

**ANDERSEN STERILIZERS 20ML CARTRIDGE EO GAS AND ANPROLENE STERILIZATION  
TECHNICAL DATA SHEET****GENERAL DESCRIPTION**

The Andersen EOGas and Anprolene Sterilizer systems have refill kits containing a 20mL cartridge which holds the sterilant, EO Gas. The 20mL cartridge is a unit dose container for Ethylene Oxide (EO). Inside the cartridge, the Ethylene Oxide is in the liquid state within a hermetically sealed glass ampoule. The cartridge cushions the ampoule during shipping and handling and facilitates the safe release of the EO once the glass ampoule is broken. Ethylene Oxide boils at a temperature of 10.7°C (51.3°F), therefore at EOGas sterilization temperatures of 30°C – 55°C (86°F – 131°F), the Ethylene Oxide liquid quickly turns to gas. When the cartridge is activated, 100% Ethylene Oxide gas leaves the cartridge and enters the sterilization liner bag.



Note: Depicted is a 20mL cartridge example. See below for current cartridge labels.

Each EOGas cartridge has an activation trigger secured with a trigger guard, which is in turn secured with green adhesive tape to prevent accidental activation. Once the items to be sterilized are prepared and placed in the sterilization liner bag, the protective tape and trigger guard are removed, the cartridge is placed in the sterilization liner bag with the sterilization load, and the bag is sealed. To activate the cartridge, it is manipulated through the flexible wall of the sterilization liner bag to depress the activation trigger.

**INDICATIONS FOR USE**

Refer to Technical Data Sheets for Indications for Use for EOGas 3, EOGas 4 and Anprolene AN75 sterilizer systems.

**DIRECTIONS FOR USE**

Items to be sterilized are prepared according to the Instructions for use found in the EOGas 3 Refill Kit and in the EOGas 3® Sterilizer User's Manual which are provided with purchase of the Refill Kit and the Sterilizer.

**APPLICATION OF USE**

- 20mL cartridges are approved for use only in the EOGas 3, EOGas 4 and Anprolene AN75 sterilization systems.
- The 20mL cartridge is designed to hold a glass ampoule which is filled with varying amounts of EO, depending on the Refill Kit contents as specified below in Specifications.

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Refill Kit Number	Liquid Ethylene Oxide Contents (grams +/- 5%)*
AN1004.16	17.6
AN1006.00	10.5
AN2011.00	10.5
AN2018.00	17.6
AN7514.00	17.6

\*Ethylene Oxide Safety Data Sheet contains safety information and specifications for Ethylene Oxide. This Safety Data Sheet is available from Distributors.

**RAW MATERIAL COMPOSITION**

Raw material	Material	DEHP (Yes/No)	Patient Contact(Yes/No)	Colorant (Yes/No)
Cartridge, multiple pieces	Polypropylene, Natural	No	No	No
Activation Pin	Polypropylene, Blue	No	No	Yes
Cap	Polypropylene, Blue	No	No	Yes
Glass ampoule	borosilicate	No	No	No
Ethylene Oxide	Ethylene Oxide	No	No	No

**MANUFACTURING AND DESIGN**

- The EOGas and Anprolene Systems are manufactured and designed under a full Quality Management System certified (certificate number 0085440) under MDSAP and registered by Intertek, an MDSAP recognized auditing organization as conforming the requirements of ISO 13485:2016 for the Canadian Medical Device Regulations – Part 1 – SOR 98/282 and the United States USFDA 21CFR 820, 21 CFR 803, 21 CFR 806, 21CFR 807. A Risk Management Program is fully adopted per ISO14971:2019.
- Andersen Sterilizers maintains EC Certification through a full Quality Assurance System certification number 4134704-02 under Directive 93/42/EEC on Medical Devices allowing for the use of CE 0413 marking.
- The EOGas and Anprolene Sterilization System is independently certified for safety and effectiveness standards for electrical safety and electromagnetic compatibility as required by international regulations.

