Safety Data Sheet

List No. 9459, BR2 Bilirubin Calibrator

IN CASE OF EMERGENCY CALL CHEMTREC® (24 hr) 800-424-9300

SECTION 1 – PRODUCT DESCRIPTION

Product (Trade) Name: BR2 Bilirubin Calibrator

Product List Number: 9459

Product Description: Aqueous reference standard for clinical laboratory use

Other means of identification
Synonyms: calibrator, calibration standard

Recommended use of the chemical and restrictions on use

Recommended use: For In Vitro Diagnostic Use

Uses advised against: No information available

Manufacturer: Verichem Laboratories, Inc.
90 Narragansett Ave.
Providence, RI 02907
(401) 461-0180

Contact us: http://www.verichemlabs.com

Emergency telephone number: CHEMTREC® (USA): 800-424-9300

SECTION 2 – HAZARDS IDENTIFICATION

GHS Classification: Not classified

GHS Label Elements: None required.

GHS Hazard statements: PHYSICAL HAZARDS:
Not classified as a physical hazard under GHS criteria.

HEALTH HAZARDS:
Not classified as a health hazard under GHS criteria.

ENVIRONMENTAL HAZARDS:
Not classified as an environmental hazard under GHS criteria.

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

OSHA Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC): None identified

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

No ingredients are hazardous according to OSHA criteria.
No components need to be disclosed according to the applicable regulations.

Components	CAS No.	Weight %	Trade Secret	Synonyms
Bovine Serum Albumin	9048-46-8	5 – 7 %	No	BSA, bovine albumin
Bilirubin Ditaurate, Disodium	68683-34-1	< 0.1 %	No	bilirubin conjugate, bilirubin ditaurine
Proprietary Ingredients	Various	93 - 95 %	Yes	-

SECTION 4 – FIRST AID MEASURES

General Advice: Treat symptomatically and supportively.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Skin contact: In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.

Inhalation: If inhaled, remove victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms appear.

Ingestion: Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.

Most important symptoms and effects, both acute and delayed
No information available.

Indication of any immediate medical attention and special treatment needed
Treat symptomatically.

SECTION 5 – FIRE FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable Extinguishing Media: No information available.

Special hazards arising from the substance or mixture: Nature of decomposition products not known.

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Keep unnecessary personnel away. Avoid breathing vapors, mist or gas. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

Environmental precautions: Do not let product enter drains. See Section 12 for environmental precautions.

Methods and material for containment and cleaning up

Methods for containment: If emergency personnel are unavailable, contain spilled material.

Methods for cleaning up: For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

SECTION 7 – HANDLING AND STORAGE

Precautions for Safe Handling

Technical measures/ precautions: Wash thoroughly after handling.

Conditions for safe storage, including any incompatibilities

Technical measures/ conditions: Keep containers tightly closed in a dry, well-ventilated place. Containers that are opened must be carefully resealed and kept upright to prevent leakage. Store at recommended temperature.

Incompatible products: No special restrictions on storage with other products

SECTION 8 – EXPOSURE CONTROL / PERSONAL PROTECTION

Control parameters

Components with workplace control parameters:
Contains no substances with occupational exposure limit values.

Appropriate engineering controls

Engineering measures: No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Individual protection measures, such as personal protective equipment

Eye protection: Safety glasses with side-shields are recommended for laboratory and manufacturing use.

SECTION 8 – EXPOSURE CONTROL / PERSONAL PROTECTION

Hand protection: Use chemical resistant, impervious gloves.

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection: No personal respiratory protective equipment normally required.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical state:
Liquid.

Appearance:
Clear.

Color:
Colorless to orange.

Odor:
None.

Taste
No data available.

Molecular/Formula weight:
No data available.

Formula:
No data available.

Flash point (°C):
No data available.

Flashpoint (°C/°F):
No data available.

Flash Point Tested according to:
No data available.

Lower Explosion Limit (%):
No data available.

Upper Explosion Limit (%):
No data available.

Auto-ignition Temperature (°C/°F):
No data available.

pH:
7.4

Melting point/range (°C/°F):
No data available.

Boiling point/range (°C/°F):
No data available.

Decomposition temperature (°C/°F):
No data available.

Bulk density:
No data available.

Specific gravity:
No data available.

Vapor pressure @ 20°C (kPa):
No data available.

Density (g/cm3):
No data available.

Evaporation rate:
No data available.

Vapor density:
No data available.

