

Safety Data Sheet

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

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

1.1. Product identifier

Product form : Mixture

Trade name : BinaxNOW™ Malaria Positive Control

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

1.2.1. Relevant identified uses

Industrial/Professional use spec : 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]

Acute toxicity (oral) Category 4 H302
Acute toxicity (dermal) Category 4 H312
Skin corrosion/irritation Category 2 H315
Serious eye damage/eye irritation Category 2 H319
Reproductive toxicity Category 1B H360
Hazardous to the aquatic environment - Chronic Hazard Category 3 H412

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

May damage fertility or the unborn child. Harmful in contact with skin. Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS07

07 GHS08

Signal word (CLP) : Danger

Hazardous ingredients : Sodium Azide; Imidazole, 99%

Hazard statements (CLP) : H302+H312 - Harmful if swallowed or in contact with skin.

H315 - Causes skin irritation. H319 - Causes serious eye irritation.

H360 - May damage fertility or the unborn child. H412 - Harmful to aquatic life with long lasting effects.

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Precautionary statements (CLP)

: P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P264 - Wash hands thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P273 - Avoid release to the environment.

P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+P312 - IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.

P302+P352 - IF ON SKIN: Wash skin thoroughly with mild soap and water.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do. Continue rinsing.

P308+P313 - IF exposed or concerned: Get medical advice/attention.

P312 - Call a POISON CENTRE or doctor if you feel unwell.

P321 - Specific treatment: Seek medical attention if ill effect develops.

P330 - Rinse mouth.

P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse.

P405 - Store locked up.

P501 - Dispose of contents/container to hazardous or special waste collection point, in

accordance with local, regional, national and/or international regulation.

2.3. Other hazards

No additional information available

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Imidazole, 99%	(CAS-No.) 288-32-4 (EC-No.) 206-019-2 (EC Index-No.) 613-319-00-0	2	Not classified	Acute Tox. 4 (Oral), H302 Skin Corr. 1C, H314 Repr. 1B, H360D
Sodium Azide	(CAS-No.) 26628-22-8 (EC-No.) 247-852-1 (EC Index-No.) 011-004-00-7	1.4	Not classified	Acute Tox. 2 (Oral), H300 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of R- and H- phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

: IF exposed or concerned: Get medical advice/attention. Call a poison First-aid measures general

center/doctor/physician 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. Take off contaminated clothing. If skin irritation occurs: Get

medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Rinse mouth. Call a poison center/doctor/physician if you feel unwell.

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

Symptoms/effects after skin contact : Irritation. Symptoms/effects after eye contact : Eye irritation.

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 : Water spray. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

: Toxic fumes may be released. Hazardous decomposition products in case of fire

5.3. Advice for firefighters

: Do not attempt to take action without suitable protective equipment. Complete protective Protection during firefighting

clothing.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures

: Only qualified personnel equipped with suitable protective equipment may intervene.

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".

6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up

: Mechanically recover the product. Notify authorities if product enters sewers or public

Other information : Dis

: 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

Precautions for safe handling

: Ensure good ventilation of the work station. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear personal protective equipment. Do not get in eyes, on skin, or on clothing.

Hygiene measures

: Separate working clothes from town clothes. Launder separately. Wash contaminated clothing before reuse. 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

Storage conditions

Comply with instructions for use (refer to technical sheet). Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Sodium Azide (26628-22-8)		
EU	IOELV TWA (mg/m³)	0.1 mg/m³
EU	IOELV STEL (mg/m³)	0.3 mg/m³
Belgium	Limit value (mg/m³)	0.1 mg/m³
Belgium	Short time value (mg/m³)	0.3 mg/m³
France	VME (mg/m³)	0.1 mg/m³
France	VLE (mg/m³)	0.3 mg/m³
Netherlands	Grenswaarde TGG 8H (mg/m³)	0.1 mg/m³
Netherlands	Grenswaarde TGG 15MIN (mg/m³)	0.3 mg/m³
United Kingdom	WEL TWA (mg/m³)	0.1 mg/m³
United Kingdom	WEL STEL (mg/m³)	0.3 mg/m³
USA - ACGIH	ACGIH Ceiling (mg/m³)	0.29 mg/m³
USA - ACGIH	ACGIH Ceiling (ppm)	0.11 ppm

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protective equipment:

Gloves. Safety glasses. Protective clothing.

Hand protection:	
Protective gloves	
Eye protection:	
Safety glasses	

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Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Wear respiratory protection.

Personal protective equipment symbol(s):







Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Color : No data available Odor : No data available Odor threshold : No data available pΗ : No data available Relative evaporation rate (butyl acetate=1) : No data available Melting point : No data available Freezing point : Not applicable Boiling point : No data available Flash point : Not applicable Auto-ignition temperature : Not applicable : No data available Decomposition temperature Flammability (solid, gas) : Non flammable. Vapor pressure : No data available Relative vapor density at 20 °C : No data available Relative density : Not applicable Solubility : No data available Log Pow : No data available Viscosity, kinematic : No data available Viscosity, dynamic : No data available Explosive properties : No data available

9.2. Other information

Oxidizing properties

Explosion limits

No additional information 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.

