

SAFETY DATA SHEET

Oragene•ONE ON-500, ON-500.xxx, ON-600, ON-600.xxx

Section 1. Identification

GHS product identifier : Oragene•ONE ON-500, ON-500.xxx, ON-600, ON-600.xxx
Other means of identification : Not available.
Product type : Liquid.

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

Identified uses : Stabilization of DNA in collection kit.

Supplier/Manufacturer : DNA Genotek Inc., a subsidiary of OraSure Technologies, Inc.
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Emergency telephone number (with hours of operation) : Toll free: +1-866-813-6354 (North America)
 Toll free: +1-613-723-5757 (all other countries)
 24/7

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : FLAMMABLE LIQUIDS - Category 3
 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H226 - Flammable liquid and vapor.
 H319 - Causes serious eye irritation.

Precautionary statements



Section 2. Hazards identification

Prevention	: P280 - Wear protective gloves. Wear eye or face protection. P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P241 - Use explosion-proof electrical, ventilating, lighting and all material-handling equipment. P242 - Use only non-sparking tools. P243 - Take precautionary measures against static discharge. P233 - Keep container tightly closed. P264 - Wash hands thoroughly after handling.
Response	: P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical attention.
Storage	: P403 - Store in a well-ventilated place. P235 - Keep cool.
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Hazards not otherwise classified	: None known.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of identification	: Not available.

Ingredient name	% (w/w)	CAS number
Ethanol	<24	64-17-5

United States: The exact percentage (concentration) in the composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200.

Canada: The exact percentage (concentration) in the composition has been withheld as a trade secret in accordance with the amended HPR as of April 2018.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.



Section 4. First aid measures

- Skin contact** : Flush contaminated skin with plenty of water. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : Causes serious eye irritation.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : Adverse symptoms may include the following:
pain or irritation
watering
redness
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.
- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use dry chemical, CO₂, water spray (fog) or foam.
- Unsuitable extinguishing media** : Do not use water jet or water-based fire extinguishers.

- Specific hazards arising from the chemical** : Flammable liquid and vapor. Runoff to sewer may create fire or explosion hazard. In a fire or if heated, a pressure increase will occur and the container may burst, with the risk of a subsequent explosion.



Section 5. Fire-fighting measures

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
metal oxide/oxides
- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Spill** : Stop leak if without risk. Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Do not enter storage areas and confined spaces unless adequately ventilated. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Store and use away from heat, sparks, open flame or any other ignition source. Use explosion-proof electrical (ventilating, lighting and material handling) equipment. Use only non-sparking tools. Take precautionary measures against electrostatic discharges. Empty containers retain product residue and



Section 7. Handling and storage

- can be hazardous. Do not reuse container.
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

United States

Occupational exposure limits

Ingredient name	Exposure limits
Ethanol	<p>ACGIH TLV (United States, 3/2017). STEL: 1000 ppm 15 minutes. NIOSH REL (United States, 10/2016). TWA: 1000 ppm 10 hours. TWA: 1900 mg/m³ 10 hours. OSHA PEL (United States, 6/2016). TWA: 1000 ppm 8 hours. TWA: 1900 mg/m³ 8 hours.</p>

Canada

Occupational exposure limits

Ingredient name	Exposure limits
Ethanol	<p>CA Alberta Provincial (Canada, 4/2009). 8 hrs OEL: 1000 ppm 8 hours. 8 hrs OEL: 1880 mg/m³ 8 hours. CA British Columbia Provincial (Canada, 6/2017). STEL: 1000 ppm 15 minutes. CA Ontario Provincial (Canada, 1/2018). STEL: 1000 ppm 15 minutes. CA Quebec Provincial (Canada, 1/2014). TWAEV: 1000 ppm 8 hours. TWAEV: 1880 mg/m³ 8 hours. CA Saskatchewan Provincial (Canada, 7/2013). STEL: 1250 ppm 15 minutes. TWA: 1000 ppm 8 hours.</p>

- Appropriate engineering controls** : Use only with adequate ventilation. Use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.



