


SAFETY DATA SHEET

Section 1: Product and Company Identification

- 1.1 Product name** Total Bilirubin R1 Reagent and Direct Bilirubin (Sulfanilic/nitrite) R1 and R3 Reagent
- Substance/mixture** mixture
- CAS #** mixture
- Kit number** C305-0A, C314-0A
- 1.2 Recommended product use**
- Mixture's intended use** Diagnostic reagent for IN VITRO quantitative measurement of either direct bilirubin or total bilirubin in serum and plasma only.
- Product restrictions** None known
- 1.3 Details of the supplier of the safety data sheet**
- Manufacturer information**
- Corporate Headquarters** Catachem, Inc.
353 Christian Street Oxford, CT 06478
United States of America
www.catacheminc.com
- Telephone** Phone: +1 (203) 262-0330
- Email** catachem@catacheminc.com
- Distributor information**
- Distributor Headquarters** Nuuchem Diagnostics Ltd.
18 Killuney Rd. Armagh, N. Ireland
United Kingdom
- Telephone** +44 7778 925522
- Email** Trevor.templeton@nuuchem.com
- 1.4 Emergency Telephone**
- Emergency Phone #** +1 (203) 232-1979

Section 2: Hazards Identification

- 2.1 Substance or mixture classification**
- Physical state** Liquid
- Appearance** Clear solution
- Emergency overview** Keep away from all sources of ignition, may form combustible dust in the air. Do not ingest product in any way. Do not allow into drains or sewers.
- 2.2 Label Elements**
- Signal word** Danger
- Hazard Pictogram** 
- Hazardous substances** Maleic Acid, Sulfanilic Acid, Hydrochloric Acid, Arquad-16/50.
- OSHA regulatory status** This product is hazardous according to OSHA 29CFR 1910.1200.
- 2.3 Potential health effects**

Routes of exposure	Skin contact. Eye contact.
Eyes	May cause eye irritation or serious eye damage.
Skin	May cause skin irritation or skin burns.
Inhalation	In high concentrations, vapors may be irritating to the upper respiratory tract leading to chemical pneumonitis and pulmonary edema.
Ingestion	If swallowed, may cause discomfort and lead to gastrointestinal tract burns.
Target organs	Eyes, lungs and skin.
Chronic effects	Repeated skin contact may cause dermatitis.
Signs and symptoms	Direct contact with skin and eyes may cause irritation.

2.4 Potential environmental effects

The product components are not classified as environmentally hazardous. However, this does not eliminate the possibility that large or frequent spills can have a harmful or damaging impact on the environment.

Section 3: Composition / Information on Ingredients

Components:

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Maleic Acid	110-16-7	Combustible dust, Acute toxicity, Oral (Category 4), H302 Acute toxicity, Dermal (Category 4), H312 Skin irritation (Category 2), H315 Serious eye damage (Category 1), H318 Skin sensitization (Category 1), H317 Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335 Short-term (acute) aquatic hazard (Category 3), H402	<2.0%*
Sulfanilic Acid	121-57-3	Skin irritation (Category 2), H315 Eye irritation (Category 2A), H319 Skin sensitization (Category 1), H317 Short-term (acute) aquatic hazard (Category 3), H402	<0.3%*

Hydrochloric Acid	7647-01-0	Corrosive to Metals (Category 1), H290 Skin corrosion (Category 1B), H314 Serious eye damage (Category 1), H318 Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335	<2.0%*
Arquad-16/50	79728-63-5	Classifications unknown.	<1.5%*

*Exact concentrations withheld as a trade secret.

Section 4: First Aid Measures

4.1 Description of First aid measures

Eye contact	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding eyelids open. Remove contact lenses immediately if worn by the affected person. Pursue medical treatment if irritation persists.
Skin contact	In case of skin contact, remove any or all of contaminated clothing, while rinsing the affected skin with large amounts of water. Pursue medical attention if irritation develops and persists.
Inhalation	In case of inhalation, move the affected person to fresh air. Call a physician if symptoms develop or persist.
Ingestion	Do NOT induce vomiting. In case of ingestion, make the affected person either drink some water or rinse out their mouth. If any other symptoms persist, contact a medical professional or a poison control center.
Notes to physician	Provide general supportive measures and treat symptomatically.
General advice	If you feel unwell, seek medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Eye Contact	Causes serious eye damage
Skin contact	Causes skin irritation
Inhalation	Causes corrosion of the breathing system
Ingestion	Causes corrosion of the digestion system

Section 5: Fire Fighting Measures

5.1 Flammable properties This product is not flammable.

5.2 Extinguishing media

Suitable extinguishing media

Extinguish with water spray, carbon dioxide (CO₂), dry chemical or material appropriate for the surrounding fire.

Unsuitable extinguishing media

No limitations are given.

5.3 Protection of firefighters

Specific hazards arising from the chemical

Carbon oxides
Sulfur oxides
Nitrogen oxides (NOx)
Sodium oxides

Protective equipment and precautions for firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Firefighting equipment/instructions

Use standard firefighting procedures and consider the hazards of other involved materials.
Avoid contaminating surface water with fire extinguishing water.

