

**OSSAPIG-NF-NF1(NS) MINIATURE SWINE- nf1 hindiii restriction fragment length polymorphism (rflp) positive for nf1-r1947x nf1(ns) allele in ossabaw breed swine not applicable
Recombinetics, Inc.**

OssaPig-NF-NF1(NS) Miniature Swine

Identity: Transcription activator-like effector nuclease (TALEN) edit and homology dependent repair in Ossabaw breed porcine fetal fibroblasts to introduce four base substitution mutations into one copy of the NF1 gene of *Sus scrofa* chromosome 12 (NC_010454.4). The C>T base substitution at base pair 43,530,892 generates a premature stop codon in the coding sequence for the neurofibromin protein and the G>T base substitution at base pair 43,308,860 generates a HindIII restriction enzyme site used to genotype progeny from gene edited founders. The other two substitutions, C>T at 43,530,872 and T>C at 43,530,899, occur in the TALEN binding sites and are included to inhibit TALEN rebinding in the edited embryos.

Claim: Loss of NF1 gene function as a result of this gene edit in the Ossabaw breed of swine produces symptoms consistent with the National Institutes of Health (NIH) criteria for diagnosis of Neurofibromatosis Type I disease in humans.

Limitations: This is a model of progressive disease. Some of the disease symptoms associated with Neurofibromatosis Type I disease in humans take time to develop, and like the human disease, are variable in presentation from animal to animal.

Product Use: Model animals and/or materials derived from these animals are intended for purchase only under license agreement with Recombinetics, Inc., and solely for use in connection with the specific licensed biomedical research.

Conditions of Use: This model animal and any products derived from it are for biomedical research purposes only and not for use in humans. This is an investigational animal. Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

WARNINGS & PRECAUTIONS:

Caution. This intentionally genetically altered animal and any products derived from it are for biomedical research purposes only and are not for use in humans or as human or animal food.

OssaPig-NF-NF1(NS) animals are not for resale. No reproduction, distribution, transportation, or other third party transfer is allowed by the purchaser unless specifically agreed to in writing by Recombinetics, Inc.

OssaPig-NF-NF1(NS) animals, or any materials derived from the OssaPig-NF-NF1(NS) animals, are not intended to enter the human or animal food supply.

OssaPig-NF-NF1(NS) animals shall be euthanized in accordance with all applicable regulatory or industry standards, and all animal remains must be disposed of by incineration. Purchaser must maintain detailed records accounting for the location of all OssaPig-NF-NF1(NS) animals, and all materials derived from the OssaPig-NF-NF1(NS) animals, from the time the animals are delivered to Purchaser through disposition by incineration. Final disposition notification must be made to Recombinetics, Inc.



OssaPig-NF-NF1(NS) Miniature Swine



Certificate of Animal Health & Identification

Animal Identification			
Ear Notch ID		Birth Date	
Ear Tag ID		Dam ID	
Sex		Boar ID	

Genotype: *NFI* HindIII restriction fragment length polymorphism (RFLP) positive for one copy of *NFI*^{Δ190X}

Pedigree Description:

Pre-Shipment Veterinary Health Status Reviewed On: _____
Date

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OssaPig-NF-NF1(NS) Miniature Swine



from gene edited founders. The other two substitutions, C>T at 43,530,872 and T>C at 43,530,899, occur in the TALEN binding sites and are included to inhibit TALEN rebinding in the edited embryos.

Claim: Loss of *NFI* gene function as a result of this gene edit in the Ossabaw breed of swine produces symptoms consistent with the National Institutes of Health (NIH) criteria for diagnosis of Neurofibromatosis Type I disease in humans.

Limitations: This is a model of progressive disease. Some of the disease symptoms associated with Neurofibromatosis Type I disease in humans take time to develop, and like the human disease, are variable in presentation from animal to animal.

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Manufactured, packaged & distributed by Recombinetics, Inc.

For more information, contact:

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Recombinetics, Inc. www.recombinetics.com

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Eagan, MN 55121 USA

OSSAPIG-NF-NF1(NS) MINIATURE SWINE

nf1 hindiii restriction fragment length polymorphism (rf1p) positive for nf1-r1947x nf1(ns) allele in ossabaw breed swine not applicable

Product Information

Product Type	RECOMBINANT DEOXYRIBONUCLEIC ACID CONSTRUCT LABEL	Item Code (Source)	NDC:86086-005
Route of Administration	NOT APPLICABLE		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SUS SCROFA (G.(NC_010454.4)43530860G>T + 43530872C>T + 43530892C>T + 43530899T>C) ONE COPY IN OSSABAW BREED MINIATURE SWINE (UNII: J64839N3EH) (SUS SCROFA (G.(NC_010454.4)43530860G>T + 43530872C>T + 43530892C>T + 43530899T>C) ONE COPY IN OSSABAW BREED MINIATURE SWINE - UNII:J64839N3EH)	SUS SCROFA (G.(NC_010454.4)43530860G>T + 43530872C>T + 43530892C>T + 43530899T>C) ONE COPY IN OSSABAW BREED MINIATURE SWINE	1 [arb'U] in 1 [arb'U]

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86086-005-01	1 [arb'U] in 1 NOT APPLICABLE		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
unapproved drug other		05/01/2021	

Labeler - Recombinetics, Inc. (829874523)

Registrant - Recombinetics, Inc. (829874523)

Establishment

Name	Address	ID/FEI	Business Operations
Recombinetics, Inc.		080987344	manufacture

Revised: 4/2021

Recombinetics, Inc.