



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
REACH Regulation (EC) No 1907/2006, as retained in UK law by (SI 2019/758 as amended)

Revision date 10-Apr-2025

Version 4

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name Phusion™ Hot Start Flex DNA Polymerase

Product No M0535

Pure substance/mixture Mixture

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

Recommended use This product is for research and development only

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

New England BioLabs
240 County Road
Ipswich, MA 01938
USA

For further information, please contact

Contact Point 978-927-5054, 800-632-5227 (toll free)

E-mail address info@neb.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec +44 20 3885 0382

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GB CLP (SI 2020/1567 as amended)

Not classified

2.2. Label elements

Not classified

Hazard statements

Not classified.

EUH210 - Safety data sheet available on request.

2.3. Other hazards

Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

The product contains no substances which at their given concentration, are considered to be hazardous to health

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (UK REACH Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water. In the case of skin irritation or allergic reactions see a physician.
Ingestion	Rinse mouth.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms	No information available.
Effects of Exposure	No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing media Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Ensure adequate ventilation.

General hygiene considerations Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

Risk management methods [RMM] The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters**Exposure Limits**

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) - Workers

Chemical name	Oral	Dermal	Inhalation
Glycerol 56-81-5			56 mg/m ³ [5] [6]
Potassium Chloride 7447-40-7		303 mg/kg bw/day [4] [6] 910 mg/kg bw/day [4] [7]	1064 mg/m ³ [4] [6] 5320 mg/m ³ [4] [7]
Tris-HCl 1185-53-1		216.6 mg/kg bw/day [4] [6]	152.8 mg/m ³ [4] [6]
Ethylenediamine tetraacetic acid 60-00-4			1.5 mg/m ³ [5] [6] 3 mg/m ³ [5] [7]

Notes

- [4] Systemic health effects.
 [5] Local health effects.
 [6] Long term.
 [7] Short term.

Derived No Effect Level (DNEL) - General Public

Chemical name	Oral	Dermal	Inhalation
Glycerol 56-81-5	229 mg/kg bw/day [4] [6]		33 mg/m ³ [5] [6]
Potassium Chloride 7447-40-7	91 mg/kg bw/day [4] [6] 455 mg/kg bw/day [4] [7]	910 mg/kg bw/day [4] [6] 910 mg/kg bw/day [4] [7]	273 mg/m ³ [4] [6] 1365 mg/m ³ [4] [7]
Tris-HCl 1185-53-1	10.8 mg/kg bw/day [4] [6]		37.7 mg/m ³ [4] [6]
Ethylenediamine tetraacetic acid 60-00-4	25 mg/kg bw/day [4] [6]		0.6 mg/m ³ [5] [6] 1.2 mg/m ³ [5] [7]

Notes

- [4] Systemic health effects.
 [5] Local health effects.
 [6] Long term.
 [7] Short term.

Predicted No Effect Concentration (PNEC)

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
Glycerol 56-81-5	0.885 mg/L	8.85 mg/L	0.0885 mg/L		
Potassium Chloride 7447-40-7	0.1 mg/L	1 mg/L	0.1 mg/L		
Ethylenediamine tetraacetic acid	2.2 mg/L	1.2 mg/L	0.22 mg/L		

Chemical name	Freshwater	Freshwater (intermittent release)	Marine water	Marine water (intermittent release)	Air
60-00-4					

Chemical name	Freshwater sediment	Marine sediment	Sewage treatment	Soil	Food chain
Glycerol 56-81-5	3.3 mg/kg sediment dw	0.33 mg/kg sediment dw	1000 mg/L	0.141 mg/kg soil dw	
Potassium Chloride 7447-40-7			10 mg/L		
Ethylenediamine tetraacetic acid 60-00-4			43 mg/L	0.72 mg/kg soil dw	

8.2. Exposure controls

Engineering controls No information available.

**Individual protection measures,
such as personal protective
equipment**

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Liquid
Appearance Colorless
Color No information available
Odor Mild.
Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known
Autoignition temperature	392.8 °C	

Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapor pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Vapor density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	
Explosive properties	No information available	
Oxidizing properties	No information available	

9.2. Other information**SECTION 10: Stability and reactivity****10.1. Reactivity**

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information**11.1. Toxicological information****Information on likely routes of exposure****Product Information**

Inhalation Specific test data for the substance or mixture is not available.

Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity No information available.

Numerical measures of toxicity

The following ATE values have been calculated for the mixture

ATEmix (oral)	54,400.00	mg/kg
ATEmix (dermal)	20,000.00	mg/kg
ATEmix (inhalation-gas)	99,999.00	ppm
ATEmix (inhalation-vapor)	99,999.00	mg/l
ATEmix (inhalation-dust/mist)	99,999.00	mg/l

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

Other adverse effects No information available.