10.4. Conditions to avoid

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

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

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

: No data available

: Not applicable

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Oral: Harmful if swallowed.

Acute toxicity (dermal) : Dermal: Harmful in contact with skin.

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Acute toxicity (inhalation)	Not classified
ATE CLP (oral)	354.532 mg/kg body weight (oral)
ATE CLP (dermal)	1357.143 mg/kg body weight (dermal)

Sodium Azide (26628-22-8)	
LD50 oral rat	27 mg/kg body weight (oral rat)
LD50 dermal rabbit	19 - 48 mg/kg body weight (dermal rabbit)

Imidazole, 99% (288-32-4)	
LD50 oral rat	970 mg/kg body weight (Equivalent or similar to OECD 401, Rat, Experimental value)

Skin corrosion/irritation : Causes skin irritation. Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitization : Not classified Germ cell mutagenicity : Not classified Carcinogenicity : Not classified

Reproductive toxicity : May damage fertility or the unborn child.

: Not classified STOT-single exposure STOT-repeated exposure : Not classified Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.

Hazardous to the aquatic environment, short-term : Not classified

(acute)

Hazardous to the aquatic environment, long-term : Harmful to aquatic life with long lasting effects.

(chronic)

Sodium Azide (26628-22-8)	
LC50 fish 1	0.8 mg/l (Equivalent or similar to OECD 203, 96 h, Gasterosteus aculeatus, 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)

Imidazole, 99% (288-32-4)	
LC50 fish 1	283.6 mg/l (Other, 48 h, Leuciscus idus, Static system, Fresh water, Experimental value)
EC50 Daphnia 1	341.5 mg/l (EU Method C.2, 48 h, Daphnia magna, Static system, Fresh water, Experimental value)
ErC50 (algae)	133 mg/l (DIN 38412: German standard methods for the examination of water, waste water and sludge, 72 h, Desmodesmus subspicatus, Static system, Fresh water, Experimental value)
12.2 Persistence and degradability	

12.2. Persistence and degradability

Sodium Azide (26628-22-8)		
Persistence and degradability	Biodegradability in soil: not applicable. Biodegradability: not applicable.	
Biochemical oxygen demand (BOD)	Not applicable	
Chemical oxygen demand (COD)	Not applicable	
ThOD	Not applicable	
BOD (% of ThOD)	Not applicable	

Imidazole, 99% (288-32-4)	
Persistence and degradability	Readily biodegradable in the soil. Readily biodegradable in water.

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according to regulation (20) for recording to the first term of the first regulation (20) 2018/000		
12.3. Bioaccumulative potential		
Sodium Azide (26628-22-8)		
Bioaccumulative potential	not bioaccumulable.	

Imidazole, 99% (288-32-4)	
Log Pow	-0.02 (Weight of evidence approach, OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method, 25 °C)
Bioaccumulative potential Not bioaccumulative.	
12.4. Mobility in soil	
Sodium Azide (26628-22-8)	
Ecology - soil Highly mobile in soil.	

Imidazole, 99% (288-32-4)	
Log Koc	1.36 - 2.32 (log Koc, Calculated value)
Ecology - soil	Low potential for adsorption in soil.
12.5. Results of PRT and vPvR assessment	

Component	
(26628-22-8)	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
(288-32-4)	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.

: Not applicable

: Dispose of contents/container in accordance with licensed collector's sorting instructions. Waste treatment methods

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

14.2. UN proper shipping name

: Not applicable Proper Shipping Name (ADR) 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

UN-No. (RID)

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

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

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

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Inland waterway transport

Not applicable

Rail transport

Not applicable

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 no REACH candidate substance Contains no REACH Annex XIV substances.

Directive 2012/18/EU (SEVESO III)

15.1.2. National regulations

Germany

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

AwSV, Annex 1)

12th Ordinance Implementing the Federal Immission Control Act - 12.BlmSchV

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

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 : None of the components are listed

giftige stoffen – Borstvoeding

gittige stoffen – Borstvoeding

: None of the components are listed

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen – Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling

: 1H-imidazole is listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Pregnant/breastfeeding women working with the product must not be in direct contact with

the product

The requirements from the Danish Working Environment Authorities regarding work with carcinogens must be followed during use and disposal

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

Date of issue. 2020 06 22

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Data sources

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of R-, H- and EUH-phrases:		
Acute Tox. 2 (Oral)	Acute toxicity (oral) Category 2	
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	
Repr. 1B	Reproductive toxicity Category 1B	
Skin Corr. 1C	Skin corrosion/irritation Category 1C	
H300	Fatal if swallowed	
H302	Harmful if swallowed	
H312	Harmful in contact with skin	
H314	Causes severe skin burns and eye damage	
H315	Causes skin irritation	
H319	Causes serious eye irritation	
H360	May damage fertility or the unborn child	
H360D	May damage the unborn child.	
H400	Very toxic to aquatic life	
H410	Very toxic to aquatic life with long lasting effects	
H412	Harmful 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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