

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Trade name : BinaxNOW™ Malaria Reagent A

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Main use category : For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 - United States
T +1 (207) 730-5750
ts.scr@abbott.com

1.4. Emergency telephone number

Emergency number : +1-703-741-5970

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Serious eye damage/eye irritation, Category 2 H319
Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H319 - Causes serious eye irritation.

Precautionary statements (CLP) :

P264 - Wash hands, forearms and face thoroughly after handling.
P280 - Wear eye protection, protective clothing, protective gloves.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

Other hazards not contributing to the classification : None under normal conditions.

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according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Triton™ X-100 polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether substance listed as REACH Candidate (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]) substance listed in REACH Annex XIV (4-(1,1,3,3-Tetramethylbutyl) phenol, ethoxylated (covering well-defined substances and UVCB substances, polymers and homologues))	(CAS-No.) 9002-93-1	1	Acute Tox. 4 (Oral), H302 Eye Dam. 1, H318 Aquatic Chronic 2, H411
Sodium Azide	(CAS-No.) 26628-22-8 (EC-No.) 247-852-1 (EC Index-No.) 011-004-00-7	0.02	Acute Tox. 2 (Oral), H300 Acute Tox. 1 (Dermal), H310 Acute Tox. 3 (Inhalation:dust,mist), H331 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after eye contact	: Causes serious eye irritation.
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4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Sand. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: None known.
Explosion hazard	: Product is not explosive.
Reactivity in case of fire	: None under normal conditions.
Hazardous decomposition products in case of fire	: No data available.

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5.3. Advice for firefighters

Precautionary measures fire	: Evacuate area. Stop leak if safe to do so.
Firefighting instructions	: No specific measures are necessary.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area.

6.1.1. For non-emergency personnel

Protective equipment	: Wear suitable protective clothing.
Emergency procedures	: Evacuate area.
Measures in case of dust release	: None known.

6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures	: Containment as appropriate.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment	: Cover spill with non combustible material, e.g.: sand, earth, vermiculite.
Methods for cleaning up	: Take up liquid spill into absorbent material.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: None known.
Precautions for safe handling	: Ensure good ventilation of the work station. Wear personal protective equipment. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor.
Hygiene measures	: Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures	: Comply with applicable regulations.
Storage conditions	: Comply with instructions for use (refer to technical sheet). Keep only in original container.
Incompatible products	: None known.
Incompatible materials	: None known.
Heat-ignition	: None known.
Information on mixed storage	: None known.

7.3. Specific end use(s)

For professional use only.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium Azide (26628-22-8)	
EU - Occupational Exposure Limits	
IOELV TWA (mg/m ³)	0.1 mg/m ³
IOELV STEL (mg/m ³)	0.3 mg/m ³
Belgium - Occupational Exposure Limits	
Limit value [mg/m ³]	0.1 mg/m ³ (La mention "M" indique que lors d'une exposition supérieure à la valeur limite, des irritations apparaissent ou un danger d'intoxication aiguë existe. Le procédé de travail doit être conçu de telle façon que l'exposition ne dépasse jamais la valeur limite. Lors des mesurages, la période d'échantillonnage doit être aussi courte que possible afin de pouvoir effectuer des mesurages fiables. Le résultat des mesurages est calculé en fonction de la période d'échantillonnage.)
Short time value [mg/m ³]	0.3 mg/m ³ (La mention "M" indique que lors d'une exposition supérieure à la valeur limite, des irritations apparaissent ou un danger d'intoxication aiguë existe. Le procédé de travail doit être conçu de telle façon que l'exposition ne dépasse jamais la valeur limite. Lors des mesurages, la période d'échantillonnage doit être aussi courte que possible afin de pouvoir effectuer des mesurages fiables. Le résultat des mesurages est calculé en fonction de la période d'échantillonnage.)
France - Occupational Exposure Limits	
VME [mg/m ³]	0.1 mg/m ³
VLE [mg/m ³]	0.3 mg/m ³
Netherlands - Occupational Exposure Limits	
Grenswaarde TGG 8H (mg/m ³)	0.1 mg/m ³
Grenswaarde TGG 15MIN (mg/m ³)	0.3 mg/m ³
United Kingdom - Occupational Exposure Limits	
WEL TWA (mg/m ³)	0.1 mg/m ³
WEL STEL (mg/m ³)	0.3 mg/m ³
USA - ACGIH - Occupational Exposure Limits	
ACGIH Ceiling (mg/m ³)	0.29 mg/m ³
ACGIH Ceiling (ppm)	0.11 ppm

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protective equipment:

Protective clothing. Protective goggles. Gloves.

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

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Respiratory protection:

A risk assessment is required

Personal protective equipment symbol(s):



Thermal hazard protection:

Not applicable.