**TESTING AND INSPECTION**

- Verification of Ethylene Oxide fill weights
- Pressure testing of all filled ampoules to ensure ampoule integrity
- Cartridge seal testing on all completed cartridges
- Certificate of Analysis confirming Ethylene Oxide has a purity of 99.99%
- g-shock testing to verify compliance with Federal D.O.T. shipping regulations.

**PACKAGING AND LABELING**

**ANDERSEN STERILIZERS 20ML CARTRIDGE EO GAS AND ANPROLENE STERILIZATION  
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Refer to the individual refill kit Technical Data Sheets for packaging information.

Cartridges are labeled according to the individual refill kit. An example of the cartridge label is within this technical documentation.

**STORAGE CONDITIONS**

Store in a cool, well-ventilated area away from heat and direct sunlight. Store in accordance with 28CFR 1910.1047. When properly stored for the stated shelf life, Ethylene Oxide will retain its clear liquid appearance and consistency, comparable to denatured alcohol.

**DISPOSAL**

Pesticide wastes are toxic. Improper disposal of excess pesticides is a violation of Federal Law. If the waste cannot be disposed of by use according to label instructions, contact Andersen Products Inc. (336-276-3000). Do not puncture or incinerate unused cartridges. Aerate empty cartridges and used sterilization bags according to complete Directions for Use. After aeration, dispose of in sanitary landfill.

**SHELF LIFE**

The shelf life of an EO Gas cartridge depends on the fill weight of the Ethylene Oxide gas within the cartridge. The following table lists the shelf life of the Cartridges and the Refill Kits:

Refill Kit	Cartridge Expiration (Years)	Refill Kit Expiration* (Years)
AN1004.16	5	3
AN1006.00	5	3
AN2011.00	5	5
AN2018.00	5	5
AN7514.00	5	3

\*Expiration of the refill kit is determined by the kit component with the shortest shelf life.

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AN1004.16, AN2018 and AN7514.00 Cartridge Label

**AN 1004**  
**AN 7514**  
**AN 2018** **EOGas®**  
**ANPROLENE****DANGER****KEEP OUT OF REACH OF CHILDREN**  
**CONTENTS FLAMMABLE**  
**DO NOT OPEN THIS PACKAGE**  
**DISPOSE OF EMPTY CARTRIDGE IN TRASH**

Active Ingredient: Ethylene Oxide.....97.0%  
Other Ingredients:.....3.0%  
Total: .....100.0%

Net Contents: 0.64 av. oz. (18.15 g)

For use in Andersen EOGas 4®, AN74/AN75 Anprolene®, and EOGas® 3 Ethylene Oxide Gas Sterilizers according to manufacturer's instructions. See outer box and package insert for precautions and sterilization instructions. Users must follow requirements of the OSHA Occupational Exposure Standard for Ethylene oxide (29 CFR 1910.1047).

**REMOVE TAPE AND TRIGGER GUARD, PLACE ON TOP OF LOAD, SEAL AND PURGE STERILIZATION BAG. PRESS BUTTON TO ACTIVATE CARTRIDGE**

Manufactured and Distributed by: Andersen Sterilizers, Inc • 3154 Caroline Drive • Haw River, NC 27258 U.S.A.  
EPA Registration No. 69340-7 • EPA Est. No. 69340-NC-001

AN14.01 Rev 1

AN1006.00 Cartridge Label

**AN 1006**  
 **EOGas®**

Active Ingredient: Ethylene Oxide.....96.0%  
Other Ingredients:.....4.0%  
Total: .....100.0%  
Net Contents: 0.39 av. oz. (11.0 g)

**REMOVE TAPE AND TRIGGER GUARD,  
IMMEDIATELY PLACE INSIDE STERILIZATION BAG**

Users must follow requirements of the OSHA Occupational Exposure Standard for Ethylene oxide (29 CFR 1910.1047). Use only in an Andersen EOGas Sterilizer with a #6 Diffusion Bag and according to manufacturer's instructions. See outer box and package insert for precautions and sterilization instructions.

