



## SAFETY DATA SHEET

### 1. Product and Company Identification

<b>Material name</b>	<b>Bilirubin Direct and Bilirubin Total (Sulfanilic/nitrite) R1 Reagent</b>
<b>Version #</b>	2
<b>Issue date</b>	06/01/12
<b>Revision date -</b>	04/08/16
<b>Supersedes date -</b>	
<b>CAS #</b>	Mixture
<b>Kit number</b>	C304 series, V304 series, C314 series, V314 series
<b>Product use</b>	For the IN VITRO quantitative measurement of either direct bilirubin or total bilirubin in serum and plasma.
<b>Manufacturer information</b>	
<b>Corporate Headquarters</b>	Catachem 353 Christian Street Oxford, CT 06478 www.catacheminc.com Phone: +1203-262-0330
<b>Emergency Telephone Numbers</b>	
	+1203-232-1979

### 2. Hazards Identification

<b>Physical state</b>	Liquid.
<b>Appearance</b>	Clear liquid
<b>Emergency overview</b>	Health injuries are not known or expected under normal use.
<b>OSHA regulatory status</b>	This product is not hazardous according to OSHA 29CFR 1910.1200.
<b>Potential health effects</b>	
<b>Routes of exposure</b>	Skin contact. Eye contact.
<b>Eyes</b>	May cause eye irritation.
<b>Skin</b>	May cause skin irritation.
<b>Inhalation</b>	In high concentrations, vapors may be irritating to the respiratory system.
<b>Ingestion</b>	May cause discomfort if swallowed.
<b>Target organs</b>	Eyes.
<b>Chronic effects</b>	No data available.
<b>Signs and symptoms</b>	Direct contact with skin and eyes may cause irritation.
<b>Potential environmental effects</b>	The product components are 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.

### 3. Composition / Information on Ingredients

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

## 4. First Aid Measures

### First aid procedures

**Eye contact** In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.

**Skin contact** For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.

**Inhalation** Move to fresh air. Call a physician if symptoms develop or persist.

**Ingestion** If material is ingested, immediately contact a poison control center.

**Notes to physician** Provide general supportive measures and treat symptomatically.

**General advice** If you feel unwell, seek medical advice.

## 5. Fire Fighting Measures

**Flammable properties** This product is not flammable.

### Extinguishing media

**Suitable extinguishing media** Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.

**Unsuitable extinguishing media** None known.

### Protection of firefighters

**Specific hazards arising from the chemical** None known.

**Protective equipment and precautions for firefighters** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

### Fire fighting

**equipment/instructions** Use standard firefighting procedures and consider the hazards of other involved materials.

### Hazardous combustion

**Products** None known.

## 6. Accidental Release Measures

**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.

**Environmental precautions** Do not allow to enter drains, sewers or watercourses.

**Methods for containment** Absorb spillage with non-combustible, absorbent material.

**Methods for cleaning up** Absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

**Other information** Clean up in accordance with all applicable regulations.

## 7. Handling and Storage

<b>Handling</b>	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
<b>Storage</b>	Store at 15-30°C (59-89°F). Store in a closed container away from incompatible materials.

## 8. Exposure Controls / Personal Protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Exposure guidelines</b>	Follow standard monitoring procedures.
<b>Engineering controls</b>	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.
<b>Personal protective equipment</b>	
<b>Eye / face protection</b>	Wear approved safety glasses or goggles.
<b>Skin protection</b>	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
<b>Respiratory protection</b>	Under normal conditions, respirator is not normally required.
<b>General hygiene considerations</b>	Handle in accordance with good industrial hygiene and safety practice.

## 9. Physical & Chemical Properties

<b>Appearance</b>	Colorless
<b>Physical state</b>	Liquid.
<b>Form</b>	Liquid.
<b>Color</b>	Colorless
<b>Odor</b>	Odorless
<b>Odor threshold</b>	Not available.
<b>pH</b>	<2.0 @ ( 25°C)
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Boiling point</b>	Not available.
<b>Melting point/Freezing point</b>	Not applicable.
<b>Solubility (water)</b>	Soluble.
<b>Specific gravity</b>	1-1.1
<b>Flash point</b>	Not available.
<b>Flammability limits in air, upper, % by volume</b>	Not available.
<b>Flammability limits in air, lower, % by volume</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Evaporation rate</b>	Not available.

