

Safety Data Sheet Template

Section 1: Identification of the substance/media and of the company/undertaking

Product identifier

Product name: Enable-NK[™] Duo

- Enable-NK™ Grow medium

- Enable-NK™ Activate medium

Onkologic, Inc. part number:121X-XXXXX, 126X-XXXXX

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

<u>Statement to be used for non-GMP Research Use Only (RUO) product</u>: For the ex vivo expansion and activation of NK cells. For research use only. Not for human or animal therapeutic or clinical diagnostic use.

<u>Statement to be used for GMP manufactured product</u>: GMP version is intended for research use and/or use as ancillary material for ex vivo cell expansion for clinical trials and commercial NK cell immunotherapy product manufacturing.

Details of the supplier of the SDS

Onkologic, Inc. 17 Briden Street, Worcester, MA 01605 508-216-0009 <u>contact@onkologic.com</u>

Emergency telephone number

Dial local emergency number (eg. 911 in the US).

Section 2: Hazards identification

Classification of the substance or mixture

GHS classification: none

Labeling Elements

Signal word: none Hazard pictograms: none

Other hazards

Physical hazard: none Environmental hazard: none Health hazard: none

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HMIS

Health	0
Flammability	0
Reactivity	0

Precautionary statements

Not applicable

Section 3: Composition/information on ingredients

The product contains no substances that are considered to be hazardous to health. We recommend handling all chemicals with caution.

Section 4: First aid measures

Description of first aid measures

Use standard first aid measures, and if needed seek medical attention.

Skin contact: Rinse skin with soap and water. Remove contaminated clothing.

Eve contact: Rinse open eyes with water. If applicable, remove contact lenses and rinse eyes.

Ingestion: Rinse mouth and drink plenty of water.

Inhalation: Not expected to be an inhalation hazard under anticipated conditions of normal use of this material.

Most important symptoms and effects, both acute and delayed

No additional information available.

Indication of any immediate medical attention and special treatment needed Treat symptomatically

Section 5: Firefighting measures

Extinguishing media

Suitable extinguishing media

Unsuitable extinguishing media

Water. Carbon dioxide (CO₂). Foam. Dry chemical. No information available

Special hazards arising from the substance or mixture

Not known

Advice for firefighters

Standard procedure for chemical fires.

Section 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. In case of inadequate ventilation, wear suitable respiratory devices. Avoid contact with skin and eyes. Always wear recommended Personal Protective Equipment.

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Environmental Precautions

No special environmental precautions required.

Methods and material for containment and clean up

Soak up with an inert absorbent material.

Reference to other sections

See Section 8 for more information.

Section 7: Handling and storage

Precautions for safe handling

Use standard precautions when handling any material.

Conditions for safe storage, including any incompatibilities

Store the medium at 2-8°C.

Specific end use(s)

For research use only, not for clinical use. See Instructions for Use.

Section 8: Exposure controls/personal protection

Control parameters

No exposure limit. Ensure adequate ventilation.

Exposure controls

Wear proper protective equipment.

Section 9: Physical and chemical properties

Information on basic physical and chemical properties

Physical state :	Liquid
Color :	Red with phenol red, colorless without phenol red
Odor :	Odorless
Odor threshold :	Not applicable
pH :	6.9 - 7.9
Relative evaporation rate (butylacetate=1) :	Not applicable
Melting point :	Not determined
Freezing point :	No data available
Boiling point :	Not determined
Flash point :	Not applicable
Auto-ignition temperature :	Not determined
Decomposition temperature :	Not determined
Flammability (solid, gas) :	Not applicable
Vapor pressure :	Not determined
Relative vapor density at 20 °C :	No data available
Relative density :	Not determined
Solubility :	Water soluble
Log Pow :	Not determined

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Log Kow : Viscosity, kinematic : Viscosity, dynamic : Explosive properties : Oxidizing properties : Explosive limits : Other information

none

Not determined Not determined Not known. Not known No data available

Section 10: Stability and reactivity

Reactivity

No data available. **Chemical stability** Stable under recommended storage conditions (2 - 8 °C) **Possibility of hazardous reactions**

No data available.

Conditions to avoid

No information available.

Incompatible materials

No data available.

Hazardous decomposition products

No data available.

Section 11: Toxicological information

Information on toxicological effects

Acute toxicity Not classified Not classified Skin corrosion/irritation Not classified Serious eye damage/irritation Respiratory or skin sensitization Not classified Specific target organ toxicity (STOT)- single exposure Not classified Specific target organ toxicity (STOT)- repeated exposure Not classified Not classified Carcinogenicity Germ cell mutagenicity Not classified Reproductive toxicity Not classified Aspiration hazard Not classified

Section 12: Ecological information

Toxicity

No data available.

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Persistence and degradability

No data available.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or vPvB.

Other adverse effects

No data available.

Section 13: Disposal considerations

Waste treatment methods

This material and its container must be disposed of by following local standard practice and legislation.

Section 14: Transport information

In accordance with IATA / ADR / DOT-US / IMDG

Not regulated in the meaning of transport regulations	
UN number	Not Applicable
UN proper shipping name	Not Applicable
Transport hazard class(es)	Not Applicable
Packing group	Not Applicable

Environmental hazards

Not applicable. Special precautions for user Not applicable. Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable.

Section 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the substance or mixture

US National regulations	
SARA 313	Not Applicable.
Clean Air Act, Section 112 Hazardous Air Pollutants	Not Applicable.

US State regulations

California Proposition 65

Not Applicable.

WHMIS Hazard Class

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Non-controlled

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

EU-regulations

Contains no REACH substances with Annex XVII restrictions Contains no substance on the REACH candidate list Contains no REACH Annex XIV substances

Other information,	: Export and import of dangerous chemicals: Not subject to
restriction and prohibition	Regulation (EC) No 649/2012. Ozone layer depleting substances:
regulations	Not subject to Regulation (EC) No 1005/2009. Persistent organic
	pollutants (POPs): Not subject to Regulation (EC) No 850/2004.
	Control of major-accident hazards (COMAH, Seveso III): Not subject
	to Directive 2012/18/EC.

Chemical safety assessment

Not specifically applicable.

Section 16: Other information

Acronyms:

- ADR Agreements Concerning the International Carriage of Dangerous Goods by Road
- DOT-US US Department of Transportation
- GMP Good Manufacturing Practices
- IATA International Air Transport Association
- IMDG International Maritime Dangerous Goods
- RUO Research Use Only

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product. The SDS does not constitute a warranty, expressed or implied, including any implied warranty of merchantability or fitness for any particular purpose.