

Guide for Identifying FDA EUA Authorized N95 Respirators for Battelle CCDS™ Processing – April 24, 2020

Battelle, using the Battelle CCDS Critical Care Decontamination System™, has been authorized under the [FDA EUA](#)¹ to decontaminate N95 or N95 equivalent filtering facepiece respirators (FFR or respirators) that do not contain cellulose. Respirators that contain cellulose-based materials are excluded from the Battelle CCDS™ EUA and cannot be processed using Battelle CCDS™.

Battelle is providing the following information to assist hospitals with identifying N95 or N95 equivalent respirators containing cellulose from being collected and transported for decontamination. It is the responsibility of the organization to ensure only non-cellulose N95 and N95 equivalent respirators are transported to Battelle for decontamination.

NIOSH Respirators: A list of NIOSH-approved N95 Particulate FFRs can be found at this [CDC website](#)². Only non-cellulose containing, approved models should be submitted to the Battelle CCDS™ program for decontamination.

Non-NIOSH Respirators: Respirators must be certified by NIOSH or be listed in the FDA [EUA issued March 28, 2020](#)³ approving the use of certain imported non-NIOSH disposable FFRs. [Exhibit 1](#)⁴ of the EUA provides a detailed list of the makes and models that are approved. Only non-cellulose containing, approved models should be submitted to the Battelle CCDS™ program for decontamination.

Expired N95 Respirators: The FDA has also approved the use of certain makes and model of N95s that FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, are not damaged, and have been held in accordance with manufacturers' storage conditions in strategic stockpiles. The criteria under which these FFRs can be used can be [found in the EUA](#)⁵. You should review this information to ensure what types of FFRs are authorized. Expired, EUA authorized, non-cellulose containing N95s are able to be decontaminated with the Battelle CCDS™.

If you have a question about your specific respirator model, including if it contains cellulose or not, please contact the manufacturer directly.

- **3M** - please call 3M Personal Safety Division Technical Service at 1-800-243-4630
- **Kimberly-Clark Professional** - please contact our Customer Service Team at (888) 346-GOKC (4652) or your local Kimberly-Clark Sales Representative.
- **Moldex** – please contact at 1-800-421-0668 Ext 512
- **Gerson** – please contact at 508-947-4000
- **Halyard** – please contact at 844-425-9273
- **Honeywell** – please contact at 877-841-2840

Below are tables containing common N95 respirator manufacturers and product models. Included is information if the model is known to contain cellulose and if it is able to be processed using the Battelle CCDS™ process. *This list is not exhaustive. If you have questions about a different respirator type, please call the manufacturer directly to understand if the respirator contains cellulose.*

Select 3M N95 models, cellulose inclusion, and processability using Battelle CCDS™

| Manufacturer | Model | Known to contain cellulose ⁶ | Battelle CCDS™ processable (Yes / No) |
|--------------|---|---|---------------------------------------|
| 3M | Health Care Particulate Respirator and Surgical Mask 1860 and 1860S , N95 | NO | YES |
| 3M | Aura™ Health Care Particulate Respirator and Surgical Mask 1870+ , N95 | NO | YES |
| 3M | Particulate Respirator 8110S , N95 | NO | YES |
| 3M | Particulate Respirator 8210 , N95 | NO | YES |
| 3M | Particulate Respirator 8210Plus , N95 | NO | YES |
| 3M | Particulate Respirator 8210V , N95 | NO | YES |
| 3M | Particulate Respirator 8211 , N95 | NO | YES |
| 3M | Particulate Respirator 8511 , N95 | NO | YES |
| 3M | Particulate Welding Respirator, N95, 8515/07189(AAD) | NO | YES |
| 3M | Particulate Respirator 8516 , N95, with Nuisance Level Acid Gas Relief | NO | YES |
| 3M | Aura™ Particulate Respirator N95, 9210+/37192 | NO | YES |
| 3M | Aura™ Particulate Respirator, N95, 9211+/37193 (AAD) | NO | YES |
| 3M | VFlex™ Healthcare Particulate Respirator and Surgical Mask 1804 and 1804S , N95 | YES | NO |
| 3M | VFlex™ Health Care Particulate Respirator and Surgical Mask 1805 and 1805S , N95 | YES | NO |
| 3M | Particulate Respirator, N95, 8200/07023(AAD) | YES | NO |
| 3M | Particulate Welding Respirator 8212 with Face seal, N95 | YES | NO |
| 3M | Particulate Respirator 8214 with Faceseal and Nuisance Level Organic Vapor Relief, N95 | YES | NO |
| 3M | Particulate Welding Respirator 8512 , N95 | YES | NO |
| 3M | Particulate Respirator 8514 , with Nuisance Level Organic Vapor Relief, N95 | YES | NO |
| 3M | Particulate Respirator 9010 , N95 | YES | NO |
| 3M | VFlex™ Particulate Respirator 9105 and 9105S , N95 | YES | NO |

