Material Safety Data Sheet

1- Identification of the biological product (or preparation) and of the Company

1.1 – Identification of the biological product or preparation

Biological product:

- ✓ Replication-defective Lentiviral vectors, VSV-g pseudotyped (rLV),
- ✓ Non-integrating lentiviral particle, VSV-G pseudotyped (RLP).

Identified uses: For research use only. Not for clinical diagnostic or therapeutic use. The safety and efficacy of this product in diagnostic or other clinical uses has not been established.

1.2 – Company product identification

FLASH THERAPEUTICS SAS
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3, rue des Satellites
31400 Toulouse
☎ + 33 (5) 61 28 70 75
💻 + 33 (5) 62 26 12 44
✉ flashtherapeutics@flashtherapeutics.com

1.3 – Emergency phone number

North America:

CDC Center for Disease Control and Prevention: ☎ 911

CDC National Center for Environmental Health & Agency for Toxic Substances and Disease Registry: ☎ + 1 770-488-7100

Europe:

List of national helpdesks - ECHA

France: ORFILA number (INRS): ☎ + 33 (0)1 45 42 59 59

German emergency telephone number ☎ + 49 (0) 231 9071 2971

2- Composition – Information on Ingredients

Biological product:

Viral vector name: rLV-promoter- transgene -WPRE / RLP-transgene-WPRE
Type: Lentiviral vector / non-integrative lentiviral particle (LentiFlash®)
Promoter (rLV) : hEF1 (human elongation factor one) / TRE3G / Oct4 / NES / TH / hSyn / hGFAP / MBP / APOA2 / CYP3A4 / INS / Myh6 / MYL2 / ENG / p16 / p21 / p53RE / PCNA / MKI67 / NFkappaB-RE.
Promoter (LentiFlash®) : EF1
Replicative: NO
LTR: HIV ΔU3 (deletion) RU5 (self-inactivating)

3- Hazards identification

Lentiviral vector	RLP
Pathogenicity of the GMO lentiviruses-derived: non-replicating vectors, derived from HIV-1, they do not encode the viral proteins required for viral replication. Replication-defective lentiviral vectors are not known to cause any diseases in humans or animals. However, they can integrate into the cell genome and thus pose some risk of insertional mutagenesis.	Pathogenicity of RLP: Non-replicative and Non-integrating vectors. Chimeric particle from HIV-1 and MS2 bacteriophage, they do not encode the viral proteins required for viral replication.

Symbol:

 Biohazard

Classification: Biohazard of Biosafety level 2 BSL-2

Potential health effects:

Avoid contact with skin and eyes.

Principles routes of Exposure:	Skin cut with accidental exposure to blood, Splashing into eyes, Ingestion
Acute toxicity:	
Eye	May cause irritation
Skin	May be harmful if absorbed through the skin
Inhalation	/
Ingestion	May be harmful if swallowed
Chronic toxicity:	Not available
Environmental hazard:	See section 13 (Disposal of care activities involving infectious risks)

Precautionary statements :
P270 - Do not eat, drink or smoke when using this product.
P262 - Do not get in eyes, on skin, or on clothing.
P273 - Avoid release to the environment.
P280 - Wear protective gloves/protective clothing/eye protection/face protection.

4- First Aid measures

General advice	• An accident/incident investigation form should be initiated and should document the route(s) of exposure, the circumstances under which the exposure incident occurred, the viral vectors titer, description of the transgene and if human blood, fluids, tissues or cells are involved, the identification and documentation of the source individual or material.
Skin contact without lesion caused	• Clean affected area with soap and water, then rinse. Decontaminate the affected area with disinfectant adapted and validated
If splashed on mucous membranes or eyes	Flush thoroughly with water or saline solution (if wearing contact lenses, allowing the water to loosen, ***not wear contact lenses when handling viral vectors***)
In the event of puncture or injury:	Clean the injured area of skin with water and soap, then rinse. Decontaminate the affected area with a prolonged bath (at least 5 minutes) using an adapted and validated disinfectant with appropriate spectrum of activity.

5- Fire fighting measures

Not applicable

6- Accidental release measures

Safety personal precautions :

- Use personal protective equipment: see section 8.
- Person to contact: Head of Health and Safety
- Keeping records of incidents.

