Sekisui Diagnostics, LLC
500 West Avenue, Stamford, CT 06902
Tel. (203) 602-7777 Fax (203) 602-2221

MATERIAL SAFETY DATA SHEET

1. PRODUCT IDENTIFICATION

1.1 Product Name: DVVconfirm® 5, DVVconfirm® 10

1.2 Product REF: 815, 815L

1.3 Configuration: 815 – 10 vials x 1.0 mL per vial set
815L – 10 vials x 2.0 mL per vial set

1.4 Use of Product: For In Vitro Diagnostic Use

1.5 Company

Manufacturer:
Sekisui Diagnostics, LLC
500 West Avenue
Stamford, CT 06902 USA
Tel: (203) 602 7777
Fax: (203) 602 2221
Email: linus@amdiag.com

Distributor EU:
American Diagnostica GmbH
Kaplangeisse 35
Pfungstadt 64319 Germany
Tel: +49 6157 990899
Fax: +49 6157 990808
Email: info@amdiag.de

2. HAZARDS IDENTIFICATION

2.1 Classification: Toxic, Dangerous

2.2 Potential Health and Environmental Effects

Skin Exposure: May be fatal if absorbed through skin. May cause skin irritation.

Eye Exposure: May damage the eye

Inhalation Exposure: May be fatal if inhaled

Ingestion: Very harmful if swallowed

Environmental Exposure: Might cause adverse effects to the environment.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Reagent/Component	Chemical Name	CAS No.	EINECS No.	Concentration, w/v, %
DVVconfirm	Russell's Viper Venom	NA	NA	< 0.01%
	Phospholipids	NA	NA	NA
	HEPES	7365-45-9	230-907-9	< 1.0%
	Imidazole	288-32-4	206-019-2	< 1.0%
	Calcium Chloride	10043-52-4	233-140-8	< 1.0%
	Sodium Chloride	7647-14-5	231-598-3	< 1.0%
	Hexadimethrine Bromide	28728-55-4	NA	< 0.1%
	Butylated Hydroxytoluene	128-37-0	204-881-4	NA
	D-Trehalose Dihydrate	6138-23-4	202-739-6	< 1.0%
	D-Mannitol	69-65-8	200-711-8	< 1.0%
	Sodium Azide	26628-22-8	247-852-1	< 0.05%

NA – Not Available

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4. FIRST AID MEASURES

Skin Exposure:	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing. Seek medical attention if adverse symptoms appear.
Eye Exposure:	In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Seek medical attention if adverse symptoms appear.
Inhalation Exposure:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen and seek medical attention.
Ingestion:	If swallowed, wash out mouth with water provided person is conscious. Seek medical attention if adverse symptoms appear.

5. FIRE FIGHTING MEASURES

Flammability:	Solutions are non-flammable. Boxing and instruction papers are flammable.
Suitable Extinguishing Media:	Use extinguishing media appropriate to the surrounding fire conditions, such as carbon dioxide, dry chemical powder, foam or water spray.
Unsuitable Extinguishing Media:	None known.
Equipment for fire fighting:	Wear self-contained breathing apparatus and protective clothing appropriate for fighting a fire involving chemical materials to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. In case of skin contact, flush with copious amounts of water and remove contaminated clothing.
Environmental Precautions:	Do not let the product enter the drainage system.
Methods For Cleaning Up:	Soak up with inert absorbent material, place in a bag and hold for waste disposal. Wash spill site after material pickup is complete.

7. HANDLING AND STORAGE

7.1 Handling

Handling Procedure:	Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged exposure. Provide adequate ventilation in all work areas.
Hygienic Practice:	Wash hands with soap and water following use.

7.2 Storage

Container:	Keep container tightly closed and labeled with the name of the product.
Recommended Temperature:	2°-8°C.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure Limit Values

TWA: 10 mg/m^3 for Butylated Hydroxytoluene per OSHA
TLV/TWA: 2 mg/m^3 for Butylated Hydroxytoluene per ACGIH

TLV/TWA: 0.1 mg/m³ for Sodium Azide
TLV/STEL: 0.3 mg/m³ for Sodium Azide
TLV/Ceiling: 0.29 mg/m³ for Sodium Azide, 0.11 ppm for Hydrazoic acid vapor per ACGIH
EU IOELV: 0.1 mg/m³ (TWA) for Sodium Azide, 0.3 mg/m³ (STEL) for Sodium Azide

