

Doc. ID: OSR6111-75 Rev. 04 Revised (year/month/day) 2014/07/03

### Section 1 Identification of the Substance/mixture and of the Company/undertaking

1.1 Product Identifier

Product Name Direct Bilirubin Blank R1

Part Number Component of P/N OSR6111, OSR6211, OSR6511, OSR6611

1.2 Relevant identified uses of the substance or mixture and uses advised against

**Product Use** For In Vitro Diagnostic Use. See product literature for details.

1.3 Details of supplier of the safety data sheet

Manufacturer EC REP Address

Beckman Coulter, Inc. Beckman Coulter Ireland Inc.

250 S. Kraemer Blvd Lismeehan

Brea, CA 92821, U.S.A. O'Callaghan's Mills

Tel: 353 (0)65 6831100

e-mail address SDSNT@beckman.com

Further information Contact:

Customer support Unit, Beckman Coulter Ireland Inc.

Technical Service Department Tel. +001-800-223-0130 (PST)

E-mail CC Support.ie@beckman.com

1.4 Emergency telephone number

**Telephone number (24H)** Chemtrec Emergency Tel No. U.S.A. 800-424-9300, International (001)

703-527-3887

Tel +353 (0)65 683 1170; 08:00 - 16:30 hrs Mon-Thur, 08:00 - 15:30 hrs Fri

(GMT) Tel +001-800-223-0130 (PST)

Distributor and Emergency Phone No.

Refer to attached list, Document ID: 472050, for local distributor and emergency

phone numbers.

#### **Section 2 Hazards Identification**

2.1 Classification of substance or mixture

**Product Description** In vitro diagnostic reagent.

Colorless; Clear; Liquid; Characteristic odor

Classification according to EC Directives 1999/45/EC and 67/548/EEC

C:R35

**US OSHA** 

Hazardous

2.2 Label Elements



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## **Section 2 Hazards Identification (Continued)**

2.3 Other Hazard Results of PBT and vPvB assessment

PBT: Not applicable. vPvB: Not applicable.

See Section 11 Toxicological Information for more detailed health information.

### **Section 3 Composition and Information on Ingredients**

#### 3.2 Mixture

Hazardous Ingredients:		Hazard Classification of Pure Ingredients			
Chemical Name	% by wt.	EU-67/548/EEC	EU 1272/2008 CLP/GHS	US OSHA	
Sulfuric Acid  CAS # 7664-93-9  EINECS # 231-639-5 Index # 016-020-00-8	20 - 50	C;R35	Eye Dam. 1 Skin Corr. 1A H314; H318	Water-Reactive Carcinogen Corrosive Highly Toxic	
Hydrochloric Acid%  CAS # 7647-01-0  EINECS # 231-595-7 Index # 017-002-01-X	2 - 5	C;R34-37	Acute Tox. Oral 4 STOT SE 3 Skin Corr. 1B H302; H314; H335	Corrosive Toxic	
Sulfosalicylic Acid, Dihydrate  CAS # 5965-83-3  EINECS # 202-555-6 Index # Not available	0.5 - 1	C;R22-34	Acute Tox. Oral 4 Eye Dam. 1 Skin Corr. 1B H302; H314; H318	Corrosive	

See section 8 for available Occupational exposure limits

See Section 15 for additional regulatory information

See Section 16 for hazard class, hazard statements and risk phrase description

#### Section 4 First Aid Measures

#### 4.1 Description of first aid measures

**Inhalation** If product is inhaled, move exposed individual to fresh air. If individual is not

breathing, begin artificial respiration immediately and obtain medical attention.

**Eye Contact** If product enters eyes, wash eyes gently under running water for 15 minutes

or longer, making sure that the eyelids are held open. If pain or irritation occur,

obtain medical attention.

**Skin Contact** In case of skin contact, flush with copious amounts of water for at least 15

minutes. If pain or irritation occur, obtain medical attention.

**Ingestion** If ingested, wash mouth out with water. If irritation or discomfort occurs, seek

medical attention.

#### 4.2 Most important symptoms and effects, both acute and delayed

Carcinogen.

Toxic by inhalation and if swallowed.

Corrosive. May cause burns to eyes, skin and respiratory tract.

See Section 11 Toxicological Information for more detailed health information.



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## **Section 4 First Aid Measures (Continued)**

#### 4.3 Indication of any immediate medical attention and special treatment needed

No specific medical attention or treatment required.

### **Section 5 Fire Fighting Measures**

Flammable Properties Nonflammable solution.

