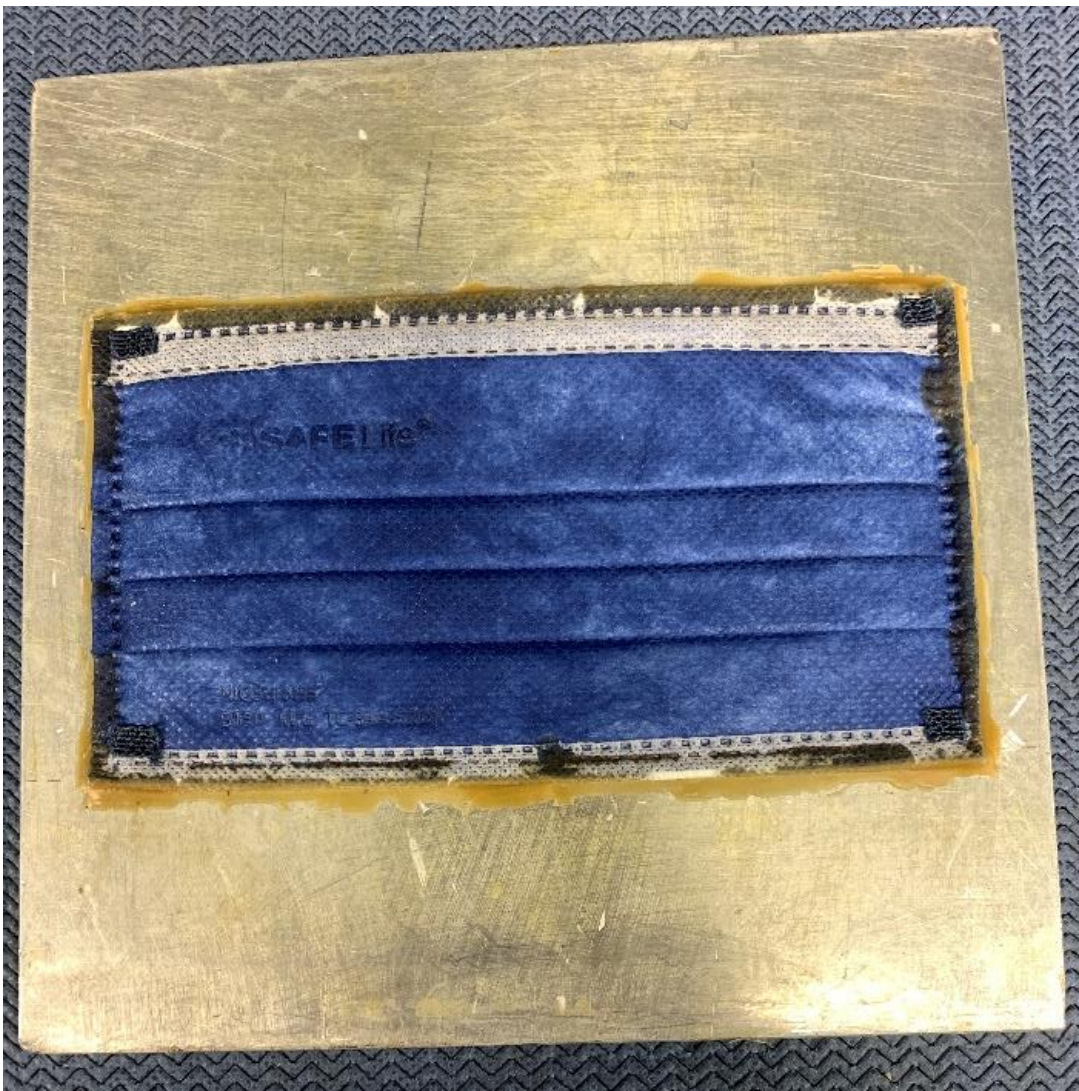
Pictures have been added to the end of this report.