8.2 Personal Protection

Respiratory Protection:	Respirator protection is not required. Where protection is desired, use type N95 (US) or type P1 (EN 143) dust masks or for higher level protection, use NIOSH (USA) or CEN (EU) approved respirators and filters.
Eye Protection:	Chemical safety goggles.
Hand Protection:	Compatible chemical resistant gloves. Use proper glove removal technique to avoid skin contact. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices.
Skin Protection:	Compatible chemical resistant gloves and other protective clothing as required to prevent skin contact.
General Hygiene Practices:	Wash promptly if skin comes into contact with product. Wash thoroughly after handling. Remove any clothing that comes into contact with the product. Do not smoke or eat in the work environment.

9. PHYSICAL AND CHEMICAL PROPERTIES

Property	DVVconfirm
Appearance	white power
Odor	None
pH	NA
Freezing Point	NA
Vapor Pressure	NA
Specific Gravity	NA
Solubility	water soluble
Evaporation Rate	NA
Viscosity	NA
Surface Tension	NA
Boiling Point	NA
Melting Point	NA
Flash Point	NA
Lower Explosive Limit	NA
Upper Explosive Limit	NA
Flammability	NA
Autoignition Temp.	NA

NA = not available

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10. STABILITY AND REACTIVITY

10.1 Stability: The product is stable until the expiration date stated on its label when properly stored at 2°-8°C.

10.2 Conditions To Avoid: Keep away from heat.

10.3 Materials To Avoid: Strong acids, strong reducing agents, strong oxidizing reagents.

10.4 Hazardous Decomposition Products: Hazardous decomposition products due to combustion may include carbon monoxide, carbon dioxide, and nitrogen oxides.

Warning: Sodium Azide may form explosive compounds, copper azide or lead azide, when in contact with laboratory plumbing.

11. TOXICOLOGICAL INFORMATION

11.1 Acute Toxicity

Reagent/ Component	Chemical Name	Oral LD_{50}	Inhalation LC_{50}	Dermal LD_{50}	Intravenous LD_{50}
DVVconfirm	Russell's Viper Venom	No Data Available	No Data Available	No Data Available	mouse, 0.035 mg/kg
	Phospholipids	No Data Available	No Data Available	No Data Available	No Data Available
	Calcium Chloride	rat, 1,000 mg/kg	No Data Available	No Data Available	No Data Available
	Sodium Chloride	NA	rat,1 hr >42,000 mg/m^3	rabbit, >10,000 mg/kg	No Data Available
	Hexadimethrine Bromide	rat, >1,000 mg/kg	No Data Available	No Data Available	No Data Available
	Butylated Hydroxytoluene	rat, 890 mg/kg	No Data Available	No Data Available	No Data Available
	HEPES	No Data Available	No Data Available	No Data Available	No Data Available
	Imidazole	rat, 970 mg/kg	No Data Available	No Data Available	No Data Available
	D-Trehalose Dihydrate	No Data Available	No Data Available	No Data Available	No Data Available
	D-Mannitol	rat, 13,500 mg/kg	No Data Availabale	No Data Available	No Data Available
	Sodium Azide	No Data Available	rat, 37 mg/m^3	rabbit, 20 mg/kg	No Data Available

11.2 Irritation

Skin: Skin irritation in rabbit (due to Butylated Hydroxytoluene)
Corrosive to skin in rabbit (due to Imidazole)

Eye: Severe eye irritation in rat (due to Calcium Chloride)
May damage the eye in rabbit (due to Imidazole)

Inhalation: No Data Available

11.3 Sensitization

Skin: Prolonged exposure may cause an allergic reaction.

Inhalation: No Data Available

11.4 Carcinogenicity

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen.

11.4 Mutagenicity

No data available

11.4 Teratogenicity

Imidazole is a presumed human reproductive toxicant. It may damage the unborn child. No data available.

For the other components of this product, the health effects noted above are based on the extrapolation of data on the pure product ingredients. To the best of our knowledge, no health effects have been identified for the product mixture under normal conditions of use, although the health effects of the product have not been thoroughly investigated.

