



T.F.H. PUBLICATIONS, INC. & NYLABONE PRODUCTS • FOUR PAWS • IMS TRADING, LLC
85 WEST SYLVANIA AVENUE, NEPTUNE CITY, NEW JERSEY 07753 | 965 CRANBURY SOUTH RIVER ROAD, JAMESBURG, NEW JERSEY 08831

NYLABONE ADVANCED ORAL CARE DENTAL SPRAY FRESH BREATH 4OZ

INVESTIGATION AND QUALITY ASSURANCE

Our GMP processes and Quality System programs are based on 21 CFR 210 and 211 for pharmaceutical manufacturing, same principles are applied to the manufacture of our non-pharmaceutical products for consistency and a consolidated Quality System.

There are no known side effects to this product, and nor changes in sourcing/manufacturing.

Batch records for the referenced lots (below) were reviewed. All lines checks were satisfactory, and no deviations were noted in the batch record review by QA. COAs were satisfactory. Retain samples conformed to product specifications. Review of the retains did not confirm the complaint, therefore no corrective actions are being taken at this time.

AOC INGREDIENT PROFILE

Please reference the below table which demonstrates the function and safety of the ingredients used in this product.

Ingredient	Description	Technical Effects (FDA)
Purified water	Water that has been filtered or processed to remove impurities like chemicals and other contaminants.	GRAS
Vegetable Glycerin	Glycerin is a clear liquid typically made from soybean, coconut or palm oils.	Miscellaneous/GRAS
Polysorbate 20	Polysorbate 20 is an emulsifier often used in foods.	Emulsifier
Zinc Gluconate	Mineral added to oral products help control plaque.	Nutritional Supplement/GRAS
Sodium Benzoate	Prevents food spoilage from bacteria, molds, fungi, or yeast (antimicrobials); and delay rancidity (antioxidants); maintain freshness; also commonly used in human toothpaste.	Chemical preservative/GRAS
Citric Acid	Natural organic acid that helps reduce the tartar buildup.	Sequestrant/Neutralizing agent, GRAS
Sodium Ascorbyl Phosphate	Inactivates harmful oral bacteria, powerful antioxidants, and free radical scavenger, stable in tooth paste and other oral care products.	Chemical preservative/GRAS
Sodium Hexametaphosphate	Inorganic salt. Has multiple binding sites and antitartar properties that help prevent staining of teeth. Also, removes existing stains on the tooth surface.	GRAS



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Peppermint Oil	Peppermint oil is a common flavoring agent in foods and beverages.	Essential Oil/GRAS
Sodium Copper Chlorophyllin	Sodium Copper Chlorophyllin is a green food colorant.	Food Colorant
Potassium Sorbate	Is an important commercial chemical that is used as a preservative and antibacterial in food, wines, and cosmetics.	Preservative/GRAS

The FDA uses the acronym GRAS for the phrase Generally Recognized as Safe.

COA RESULTS

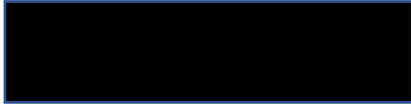
As no specific lots were provided with the complaints, our investigation was conducted utilizing data for this item (AOC Dental Spray Fresh Breath) from the last two production runs. Please see COA's below from a third-party accredited laboratory, demonstrating acceptable results for Appearance, Odor, Total Aerobic Count, and Pathogen Testing. Note that some information unrelated to this request have been redacted.

Please see the lot information below, as it relates to the supportive documentation included below:

Product Name	MFG Date	Packaging Lot
AOC Dental Spray Fresh Breath 4oz	10/15/2020	309080
AOC Dental Spray Fresh Breath 4oz	10/01/2021	109141



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Certificate of Analysis Advanced Liquid Dental Spray

CMC Product Code:	G044NYL	Packaging P/N:	G044NYL004.00AH
Customer Product Code:	NPD602P	Packaging Lot:	200906
Manufacture Date:	09/10/2020	Packaging Type:	4 oz
Bulk Lot:	200906	Label:	NA
Bulk Size:	4500 lbs	Container Code:	309080
		Best By Date:	09/2023

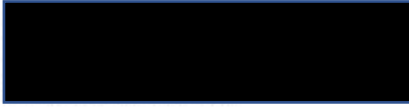
Test	Method	Specification	Result
Appearance	Organoleptic	Clear Colorless Liquid	Pass
Odor	Organoleptic	Mint	Pass
Total Aerobic Count	QCL-800	≤ 200 cfu/g	<1 cfu/g
Pathogens	QCL-800	No Detectable Pathogens	No Pathogens Detected

