DWK Life Sciences Limited	Doc Reference	Revision	Release Date	Page	r	DWK LIFE SCIENCES
Regulatory Compliance	7.16	4	27.03.2025	Page 1 of 3	L	DURAN WHEATON KIMBLE

Unit S77, St. Modwen Park Stoke South, Gordon Banks Drive, Stoke-on-Trent, Staffordshire, ST4 4TW

## **PRODUCT SPECIFICATION – COMPLIANCE STATEMENTS**

Brand	AZLON®
Name	WGW446VT
Product Description	Wide Neck Wash Bottles, Safety venting, LDPE
Country of Origin	GB

## Specification

Composition	Capacity (ml)	Closure Colour	Pack Quantity
Low Density Polyethylene	1000	Green	5

## **Declarations**

1. REACH (EC 1907/2006):	Compliant	$\boxtimes$
The Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation aims to protect	Non-Compliant	
human health and the environment from risks posed by chemicals. We confirm that this product does not	Not Assessed	
contain any of the substances of very high concern (SVHC) listed in the REACH Candidate List, as updated on		
21 January 2025, in concentrations above the threshold limit of 0.1% by weight.		
2. RoHS (Directive 2011/65/EU and Directive (EU) 2015/863):	Compliant	$\boxtimes$
The Restriction of Hazardous Substances (RoHS) directive restricts the use of certain hazardous substances in	Non-Compliant	
electrical and electronic equipment. We confirm that this product complies with the RoHS directives, including	Not Assessed	
the amendment introduced by Directive (EU) 2015/863, which restricts the following substances:		
• Lead (Pb): 0.1%		
Mercury (Hg): 0.1%		
• Cadmium (Cd): 0.01%		
Hexavalent Chromium (Cr6+): 0.1%		
<ul> <li>Polybrominated Biphenyls (PBB): 0.1%</li> </ul>		
Polybrominated Diphenyl Ethers (PBDE): 0.1%		
Bis(2-ethylhexyl) phthalate (DEHP): 0.1%		
Butyl benzyl phthalate (BBP): 0.1%		
Dibutyl phthalate (DBP): 0.1%		
Diisobutyl phthalate (DIBP): 0.1%		
3. PFAS Compliance:	Compliant	$\boxtimes$
Per- and polyfluoroalkyl substances (PFAS) are synthetic chemicals regulated due to their persistence in the	Non-Compliant	
environment and potential health impacts. We confirm that this product:	Not Assessed	
Do not intentionally include PFAS or their derivatives.		
•Meets regulatory standards for PFAS restrictions as established by applicable laws, including REACH Annex		
XVII, Persistent Organic Pollutants (POPs) EU Regulation (EU) 2019/1021 Annex I and other global standards.		
DWK Life Sciences will carefully monitor the legislation process for PFAS and will take necessary measure to		
fulfil upcoming legal requirements for the products we supply.		
4. Food Contact Compliance:	Compliant	$\boxtimes$
We confirm that this product complies with relevant regulations for food contact materials, including but not	Non-Compliant	
limited to:	Not Assessed	
•EU Regulation (EC) No 1935/2004 concerning materials and articles intended to contact with food.		
•EU Regulation (EU) No 10/2011 Where applicable, governs plastic materials and articles intended to contact		
with food, where applicable.		
•US FDA 21 CFR requirements for materials intended for food contact use, where applicable.		
We ensure that the material has been tested and verified to ensure safe food contact, preventing excessive		
melamine migration, meeting required safety and migration limits.		
5. BPA Compliance (EU Regulation):	Compliant	$\boxtimes$
We confirm that this product complies with the EU Regulation (EU) No $10/2011$ and its amendments regarding	Non-Compliant	
Bisphenol A (BPA) restrictions in food contact materials. Specifically:	Not Assessed	
•BPA is not intentionally added to our products intended for food contact.		
•Our products meet the EU-specific migration limit (SML) of 0.05 mg/kg for BPA in food contact materials, as		
outlined in the regulation.		
•Testing is conducted to ensure compliance, and supporting documentation is available upon request.		

