

# SAFETY DATA SHEET

300153\_05

 Revision Date 06/11/2018  
 According to REACH 1907/2006

## 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifiers

Product name : HPV OncoTect 3Dx™ Reagent 1

 Product Number : 200109  
 Brand : IncellDx, Inc.

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

Identified uses : Laboratory chemicals, Manufacture of substances

### 1.3 Details of the supplier of the safety data sheet

 Company : IncellDx, Inc.  
 1541 Industrial Road  
 San Carlos, CA 94070  
 USA

 Telephone : +1 650-777-7630 From the hours of 9:00am - 5:00pm PST  
 Fax : +1 650-587-1528  
 Email : info@incelldx.com

### 1.4 Emergency telephone number

 Emergency Phone : For Europe: Call your local emergency centre  
 For US: +1 650-777-7630

## 2. HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

#### GHS Classification in accordance with 29 CFR 1910 (OSHA HCS) and CLP 1272/2008

 Skin irritation (Category 2), H315  
 Eye irritation (Category 2A), H319  
 Skin sensitisation (Category 1), H317  
 Germ cell mutagenicity (Category 2), H341  
 Carcinogenicity (Category 1A), H350

For the full text of the H-Statements mentioned in this Section, see Section 16.

### 2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word

Danger

Hazard statement(s)

 H315 Causes skin irritation.  
 H317 May cause an allergic skin reaction.  
 H319 Causes serious eye irritation.  
 H341 Suspected of causing genetic defects.  
 H350 May cause cancer.

Precautionary statement(s)

 P201 Obtain special instructions before use.  
 P202 Do not handle until all safety precautions have been read and understood.  
 P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.  
 P264 Wash skin thoroughly after handling.

P272	Contaminated work clothing should not be allowed out of the workplace.
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.
P308 + P313	IF exposed or concerned: Get medical advice/ attention.
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.
P405	Store locked up.
P501	Dispose of contents/ container to an approved waste disposal plant.

### 2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.2 Mixtures

Component	Classification	Concentration
<b>Organic sulfoxide</b>		
	Flam. Liq. 4; H227	>= 10 - < 20 %
<b>Formaldehyde</b>		
CAS-No. 50-00-0 EC-No. 200-001-8 Index-No. 605-001-00-5	Acute Tox. 3; Skin Corr. 1B; Skin Sens. 1; Muta. 2; Carc. 1A; H301 + H311 + H331, H314, H317, H341, H350,	>= 1 - < 5 %
<b>2,4 Dinitrobenzenesulfonic Acid, Sodium Salt</b>		
CAS-No. 885-62-1 EC-No. 212-943-7	Skin Irrit. 2; Eye Irrit. 2A; STOT SE 3; H315, H319, H335	>= 1 - < 5 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

## 4. FIRST AID MEASURES

### 4.1 Description of first aid measures

#### General advice

Move out of dangerous area. Consult a physician. Show this safety data sheet to the doctor in attendance.

#### If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

#### In case of skin contact

Wash off with soap and plenty of water. Consult a physician.

#### In case of eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Continue rinsing eyes during transport to hospital.

#### If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

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

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

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

No data available

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## 5. FIREFIGHTING MEASURES

### 5.1 Extinguishing media

#### Suitable extinguishing media

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

### 5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Sodium oxides

### 5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

### 5.4 Further information

No data available

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## 6. ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

For personal protection see section 8.

### 6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

### 6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

For disposal see section 13.

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## 7. HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

For precautions see section 2.2.

### 7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.

Storage class (TRGS 510): Non-combustible, acute toxic Cat.3 / toxic hazardous materials or hazardous materials causing chronic effects

### 7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

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## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

#### Components with workplace control parameters

Component	CAS-No.	Value	Control parameters	Basis
Organic sulfoxide	-	TWA	250.000000 ppm	USA. Workplace Environmental Exposure Levels (WEEL)
Formaldehyde	50-00-0	C	0.300000 ppm	USA. ACGIH Threshold Limit Values (TLV)
	Remarks	Upper Respiratory Tract irritation Eye irritation Suspected human carcinogen Sensitizer		

		TWA	0.016000 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen See Appendix A		
		C	0.100000 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen See Appendix A 15 minute ceiling value		
		Substance listed; for more information see OSHA document 1910.1048		
		Substance listed; for more information see OSHA document 1910.1048		
		PEL	0.750000 ppm	OSHA Specifically Regulated Chemicals/Carcinogens
		1910.1048 This standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde OSHA specifically regulated carcinogen		
		STEL	2.000000 ppm	OSHA Specifically Regulated Chemicals/Carcinogens
		1910.1048 This standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde OSHA specifically regulated carcinogen		
		TWA	0.016000 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen Formalin is an aqueous solution that is 37% formaldehyde by weight; inhibited solutions usually contain 6-12% methyl alcohol. Also see specific listings for Formaldehyde and Methyl alcohol. See Appendix A		
		C	0.100000 ppm	USA. NIOSH Recommended Exposure Limits
		Potential Occupational Carcinogen Formalin is an aqueous solution that is 37% formaldehyde by weight; inhibited solutions usually contain 6-12% methyl alcohol. Also see specific listings for Formaldehyde and Methyl alcohol. See Appendix A 15 minute ceiling value		
		C	0.3 ppm	USA. ACGIH Threshold Limit Values (TLV)
		Upper Respiratory Tract irritation Eye irritation Adopted values or notations enclosed are those for which changes are proposed in the NIC See Notice of Intended Changes (NIC) Suspected human carcinogen Sensitizer		

## 8.2 Exposure controls

### Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

## Personal protective equipment

### Eye/face protection

Face shield and safety glasses 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.

### Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

### Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

### Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

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|---|-------------------|
| a) Appearance                                   | Form: liquid      |
| b) Odour  | No data available |
| c) Odour Threshold                              | No data available |
| d) pH   | No data available |
| e) Melting point/freezing point                 | No data available |
| f) Initial boiling point and boiling range      | No data available |
| g) Flash point                                  | Not applicable    |
| h) Evaporation rate                             | No data available |
| i) Flammability (solid, gas)                    | No data available |
| j) Upper/lower flammability or explosive limits | No data available |
| k) Vapour pressure                              | No data available |
| l) Vapour density                               | No data available |
| m) Relative density                             | No data available |
| n) Water solubility                             | No data available |
| o) Partition coefficient: n-octanol/water       | No data available |
| p) Auto-ignition temperature                    | No data available |
| q) Decomposition temperature                    | No data available |
| r) Viscosity                                    | No data available |
| s) Explosive properties                         | No data available |
| t) Oxidizing properties                         | No data available |

## 9.2 Other safety information

No data available

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## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

No data available

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No data available

### 10.4 Conditions to avoid

No data available

### 10.5 Incompatible materials

Acid chlorides, Phosphorus halides, Strong acids, Strong oxidizing agents, Strong reducing agents

### 10.6 Hazardous decomposition products

Other decomposition products - No data available

In the event of fire: see section 5

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## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

#### Acute toxicity

No data available

Inhalation: No data available

Dermal: No data available

No data available

#### Skin corrosion/irritation

No data available

#### Serious eye damage/eye irritation

No data available

#### Respiratory or skin sensitisation

No data available

#### Germ cell mutagenicity

No data available

#### Carcinogenicity

IARC: 1 - Group 1: Carcinogenic to humans (Formaldehyde)

NTP: Known to be human carcinogen (Formaldehyde)

OSHA: OSHA specifically regulated carcinogen (Formaldehyde)

#### Reproductive toxicity

No data available

No data available

#### Specific target organ toxicity - single exposure

No data available

#### Specific target organ toxicity - repeated exposure

No data available

#### Aspiration hazard

No data available

**Additional Information**

RTECS: Not available

Effects due to ingestion may include:, Nausea, Fatigue, Headache

Eyes - Eye disease - Based on Human Evidence

Liver - Irregularities - Based on Human Evidence

Eyes - Eye disease - Based on Human Evidence (Dimethyl sulfoxide)

Liver - Irregularities - Based on Human Evidence (Formaldehyde)

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**12. ECOLOGICAL INFORMATION****12.1 Toxicity**

No data available

**12.2 Persistence and degradability**

No data available

**12.3 Bioaccumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

**12.6 Other adverse effects**

No data available

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**13. DISPOSAL CONSIDERATIONS****13.1 Waste treatment methods****Product**

Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

**Contaminated packaging**

Dispose of as unused product.

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**14. TRANSPORT INFORMATION****DOT (US)**

Not dangerous goods

**IMDG**

Not dangerous goods

**IATA**

Not dangerous goods

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**15. REGULATORY INFORMATION****SARA 302 Components**

The following components are subject to reporting levels established by SARA Title III, Section 302:

	CAS-No.	Revision Date
Formaldehyde	50-00-0	2007-07-01

**SARA 313 Components**

The following components are subject to reporting levels established by SARA Title III, Section 313:

	CAS-No.	Revision Date
Formaldehyde	50-00-0	2007-07-01

**SARA 311/312 Hazards**

Acute Health Hazard, Chronic Health Hazard

**Massachusetts Right To Know Components**

	CAS-No.	Revision Date
Formaldehyde	50-00-0	2007-07-01

**Pennsylvania Right To Know Components**

	CAS-No.	Revision Date
Organic sulfoxide		
Formaldehyde	50-00-0	2007-07-01

**New Jersey Right To Know Components**

	CAS-No.	Revision Date
Organic sulfoxide		
Formaldehyde	50-00-0	2007-07-01

**California Prop. 65 Components**

	CAS-No.	Revision Date
Formaldehyde	50-00-0	2007-09-28

WARNING! This product contains a chemical known to the State of California to cause cancer.

**16. OTHER INFORMATION****Full text of H-Statements referred to under sections 2 and 3.**

Acute Tox.	Acute toxicity
Aquatic Acute	Acute aquatic toxicity
Carc.	Carcinogenicity
Eye Dam.	Serious eye damage
Eye Irrit.	Eye irritation
Flam. Liq.	Flammable liquids
H227	Combustible liquid.
H301 + H311 + H331	Toxic if swallowed, in contact with skin or if inhaled
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H402	Harmful to aquatic life.
Muta.	Germ cell mutagenicity
Skin Corr.	Skin corrosion
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitisation
STOT SE	Specific target organ toxicity - single exposure

**HMIS Rating**

Health hazard:	3
Chronic Health Hazard:	*
Flammability:	0
Physical Hazard	0

**NFPA Rating**

Health hazard:	3
Fire Hazard:	0
Reactivity Hazard:	0



**Further information**

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. IncellDx, Inc. and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See [www.incelldx.com](http://www.incelldx.com) and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.