



U.S. Department  
of Transportation

**Pipeline and Hazardous  
Materials Safety  
Administration**

1200 New Jersey Avenue, SE  
Washington, DC 20590

MAY 23 2019

Nick Conley, PhD  
Principal Scientist  
Locus Biosciences, Inc.  
523 Davis Drive, Ste. 350  
Morrisville, NC 27560

Reference No. 19-0032

Dear Dr. Conley:

This letter is in response to your March 6, 2019, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to classification of a specific strain of *E. coli* bacteria. Specifically, you ask whether a culture of non-pathogenic *E. coli* that is believed to be not capable of causing disease in humans is subject to the HMR.

The HMR defines a Division 6.2 material in § 173.134 as a material known to contain or suspected of containing a pathogen. A pathogen is a microorganism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion) that can cause disease in either humans or animals. In accordance with § 173.22, it is the shipper's responsibility to properly class and describe a hazardous material. This Office does not perform that function. If your material consists wholly of microorganisms that cannot cause disease in either humans or animals, and does not meet the definition of any other class of hazardous material, then it is not subject to the HMR.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,

Dirk Der Kinderen  
Chief, Standards Development Branch  
Standards and Rulemaking Division

Patrick  
§173.134  
19-0032

**Dodd, Alice (PHMSA)**

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**From:** INFOCNTR (PHMSA)  
**Sent:** Monday, March 18, 2019 12:18 PM  
**To:** Hazmat Interps  
**Subject:** FW: request for written opinion: 49 CFR 173.134 Class 6, Division 6.2, Section b  
**Attachments:** 35382.pdf

Hello Alice and Ikeya,

Below is a request for letter of interpretation. Breanna provided 09-0065. Caller still wants a letter.

Thanks,

Jonathon

**From:** Nick Conley [mailto:nick.conley@locus-bio.com]  
**Sent:** Wednesday, March 06, 2019 2:21 PM  
**To:** INFOCNTR (PHMSA) <INFOCNTR.INFOCNTR@dot.gov>  
**Cc:** Beverly Green <beverly.green@locus-bio.com>  
**Subject:** request for written opinion: 49 CFR 173.134 Class 6, Division 6.2, Section b

Hi,

My name is Nick Conley, and I am a principal scientist at Locus Biosciences.

I work with a Biosafety Level 1 (BSL1) *E. coli* bacteria strain, which is not believed to cause disease in healthy humans. The product can be found [here](#), and the SDS is attached. As an employee, I would like to transport this material by private vehicle between two sites of my company that are located about 1.5 miles apart. The addresses are listed in my signature line below.

I am writing to request a written opinion from US DOT confirming that this material is not subject to regulation as a Category A or Category B infectious substance due to the following two exemptions under 49 CFR 173.134 Class 6, Division 6.2, Section b:

- (1) a material that does not contain an infectious substance or that is unlikely to cause disease in humans or animals
- (3) a material containing micro-organisms that are non-pathogenic to humans or animals.

Can you please provide a written opinion on this? You can reach me by e-mail or at 650-200-9569 if you have any questions.

Best,  
Nick

**Nick Conley, PhD**  
Principal Scientist

Locus Biosciences, Inc.  
GMP Mfg.: 7020 Kit Creek Rd., Ste. 270, Morrisville, NC 27560  
R&D: 523 Davis Dr., Ste. 350, Morrisville, NC 27560  
+1.650.200.9569 mobile | [nick.conley@locus-bio.com](mailto:nick.conley@locus-bio.com)

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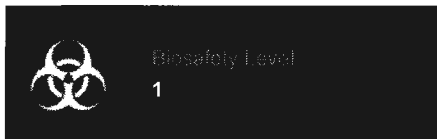
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Product Sheet

# *Escherichia coli* (ATCC® 35382™)

## Please read this FIRST



## Intended Use

This product is intended for research use only. It is not intended for any animal or human therapeutic or diagnostic use.

## Citation of Strain

If use of this culture results in a scientific publication, it should be cited in that manuscript in the following manner: *Escherichia coli* (ATCC® 35382™)

## Description

**Designation:** ECOR 63

**Deposited Name:** *Escherichia coli* (Migula) Castellani and Chalmers

## Propagation

### Medium

ATCC® Medium 3: Nutrient agar or nutrient broth

### Growth Conditions

**Temperature:** 37.0°C

## References

References and other information relating to this product are available online at [www.atcc.org](http://www.atcc.org).

## Biosafety Level: 1

Appropriate safety procedures should always be used with this material. Laboratory safety is discussed in the current publication of the *Biosafety in Microbiological and Biomedical Laboratories* from the U.S. Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes for Health.

## ATCC Warranty

ATCC® products are warranted for 30 days from the date of shipment, and this warranty is valid only if the product is stored and handled according to the information included on this product information sheet. If the ATCC® product is a living cell or microorganism, ATCC lists the media formulation that has been found to be effective for this product. While other, unspecified media may also produce satisfactory results, a change in media or the absence of an additive from the ATCC recommended media may affect recovery, growth and/or function of this product. If an alternative medium formulation is used, the ATCC warranty for viability is no longer valid.

## Disclaimers

This product is intended for laboratory research purposes only. It is not intended for use in humans. While ATCC uses reasonable efforts to include accurate and up-to-date information on this product sheet, ATCC makes no warranties or representations as to its accuracy. Citations from scientific literature and patents are provided for informational purposes only. ATCC does not warrant that such information has been confirmed to be accurate.

This product is sent with the condition that you are responsible for its safe storage, handling, and use. ATCC is not liable for any damages or injuries arising from receipt and/or use of this product. While reasonable effort is made to insure authenticity and reliability of materials on deposit, ATCC is not liable for damages arising from the misidentification or misrepresentation of such materials.

Please see the enclosed Material Transfer Agreement (MTA) for further details regarding the use of this product. The MTA is also available on our Web site at [www.atcc.org](http://www.atcc.org)

Additional information on this culture is available on the ATCC web site at [www.atcc.org](http://www.atcc.org).

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American Type Culture Collection  
PO Box 1549  
Manassas, VA 20108 USA  
[www.atcc.org](http://www.atcc.org)

800.638.6597 or 703.365.2700  
Fax: 703.365.2750  
Email: [Tech@atcc.org](mailto:Tech@atcc.org)

Or contact your local distributor