Material Safety Data Sheet

Kit name	Reference Number
Simtomax® (DGP), 1-unit kit with accessories	A011, A021, A201, A211, A221
Simtomax® (DGP), 10-units kit	A012
Simtomax® (DGP), 10-units kit with accessories	A013, A023, A413

Content

Version: 0.4
Effective date: 2014-09-17 (yyyy-mm-dd)

	Date	Name	Signature
Written by :			
Approved by :			

1 IDENTITY OF THE MANUFACTURER AND PRODUCT

1.1 PRODUCT IDENTITY

Name: Simtomax® (DGP)
Description: In-vitro diagnostic rapid test for the qualitative detection of Celiac Disease and IgA deficiency.
For In Vitro Diagnostic Use Only.

Reference number and description of the content of each kit:

	1 unit with accesories	10 units	10 units with accessories
Test device (with desiccant)	1	10	10
Plastic buffer bottle	1	1	1
Sterile automatic blood lancet	1	-	10
Alcohol-soaked swab	1	-	10
Plastic (25µl) pipette	1	-	10
Adhesive plaster	1	-	10
Instructions for use leaflet	1	1	1

1.2 MANUFACTURER

Name: Augurix SA
Address: Route de l'Ile-aux-Bois 1a
1870 Monthey
SWITZERLAND
Telephone number: +41 (0)24 471 99 90

2 INFORMATION OF INGREDIENTS

2.1 INFORMATION

The hazardous ingredients are the animals'blood components and the Sodium Azide, they are both in a concentration <0.5% w/w.

2.2 CONTENTS

Device

Chemical	**CAS#**	**%w/w**
Polypropylene	9003-07-0	>98%
Nitrocellulose	9004-70-0	<1%
Fiberglass	NA	<1%
Gold Conjugate	NA	<0.01%
Animals' Blood Components	NA	<0.01%

Buffer

Chemical	CAS#	%w/w
Sodium azide	26628-22-8	<0.5%
Sodium chloride	7647-14-5	<1%
di-Sodium Hydrogen Orthophosphate	7558-79-4	<1%
Potassium di-Hydrogen Orthophosphate	7778-77-0	<1%
Tween 20	9005-64-5	<5%
Demineralized water	7732-18-5	>92%

3 HAZARDS IDENTIFICATION

3.1 DEVICE

Ingestion: The ingestion of the device may cause suffocation

3.2 BUFFER

Skin contact: Skin contact may cause irritation, dryness and redness
Eye contact: Eye exposure may cause irritation, redness and watering
Ingestion: Ingestion may produce nausea, vomiting and diarrhea

3.3 TEST COMPONENTS

Ingestion: The ingestion of the test components may cause suffocation

4 FIRST AID MEASURES

4.1 DEVICE

Skin Contact: NA

Eye Contact: NA

Inhalation: NA

Ingestion: In case of ingestion, try to expulse the component or consult a physician.

4.2 BUFFER

Skin Contact: In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

Eye Contact: Flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if irritation or other symptoms develop.

Inhalation: NA

Ingestion: In case of ingestion, contact a poison control centre or physician for instructions.

4.3 TEST COMPONENTS

Skin Contact:	NA
Eye Contact:	NA
Inhalation:	NA
Ingestion:	In case of ingestion, try to expulse the component or consult a physician.

5 FIRE-FIGHTING MEASURES

5.1 SUITABLE EXTINGUISHING MEDIA

Use extinguishing media suitable for surrounding fire, such a carbon dioxide, chemical foam, dry chemical or water spray.

5.2 UNSUITABLE EXTINGUISHING MEDIA

Unknown.

5.3 SPECIFIC HAZARDS ARISING FROM THE CHEMICALS

The Alcohol swab is flammable, do not use it near a source of heat.
The buffer is a diluted aqueous solution not considered a fire hazard.
Do not expose the product under extreme temperature to avoid fire or melting of components and the concentration by evaporation of the buffer solution.

5.4 STANDARD PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self contained breathing apparatus for fire fighting if necessary.

6 ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS

Avoid skin and eye contact with the buffer.

