

[SDS]

Direct Bilirubin

1268 N. Lakeview Ave. Anaheim, CA 92807 Phone: (714) 463-1111 Fax: (714) 463-1169 www.tecodiagnostics.com

Section 1 – Identification

Product Name Catalog Number Product Type	Direct Bilirubin B538-480 Clinical Chemistry Reagent	Emergency Telephone No. CHEMTREC (800) 424-9300 International CHEMTREC (703) 527-3887
Company Name Street Address City, State, Zip Code, Country	Teco Diagnostics 1268 N. Lakeview Avenue Anaheim, CA 92807 USA	Company Telephone No. (800) 222-9880 or (714) 463-1111 Monday - Friday 8:00-5:00 PST Fax No. (714) 463-1169
Recommended Use: For <i>in vitro</i> diagnostic use only. For professional use only.		
Restrictions on Use: Not for <i>in vivo</i> use.		

Section 2 – Hazard(s) identification


Component	Classification of the substance or mixture
Direct Bilirubin Reagent Hazardous components: Hydrochloric acid Sulfanilic Acid	Product Description: Mixture This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200) Corrosive to metals (Category 1), H290 Skin corrosion/irritation (Category 1B), H314 Serious eye damage (Category 1), H318 Specific target organ toxicity (single exposure) Target Organs - Respiratory system. (Category 3), H335 Specific target organ toxicity - (repeated exposure) Target Organs - Kidney, Liver. (Category 2), H373 This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200) Skin irritation (Category 2), H315 Skin sensitization (Category 1), H317 Eye irritation (Category 2A), H319 Acute aquatic toxicity (Category 3) H402
Bilirubin Nitrite Reagent Hazardous component: Sodium Nitrite (<1%)	Product Description: Mixture This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200) Acute aquatic toxicity (Category 3) H402 Chronic aquatic toxicity (Category 3) H412
Bilirubin Calibrator Hazardous component: N-(1-naphthyl)ethylenediamine dihydrochloride	Product Description: Mixture This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). H315 Skin irritation (Category 2), H319 Eye irritation (Category 2A), H335 Specific target organ toxicity - single exposure (Category 3), Respiratory system


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Section 2 – Hazard(s) identification (continued)

Component	GHS Label elements, including precautionary statements	
Hydrochloric acid (Component of Direct Bilirubin Reagent)	Pictogram	
	Signal Word	Danger
	Hazard Statements	H290 May be corrosive to metals. H314 Causes severe skin burns and eye damage. H318 Causes serious eye damage. H335 May cause respiratory irritation. H373 May cause damage to organs through prolonged or repeated exposure.
	Precautionary Statements	P234 Keep only in original container. P261 Avoid breathing dust/fume/gas/mist/vapors/spray. P264 Wash hands and skin thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331 IF SWALLOWED: Rinse mouth. DO NOT induce vomiting. P303+P361+P353 IF ON SKIN: Take off immediately all contaminated clothing. Rinse skin with water/shower. P304+P340+P310 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a POISON CENTER or doctor/physician. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P363 Wash contaminated clothing before reuse. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P501 Dispose of contents/ container to an approved waste disposal plant.
Hazards not Otherwise classified (HNOC)	None	

Component	GHS Label elements, including precautionary statements	
Sulfanilic acid [Other name: 4-Amino-benzenesulfonic acid] (Component of Direct Bilirubin Reagent)	Pictogram	
	Signal Word	Warning
	Hazard Statements	H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H402 Harmful to aquatic life.
	Precautionary Statements	P261 Avoid breathing dust/ fume/ gas/ mist/vapors/ spray. P264 Wash hands and skin thoroughly after handling. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection P302+P352 IF ON SKIN: Wash with plenty of 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. P333+P313 If skin irritation or rash occurs: Get medical advice/ attention. P337+P313 If eye irritation persists: Get medical advice/ attention. P362 Take off contaminated clothing and wash before reuse. P501 Dispose of contents/ container to an approved waste disposal plant.
Hazards not Otherwise classified (HNOC)	None	


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Section 2 – Hazard(s) identification (continued)

Component	GHS Label elements, including precautionary statements	
Sodium Nitrite (<1%) (Component of Bilirubin Nitrite Reagent)	Pictogram	None
	Signal Word	None
	Hazard Statements	H412 Harmful to aquatic life with long lasting effects.
	Precautionary Statements	P273 Avoid release to the environment. P501 Dispose of contents/container to an approved waste disposal plant.
Hazards not Otherwise classified (HNOC)	None	