## 10. Chemical Stability & Reactivity Information

<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Conditions to avoid</b>	No data available.
<b>Incompatible materials</b>	No data available.

## **Hazardous decomposition**

<b>Products</b>	None known.
<b>Possibility of hazardous Reactions</b>	Hazardous polymerization does not occur.

## **11. Toxicological Information**

<b>Sensitization</b>	Not classified.
<b>Acute effects</b>	May cause discomfort if swallowed.
<b>Local effects</b>	Ingestion may cause irritation and nausea.
<b>Chronic effects</b>	No data available.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans.
<b>Epidemiology</b>	No epidemiological data is available for this product.
<b>Mutagenicity</b>	Not classified.
<b>Reproductive effects</b>	Not classified.
<b>Symptoms and target organs</b>	Direct contact with skin and eyes may cause irritation.
<b>Further information</b>	No other specific acute or chronic health impact noted.

## **12. Ecological Information**

<b>Ecotoxicity</b>	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.
<b>Environmental effects</b>	An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
<b>Persistence and degradability</b>	No data is available on the degradability of this product.
<b>Bioaccumulation / Accumulation</b>	Not available.
<b>Mobility in environmental media</b>	The product is completely soluble in water.

## **13. Disposal Considerations**

<b>Disposal instructions</b>	Contaminated instruments and surfaces should be disinfected in accordance with your employer's chemical-specific and universal/standard precautions.
<b>Waste from residues / unused products</b>	Dispose in accordance with all applicable regulations.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal.

## **14. Transport Information**

<b>DOT</b>	Not regulated as a hazardous material by DOT.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>TDG</b>	Not regulated as dangerous goods.

## 15. Regulatory Information

**US federal regulations** This product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

**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** No

**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).

## 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.

## 1. Product and Company Identification

**Material name** Direct and Total Bilirubin R2 Reagent component

**Version #** 2

**Issue date** 06/01/12

**Revision date -** 04/08/16

**Supersedes date -**

**CAS #** Mixture

**Kit number** C304 series, V304 series, C314 series, V314 series

**Product use** For the IN VITRO quantitative measurement of direct and total bilirubin in serum and plasma.

### Manufacturer information

**Corporate Headquarters** Catachem  
353 Christian Street Oxford, CT 06478  
www.catacheminc.com  
Phone: +1203-262-0330

## Emergency Telephone

**Numbers** +1203-232-1979

## 2. Hazards Identification

<b>Physical state</b>	Liquid
<b>Appearance</b>	Clear, colorless
<b>Emergency overview</b>	Health injuries are not known or expected under normal use.
<b>OSHA regulatory status</b>	This product is not hazardous according to OSHA 29CFR 1910.1200.
<b>Potential health effects</b>	
<b>Routes of exposure</b>	Skin contact. Eye contact.
<b>Eyes</b>	May cause eye irritation.
<b>Skin</b>	May cause skin irritation.
<b>Inhalation</b>	May be irritating to the respiratory system.
<b>Ingestion</b>	May cause discomfort if swallowed.
<b>Target organs</b>	Eyes.
<b>Chronic effects</b>	No data available.
<b>Signs and symptoms</b>	Direct contact with skin and eyes may cause irritation.
<b>Potential environmental effects</b>	The product components are 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.

## 3. Composition / Information on Ingredients

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

## 4. First Aid Measures

### First aid procedures

<b>Eye contact</b>	In case of contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
<b>Skin contact</b>	For skin contact flush with large amounts of water while removing contaminated clothing. Get medical attention if irritation develops and persists.
<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Ingestion</b>	If material is ingested, immediately contact a poison control center.
<b>Notes to physician</b>	Provide general supportive measures and treat symptomatically.
<b>General advice</b>	If you feel unwell, seek medical advice.