6.2 ENVIRONMENTAL PRECAUTIONS

Do not pour the buffer down the drain. Discharge into the environment must be avoided. In certain concentration Sodium Azide is harmful to aquatic organisms – see section 12.

6.3 CLEANING MEASURES

If a part of the buffer solution is spilled, soak it up with inert absorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with applicable state environmental / hazardous waste regulations.

7 HANDLING AND STORAGE

7.1 HANDLING

No special precautions required.

7.2 STORAGE

Stored at 5 to 25°C (41 to 77°F).

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 EXPOSURE LIMIT VALUES

The buffer is a solution containing less than 0.5% of Sodium Azide, which can not be dispersed in the air if manipulated in an adequate manner. The limit values are not available for this preparation.

8.2 PERSONAL PROTECTION

No specific equipment is required. The buffer must be manipulated conscientiously.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 DEVICE AND TEST COMPONENTS

The device and the test components are odourless.

9.2 BUFFER

Appearance:	clear, colourless liquid	Solubility:	water soluble
Odour:	odourless	Vapour pressure:	not available
pH:	7.1-7.3	Relative density:	1.01 g/ml at 20°C (68°F)
Boiling point:	not available	Evaporation rate:	not available
Flash point:	not available	Viscosity:	not available

10 STABILITY AND REACTIVITY

10.1 STABILITY

The device, test components and buffer are stable at room temperature.

10.2 CONDITIONS TO AVOID

Extreme temperature must be avoided (melting of components and concentration by evaporation of the buffer solution).

10.3 MATERIALS TO AVOID

The incompatible materials with Sodium Azide are Methylene Chloride, Dimethyl Sulfoxide, and Sulphuric Acid Halogenated hydrocarbon, Metals, Acids and Acid Chlorides. Do not pour a solution of Sodium Azide down the drains it might react with the metal part of the canalisations.

10.4 HAZARDOUS DECOMPOSITION PRODUCTS

The reaction of sodium Azide and acids formed the Hydrazoic acid (HN_3) which is volatile, toxic and unstable.

11 TOXICOLOGICAL INFORMATION

Effects of the substances at the concentration present in the preparation:

Acute Effects:	no data available	Mutagenicity:	no data available
Local Effects:	no data available	Teratogenicity:	no data available
Chronic Effects:	no data available	Sensitization:	no data available

12 ECOLOGICAL INFORMATION

Effects of the substances at the concentration present in the preparation:

Ecotoxicity:	no data available
Persistance and degradability:	no data available
Bioaccumulative Potential:	no data available
Mobility:	no data available

Sodium Azide is harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

13 DISPOSAL CONSIDERATIONS

13.1 DISPOSAL OF PREPARATION LEFT

Do not pour the buffer down the drain. Dispose of materials in accordance with applicable state environmental / hazardous waste regulations.

13.2 CONTAMINATED PACKAGING

Dispose of as unused product.

14 TRANSPORTATION INFORMATION

During the transport can be kept between 2°C (36°F) and 5°C (41°F) and between 25°C (77°F) and 37°C (99°F) for maximum 48h.

Road/Railway Haulage ADR/RID: no other restriction
Sea Freight IMO (IMDG): no other restriction
Air Freight IATA (ICAO): no other restriction

15 OTHER REGULATORY INFORMATION

This MSDS is based on the European Communities directive 2001/58/EC.
This product is based on the European Communities directive 98/79/EC relative to the in-vitro medical device.

16 OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall only be used as a guide. Augurix SA is not responsible for any damage resulting from incorrect use of the product. This product is sold with an instruction for use leaflet (in English, French, German, Italian and other requested languages). The recipient is responsible for applying the guidelines. This test must be performed by healthcare professionals.

Version History

Date	Version	Author	Description
2011-04-07	0.1	IDorsaz	Creation of this document
2011-04-27	0.2	IDorsaz	Addition of the CAS number of Demineralized Water
2011-06-03	0.3	IDorsaz	Update of the new Manufacturer address
2014-09-17	0.4	IDorsaz	Correction of chapter 4.2, update of the table of content of Simtomax, update of the Simtomax articles number on 1st page, suppression of the term « Blood Drop » in the product name, addition of the Version History table MOD-14260-01