Component	GHS Label elements, including precautionary statements	
N-(1-naphthyl) ethylenediamine dihydrochloride [Other name: N-2-Aminoethyl-1-naphthylamine dihydrochloride] (Component of Bilirubin Calibrator)	Pictogram	
	Signal Word	Warning
	Hazard Statements	H315 Causes skin irritation. H319 Causes serious eye irritation. H335 May cause respiratory irritation.
	Precautionary Statements	P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray. P264 Wash skin thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves/ eye protection/ face protection. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312 Call a POISON CENTER or doctor/ physician if you feel unwell. P332+P313 If skin irritation occurs: Get medical advice/ attention. P337+P313 If eye irritation persists: Get medical advice/ attention. P362 Take off contaminated clothing and wash before reuse. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P501 Dispose of contents/ container to an approved waste disposal plant.
Hazards not Otherwise classified (HNOC)	None	

Section 3 – Composition/information on ingredients

Component	Type	Chemical Concentration	CAS#
Direct Bilirubin Reagent	Mixture	165 mM, Hydrochloric acid 32 mM Sulfanilic acid	7647-01-0 121-57-3
Bilirubin Nitrite Reagent	Mixture	60 mM (<1%), Sodium nitrite	7632-00-0
Bilirubin Calibrator	Mixture	5 mg/dl, N-(1-naphthyl)ethylenediamine dihydrochloride	1465-25-4

Section 4 – First-aid measures

General Advice	Immediately remove any clothing contaminated by the product. Move out of dangerous area. Consult a physician.
Ingestion	Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.
Inhalation	Move person into fresh air. If not breathing, give artificial respirations and seek medical attention.
Skin Contact	Wash off skin immediately with soap and plenty of water. Remove contaminated clothing and shoes. Wash clothing before reuse. Get medical attention if irritation occurs.
Eye Contact	Immediately wash with plenty of water for at least 15 minutes. Assure adequate flushing of the eyes by separating the eyelids with fingers. If irritation persists, consult a physician.

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Section 5 - Fire-fighting measures

Extinguishing Media

Suitable: Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide.

Unsuitable: No information available.

Specific Hazards

Hazardous combustion products: Carbon oxides, hydrogen chloride gas, nitrogen oxides, sodium oxides, sulfur oxides

Special protective equipment and precautions for fire-fighters

Wear self-contained breathing apparatus and appropriate protective clothing for firefighting.

Section 6 – Accidental release measures

Personal precautions, protective equipment and emergency procedures

Wear proper personal protective equipment (PPE) as indicated in section 8. Exercise appropriate precautions to avoid contact with skin or eyes and prevent inhalation.

Environmental Precautions

Do not let product enter drains. Discharge into the environment must be avoided. Refer to section 12 for ecological information.

Methods for Cleaning Up and Disposal

Prevent further leak or spill if safe to do so. Vacuum, sweep up, or absorb with inert material and place into a suitable disposal container.

Consult local regulations for disposal. Avoid dust formation. Avoid inhaling. Wash and ventilate spill site after material pickup is complete.

Section 7 – Handling and storage

Handling

Wear appropriate personal protective equipment (PPE) as indicated in section 8. Avoid contact with skin, eyes, and personal clothing. Avoid inhalation and ingestion.

Storage

Store in the original containers at room temperature (15-30°C) and protected from direct sunlight according to the label instructions. Keep containers tightly closed when not in use.

Section 8 – Exposure controls / personal protection

Components with workplace control parameters

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Hydrochloric acid	Ceiling: 2 ppm	Ceiling: 5 ppm Ceiling: 7 mg/m ³ (Vacated) Ceiling: 5 ppm (Vacated) Ceiling: 7 mg/m ³	IDLH: 50 ppm Ceiling: 5 ppm Ceiling: 7 mg/m ³
	Quebec	Mexico OEL (TWA)	Ontario TWA/EV
	Ceiling: 5 ppm Ceiling: 7.5 mg/m ³	Ceiling: 5 ppm Ceiling: 7 mg/m ³	CEV: 2 ppm

Engineering Controls

No special ventilation is required. Good ventilation is sufficient. Handle in accordance with food industrial hygiene and safety practices.

Ensure that eyewash stations and safety showers are close to the work area.

