



SAFETY DATA SHEET
Intercept® I2 Oral Fluid Collection Device

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Intercept® I2 Oral Fluid Collection Device

GENERAL USE: The Intercept® I2 Oral Fluid Collection Device intended for use in the collection, preservation and transport of oral specimens. This device is intended for use by trained professionals only and is not intended for home use.

ORASURE PRODUCT NUMBER: 1001-0362, 1001-0363, 1001-0383

MANUFACTURER

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EMERGENCY CONTACT INFORMATION

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COMMENTS: To the best of our knowledge, this Safety Data Sheet conforms to the requirements of the US OSHA 29 CFR 1910.1200, Regulation EC 1907/ 2006 and Canadian Hazardous Products Act.

2. HAZARD IDENTIFICATION

This Oral Specimen Collection Device should be used only by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Specific warnings are given in the instructions for use. The absence of a specific warning should not be interpreted as an indication of safety.

NOTE: Handling, storing or shipping of the complete packaged Oral Specimen Collection Device should pose no threat to the individual. If no leak or excessive damage is noted, there is no recommended Personal Protective Equipment (PPE) required.

GHS Classification

Skin Irritation (Category 3)

GHS LABEL:

Signal Word

Table with 2 columns: Label Component and Description. Rows include Signal Word (Warning), Pictogram (Warning symbol), Hazard Statements (H316 Causes mild skin irritation), and Precautionary Statements (P264, P280, P302+P352, P362+P364, P305+P351+P338, P332+P313).

ROUTES OF ENTRY: Absorption and ingestion.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Component	Contents			
Oral Specimen Collection Device	Device consists of a treated, absorbent cotton fiber pad affixed to a plastic shaft (Oral Specimen Collection Pad). The collection pad is impregnated with common salts, creating the required atmosphere to properly collect the oral sample.			
	Chemical	CAS	Percent (by wt)	Hazardous at present conc.?
	Sodium Chloride	7647-14-5	<1	N
	Sodium Citrate Dihydrate	6132-04-3	<1	N
	Citric Acid Monohydrate	5949-29-1	<0.1	N
Preservative Solution	Preservative solution is a significantly diluted aqueous solution.			
	Chemical	CAS	Percent (by wt)	Hazardous at present conc.?
	Water	7732-18-5	>80	N
	Sodium Chloride	7647-14-5	<1	N
	Sodium Citrate Dihydrate	6132-04-3	<1	N
	Potassium Sorbate	590-00-1	<1	N
	Sodium Benzoate	532-32-1	<1	N
	Citric Acid	77-92-9	<0.1	N
	Dextran Sulfate	9011-18-1	<0.1	N
	ProClin 950	2682-20-4, 7732-18-5	<0.1	N
	Tween 20	9005-64-5	<0.1	N

4. FIRST AID MEASURES

EYES: Check for and if possible remove contact lenses. Flush eyes with copious water for at least 15 minutes. Ensure adequate flushing by separating the eyelids with fingers while flushing with water. OBTAIN MEDICAL ATTENTION.

SKIN: Remove contaminated clothing. Flush skin with copious water and wash affected area with soap and water. Obtain medical attention if symptoms occur.

INGESTION: If ingested, rinse out mouth thoroughly with water, provided the person is conscious, and OBTAIN MEDICAL ATTENTION. Call a physician or the local poison control center. Treat symptomatically and supportively. If vomiting occurs, keep head lower than hips to prevent aspiration.

INHALATION: Remove person from exposure area to fresh air. Generally, this aqueous product is not a significant inhalation hazard in the volumes and concentrations found in this product. Treat symptomatically and supportively. If breathing is difficult give oxygen. If not breathing provide artificial respiration.

5. FIRE FIGHTING MEASURE

EXTINGUISHING AGENT: Use extinguishing media appropriate for the surrounding fire.

FIRE FIGHTING PROCEDURES: Conventional firefighting full protective equipment (with NIOSH-approved self-contained breathing apparatus) and procedures appropriate for the surrounding fire should be sufficient.

6. ACCIDENTAL RELEASE MEASURES

SMALL SPILL/ LEAK: Clean the spill area with water and wipe dry. Spills can also be absorbed with an appropriate inert material (e.g. spill pillows, acid absorbent pads, etc.) which is secured in an appropriate, labeled, sealed container. Material used to absorb the spill may require hazardous material waste disposal in accordance with all Local, State and Federal regulations. Utilize appropriate Personal Protective Equipment (PPE), including gloves, lab coat or apron and eye/face protection.

GENERAL PROCEDURES: Avoid creating dust or direct contact with skin, eyes, mucous membranes and clothing by wearing appropriate lab Personal Protective Equipment (PPE) including gloves, lab coat and eye/face protection. In the event of a hazardous material spill, contain the spill if it is safe to do so and immediately move to a safe area. Isolate the hazard area and ventilate if appropriate. Ensure that appropriate spill cleanup materials and PPE are available and used.