**5.1 Extinguishing Media** Use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

**Special Fire and Explosion Hazards** 

No special hazards determined.

**Hazardous Combustion Products** 

No combustion products posing significant hazards are expected from this

product.

5.3 Advice for fire fighters

**Protective Equipment** Self-contained breathing apparatus is recommended for firefighters in all

chemical fire situations.

**5.4** Additional information No further relevant information available.

#### **Section 6 Accidental Release Measures**

6.1 Personal precaution, protective equipment and emergency procedures

**Personal Precautions** Wear protective gloves, protective clothing and eye/face protection.

**6.2 Environmental Precautions** Contain spill to prevent migration.

Do not allow the undiluted product to enter sewers/surface or ground water.

6.3 Methods and material for containment and cleaning up

Spill and Leak Procedures Absorb spilled material with an appropriate inert, non-flammable absorbent and

dispose according to local regulations.

**6.4 Reference to other sections** Refer sections 8 and 13.

## Section 7 Handling and Storage

7.1 Precautions for safe handling Use good laboratory procedures; avoid eye and skin contact.

7.2 Conditions for safe storage, including any incompatibilities

Keep away from incompatible material (see Section 10).

To maintain efficacy, store according to the instructions in the product labeling.

**7.3** Specific end uses No further relevant information available.



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### **Section 8 Exposure Controls and Personal Protection**

#### 8.1 **Control parameters**

#### **Exposure Limits**

#### **US OSHA**

Hydrochloric Acid...%

CÁS # 7647-01-0

5 ppm Ceiling; 7 mg/m3 Ceiling

Sulfuric Acid CAS # 7664-93-9

1 mg/m3 TWA

**ACGIH** 

Hydrochloric Acid...%

2 ppm Ceiling

CÁS # 7647-01-0

0.2 mg/m3 TWA (thoracic fraction)

Sulfuric Acid CAS # 7664-93-9

**DFG MAK** 

Hydrochloric Acid...%

4 ppm Peak; 6 mg/m3 Peak; 2 ppm TWA MAK; 3.0 mg/m3 TWA MAK

CÁS # 7647-01-0

0.1 mg/m3 Peak (inhalable fraction); 0.1 mg/m3 TWA MAK (inhalable fraction)

Sulfuric Acid CAS # 7664-93-9

Ireland

Hydrochloric Acid...% CÁS # 7647-01-0

5 ppm TWA; 8 mg/m3 TWA; 10 ppm STEL; 15 mg/m3 STEL

Sulfuric Acid 1 mg/m3 TWA CAS # 7664-93-9

NIOSH

Hydrochloric Acid...%

CAS # 7647-01-0

50 ppm IDLH

Sulfuric Acid CAS # 7664-93-9 15 mg/m3 IDLH; 1 mg/m3 TWA

Japan

None established

**Exposure controls** 

**Engineering Controls** 

No special engineering controls are required. Use with good general ventilation.

**Eye Protection** 

Safety glasses or chemical goggles should be worn to prevent eye contact.

Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate

government standards.

**Skin Protection** 

Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin

contact.

Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.

**Respiratory Protection** 

Under normal conditions, the use of this product should not require respiratory

protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory

protection should be evaluated by a qualified professional.



9.1

# SAFETY DATA SHEET

1.141

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## **Section 9 Physical and Chemical Properties**

Information on basic physical and chemical properties

Physical State Liquid Specific Gravity

(Water=1.0)

Color Colorless Solubility

Transparency Clear Water Miscible

Odor Characteristic odor Organic Not determined

pH < 1 Coefficient of Water/Oil Not determined

Distribution

Freezing Point Similar to water, Autoignition Temp. Product is not selfigniting

approximately 0 °C

Boiling Point Similar to water, Decomposition Not determined

approximately 100 °C Temperature

Flash Point Not applicable Percent Volatiles Not applicable

Evaporation Rate Not determined Vapor Pressure Similar to water,

approximately 23 hPa

Flammability (Solid, Gas) Not applicable Viscosity Not determined

Flammable Limits Not applicable Explosive Properties Not applicable

Vapor Density Not determined Oxidizing Properties Not applicable

Odor Threshold Hydrochloric Acid...% no geometric mean air odor threshold

Sulfuric Acid no geometric mean air odor threshold

**9.2 Other Information** No further relevant information available.

## **Section 10 Stability and Reactivity**

**10.1 Reactivity** No information available

**10.2 Chemical Stability**The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions

No information available.