SECTION 12: Ecological information**12.1. Toxicity**
Ecotoxicity**12.2. Persistence and degradability**

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment The product does not contain any substance(s) classified as PBT or vPvB above the threshold of declaration.

12.6. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

14.1 UN number or ID number Not regulated

14.2

14.3 Transport hazard class(es) Not regulated

14.4 Packing group Not regulated

14.5 Environmental hazard Not applicable

14.6 Special precautions for user
Special Provisions None

IMDG

14.1 UN number or ID number Not regulated

14.2

14.3 Transport hazard class(es) Not regulated

14.4 Packing group Not regulated

14.5 Environmental hazard Not applicable

14.6 Special precautions for user
Special Provisions None

14.7 Maritime transport in bulk according to IMO instruments No information available

RID

14.1 UN number or ID number Not regulated

14.2

14.3 Transport hazard class(es) Not regulated

14.4 Packing group Not regulated

14.5 Environmental hazard Not applicable

14.6 Special precautions for user
Special Provisions None

ADR

14.1 UN number or ID number Not regulated

14.2

14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special precautions for user	
Special Provisions	None

SECTION 15: Regulatory information

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

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (UK REACH - Annex XIV). This product does not contain substances subject to restriction (UK REACH - Annex XVII).

Persistent Organic Pollutants

Not applicable

Export Notification requirements

Not applicable

Named dangerous substances per COMAH (SI 2015/483 as amended)

Not applicable

The Ozone-Depleting Substances Regulations 2015

Not applicable

The Biocidal Products Regulations 2001 (as amended)

Not applicable

The Water Environment (Water Framework Directive) (England and Wales) Regulations 2017 (as amended)

Not applicable

Poisons and Explosive Precursors

Not applicable

International Inventories

TSCA	Contact supplier for inventory compliance status
DSL/NDSL	Contact supplier for inventory compliance status
EINECS/ELINCS	Contact supplier for inventory compliance status
ENCS	Contact supplier for inventory compliance status
IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status
NZIoC	Contact supplier for inventory compliance status
TCSI	Contact supplier for inventory compliance status

Legend:

TSCA	- United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL	- Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS	- European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS	- Japan Existing and New Chemical Substances
IECSC	- China Inventory of Existing Chemical Substances
KECL	- Korean Existing Chemicals Inventory
PICCS	- Philippines Inventory of Chemicals and Chemical Substances
AICS	- Australian Inventory of Chemical Substances
NZIoC	- New Zealand Inventory of Chemicals
TCSI	- Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment**Chemical Safety Report**

No information available

SECTION 16: Other information**Key or legend to abbreviations and acronyms used in the safety data sheet****Legend**

SVHC: Substances of Very High Concern for Authorization:

PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances

vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances

STOT: Specific Target Organ Toxicity

ATE: Acute Toxicity Estimate

LC50: 50% Lethal Concentration

LD50: 50% Lethal Dose

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average)

STEL

STEL (Short Term Exposure Limit)

Ceiling Maximum limit value

Sk*

Skin designation

+ Sensitizers

Classification procedure

Classification according to GB CLP (SI 2020/1567 as amended)

Method Used

Acute oral toxicity

Calculation method

Acute dermal toxicity

Calculation method

Acute inhalation toxicity - gas

Calculation method

Acute inhalation toxicity - vapor

Calculation method

Acute inhalation toxicity - dust/mist

Calculation method

Skin corrosion/irritation

Calculation method

Serious eye damage/eye irritation

Calculation method

Respiratory sensitization

Calculation method

Skin sensitization

Calculation method

Mutagenicity

Calculation method

Carcinogenicity

Calculation method

Reproductive toxicity

Calculation method

STOT - single exposure

Calculation method

STOT - repeated exposure

Calculation method

Acute aquatic toxicity

Calculation method

Chronic aquatic toxicity

Calculation method

Aspiration hazard

Calculation method

Ozone

Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA_RAC)

European Chemicals Agency (ECHA) (ECHA_API)

Environmental Protection Agency

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

U.S. National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 10-Apr-2025

Further information SDS is valid 3 years from revision date. Contact info@neb.com for latest revision

This SDS complies with the requirements of UK REACH Regulations SI 2019/758 (as amended)

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge and belief at the date of publication. This information is intended only as a guide for safe handling, use, processing, storage, transportation, disposal and release and should not be taken as a warranty or quality specification. The information relates only to the specific material and may not be valid for such material used in combination with any other materials or in any process unless expressly specified in the text. New England Biolabs will not be liable for any damages resulting from handling or contact with the product.

End of Safety Data Sheet