

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

Manufacturer: Safe Life and TrioMed

Models Tested: Safe Life B130 (LOT # 100615), TrioMed B130 (LOT # 101115),
Safe Life B150 (LOT # 100729)

Date Tested: April 14, 2020

Report Prepared: April 15, 2020

These findings pertain to the Safe Life B130 and B150 units from the facility in Fort Detrick, Maryland. 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.

The TrioMed model B130 (LOT # 101115) samples passed the NIOSH filtration efficiency testing. Four (4) of the samples from the Safe Life model B130 (LOT # 100615) failed the NIOSH filtration efficiency testing. All samples from the Safe Life model B150 (LOT # 100729) failed the NIOSH filtration efficiency test.

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 the TrioMed B130 products may perform as intended. NIOSH supports any requests the US Air Force makes to the FDA regarding the TrioMed B130 inclusion in an FDA Emergency Use Authorization.

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 unreasonable to assume that the Safe Life B130 and Safe Life B150 products perform as intended. NIOSH supports any requests the US Air Force makes to the FDA regarding the use of these products as surgical masks.

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.

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

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 14, 2020

Report Prepared: April 15, 2020

Manufacturer: Safe Life

Item Tested: B130 N95 RESPIRATOR & SURGICAL MASK LOT # 100615

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	7.2	5.39	5.80	94.20
2	85	8.3	5.02	5.63	94.37
3	85	10.1	2.67	2.71	97.29
4	85	8.9	2.05	2.15	97.85
5	85	8.6	1.84	1.84	98.16
6	85	7.4	4.44	5.28	94.72
7	85	10.3	1.79	1.83	98.17
8	85	8.7	2.31	2.33	97.67
9	85	11.3	2.60	2.60	97.40
10	85	8.4	4.24	4.80	95.20
11	85	7.3	9.85	10.20	89.80
12	85	8.3	1.90	2.02	97.98
13	85	9.2	2.99	3.05	96.95
14	85	8.3	2.98	3.13	96.87
15	85	9.8	2.56	2.58	97.42
16	85	10.4	2.94	2.94	97.06
17	85	8.8	3.39	3.39	96.61
18	85	8.9	2.02	2.13	97.87
19	85	10.1	3.08	3.12	96.88
20	85	9.8	4.06	4.06	95.94

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

Test: TEB-APR-STP-0059

Date Tested: April 14, 2020

Report Prepared: April 15, 2020

Manufacturer: TrioMed

Item Tested: B130 N95 RESPIRATOR & SURGICAL MASK LOT # 101115

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	15.2	0.373	0.375	99.63
2	85	13.9	0.271	0.271	99.73
3	85	12.4	0.218	0.218	99.78
4	85	11.8	0.36	0.236	99.76
5	85	12.8	0.076	0.076	99.92
6	85	14.3	0.211	0.211	99.79
7	85	12.1	0.268	0.268	99.73
8	85	16.3	0.393	0.393	99.61
9	85	12.3	0.257	0.257	99.74
10	85	14.3	0.403	0.585	99.42
11	85	11.9	0.235	0.235	99.77
12	85	12.9	0.341	0.341	99.66
13	85	12.1	0.264	0.264	99.74
14	85	13.4	0.404	0.404	99.60
15	85	12.2	0.189	0.189	99.62
16	85	13.3	0.318	0.318	99.68
17	85	14.1	0.388	0.388	99.61
18	85	12.1	0.213	0.213	99.79
19	85	13.4	0.288	0.288	99.71
20	85	13.2	0.277	0.277	99.72

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

Manufacturer-Designated Shelf Life 95s

Date Tested: April 14, 2020

Report Prepared: April 15, 2020

Manufacturer: Safe Life

Item Tested: B150 N95 RESPIRATOR & SURGICAL MASK LOT # 100729

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	6.6	8.86	10.30	89.70
2	85	8.6	6.39	6.70	93.30
3	85	5.4	7.44	8.52	91.48
4	85	9.0	6.01	6.26	93.74
5	85	12.5	8.06	8.06	91.94
6	85	11.0	12.66	12.88	87.12
7	85	10.1	12.00	12.30	87.70
8	85	11.0	7.78	7.78	92.22
9	85	11.4	10.90	11.03	88.97
10	85	13.4	7.11	7.11	92.89
11	85	11.8	11.20	11.20	88.80
12	85	7.7	12.00	12.66	87.34
13	85	9.5	9.73	10.10	89.90
14	85	11.2	14.60	14.80	85.20
15	85	9.3	6.92	7.57	92.43
16	85	10.4	11.10	11.50	88.50
17	85	11.6	13.30	13.40	86.60
18	85	10.6	11.38	11.64	88.36
19	85	10.9	10.50	12.90	87.10
20	85	10.8	12.10	12.20	87.80

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



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