7. HANDLING AND STORAGE

HANDLING: The individual components within the product should be handled only by qualified personnel. Utilize Good Laboratory Practices and safety guidelines for handling chemicals and other hazards. Wear appropriate Personal Protective Equipment (PPE) including gloves, lab coat or equivalent and eye/face protection. Keep containers tightly closed; avoid splashing, spills and the generation of aerosols.

STORAGE: Store according to product and label instructions. All reagents should be stored refrigerated 18-25°C (64-77°F) when not in use. Exposure to higher temperatures should be avoided. Protect from long exposure to sunlight.

NOTE: Handling and storing of the product should not pose any threat to the shipper. If the product integrity is in question due to excessive damage, utilize proper safety procedures and handle using appropriate PPE.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

VENTILATION: Adequate ventilation is required. Respiratory protection is not required under normal use of this product. If respiratory protection is needed, follow the OSHA regulation, 29CFR1910.134. Always use a NIOSH approved respirator when necessary.

EYE PROTECTION: Wear appropriate eye protection to prevent eye contact conforming to ANSI Z87.1-2003 (US) or EN 166 (EU) Standards.

PROTECTIVE GLOVES: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

SKIN AND BODY: Wear appropriate body protection to the amount and concentration of the chemical present at the location to prevent contact.

COMMENTS: Exposure limit values and health hazard data were given in Section 9 for the individual chemicals. General chemical/ industrial hygiene practices are recommended when working with the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Preservative Solution:

pH: 6.0

COMMENTS: The following information is furnished for the constituents found in the product. Note that the information here is for the chemical raw material.

Chemical Ingredient	Chemical Information
Sodium Chloride	Molecular Weight: 58.44 Melting Point: 801°C Specific Gravity: 2.165 LD50 (Oral): 3000 mg/kg (rat) LC50 (Inhalation): >42 mg/m ³ – 1h LD50 (Skin): >10gm/kg (rabbit) Synonyms: Salt, Saline. Sodium Chloride may cause skin, eye and respiratory irritation. In case of contact with eyes, rinse with water for at least 15 minutes then seek medical attention. This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. Utilize Good Laboratory Practices.
Sodium Citrate Dihydrate	Molecular Weight: 294.10 Melting Point: 150°C LD50 (Oral): Not available for normal routes of exposure Synonyms: Citrosodine. Sodium Citrate may cause skin, eye and respiratory irritation. In case of contact with eyes, rinse with water for at least 15 minutes then seek medical attention. This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this product. Utilize Good Laboratory Practices.
Citric Acid (Anhydrous) CAS: 77-92-9 (Monohydrate) CAS: 5949-29-1	Molecular Weight: 210.14 Melting Point: 153 -159°C Specific Gravity: 1.542 pH: 1.8 @ 50 g/l LD50 (Oral): 5400 mg/kg (rat) LD50 (Skin): >2000 mg/kg (rat) Synonyms: 2-Hydroxy-1,2,3-propanetricarboxylic Acid, Monohydrate. Citric Acid causes serious eye irritation. Causes irritation to skin and respiratory tract. In case of contact with eyes, rinse with water for at least 15 minutes then seek medical attention. This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this product. Utilize Good Laboratory Practices.
Potassium Sorbate	Molecular Weight: 150.22 Melting Point: 270°C (Decomp Temp) Specific Gravity: 1.363 LD50 (Oral): 3800 mg/kg (mouse) Synonyms: 2,4-hexadienoic Acid, Potassium Salt, Potassium 2,4-hexadienoate.n Potassium Sorbate may cause skin, eye and respiratory irritation. Slightly hazardous in case of ingestion. In case of contact with eyes, rinse with water for at least 15 minutes then seek medical attention if necessary. This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this product. Utilize Good Laboratory Practices.
Sodium Benzoate	Molecular Weight: 144.10 Melting Point: >300°C (>572°F) Flash Point: >100°C LD50 (Oral): 2100 mg/kg (rat) Synonyms: Benzoic Acid, Sodium Salt, Benzoate of Soda, Antimol. Sodium Benzoate may be harmful if swallowed or inhaled. May cause irritation to skin, eye and respiratory tract. May form combustible dust concentration in air. In case of contact with eyes, rinse with water for at least 15 minutes then seek medical attention. This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this product. Utilize Good Laboratory Practices.
Dextran Sulfate	Water Solubility: 100 g/l at 25°C LD50 (Oral): 20600 mg/kg (rat) Dextran Sulfate may be harmful if swallowed or inhaled. May cause irritation to skin, eye and respiratory tract. In case of contact with eyes, rinse with water for at least 15 minutes then seek medical attention. This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this product. Utilize Good Laboratory Practices.