Notes:

Prepared By: [Signature] Date: 9-21-2020 Approved By: [Signature] Date: 9/22/2020
Form # QCL-006A G044NYL Certificate of Analysis Effective Date: 01/14/2020
Page 1 of 1



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Certificate of Analysis AOC Liquid Dental Spray

CMC Product Code:	G044NYL	Packaging P/N:	G044NYL004.00AH
Customer Product Code:	NPD602P	Packaging Lot:	211067
Manufacture Date:	09/07/2020	Packaging Type:	4 oz
Bulk Lot:	211067	Label:	NA
Bulk Size:	4,300 lbs	Container Code:	109141
		Best By Date:	09/2024

Test	Method	Specification	Result
Appearance	Organoleptic	Clear Colorless Liquid	Pass
Odor	Organoleptic	Mint	Pass
[Redacted]			
Total Aerobic Count	QCL-800	≤ 200 cfu/g	<1 cfu/g
Pathogens	QCL-800	No Detectable Pathogens	No Pathogens Detected

Notes:

Prepared By: *[Signature]* Date: 09-29-21 Approved By: *[Signature]* Date: 25-Sep-2021
Form# QCL-006A G044NYL Certificate of Analysis Effective Date: 01/14/2020
Page 1 of 1

CONFIDENTIAL

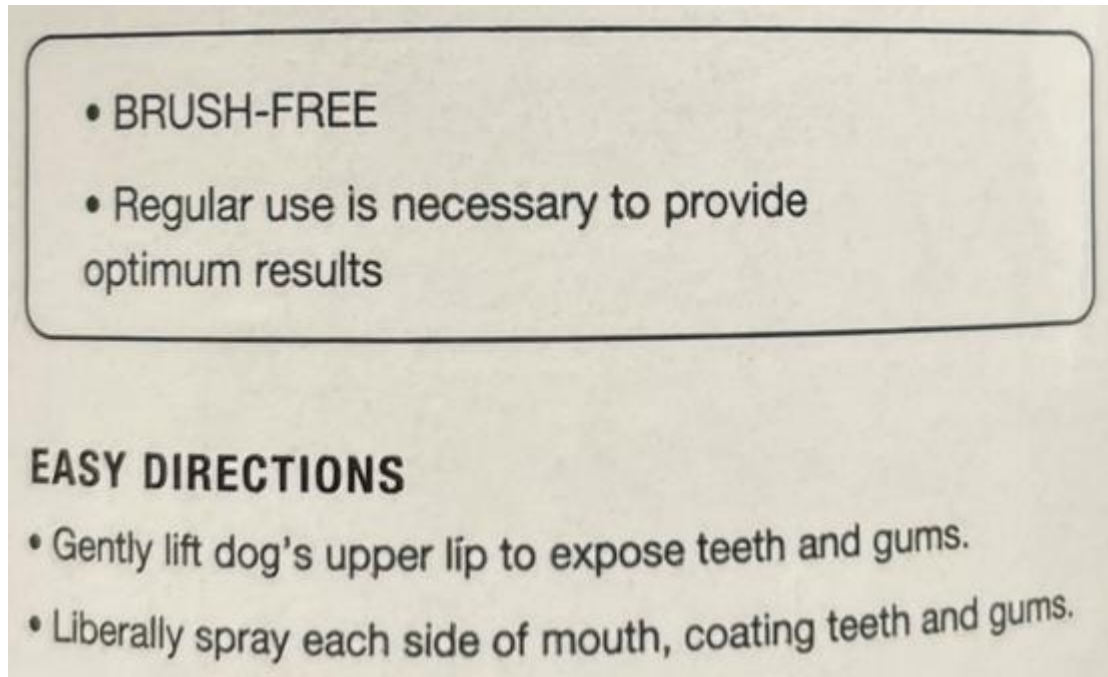
4



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INSTRUCTIONS FOR PROPER USE OF PRODUCT

Reference the below direction included on the packaging for Nylabone Advanced Oral Care Dental Spray Fresh Breath. It is always important for consumers to read and follow the guidelines to ensure proper use of our products.



FURTHER DISCUSSION

As requested, here is the contact information consumers can use to reach our company directly: 1-855-273-7527.

We would also be happy to discuss this matter further with the Amazon Food Safety Team directly. Please advise if you would like to arrange a call.