**10.4 Conditions to Avoid** Avoid contact with incompatible materials.

**10.5 Incompatible materials** Strong bases

Strong oxidizers

10.6 Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from

this product.



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## **Section 11 Toxicological Information**

#### 11.1 Information on toxicological effects

#### **Toxicity Data for Hazardous Ingredients**

Hydrochloric Acid...% Inhalation LC50 Rat 3124 ppm 1 h; Oral LD50 Rat 700 mg/kg; Dermal LD50

CÁS # 7647-01-0 Rabbit >5010 mg/kg

Sulfuric Acid Inhalation LC50 Mouse 320 mg/m3 2 h; Inhalation LC50 Rat 510 mg/m3 2 h;

CAS # 7664-93-9 Inhalation LC50 Rat 347 ppm 1 h; Oral LD50 Rat 2140 mg/kg

**Primary Routes of Exposure** Eye contact, ingestion, inhalation, and skin contact.

**Skin Corrosion/Irritation** Contact may cause severe skin burns.

Serious eye damage/eye

irritation

Contact may cause serious eye damage.

Skin/Respiratory sensitization None identified

Carcinogenicity Sulfuric Acid is listed with OSHA as a carcinogen; IARC as Group 1 carcinogen to

humans; ACGIH as A2 Suspected Human Carcinogen.

MutagenicityNone identifiedReproductive ToxicityNone identified

**Potential Effects of Acute Exposure** 

Inhalation of dilute acidic mists may cause respiratory tract irritation or burns to mucous membranes resulting in coughing, choking and difficulty in breathing. Results of skin contact may range from irritation and inflammation to burns with blistering. Eye contact may cause severe irritation with painful, watery eyes or burns with possible blindness. Ingestion may cause irritation or burns to the mouth and throat resulting in pain, difficulty in speaking and swallowing, intense

thirst, nausea and vomiting.

Toxic by inhalation and if swallowed.

#### **Potential Effects of Chronic Exposure**

Depending upon concentration and duration of exposure, effects may be similar to those described for acute exposure. Repeated or prolonged contact with dilute acid may result in dermatitis and conjunctivitis with inflamed skin and eyes.

**Symptoms of Overexposure** 

Symptoms of overexposure may include: redness, burning and watering of the eyes; dry, red, cracked skin; coughing and difficult breathing; nausea and vomiting.

#### Conditions Aggravated by Exposure

Individuals with skin, eye, or respiratory tract disorders may find these conditions

aggravated by exposure to this product.

Other Information None identified



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## **Section 12 Ecological Information**

12.1 Ecotoxicity

Fresh Water Species

Hydrochloric Acid...% 96 h LC50 Gambusia affinis: 282 mg/L [static]

CAS # 7647-01-0

Sulfuric Acid 96 h LC50 Brachydanio rerio: >500 mg/L [static]

CAS # 7664-93-9

**Microtox** No information available.

Water Flea

Sulfuric Acid 24 h EC50 Daphnia magna: 29 mg/L

CAS # 7664-93-9

Fresh Water Algae No information available.

12.2 Persistence and degradability No information available.

**12.3 Bioaccumulation**No information available.

12.4 Mobility in soil No information available.

12.5 Results of PBT and vPvB assessment

Not applicable

**12.6 Other Adverse Effects**No information available.

### **Section 13 Disposal Considerations**

13.1 Waste treatment methods

**Product Waste Disposal** Chemical residues and remains should be routinely handled as special waste. This

must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.

Package disposal Dispose of waste product, unused product and contaminated packaging in

compliance with federal, state and local regulations. If unsure of the applicable

requirements, contact the authorities for information.

**13.2 Additional information** European waste catalogue 18 01 06\* - chemicals consisting of or containing

dangerous substances.

## **Section 14 Transport Information**

	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1	UN/ID Number	3264	3264	3264	3264	PIN - 3264
14.2	Shipping Name	Corrosive liquid, acidic, inorganic, n.o.s. (sulphuric acid, hydrochloric acid)				
14.3	Hazard Class	8 Corrosives	8 Corrosive substances	8 Corrosive material	8 Corrosive substances	8 Corrosives
	Subsidiary Risk	None	None	None	None	None
	Classification Code	Not applicable	Not applicable	Not applicable	C1	Not applicable
14.4	Packing Group	II	II	II	II	II

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## **Section 14 Transport Information (Continued)**