Select Kimberly-Clark N95 models, cellulose inclusion, and processability using Battelle CCDS™

| Manufacturer | Model | Known to contain cellulose ⁷ | Battelle CCDS™ Processable (Yes / No) |
|----------------|-------------------|---|---------------------------------------|
| Kimberly-Clark | N95, 46727 | NO | YES |
| Kimberly-Clark | N95, 46767 | NO | YES |
| Kimberly-Clark | N95, 46867 | NO | YES |
| Kimberly-Clark | N95, 62126 | NO | YES |
| Kimberly-Clark | N95, 62355 | NO | YES |

Select Moldex N95 models, cellulose inclusion, and processability using Battelle CCDS™

| Manufacturer | Model | Known to contain cellulose ⁸ | Battelle CCDS™ Processable (Yes / No) |
|--------------|------------------|---|---------------------------------------|
| Moldex | N95, 1512 | NO | YES |
| Moldex | N95, 2200 | NO | YES |

Select Honeywell N95 models, cellulose inclusion, and processability using Battelle CCDS™

| Manufacturer | Model | Known to contain cellulose ⁸ | Battelle CCDS™ Processable (Yes / No) |
|--------------|-------------------|---|---------------------------------------|
| Honeywell | N95, N1105 | NO | YES |
| Honeywell | N95, N1125 | NO | YES |
| Honeywell | N95, NBW95 | NO | YES |

Select ProTech N95 models, cellulose inclusion, and processability using Battelle CCDS™

| Manufacturer | Model | Known to contain cellulose ⁸ | Battelle CCDS™ Processable (Yes / No) |
|--------------|----------------------|---|---------------------------------------|
| ProTech | N95, NON27501 | YES | NO |

References

- ¹ FDA Emergency Use Authorization for Battelle CCDS Critical Care Decontamination System™ Dated March 29, 2020 https://battelle-cms.ae-admin.com/docs/default-source/commercial-offerings/industry-solutions/battelle-eua.pdf?sfvrsn=646b94e_2
- ² CDC list of NIOSH-Approved Particulate Filtering Facepiece Respirators https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/N95list1.html
- ³ FDA Emergency Use Authority (EUA) for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators; Dated March 28, 2020 <https://www.fda.gov/media/136403/download>
- ⁴ FDA EUA Non-NIOSH-Approved Disposable Filtering Facepiece Respirators; Exhibit 1: Authorized Respirators Updated: April 14, 2020 <https://www.fda.gov/media/136731/download>
- ⁵ FDA Emergency Use Authority (EUA) for Approved Expired Respirators <https://www.fda.gov/media/135763/download>
- ⁶ 3M letter to Battelle dated March 31, 2020 Re: Response to Request for information on Products (attached to this document)
- ⁷ Kimberly-Clark letter to Battelle dated April 9, 2020 Re: Mask Composition (attached to this document)
- ⁸ Assumed to not contain cellulose based on N95 Respirator characterization at Battelle. Materials of construction did not appear to contain cellulose during materials analysis of limited quantity respirator samples.