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: ≈ 7.8
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion limits	: No data available

9.2. Other information

Minimum ignition energy : No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

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10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

LD50 oral rat	1800 mg/kg (Rat, Literature study, Oral)
LD50 dermal rabbit	8000 mg/kg (Rabbit, Literature study, Dermal)

Sodium Azide (26628-22-8)

LD50 oral	27 mg/kg body weight (Mouse, Experimental value, Oral)
LD50 dermal rabbit	19 – 48 mg/kg body weight (Rabbit, Inconclusive, insufficient data, Dermal)
LC50 Inhalation - Rat	0.05 – 0.52 mg/l (EPA OPPTS 870.1300: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (dust), 14 day(s))

Skin corrosion/irritation : Not classified
pH: ≈ 7.8
Serious eye damage/irritation : Causes serious eye irritation.
pH: ≈ 7.8
Respiratory or skin sensitization : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
Aquatic acute : Not classified
Aquatic chronic : Not classified

polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

LC50 fish 1	8.9 mg/l (96 h, Pimephales promelas, Literature study)
EC50 Daphnia 1	26 mg/l (48 h, Daphnia magna, Literature study)

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Sodium Azide (26628-22-8)	
LC50 fish 1	2.75 – 3.28 mg/l (Equivalent or similar to OECD 203, 96 h, Oncorhynchus mykiss, Flow-through system, Fresh water, Experimental value)
LC50 other aquatic organisms 1	1 (1 – 10) mg/l (96 h)
EC50 other aquatic organisms 1	5 (5 – 14) mg/l (Protozoa; TOXICITY TEST)
EC50 96h algae (1)	0.35 mg/l (Equivalent or similar to OECD 201, Pseudokirchneriella subcapitata, Static system, Fresh water, Experimental value, Cell numbers)

12.2. Persistence and degradability

BinaxNOW Malaria Reagent A	
Persistence and degradability	not readily degradable in water.

polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	
Persistence and degradability	Not readily biodegradable in water.
Chemical oxygen demand (COD)	2.19 mg/g
ThOD	2.16 g O ₂ /g substance

Sodium Azide (26628-22-8)	
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable
BOD (% of ThOD)	Not applicable

12.3. Bioaccumulative potential

BinaxNOW Malaria Reagent A	
Bioaccumulative potential	Low bioaccumulation potential.

polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)	
Partition coefficient n-octanol/water (Log Pow)	4.86 (Estimated value)
Bioaccumulative potential	Potential for bioaccumulation ($4 \geq \text{Log Kow} \leq 5$).

Sodium Azide (26628-22-8)	
Bioaccumulative potential	not bioaccumulable.

12.4. Mobility in soil

BinaxNOW Malaria Reagent A	
Ecology - soil	Expected to be highly mobile in soil.

Sodium Azide (26628-22-8)	
Surface tension	No data available (test not performed)
Ecology - soil	Low potential for adsorption in soil.

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12.5. Results of PBT and vPvB assessment

Component

polyethyleneglycol para-(1,1,3,3-tetramethylbutyl)phenyl ether (9002-93-1)

This substance/mixture does not meet the PBT criteria of REACH, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Do not discharge into drains or the environment.
Additional information	: Clean up even minor leaks or spills if possible without unnecessary risk.
Ecology - waste materials	: Do not discharge into drains or the environment.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR)	: Not applicable
UN-No. (IMDG)	: Not applicable
UN-No. (IATA)	: Not applicable
UN-No. (ADN)	: Not applicable
UN-No. (RID)	: Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not applicable
Proper Shipping Name (IMDG)	: Not applicable
Proper Shipping Name (IATA)	: Not applicable
Proper Shipping Name (ADN)	: Not applicable
Proper Shipping Name (RID)	: Not applicable

14.3. Transport hazard class(es)

ADR	
Transport hazard class(es) (ADR)	: Not applicable
IMDG	
Transport hazard class(es) (IMDG)	: Not applicable
IATA	
Transport hazard class(es) (IATA)	: Not applicable
ADN	
Transport hazard class(es) (ADN)	: Not applicable
RID	
Transport hazard class(es) (RID)	: Not applicable

14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

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14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

14.6. Special precautions for user

Overland transport

No data available

Transport by sea

No data available

Air transport

No data available

Inland waterway transport

No data available

Rail transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains substance on the candidate list in concentration $\geq 0.1\%$ or with a lower specific limit: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (CAS 9002-93-1)

Contains REACH Annex XIV substances: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] (CAS 9002-93-1)

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance(s) subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 2, significant hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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SECTION 16: Other information

Data sources	: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Other information	: Date of issue. 2021 01 29

Full text of H- and EUH-phrases:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Oral)	Acute toxicity (oral) Category 2
Acute Tox. 3 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment - Chronic Hazard Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard Category 2
Eye Dam. 1	Serious eye damage/eye irritation Category 1
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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