## 5. Fire Fighting Measures

<b>Flammable properties</b>	This product may be flammable at temperatures in excess of 100 C..
<b>Extinguishing media</b>	
<b>Suitable extinguishing</b>	

<b>media</b>	Extinguish with water spray, carbon dioxide, dry chemical or material appropriate for the surrounding fire.
<b>Unsuitable extinguishing media</b>	None known.
<b>Protection of firefighters</b>	
<b>Specific hazards arising from the chemical</b>	None known.
<b>Protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>Hazardous combustion Products</b>	None known.

## 6. Accidental Release Measures

<b>Personal precautions</b>	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.
<b>Environmental precautions</b>	Do not allow to enter drains, sewers or watercourses.
<b>Methods for containment</b>	Dilute with water.
<b>Methods for cleaning up</b>	After dilution with water absorb spill with vermiculite or other inert material. Dispose of waste in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.
<b>Other information</b>	Clean up in accordance with all applicable regulations.

## 7. Handling and Storage

<b>Handling</b>	Avoid contact with skin and eyes. Wash thoroughly after handling. In case of insufficient ventilation, wear suitable respiratory equipment. Handle and open container with care.
<b>Storage</b>	Store at 2-8°C (35-46°F). Store in a closed container away from incompatible materials.

## 8. Exposure Controls / Personal Protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Exposure guidelines</b>	Follow standard monitoring procedures.
<b>Engineering controls</b>	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.
<b>Personal protective equipment</b>	
<b>Eye / face protection</b>	Wear approved safety glasses or goggles.
<b>Skin protection</b>	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
<b>Respiratory protection</b>	Under normal conditions, respirator is not normally required.
<b>General hygiene</b>	



**considerations**

Handle in accordance with good industrial hygiene and safety practice.

**9. Physical & Chemical Properties**

<b>Appearance</b>	Clear colorless Liquid
<b>Physical state</b>	Clear colorless
<b>Form</b>	Liquid
<b>Color</b>	Clear colorless
<b>Odor</b>	Odorless
<b>Odor threshold</b>	Not available.
<b>pH</b>	<2.0 @ ( 25°C)
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Boiling point</b>	Not available.
<b>Melting point/Freezing point</b>	Not applicable.
<b>Solubility (water)</b>	Soluble.
<b>Specific gravity</b>	N/A
<b>Flash point</b>	Not available.
<b>Flammability limits in air, upper, % by volume</b>	Not available.
<b>Flammability limits in air, lower, % by volume</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Evaporation rate</b>	Not available.

**10. Chemical Stability & Reactivity Information**

<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Conditions to avoid</b>	No data available.
<b>Incompatible materials</b>	No data available.
<b>Hazardous decomposition</b>	
<b>Products</b>	None known.
<b>Possibility of hazardous</b>	
<b>Reactions</b>	Hazardous polymerization does not occur.

**11. Toxicological Information**

<b>Sensitization</b>	Not classified.
<b>Acute effects</b>	May cause discomfort if swallowed.
<b>Local effects</b>	Ingestion may cause irritation and nausea.
<b>Chronic effects</b>	No data available.
<b>Carcinogenicity</b>	Not classifiable as to carcinogenicity to humans.
<b>Epidemiology</b>	No epidemiological data is available for this product.
<b>Mutagenicity</b>	Not classified.
<b>Reproductive effects</b>	Not classified.
<b>Symptoms and target organs</b>	Direct contact with skin and eyes may cause irritation.

**Further information** No other specific acute or chronic health impact noted.

## 12. Ecological Information

**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.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulation /  
Accumulation** Not available.

**Mobility in environmental  
media** The product is completely soluble in water.

## 13. Disposal Considerations

**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 regulations.

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 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.

## 15. Regulatory Information

**US federal regulations** This product is not hazardous according to OSHA 29CFR 1910.1200. This mixture is a component of an in vitro diagnostic device regulated by the U.S. Food and Drug Administration.

**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).

## 16. Other Information

<b>Recommended restrictions</b>	Use in accordance with supplier's recommendations.
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 0 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	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.