**DANGER****KEEP OUT OF REACH OF CHILDREN**  
**CONTENTS FLAMMABLE**  
**DO NOT OPEN THIS PACKAGE**  
**DISPOSE OF EMPTY EOGas CARTRIDGE IN TRASH** 0413

Manufactured by: Andersen Sterilizers, Inc • Health Science Park • Haw River, NC 27258 U.S.A.  
Distributed by: Andersen Products, Inc. • Health Science Park • Haw River, NC 27258 U.S.A.

EPA Registration No. 69340-6 • EPA Est. No. 69340-NC-001 • U.S. Patent No. 4,937,046 &amp; 5,160,700

**REMOVE TAPE AND TRIGGER GUARD, PRESS BUTTON TO ACTIVATE CARTRIDGE**

AN2986.00\_Rev2

ANDERSEN STERILIZERS 20ML CARTRIDGE EO GAS AND ANPROLENE STERILIZATION  
TECHNICAL DATA SHEET

AN2011 Cartridge Label

**AN  
2011**

Active Ingredient: Ethylene Oxide...96.0%  
Other Ingredients:.....4.0%  
Total: .....100.0%  
Net Contents: 0.39 av. oz. (11.00 g)

Manufactured by: Andersen Sterilizers, Inc • Health Science Park • Haw River, NC 27258 U.S.A.  
Distributed by: Andersen Products, Inc. • Health Science Park • Haw River, NC 27258 U.S.A.

EPA Registration No. 69340-6 • EPA Est. No. 69340-NC-001 • U.S. Patent No. 4,937,046 &amp; 5,160,700

**REMOVE TAPE AND TRIGGER GUARD, PRESS BUTTON TO ACTIVATE CARTRIDGE****REMOVE TAPE AND TRIGGER GUARD,  
IMMEDIATELY PLACE INSIDE STERILIZATION BAG**

Use only in an Andersen EOGas Sterilizer and according to manufacturer's instructions. See outer box and package insert for precautions and sterilization instructions. Users must follow requirements of the OSHA Occupational Exposure Standard for Ethylene oxide (29 CFR 1910.1047).

**DANGER**  
**KEEP OUT OF REACH OF**  
**CHILDREN**  
**CONTENTS FLAMMABLE**  
**DO NOT OPEN THIS PACKAGE**  
**DISPOSE OF EMPTY EOGas**  
**CARTRIDGE IN TRASH**







AN4968.00\_Rev1

ANDERSEN STERILIZERS 20ML CARTRIDGE EO GAS AND ANPROLENE STERILIZATION  
TECHNICAL DATA SHEET

Revision History			
ECN Number	Revision	Effective Date	Reason for Change
2021078	0	2021-10-22	Updated to include data requested by international customers. Updated for shelf-life changes. Created as controlled documents under revision control in document management system.
2021178	1	2021-10-22	Updated to include kit expiration column on shelf-life table.
2022001	2	2022-02-16	Update cartridge labels
2024002	3	2024-06-10	Remove AN2014 references. Remove AN2018.01 references.
2024159	4	2024-12-16	Updated AN1004/ AN7514/ AN2018 Label to the latest revision. Removed AN2018 label refer to the label listed under AN1004.16, AN2018.00, AN7514.00 for the correct label (AN14.01 REV 1)

Signatures:

<b>Content Approval:</b>		I have approved the content of this document	
Name:	<b>Ethan Marshall</b> emarshall	Title:	<b>Director of Operations</b>
		2024-12-11 17:13:52 (UTC+00:00)	
Electronically Signed in 		Timestamp	

<b>Controlled Quality Document Authorized for Release:</b>		I authorize this controlled quality document for release.	
Name:	<b>Faith Rios</b> ANDERSEN\Faith.Rios	Title:	<b>Director of Quality Assurance and Regulatory Affairs</b>
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Electronically Signed in 		Timestamp	

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