ProClin 950 [2-Methyl-4-isothiazolin-3-one (5-10%) + Water (90-95%)]	pH: 5-8 LD50 (Oral): not available ProClin 950 causes severe skin burns and eye damage, toxic when inhaled, and harmful when ingested or absorbed through the skin. In case of contact with eyes and skin, rinse with water for at least 15 minutes then seek medical attention. This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this product. Utilize Good Laboratory Practices.
Tween 20	Vapor Pressure: <1.33hPa Density: 1.095 g/cm ³ LD50 (Oral): 40,554 mg/kg (rat) Synonyms: Polyoxyethylenesorbitan Monolaurate, Polyethylene Glycol Sorbitan Monolaurate. Although not considered a hazardous material by OSHA, this chemical may be slightly irritating in cases of skin or eye contact, ingestion and inhalation (irritant). In case of contact with eyes, rinse with water for at least 15 minutes then seek medical attention if necessary. This material and its container must be disposed of in a safe way and in accordance with Local, State and Federal Regulations. No known or anticipated adverse health hazards are likely for the small amount of chemical provided within the mixtures of this product. Utilize Good Laboratory Practices.

10. STABILITY AND REACTIVITY

STABLE: The product is known to be stable under normal use and storage conditions.

CONDITIONS TO AVOID: Avoid excessive heat; maintain ambient temperatures. Avoid exposure to direct sunlight.

HAZARDOUS DECOMPOSITION PRODUCTS: Carbon oxides, Nitrous Oxides, Sulphur Oxides, Sodium Oxides

11. TOXICOLOGICAL INFORMATION

ACUTE: The product is not known to have any specific health or toxicological effects if used as offered for its intended purpose.

CHRONIC TOXICITY: None known if used as offered for its intended purpose.

COMMENTS: Individual chemical toxicological information has been made available in section 9.

12. ECOLOGICAL INFORMATION

NOTE: As offered, the product is not known to have a negative effect on the environment. The below Ecological information will be provided based on the individual chemicals contained in the product.

Component	Ecological Information
Sodium Chloride	EC50 (<i>D. magna</i>): 1000 mg/L 48h LC50 (<i>P. promelas</i>): 7650 mg/L 96h
Citric Acid	EC50 (<i>D. magna</i>): 1535 mg/L 24h LC50 (<i>C.maenass</i>): 160 mg/L 48h LC50 (<i>L. idus melanotus</i>): 440 mg/L 48h
Sodium Benzoate	LC50 (<i>P. promelas</i>): 484 mg/l 96h Biodegradability: 90% - Readily Biodegradable.
Proclin 950	Very toxic to aquatic life.
Tween 20	LC50 (Other fish): 350mg/l 24h

13. DISPOSAL CONSIDERATION

DISPOSAL METHOD: Disposal of hazardous wastes, product or packaging must be conducted in accordance with all applicable Local, State and Federal Regulations. This section specifies the general and United States RCRA requirements. Processing, use or contamination of the product components may change waste management requirements and options. Contact the authority having jurisdiction for your area for specific disposal requirements.

14. TRANSPORTATION INFORMATION

Must be shipped in accordance with all applicable Local, State and Federal Regulations. Processing, use or contamination of this product or its components may change shipping requirements and options. As offered for shipping (single device):

DOT: Not a dangerous good. **IMDG:** Not a dangerous good. **IATA:** Not a dangerous good.

15. REGULATORY INFORMATION

NOTE: The information here is often based on data for the chemical raw material. The product contains a significantly diluted concentration in an aqueous solution; thus, unless otherwise noted the assessment below has NOT taken hazard reduction processing into consideration when possible.

Component	Additional Requirements
Sodium Chloride (100%)	Chemical Inventory List (Part 1): EC, Japan, TSCA & Australia. Chemical Inventory List (Part 2): Korea, DSL & Philippines. SARA 311/312: Acute Health Hazard.
Sodium Citrate (100%)	Chemical Inventory List (Part 1): EC, Japan, TSCA & Australia. Chemical Inventory List (Part 2): Korea, DSL & Philippines.
Citric Acid (100%)	Chemical Inventory List (Part 1): EC, Japan, & Australia. Chemical Inventory List (Part 2): Korea, DSL & Philippines. SARA 311/312: Acute Health Hazard. Pennsylvania & New Jersey Right To Know Components
Potassium Sorbate (100%)	Chemical Inventory Listed: TSCA, China, Japan & Philippines
Sodium Benzoate (100%)	Chemical Inventory List (Part 1): EC, Japan, TSCA & Australia. Chemical Inventory List (Part 2): Korea, DSL, & Philippines. SARA 311/312: Acute Health Hazard. Pennsylvania & New Jersey Right To Know Components
Dextran Sulfate (100%)	Chemical Inventory List (Part 1): EC, Japan, TSCA & Australia. Chemical Inventory List (Part 2): China, Korea, DSL SARA 311/312: Chronic Health Hazard. Pennsylvania & New Jersey Right To Know Components
ProClin 950 (2-Methyl-4-isothiazolin-3-one)	SARA 311/312: Acute Health Hazard. Pennsylvania & New Jersey Right To Know Components
Tween 20 (100%)	Canada DSL: Listed TSCA: Listed Pennsylvania & New Jersey Right To Know Components

16. OTHER INFORMATION

The information contained herein is accurate to the best of our knowledge. OraSure Technologies Inc. makes no warranty of any kind, expressed or implied, concerning the safe use of this material in the process or in combination with other substances.

SUMMARY OF CHANGES:

07/17/2013 – New SDS

02/04/2014 – Added 1001-0383; I2 Preservative 1 L, Generic