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12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Toxicity to fish (Calcium Chloride)	LC50, Lepomis macrochirus – 10,650 mg/L, 96 hours
Toxicity to fish (Butylated Hydroxytoluene)	LC50, Oryzias latipes – 5.3 mg/L, 48 hours
Toxicity to fish (Imidazole)	LC50, Leuciscus idus (Golden orfe) – 280 mg/L, 48 hours
Toxicity to daphnia (Calcium Chloride)	EC50, Daphnia magna (water flea) – 52 mg/L, 48 hours
Toxicity to daphnia (Sodium Chloride)	EC50, Daphnia magna (water flea) – 1,661 mg/L, 48 hours
Toxicity to daphnia (Sodium Chloride)	Mortality NOEC, daphnia – 1,500 mg/L, 7 days
Toxicity to daphnia (Sodium Azide)	EC50, Daphnia pulex (water flea) – 4.2 mg/L, 48 hours
Toxicity to daphnia (Butylated Hydroxytoluene)	EC50, Daphnia pulex (water flea) – 1.44 mg/L, 48 hours
Toxicity to daphnia (Imidazole)	EC50, Daphnia – 341.5 mg/L, 48 hours
Toxicity to algae (Imidazole)	EC50, Scenedesmus quadricauda (Green algae) – 133 mg/L, 72 hours

12.2 Mobility: No Data Available

12.3 Persistence and degradability degradability: Aerobic, 86% readily biodegradable

12.4 Bioaccumulative potential: No Data Available

12.5 PBT assessment: No Data Available

12.6 Other adverse effects: No Data Available

13. DISPOSAL CONSIDERATIONS

Contact a licensed professional waste disposal service to dispose of this material. Disposal should be made in accordance with existing disposal practices employed for infectious waste at your institution. Observe all federal, state and local environmental regulations and laws.

14. TRANSPORT INFORMATION

DOT (US):	Proper Name For Shipping:	Corrosive solid, basic, organic, n.o.s. (Imidazole)
	UN Number:	3263
	Hazard Class:	8
	Reportable Quantity:	Not Available
	Packing Group:	II
	Marine Pollutant:	No
	Poison Inhalation Hazard:	No

IMDG:
UN Number: 3077
Class: 9
Packing Group III
Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (Butylated Hydroxytoulene)
Marine Pollutant

IATA:/ICAO
UN Number: 3077
Class: 9
Packing Group III
Proper Shipping Name: Environmentally hazardous substance, solid, n.o.s. (Butylated Hydroxytoulene)

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15. REGULATORY INFORMATION

This product is classified and labeled in accordance with Directives 1999/45/EC and 67/548/EEC. The health hazard classification has been determined based upon the composition and hazard data of each ingredient. Physical and health hazard information on the reagent mixture has not been determined. Any physical and health hazard information noted is based on a) evaluation of data of the pure ingredient and b) the concentration of each ingredient.

Hazard Classification

EC Symbol:	T
Indication of Danger:	Toxic
Risk Code:	R21/22, R28, R32, R50/53
Safety Code:	S24/25, S26, S37/39, S46, S29/56
Hazard Code:	H300, H302, H313, H314, H315, H318, H319, H360, H400, H410,

OSHA Hazards:	Sodium Azide is highly toxic by ingestion. Target organs are primarily the central nervous system and the brain. Imidazole is a teratogen and corrosive to the skin and harmful by ingestion.
SARA 302 Components:	Sodium Azide in this product, however it's level does not exceed the threshold reporting levels subject to the reporting requirements of SARA Title III, Section 302.
SARA 313 Components:	Sodium Azide in this product, however it's level does not exceed the threshold reporting levels by SARA Title III, Section 313.
SARA 311/312 Hazards:	Acute Health Hazard (Butylated Hydroxytoluene, Imidazole). Chronic Health Hazard (Russell's Viper Venom)
California Prop 65 Components:	This product does not contain any chemicals known to the State of California to cause cancer, birth defects or any other reproductive harm.

16. OTHER INFORMATION

The information supplied in this Material Safety Data Sheet represents the data and best information available on the date of preparation. It is provided to allow for the proper and safe use, storage, transport and disposal of the product. It is not to be considered as a warranty, guarantee or specification of the product quality. It is related to the materials specifically indicated and does not apply if these are used in combination with other materials or during processes not indicated in the text of this safety data sheet.

Sekisui Diagnostics, LLC and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.