			•	•	•	
	Shipping Information	IATA	IMDG	US DOT	European ADR	Canadian TDG
	Special Provisions	A803	274	None	274	16
	Additional information	ı				
	IATA ERG Code	8L	Not applicable	Not applicable	Not applicable	Not applicable
	EmS	Not applicable	F-A, S-B	Not applicable	Not applicable	Not applicable
	NAERG Code	Not applicable	Not applicable	154	Not applicable	154
14.5	Environmental Hazard	I				
	Marine Pollutant	Not applicable	No	Not applicable	Not applicable	Not applicable
146	Special Procautions	for usors				

14.6 Special Precautions for users

Warning: Corrosive substances.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

### **Section 15 Regulatory Information**

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture
	US Federal and State Regulations

SARA 313 Hydrochloric Acid...% is subject to reporting requirements of Section 313, Title III

of SARA. 1.0 % de minimis concentration (acid

Sulfuric Acid is subject to reporting requirements of Section 313, Title III of SARA.

1.0 % de minimis concentration (acid

CERCLA RG's, 40 CFR 302.4 Hydrochloric Acid...% is listed.

Sulfuric Acid is listed.

California Proposition 65 No ingredients listed.

Massachusetts MSL Hydrochloric Acid...% is listed.

Sulfuric Acid is listed.

**New Jersey Dept. of Health RTK List** 

Hydrochloric Acid...% is listed.

Sulfuric Acid is listed.

Pennsylvania RTK Hydrochloric Acid...% is listed.

Sulfuric Acid is listed.

**EU Regulations** 

This SDS complies with EC Regulations 1907/2006 (REACH) and amendments.

Water Hazard Class (Germany) WGK 2, water endangering

REACH 1907/2006 EC - Annex XIV - list of substances subject to authorization.

No ingredients listed.



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### **Section 15 Regulatory Information (Continued)**

#### According to EC Directives (1999/45/EC and 67/548 EEC)

Corrosive

#### Risk and Safety Phrases

- R35 Causes severe burns.
- S20 When using do not eat or drink.
- S26 In case of contact with eyes, rinse immediately with plenty of water and
- seek medical advice.
- S30 Never add water to this product.
- S60 This material and/or its container must be disposed of as hazardous waste. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. S45 In case of accident or if you feel unwell, seek medical advice immediately.

#### Canada

This product is exempt from WHMIS label and SDS requirements.

**PIN** 3264

**Ingredients on Ingredient Disclosure List** 

Hydrochloric Acid...%

Sulfuric Acid

Ingredients with unknown toxicological properties

Product is exempt

15.2 Chemical Safety Assessment A Chemical Safety Assessment has not been carried out.

Some hazardous ingredients listed in Section 15 are below OSHAs and WHMIS' 1.0% w/w (0.1% for carcinogens) or EU's ingredient specific concentrations required for reporting in Section 3.

#### Section 16 Other Information

Beckman Coulter Safety Rating	Flammability: 0 Health: 3 Reactivity with Water: 0 Contact: 3	Code 0=None 1=Slight 2=Caution 3=Severe

#### **Revision Changes**

Add new product part number to SDS.

Updated Section 11.

#### Hazard Class, hazard statements and risk phrase description from section 3

C - Corrosive

R22 Harmful if swallowed.

R34 Causes burns.

R37 Irritating to respiratory system.

R35 Causes severe burns.

D1A - Poisonous and Infections Material: Division 1 - Immediate and Serious

Toxic Effects: Very Toxic (Acute Inhalation Toxicity)

E - Corrosive Material

E - TDG Class 8 - corrosive substance

Acute Tox. Oral 4 - Acute Toxicity Oral, Category 4

Eye Dam. 1 - Eye Damage Category 1 Skin Corr. 1A - Skin Corrosion Category 1A Skin Corr. 1B - Skin Corrosion Category 1B



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### **Section 16 Other Information (Continued)**

STOT SE 3 - Specific Target Organ Toxicity Single Exposure Category 3

H302 - Harmful if swallowed.

H314 - Causes severe skin burns and eye damage.

H318 - Causes serious eye damage.

H335 - May cause respiratory irritation.

**Abbreviations and Acronyms** ACGIH - American Conference of Governmental Industrial Hygienists

DFGMAK - Republic Germany's maximum exposure limit

IARC - Internal Agency for Research on Cancer

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

LD50 - Lethal Dose, 50%

LC50 - Lethal Concentration, 50% EC50 - Effective Concentration, 50%

For further information, please contact your local Beckman Coulter representative.

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