VOC content (g/L):
No data available.

Odor threshold (ppm):
No data available.

Partition coefficient (n-octanol/water):
No data available.

Viscosity:
No data available.

Solubility:
Soluble in water

Other safety information: No data available

SECTION 10 – STABILITY AND REACTIVITY

Reactivity
No data available

Incompatible materials
Strong oxidizing agents

Chemical Stability
Stable under recommended storage conditions.

Hazardous Decomposition Products
No data available.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to Avoid
No information available.

SECTION 11 – TOXICOLOGY INFORMATION

Information on likely routes of exposure

Inhalation: Inhalation not likely under normal use conditions.

Eye contact: May cause irritation and/or allergic reactions.

Skin contact: May cause irritation and/or allergic reactions.

Ingestion: Hypersensitivity (may include drug fever, rash, itching, anaphylaxis).

Information on Toxicological Effects

Symptoms: No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Acute toxicity No data available

Inhalation: No data available

Dermal: No data available

Skin corrosion/irritation: No data available

Serious eye damage/ eye irritation: No data available

Respiratory or skin Sensitization: No data available

Germ cell mutagenicity: No data available

SECTION 11 – TOXICOLOGY INFORMATION

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

Reproductive toxicity: Reproductive studies have not been conducted on the product itself.

STOT - single exposure: No information available.

STOT - repeated exposure: No information available.

Aspiration Hazard: No information available.

SECTION 11 – TOXICOLOGY INFORMATION

Additional Information

RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity: No information available.

SECTION 12 – ECOLOGICAL INFORMATION

Ecotoxicity
No information available.

Persistence and degradability
No information available.

Bioaccumulative potential
No information available

Mobility in soil
No information available.

Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

Other adverse effects:
No information available.

SECTION 13 – DISPOSAL CONSIDERATIONS

Disposal Methods

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal in accordance with Federal, State and Local regulation.

SECTION 14 – TRANSPORATION INFORMATION

DOT:	Not Regulated
TDG (Canada):	Not Regulated
ADR:	Transport Document Description
IMO / IMDG	Not Regulated
IATA:	Not Regulated

SECTION 15 – REGULATORY INFORMATION

U.S. Regulations:
TSCA Inventory List: The product is exempt from TSCA. It is FDA Regulated.

OTHER REGULATIONS:

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
No SARA Hazards

Reportable Quantity : lowest RQ > 999999 lbs

STATE REGULATIONS:

Component	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Know Reporting	Rhode Island Right-to-Know:	Massachusetts Right-to-Know :	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Bovine Serum Albumin	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Present	Present
Bilirubin Ditaurate, Disodium	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Proprietary Ingredients	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

Canada DSL Inventory List - Present (Bovine Serum Albumin, 9048-46-8)

Canada NDSL Inventory List - Present (Bilirubin Ditaurate, Disodium, 68683-34-1). This substance is specified on the NDSL. The NDSL is an inventory of substances that are not on the DSL but are accepted as being in use internationally.

WHMIS hazard class: Non-controlled

Canada Controlled Products Regulation:
Not classified

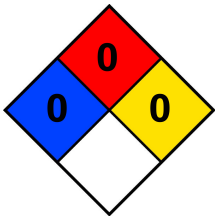
EU Classification:

R-phrase(s)
Not applicable

S -phrase(s)
S2 - Keep out of the reach of children.

Components	Classification	Concentration Limits:	Safety Phrases
Bovine Serum Albumin	Not regulated	No information	S2
Bilirubin Ditaurate, Disodium	Not regulated	No information	S2
Proprietary Ingredients	Not applicable	Not applicable	Not applicable

SECTION 16 – OTHER INFORMATION

NFPA	HMIS III	Personal Protective Equipment
		 See Section 8.

NFPA Hazard Ratings

NFPA health hazard: 0 – Normal material. Minimal Hazard
NFPA fire hazard: 0 – Not combustible
NFPA reactivity: 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.

HMIS III Ratings

Health : 0 - Minimal Hazard
Flammability: 0 - Minimal Hazard
Physical: 0 - Minimal Hazard
Personal Protection: C - (Safety Glasses, Gloves, Protective Clothing)

SECTION 16 – OTHER INFORMATION

SDS US (GHS HazCom 2012)

Preparation Date: August 27, 2015 Document No. 9459-SDS

Prepared by: Anthony DiMonte Revision: New

Disclaimer: All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Verichem Laboratories, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Verichem Laboratories assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet