

Lentiviral Product Safety Level Information

This Lentiviral Product Safety Level Information constitutes Product Documentation according to clause 1 of the Product Terms and Conditions. It is applicable to the following Dharmacon lentiviral products ("Products"):

- SMARTvector™ shRNAs
- SMARTchoice™ shRNAs
- SMARTchoice™ Inducible shRNAs
- SMARTchoice™ shMIMIC™ miRNA
- SMARTchoice™ Inducible shMIMIC™ miRNA
- GIPZ™ shRNAs
- TRIPZ™ shRNAs
- Precision LentiORFs
- Decode™ Pooled RNAi Screening Libraries

The Products are solely for internal research use (as set forth in the Product Terms and Conditions) in laboratories where the containment measures stated below and in applicable laws and regulations are met. Products may not be used for diagnostic, therapeutic or other commercial purposes and may not to be administered to humans for any purpose or to animals for therapeutic purposes. The Products are replication-incompetent, self-inactivating (SIN) and non-pathogenic (do not cause infectious human disease).

Any investigator who purchases Dharmacon lentiviral products is responsible for consulting with their institution's health and biosafety personnel for specific guidelines on the handling of lentiviral vector particles. Furthermore, each investigator is fully responsible for obtaining the required permissions for research using and the acceptance of replication-incompetent SIN lentiviral vectors and replication-defective lentiviral particles into their local jurisdiction and institution.

For questions concerning the design or production of the products, please contact:

Horizon Discovery | Dharmacon Technical Support
 Tel: 800-235-9880 (Option 2) Or 303-604-9499 (Option 2)
 Fax: 1-800-292-6088 Or 303-604-9680
 Email: ts.dharmacon@horizondiscovery.com

In the US

For US guidance on containment for lentiviral vectors, please refer to the Recombinant DNA Advisory Committee (RAC) guidelines for research with lentiviral vectors: https://osp.od.nih.gov/wp-content/uploads/2014/01/Lenti_Containment_Guidance_0.pdf.

The U.S. Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories (BMBL), Fifth Edition, Dec 2009 downloadable here: <https://www.cdc.gov/biosafety/publications/index.htm>.

See also the NIH Guidelines For Research Involving Recombinant DNA Molecules (NIH Guidelines), Apr 2016, downloadable here: https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines_PRN_1-sided.pdf.

In the EU

For the EU directives, please consult the following:

1. Council Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms. (revised version Directive of 90/219/EEC of the European Parliament and of the Council of 23 April 1990 on the contained use of genetically modified micro-organisms, amended by Council Directive 98/81/EC of 26 October 1998); and
2. Council Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

In Germany

Required Containment Measures

The containment requirements as stated in the German Genetic Safety Ordinance (Gentechnik-Sicherheitsverordnung) of Safety Level 2* or higher have been assigned to the handling of the above-mentioned lentiviral vector particles. Please note that a higher Security Level might be required if the lentiviral vector particles are used for genetic engineering operations with other products which require a higher Security Level.

Safety Level 2: activities of low risk for human health and the environment by the state of scientific knowledge (Stand der Wissenschaft).

For the German regulations, please consult the following:

1. German Genetic Engineering Act (Gentechnikgesetz - GenTG); and
2. Genetic Engineering Safety Ordinance (Gentechnik-Sicherheitsverordnung - GenTSV).

Label Licenses

The shRNA and gene expression Products, use and applications, are covered by pending and issued patents. Certain Label licenses govern the use of the products, these can be found at <https://dharmacon.horizondiscovery.com/uploadedFiles/dharmacon-licensing-statements.pdf>.

It is each Buyer's responsibility to determine which intellectual property rights held by third parties may restrict the use of Products for a particular application. Please review the Label Licenses governing all use of the shRNA and gene expression Products. dharmacon.horizondiscovery.com/uploadedFiles/dharmacon-product-terms-and-conditions.pdf

If you have any questions, contact

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