QF3.25\_Rev 1 Print Date:1 April 2025

DWK Life Sciences Limited	Doc Reference	Revision	Release Date	Page	•	DWK LIFE SCIENCES
Regulatory Compliance	7.16	4	27.03.2025	Page 2 of 3	6	DURAN WHEATON KIMBLE

Unit S77, St. Modwen Park Stoke South, Gordon Banks Drive, Stoke-on-Trent, Staffordshire, ST4 4TW

6. TSE/BSE Compliance: We confirm that this product complies with the requirements to minimize the risk of transmissible spongiform	Compliant Non-Compliant	
encephalopathies (TSE) and bovine spongiform encephalopathy (BSE).  Specifically:	Not Assessed	
•The raw materials and additives used in the manufacture of this product are not derived from animal origin or are sourced from animals compliant with EU regulations and guidelines (e.g., Commission Directive 2000/6/EC).		
•This product does not contain any materials of animal origin that pose a risk of TSE/BSE transmission. •Supporting documentation from our suppliers verifying TSE/BSE compliance is available upon request.		
7. Latex-Free Compliance: We confirm that this product is manufactured without the use of natural rubber latex, ensuring its suitability for individuals with latex allergies or sensitivities.	Compliant Non-Compliant Not Assessed	
8. Conflict Mineral Compliance: We confirm that this product complies with Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act regarding conflict minerals. Specifically:  •We ensure that the tantalum, tin, tungsten, and gold (3TG) used in this product are sourced from smelters and refiners that have been certified as conflict-free by industry-recognized initiatives such as the Responsible Minerals Initiative (RMI).	Compliant Non-Compliant Not Assessed	
•We actively work with our suppliers to trace the origin of materials and ensure that they do not contribute to funding armed conflicts in the Democratic Republic of Congo (DRC) or adjoining countries.		
9.Nitrosamines:  DWK and its material suppliers do not intentionally use N-nitrosamines as part of the manufacturing process for the referenced product. While this product is not routinely tested for the presence of N-nitrosamines, our knowledge of their composition indicates that these substances are not expected to be present in this product. However, trace levels may still be possible due to the specific characteristics of raw materials or the manufacturing process.	Compliant Non-Compliant Not Assessed	
<b>Disclaimer:</b> All dimensions, capacities and weights are approximate unless otherwise stated. Please note that analysis of the raw materials and/or finished goods for presence of the above-mentioned sub on a routine basis.	stances is not perfo	rmed
Information detailed within this document is provided in good faith and/or obtained from raw material sup reports, supplier Material Safety Data Sheets or similar provided by raw material suppliers. DWK Life Sciences en that all products supplied are tested and verified by the customer to ensure that all regulatory and compliance refer the first least that all products are tested and verified by the customer to ensure that all regulatory and compliance refer the first least that all products are tested and verified by the customer to ensure that all regulatory and compliance refer the first least that all products are the first least least least that all products are the first least	mphasise the import	tance

DOCUMENT APPROVAL (On Behalf of DWK Life Sciences Limited)	SIGNATURE	DATE
Kevin Marshall	i Maria	
Quality Manager DWK Life Sciences Limited	TMD LQ	01 April 2025

It is the responsibility of the recipient of our products to ensure that any proprietary rights, existing laws, and legislation is observed.

for the final application.

QF3.25\_Rev 1 Print Date:1 April 2025

DWK Life Sciences Limited	Doc Reference	Revision	Release Date	Page	DWK LIFE SCIENCES
Regulatory Compliance	7.16	4	27.03.2025	Page 3 of 3	DURAN WHEATON KIMBLE
Unit S77, St. Modwen Park Stoke South, Gordon Banks Drive, Stoke-on-Trent, Staffordshire, ST4 4TW					

QF3.25\_Rev 1 Print Date:1 April 2025