Hazardous combustion Products

Hazardous combustion gases or vapors may develop in the event of fire.

Section 6: Accidental Release Measures

- 6.1 Personal precautions** Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
- 6.2 Environmental precautions** Avoid contamination to enter drains, sewers or watercourses.
- 6.3 Methods for containment and cleaning up**
Absorb spillage with non-combustible, absorbent material such as sand, diatomaceous earth, vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
- 6.4 Other information** Clean up in accordance with all applicable regulations.

Section 7: Handling and Storage

- 7.1 Safe Handling** Avoid contact with skin and eyes. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
- Hygiene measures** Wash exposed skin thoroughly after handling.
- 7.2 Storage** Store at 15-30°C (59-86°C). Store in a closed container away from incompatible materials.

Section 8: Exposure Controls / Personal Protection

- 8.1 Occupational exposure limits**
No exposure limits noted for ingredient(s).
- Exposure guidelines** Follow standard monitoring procedures.
- Engineering controls** Provide adequate ventilation. Observe Occupational Exposure Limits and minimize the risk of inhalation of vapors. Provide easy access to water supply and eye wash facilities.
- 8.2 Personal protective equipment**
- Eye / face protection** Wear appropriate safety glasses, goggles or face shields.
- Skin protection** Wear lab coat or other protective garments. Wear protective gloves. Remove any contaminated clothing promptly.
- Respiratory protection** Under normal conditions, respirator is not required.
- General hygiene considerations**

Handle in accordance with good industrial hygiene and safety practice.

Other information Do NOT eat, drink or smoke during use.

Section 9: Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Appearance	Liquid
Physical state	Liquid
Form	Liquid
Color	Clear
Odor	Odorless
Odor threshold	No data available
pH	1.2-1.5 @ (25°C)
Vapor pressure	No data available
Vapor density	No data available
Boiling point	No data available
Viscosity (mm²/s)	No data available
Melting/Freezing point	No data available
Solubility (water)	Soluble
Specific gravity	1-1.1
Flash point	No data available
Flammability limits in air, upper, % by volume	No data available
Flammability limits in air, lower, % by volume	No data available
Decomposition temperature	No data available
Auto-ignition temperature	No data available
Evaporation rate	No data available

Section 10: Stability and Reactivity Information

10.1 Reactivity	No data available
10.2 Chemical stability	Material is stable under normal conditions.
10.3 Possibility of hazardous Reactions	Hazardous polymerization does not occur.
10.4 Conditions to avoid	No data available
10.5 Incompatible materials	No data available
10.6 Hazardous decomposition Products	In the event of fire, refer to Section 5.3

Section 11: Toxicological Information

11.1 Information on toxicological effects

Sensitization	Not classified.
Acute effects	May cause discomfort if swallowed.
Local effects	Ingestion may cause irritation and nausea.

Chronic effects	No data available.
Carcinogenicity	Not classified to carcinogenicity to humans.
Epidemiology	No epidemiological data is available for this product.
Mutagenicity	Not classified.
Reproductive effects	Not classified.
Symptoms and target organs	Direct contact with skin and eyes may cause irritation.
Additional information	No other specific acute or chronic health impact noted.

Section 12: Ecological Information

12.1 Toxicity

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Environmental effects	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

12.2 Persistence and degradability

No data is available on the degradability of this product.

12.3 Bioaccumulation/Accumulation

No data available.

12.4 Mobility in environmental media

The product is completely soluble in water.

Section 13: Disposal Considerations

13.1 Disposal methods

Disposal instructions	Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.
Waste from residues / unused products	Dispose in accordance with all applicable local and national regulations. Avoid releasing unused products into drainage systems and/or into the environment.
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal.

Section 14: Transport Information

DOT	Not regulated as a hazardous material by DOT.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
TDG	Not regulated as dangerous goods.

Section 15: Regulatory Information

US federal regulations	This product is hazardous according to OSHA 29CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpart. D)	Not regulated.

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

CERCLA (Superfund) reportable quantity (lb.) (40 CFR 302.4)

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

Section 302 extremely hazardous substance (40 CFR 355, Appendix A) Section 311/312 (40 CFR370) No

Drug Enforcement

Administration (DEA) (21 CFR

1308.11-15) Not controlled

Canadian regulations This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

WHMIS status Non-controlled

Inventory status

Country(s) or region Inventory name On inventory (yes/no)*

Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s)

State regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

Mexico regulations This safety data sheet was prepared in accordance with the Official Mexican Standard (NOM-018-STPS-2000).

Section 16: Other Information

Recommended restrictions Use in accordance with supplier's recommendations.

Further information HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 0
Flammability: 0
Physical hazard: 0

NFPA ratings
Health: 0
Flammability: 0
Instability: 0

Disclaimer The above information is believed to be correct, but does not purport to be all inclusive and should be used only as a guide. Catachem Inc. shall not be held liable for any damage resulting from handling or from contact with the above product.