31 March 2020

Re: Response to Request for Information on Products

Dear Valued 3M Customer,

3M™ VFlex™ Healthcare Particulate Respirator and Surgical Mask 1804, N95
3M™ VFlex™ Healthcare Particulate Respirator and Surgical Mask 1804S, N95, Small
3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1805, N95
3M™ VFlex™ Health Care Particulate Respirator and Surgical Mask 1805S, N95, Small
3M™ Particulate Respirator 8200/07023(AAD), N95
3M™ Particulate Welding Respirator 8212, N95 with Faceseal
3M™ Particulate Respirator 8214, N95, with Faceseal and Nuisance Level Organic Vapor Relief
3M™ Particulate Respirator 8233, N100
3M™ Particulate Respirator 8293, P100
3M™ Particulate Welding Respirator 8512, N95
3M™ Particulate Respirator 8514, N95, with Nuisance Level Organic Vapor Relief
3M™ Particulate Respirator 9010, N95
3M™ VFlex™ Particulate Respirator 9105, N95
3M™ VFlex™ Particulate Respirator 9105S, N95

On behalf of 3M Personal Safety Division, the following information applies to the products listed immediately above. The products listed immediately above *do contain cellulose*.

3M™ Health Care Particulate Respirator and Surgical Mask 1860, N95
3M™ Health Care Particulate Respirator and Surgical Mask 1860S, N95
3M™ Aura™ Health Care Particulate Respirator and Surgical Mask 1870+, N95
3M™ Particulate Respirator 8110S, N95
3M™ Particulate Respirator 8210, N95
3M™ Particulate Respirator 8210Plus, N95
3M™ Particulate Respirator 8210V, N95
3M™ Particulate Respirator 8211, N95
3M™ Particulate Respirator 8240, R95
3M™ Particulate Respirator 8246, R95, with Nuisance Level Acid Gas Relief
3M™ Particulate Respirator 8247, R95, with Nuisance Level Organic Vapor Relief
3M™ Particulate Respirator 8271, P95
3M™ Particulate Respirator 8511, N95
3M™ Particulate Welding Respirator 8515/07189(AAD), N95
3M™ Particulate Respirator 8516, N95, with Nuisance Level Acid Gas Relief
3M™ Particulate Respirator 8576, P95, with Nuisance Level Acid Gas Relief
3M™ Particulate Respirator 8577, P95, with Nuisance Level Organic Vapor Relief
3M™ Aura™ Particulate Respirator 9210+/37192, N95
3M™ Aura™ Particulate Respirator 9211+/37193(AAD), N95

On behalf of 3M Personal Safety Division, the following information applies to the products listed immediately above. The products listed immediately above have not been formulated to contain, and *do not knowingly contain cellulose*.

The information provided in this letter related to material content represents 3M Personal Safety Division's knowledge and belief as of the date it is provided, which may be based in whole or in part on information provided by suppliers to 3M.

In the event a 3M PSD product is proven not to conform with 3M's applicable product specifications or the information above, then, to the extent permitted by law, 3M's entire liability and customer's exclusive remedy, will be at 3M's option either: (i) repair or replacement of the non-conforming product with a conforming product; or (ii) refund of the purchase price paid by customer for each non-conforming product, within a reasonable time after written notification of said non-conformance and return of the affected product to 3M. 3M shall not under any circumstances be liable for direct, indirect, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this letter or the referenced product(s), including the use, misuse, or inability to use such product(s). Unless stated otherwise in a writing signed by 3M, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.

I trust the above information is responsive to your request.

If you have any questions about the features or performance of this 3M product, please call 3M Personal Safety Division Technical Service at 1-800-243-4630. If you have questions related to health or safety, please contact me at 651-737-5646.

Regards,



Stuart Sexton | Product Steward
3M Personal Safety Div. - Regulatory Affairs
3M Center, 235-02-E-91 | Saint Paul, MN 55144 United States
Office: 651 737 5646
ssexton@mmm.com | www.3M.com



1400 Holcomb Bridge Road
Roswell, GA 30076

April 9, 2020

Re: Mask Composition

Kimberly-Clark N95 Respirators

Codes: 46727, 46767, 46827, 46867, 62126, 62355

Dear Valued Customer,

Thank you for your inquiry concerning Kimberly-Clark N95 Respirators. Please be advised that based on our knowledge of the raw materials, the product and packaging specifications, and the manufacturing processes, Kimberly-Clark confirms that cellulose is not intentionally added to the above products, nor is it used in the manufacturing or packaging process for the product. Because of this, Kimberly-Clark does not test the above product form for the presence of cellulose.

Should you require additional information, please contact our Customer Service Team at (888) 346-GOKC (4652) or your local Kimberly-Clark Sales Representative.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Emily Adams'.

Emily Adams

Technical Support Specialist, Quality & Regulatory Team
Kimberly-Clark Professional