Personal Protective Equipment

Eye Protection	Wear appropriate protective chemical safety glasses or goggles as described in the appropriate regulations found in OSHA 29 CFR 1310.133 (US) or EN166 (EU). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin Protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands after glove removal.
Body Protection	Wear clothing that is impervious to chemicals. The type of protective clothing must be selected according to the concentration and amount of the dangerous substance at the specific workplace
Respiratory Protection	Respiratory protection is not required when using this product. If exposure limits are expected to be exceeded, wear respiratory protection as described in the appropriate regulations found in OSHA 29 CFR 1310.134 (US) or EN149 (EU). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Other Protective Equipment	Ensure the eyewash station and/or safety shower is located near the work area

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Section 9 - Physical and chemical properties

	Direct Bilirubin Reagent	Bilirubin Nitrite Reagent	Bilirubin Calibrator
Appearance	Liquid	Liquid	Liquid
Odor	No information available	No information available	No information available
Odor threshold	No information available	No information available	No information available
pH	No information available	No information available	No information available
Melting point/ freezing point	No information available	No information available	No information available
Initial boiling point and boiling range	No information available	No information available	No information available
Flash point	No information available	No information available	No information available
Evaporative rate	No information available	No information available	No information available
Flammability (solid, gas)	No information available	No information available	No information available
Upper/lower flammability or explosion limits	No information available	No information available	No information available
Vapor pressure	No information available	No information available	No information available
Vapor density	No information available	No information available	No information available
Relative density	No information available	No information available	No information available
Solubility	Soluble in water	Soluble in water	Soluble in water
Partition coefficient: n-octanol/water	No information available	No information available	No information available
Auto-ignition temperature	No information available	No information available	No information available
Decomposition temperature	No information available	No information available	No information available
Viscosity	No information available	No information available	No information available

Section 10 – Stability and reactivity

Reactivity	No dangerous reaction known under conditions of normal use.
Chemical stability	Stable under recommended storage conditions as indicated in section 7.
Possibility of hazardous reactions	Hydrochloric acid in contact with metals may result in hydrogen gas.
Conditions to avoid	Avoid high temperature. Avoid direct sunlight.
Incompatible materials	Acids, amines, metals, strong oxidizing agents, strong bases
Hazardous decomposition products	Carbon oxides, hydrogen chloride gas, nitrogen oxides, sodium oxides, sulfur oxides

Section 11 – Toxicological information

Route of entry/Exposure	Skin contact, eye contact, inhalation, ingestion
Acute Exposure	
Skin contact	May cause irritation
Eye Contact	May cause irritation
Ingestion	No information available
Inhalation	May cause allergy or asthma symptoms or breathing difficulties.
Chronic Exposure	No information available

Toxicity

Chemical	Acute Toxicity	Chronic Toxicity	Other Information
Hydrochloric acid (component of Direct Bilirubin Reagent)	LD50 Oral- 238-277mg/kg (Rat) LD50 Dermal- 5010 mg/kg (Rabbit) LC50 Inhalation- 1.68 mg/L (Rat) 1h	No data available	RTECS: MW4025000
Sulfanilic acid (component of Direct Bilirubin Reagent)	LD50 Oral- 12,300 mg/kg (Rat) LD50 Dermal- >2,000 mg/kg (Rat) LD50 Intravenous- 6,000 mg/kg (Rat)	No data available	RTECS: WP3895500
Sodium nitrite (component of Bilirubin Nitrite Reagent)	LD50 Oral- 85 mg/kg (Rat) LC50 Inhalation- 5.5 mg/l (Rat) 4h	No data available	RTECS: RA1225000

Carcinogenicity

IARC	Hydrochloric acid (Group 3) is not classifiable as to its carcinogenicity to humans. Sodium nitrite (Group 2A) is probably carcinogenic to humans.
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.