Respirator	Flow Rate Lpm	Initial Filter Resistance (mm H ₂ O)	Initial Penetration (%)	Maximum Penetration (%)	Filter Efficiency
1	85	13.3	0.407	0.407	99.59
2	85	14.1	0.473	0.473	99.53
3	85	13.2	0.376	0.376	99.62
4	85	15.2	0.464	0.464	99.54
5	85	15.3	0.638	0.638	99.36
6	85	15.8	0.564	0.564	99.44
7	85	10.7	0.345	0.345	99.66
8	85	13.1	0.635	0.635	99.36
9	85	13.2	0.472	0.472	99.53
10	85	13.9	0.474	0.474	99.53
11	85	12.7	0.360	0.360	99.64
12	85	14.1	0.553	0.553	99.45
13	85	14.8	0.627	0.627	99.37
14	85	14.3	0.575	0.575	99.42
15	85	16.3	0.525	0.525	99.47
16	85	13.2	0.734	0.734	99.27
17	85	13.1	0.401	0.401	99.60
18	85	14.8	0.436	0.436	99.56
19	85	12.8	0.610	0.610	99.39
20	85	13.3	0.350	0.350	99.65

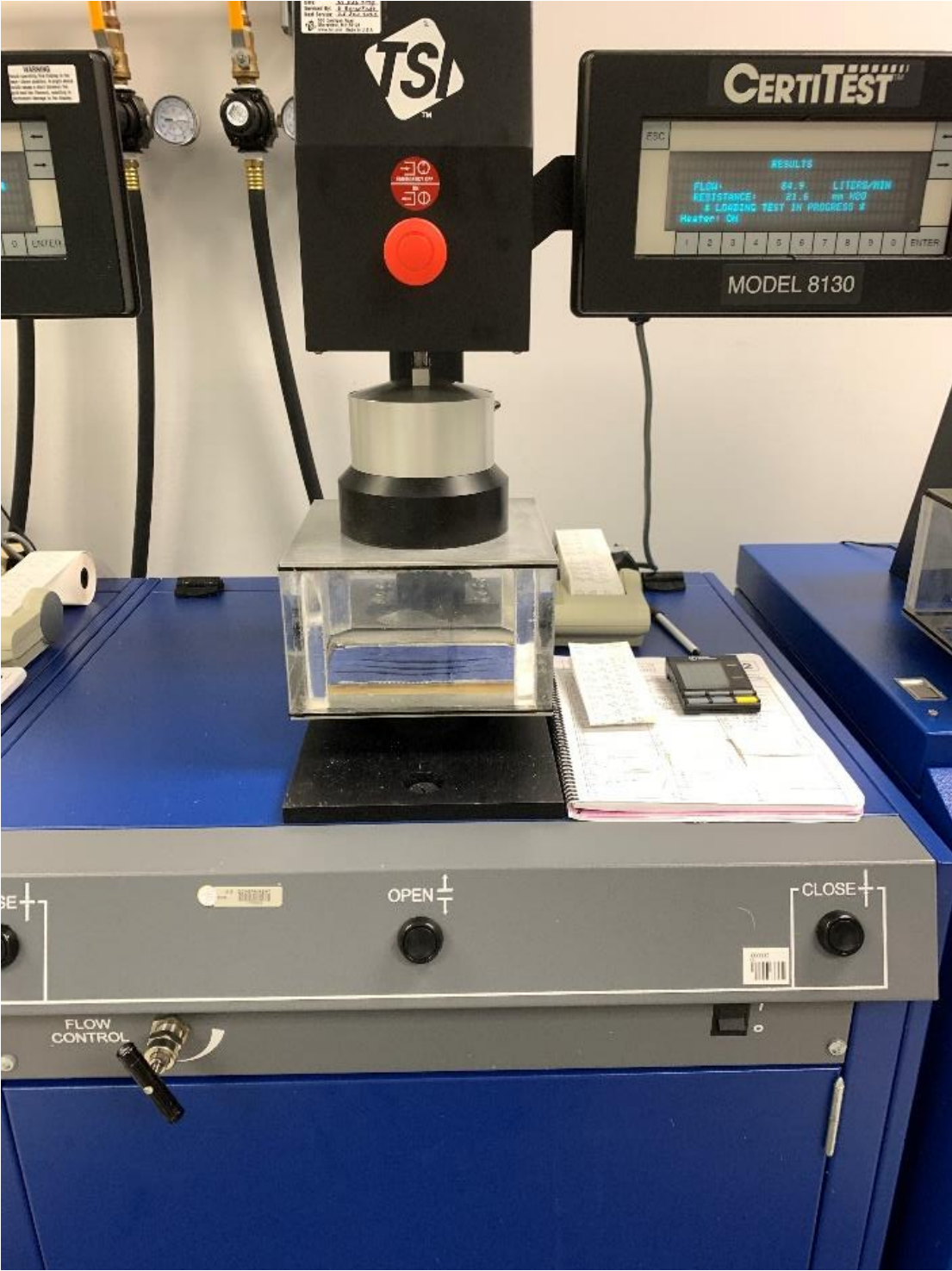
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