Environmental precautions:

The use of lentiviral derived vectors implies laboratory biosafety procedures and practices in accordance with your country regulations.

For 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/Lenti_Containment_Guidance.pdf

In the USA, download 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, Feb 2007 here:
http://www.cdc.gov/biosafety/publications/index.htm.

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

Methods for cleaning up: In case of spills of viral supernatant, soak up with inert absorbent material and decontaminate the area by using an adapted and validated disinfectant with appropriate spectrum of activity.

7- Handling and storage precautions

Advice on safe handling: Handle a biohazardous material under Biosafety Level 2 (BSL-2) containment.

- The use of gloves is strongly recommended when handling bags containing vials of viral-derived vectors.
- For laboratory use of viral derived vectors, the use of gloves and disposable lab coats is strongly recommended.
- This product must be handled only inside a biological safety cabinet with BSL-2 precautions. The use of lentiviral derived vectors implies laboratory biosafety procedures and practices in accordance with your country regulations.
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Storage conditions:

- Tank: The viral vectors must be kept at -80°C (freezer with "Biohazard" symbol) immediately upon receipt.
- Conditions: -80°C upon receipt.

8- Exposure controls, personal protection

Exposure control :

Collective protection	BSL-2 containment, BSC-2 Biosafety cabinet-2	
Personal Protective Equipment		
	Respiratory protection	
	Eye / Face protection	Mask with visor / plastic visors or goggles
	Skin and body protection	Cotton blouse / lab coats
	Hand protection	gloves
Environmental protection	BSL-2 containment	

Mandatory use of gloves and disposable lab coats are required for handling viral vectors.

Material Safety Data Sheet

9- Physical and chemical properties

Serum free medium.
Appearance: clear
Physical state: liquid
Odor: none

10- Stability and reactivity

Lentiviral vectors are stable for several years at -112 °F (-80 ° C).
Stability: They are not stable in air or water. Do not dilute in water, if required, vectors must be diluted in an appropriate buffer.
Hazardous Decomposition Products: None under normal use conditions.

11- Toxicological information

No information available

12- Ecological information

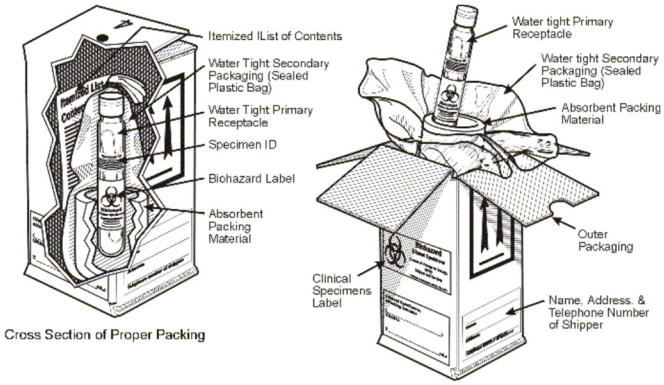
Degradability: degradation for 15 min at +122 °F (+50°C)

13- Disposal information

Lentiviral vectors are GMOs; they are classified as **Risk Group 2** by the World Health Organization (WHO). Waste must be disposed of in accordance with the country, federal, state and local environmental control regulations for biohazardous material.

14- Transport information

Number ONU/UN: 3373
Class: 6.2 if packaged with ice dry
Risk category: Biological substance, Category B
Expedition name: lentiviral vectors (GMO)
Labeling: Class 9 label, including UN1845, and net weight if packaged with dry ice
Packing instruction 650:



Packing and Labeling of Clinical Specimens

Material Safety Data Sheet

Labeling: Below are examples of labels required on biological material packages.

IATA Instruction: 650

The sender is responsible for sending even when outsourcing to a transporter

15- Regulatory information

Symbol :

Classification: Biohazard Biosafety level BSL-2

WHO (www.who.int) :

- "Transport des substances infectieuses" 2011
- « Guidance on regulations for the transport of infectious substances » September 2011

16- Other information

Disclaimer:

To the best of our knowledge, the information contained herein is accurate at the date of its publication. However, the supplier mentioned above assumes any liability whatsoever in respect to the accuracy or completeness of the information contained in this document. The user should exercise independent judgment as to the hazards based on all sources of information available. All biological products may present unknown hazards and should be used with caution. Although certain hazards are described herein, we can not guarantee that there are none others.