Section 8. Exposure controls/personal protection

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. When there is a risk of ignition from static electricity, wear anti-static protective clothing. For the greatest protection from static discharges, clothing should include anti-static overalls, boots and gloves.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

- Physical state** : Liquid.
- Color** : Not available.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 9.5
- Melting point** : Not available.
- Boiling point** : Not available.
- Boiling range** : Not available.
- Flash point** : Closed cup: 32°C (89.6°F) [Pensky-Martens.]
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- Vapor density** : Not available.



Section 9. Physical and chemical properties

Relative density	: Not available.
Solubility	: Not available.
Partition coefficient: n-octanol/water	: Not available.
Auto-ignition temperature	: Not available.
Decomposition temperature	: Not available.
Viscosity	: Not available.
Flow time (ISO 2431)	: Not available.

Section 10. Stability and reactivity

Reactivity	: No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	: The product is stable.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	: Avoid all possible sources of ignition (spark or flame). Do not pressurize, cut, weld, braze, solder, drill, grind or expose containers to heat or sources of ignition.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials.
Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Ethanol	LC50 Inhalation Vapor	Rat	124700 mg/m ³	4 hours
	LD50 Oral	Rat	7 g/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Ethanol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Eyes - Moderate irritant	Rabbit	-	0.066666667 minutes 100 mg	-
	Eyes - Moderate irritant	Rabbit	-	100 µl	-
	Eyes - Severe irritant	Rabbit	-	500 mg	-
	Skin - Mild irritant	Rabbit	-	400 mg	-

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity



Section 11. Toxicological information

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Eye contact : Causes serious eye irritation.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.
Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : No known significant effects or critical hazards.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity



Section 11. Toxicological information

Acute toxicity estimates

There is no data available.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Ethanol	Acute EC50 1074 mg/L Fresh water	Crustaceans - Cypris subglobosa	48 hours
	Acute LC50 5680 mg/L Fresh water	Daphnia - Daphnia magna - Neonate	48 hours
	Acute LC50 11000000 µg/L Marine water	Fish - Alburnus alburnus	96 hours
	Chronic NOEC 4.995 mg/L Marine water	Algae - Ulva pertusa	96 hours
	Chronic NOEC 100 µl/L Fresh water	Daphnia - Daphnia magna - Neonate	21 days
	Chronic NOEC 0.375 µl/L Fresh water	Fish - Gambusia holbrooki - Larvae	12 weeks

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Ethanol	-0.35	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Vapor from product residues may create a highly flammable or explosive atmosphere inside the container. Do not cut, weld or grind used containers unless they have been cleaned thoroughly internally. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.



Section 14. Transport information

	DOT Classification	TDG Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-	-
Transport hazard class(es)	-	-	-	-
Packing group	-	-	-	-
Environmental hazards	No.	No.	No.	No.

AERG : Not applicable

Additional information

IATA : **Remarks** Not restricted, Special Provision A58

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : FLAMMABLE LIQUIDS - Category 3
 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A



Section 15. Regulatory information

Composition/information on ingredients

Name	Classification
Ethanol	FLAMMABLE LIQUIDS - Category 2 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A

SARA 313

There is no data available.

State regulations

- Massachusetts** : The following components are listed: Ethanol
New York : None of the components are listed.
New Jersey : The following components are listed: Ethanol
Pennsylvania : The following components are listed: Ethanol

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

Canada

Canadian lists

- Canadian NPRI** : The following components are listed: Ethanol
CEPA Toxic substances : None of the components are listed.
Canada inventory (DSL NDSL) : All components are listed or exempted.

Section 16. Other information

Procedure used to derive the classification

Classification	Justification
FLAMMABLE LIQUIDS - Category 3 SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A	On basis of test data Calculation method

History

- Date of issue mm/dd/yyyy** : 03/30/2019
Date of previous issue : 01/30/2018
Version : 5
Prepared by : KMK Regulatory Services Inc.

Notice to reader

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