Section 12- Ecological information

Ecotoxicity	Hydrochloric acid	Toxicity to fish: LC50 Gambusia affinis (Mosquito fish) 282 mg/l, 96 h Toxicity to other aquatic invertebrates: EC50 Daphnia magna (Water flea) 56 mg/l, 72h
	Sulfanilic acid	Toxicity to fish: LC50 Pimephales promelas (Fathead minnow) 77.8 - 129.6 mg/l, 96h Toxicity to other aquatic invertebrates: EC50 Daphnia magna (Water flea) 85.66 mg/l, 48h Toxicity to algae: EC50 Desmodesmus subspicatus (green algae) 91 mg/l, 72h
	Sodium nitrite	Toxicity to fish: LC50 Pimephales promelas (Fathead minnow) 2.3 mg/l, 96h Toxicity to fish: flow through test LC50 Oncorhynchus mykiss (Rainbow trout) 0.9 - 1.9 mg/l, 96h Toxicity to other aquatic invertebrates: EC50 Daphnia magna (Water flea) 12.5 mg/l, 48h
	N-(1-naphthyl)ethylene diamine dihydrochloride	No information available
Persistence and degradability		Biodegradable
Bio-accumulative potential		No information available
Mobility in soil		No information available
Other adverse effects		An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Hydrochloric acid, sulfanilic acid, and sodium nitrite are harmful to aquatic life.

Section 13- Disposal considerations

Waste residues and methods of disposal	This product has to be disposed in accordance with applicable regional, national and local laws and regulations. Surplus and non-recyclable components should be taken to a licensed waste disposal contractor for disposal.
Contaminated Packaging	Waste packaging should be recycled; however, since empty containers may retain some product residues, they should be taken to an approved waste handling site or given to a licensed waste disposal contractor for recycling or disposal, if recycling is not possible.

Section 14 – Transport information

Direct Bilirubin Reagent (Hydrochloric acid)	DOT (US)	UN Number: UN1789 UN Proper Shipping name: Hydrochloric acid Hazard Class: 8 Packing Group: II
	IMDG	UN Number: UN1789 UN Proper Shipping name: Hydrochloric acid Hazard Class: 8 Packing Group: II Environmental Hazards: Marine pollutant: No
	IATA	UN Number: UN1789 UN Proper Shipping name: Hydrochloric acid Hazard Class: 8 Packing Group: II
	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not applicable
	Special Precautions	None
Bilirubin Nitrite Reagent	DOT (US)	Not regulated
	IMDG	Not regulated
	IATA	Not regulated
	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not applicable
	Special Precautions	None
Bilirubin Calibrator	DOT (US)	Not regulated
	IMDG	Not regulated
	IATA	Not regulated
	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not applicable
	Special Precautions	None

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Section 15 – Regulatory information

United States Regulations:

SARA 302 Components	No chemicals in this product are subject to the reporting requirements of SARA Title III, section 302.	
SARA 311/312 Hazards	Hydrochloric acid Sulfanilic Acid Sodium Nitrite N-2-Aminoethyl-1-naphthylamine dihydrochloride	CAS# 7647-01-0 CAS# 121-57-3 CAS# 7632-00-0 CAS# 1465-25-4
SARA 313 Components	Hydrochloric acid	CAS# 7647-01-0
Clean Water Act 307	No components of this product were found.	
Clean Water Act 311	Hydrochloric acid	CAS# 7647-01-0
Clean Air Act 112	Hydrochloric acid	CAS# 7647-01-0
U.S. State- Illinois Right to Know	Hydrochloric acid	CAS# 7647-01-0
U.S. State- Massachusetts Right to Know	Hydrochloric acid Sodium Nitrite	CAS# 7647-01-0 CAS# 7632-00-0
U.S. State- New Jersey Right to Know	Hydrochloric acid Sodium Nitrite N-2-Aminoethyl-1-naphthylamine dihydrochloride	CAS# 7647-01-0 CAS# 7632-00-0 CAS# 1465-25-4
U.S. State- Pennsylvania Right to Know	Hydrochloric acid Sodium Nitrite N-2-Aminoethyl-1-naphthylamine dihydrochloride	CAS# 7647-01-0 CAS# 7632-00-0 CAS# 1465-25-4
U.S. State- Rhode Island Right to Know	Hydrochloric acid	CAS# 7647-01-0
U.S. State- California Prop. 65	This product does not contain any Proposition 65 chemicals.	

Other International Regulations:

Canada:	This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR. Hydrochloric acid: WHMIS Hazard Class: D1A Very toxic materials, E Corrosive material Sulfanilic acid: WHMIS Hazard Class: D2B Toxic materials
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Section 16 – Other information

This product is labeled in accordance with CFR21 (Food and Drugs), Section 809.10.
The information contained herein has been compiled from data presented in various technical sources believed to be accurate. We make no warranties, express or implied, and assume no liability in connection with the use of this information. It is the user's responsibility to determine the suitability of this information and to assure the adoption of necessary safety precautions.
N/ A - Not Applicable or Not Available
Date of SDS Preparation 7/25/2016