

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 14-Jun-2023 Revision Number 1

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

1.1. Product identifier

Product Code(s) CAT 1112

Product Name Abacavir Sulfate

Form Not applicable

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No) 620-488-4

CAS No 188062-50-2

Chemical name Abacavir Sulfate

Pure substance/mixture Substance

Formula C28 H38 N12 O6 S

Molecular weight 670.74

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

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

Tel: +44 (0)20 3080 6561 eMail: bpcrs@mhra.gov.uk

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For further information, please contact

E-mail address bpcrs@mhra.gov.uk

1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008		
Europe	112	
Austria	No information available	
Bulgaria		
Croatia		
Cyprus		
Czech Republic		
Denmark		
France		
Hungary		
Ireland		
Italy		
Lithuania		
Luxembourg		
Netherlands		
Norway		
Portugal		
Romania		
Slovakia		
Slovenia		
Spain		
Sweden		
Switzerland		

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Regulation (EC) No 1272/2000	
Serious eye damage/eye irritation	Category 1 - (H318)
Respiratory sensitisation	Category 1 - (H334)
Skin sensitisation	Category 1 - (H317)
Carcinogenicity	Category 2 - (H351)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity — single exposure	Category 1 - (H370)



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2.2. Label elements

Contains Abacavir Sulfate



Signal word Danger

Hazard statements

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H351 - Suspected of causing cancer

H361 - Suspected of damaging fertility or the unborn child

H370 - Causes damage to organs

Precautionary Statements - EU (§28, 1272/2008)

P260 - Do not breathe dust/fume/gas/mist/vapours/spray

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P310 - Immediately call a POISON CENTER or doctor

2.3. Other hazards

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors.		
Chemical name	EU - REACH (1907/2006) - Article 59(1) EU - REACH (1907/2006) - Endocrine		
	- Candidate List of Substances of Very Disruptor Assessment List of		
	High Concern (SVHC) for Authorisation Substances		
Abacavir Sulfate			

SECTION 3: Composition/information on ingredients



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3.1 Substances

Chemical name	Weight-%	REACH registration	EC No (EU	Classification according	Specific	M-Factor	M-Factor
		number	Index No)	to Regulation (EC) No.	concentration		(long-term)
				1272/2008 [CLP]	limit (SCL)		
Abacavir Sulfate	90 -	=	222-748-9	Eye Dam. 1 (H318)			
188062-50-2	100%			Resp. Sens. 1 (H334)			
				Skin Sens. 1 (H317)			
				Carc. 2 (H351)			
				Repr. 2 (H361)			
				STOT SE 1 (H370)			

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

Acute Toxicity Estimate
No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice Immediate medical attention is required. Show this safety data sheet to the doctor in

attendance. IF exposed or concerned: Get medical advice/attention.

Inhalation Remove to fresh air. May cause allergic respiratory reaction. If breathing has stopped, give

artificial respiration. Get medical attention immediately. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Get immediate medical advice/attention.

Eye contact Get immediate medical advice/attention. Rinse immediately with plenty of water, also under

the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do.

Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area.

Skin contact Wash off immediately with soap and plenty of water for at least 15 minutes. May cause an

allergic skin reaction. If symptoms persist, call a doctor.

Ingestion Rinse mouth. Never give anything by mouth to an unconscious person. Do NOT induce

vomiting. May produce an allergic reaction. Get immediate medical advice/attention.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Ensure that medical personnel are aware of the

material(s) involved, take precautions to protect themselves and prevent spread of



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contamination. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as required. See section 8 for more information.

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

Symptoms Burning sensation. May cause allergy or asthma symptoms or breathing difficulties if

inhaled. Coughing and/ or wheezing. Itching. Rashes. Hives.

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

Note to doctors May cause sensitisation in susceptible persons. Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

Product is or contains a sensitiser. May cause sensitisation by inhalation and skin contact.

May cause sensitisation by skin contact.

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 Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Ensure adequate ventilation. Evacuate personnel to safe areas. Keep people away from

and upwind of spill/leak.

Other information Refer to protective measures listed in Sections 7 and 8.

For emergency responders

Use personal protection recommended in Section 8.



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6.2. Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so.

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 sectionsSee 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 Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Ensure adequate ventilation. Provide extract ventilation to points where emissions occur. In case of

insufficient ventilation, wear suitable respiratory equipment. Remove contaminated clothing

and shoes. Take off contaminated clothing and wash it before reuse.

General hygiene considerations Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before

re-use. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Please refer to the manufacturer's certificate for specific storage and transport temperature

conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

Keep out of the reach of children.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.



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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)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles). Tight sealing

safety goggles.

Hand protection Wear protective butyl rubber gloves. The protective gloves to be used must comply with the

specifications of EC Directive 89/686/EEC and the related standard EN374. Wear suitable

gloves.

Skin and body protectionWear suitable protective clothing.

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before

re-use. Wash hands before breaks and immediately after handling the product.

Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties



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9.1. Information on basic physical and chemical properties

Physical stateSolidAppearanceSolidColourOff whiteOdourOdourless.

Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing point222 - 225 °CNone knownInitial boiling point and boiling rangeNo data availableNone knownFlammabilityNo data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash pointNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNone known

pH No data available None known PH (as aqueous solution) No data available No information available

Kinematic viscosity No data available None known Dynamic viscosity No data available None known Water solubility No data available None known No data available Solubility(ies) None known No data available **Partition coefficient** None known Vapour pressure No data available None known Relative density No data available None known

Bulk density
No data available
No data available
No data available
No data available

Relative vapour density

No data available

None known

Particle characteristics

Particle Size No information available Particle Size Distribution No information available

9.2. Other information

Molecular weight 670.74

Molecular formula C28 H38 N12 O6 S

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available



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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 Strong acids. Strong bases. Strong oxidising agents.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause sensitisation in

susceptible persons. (based on components).

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye damage.

May cause irreversible damage to eyes.

Skin contact Specific test data for the substance or mixture is not available. May cause irritation.

Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

(based on components). May cause sensitisation by skin contact.



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Quality standards

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110galalis 1 (25) 1151 1557 2555 and 110galalis 1 (25) 1151 121 22555

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Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhoea. May cause additional affects as

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listed under "Inhalation".

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. Burning. May cause blindness. Symptoms of allergic reaction may include rash,

itching, swelling, trouble breathing, tingling of the hands and feet, dizziness,

lightheadedness, chest pain, muscle pain, or flushing. Coughing and/ or wheezing. Itching.

Rashes. Hives.

Numerical measures of toxicity

Acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Abacavir Sulfate	>2000 mg/kg (Rat)		

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

Skin corrosion/irritation May cause skin irritation.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes burns. Causes serious eye

damage.

Respiratory or skin sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an

allergic skin reaction.

Germ cell mutagenicity No information available.

Carcinogenicity Contains a known or suspected carcinogen. Classification based on data available for

ingredients. Suspected of causing cancer.



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Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. Suspected of damaging fertility or the unborn child.

STOT - single exposure Based on the classification criteria of the Globally Harmonized System as adopted in the

country or region with which this safety data sheet complies, this product has been determined to cause systemic target organ toxicity from acute exposure. (STOT SE).

Causes damage to organs.

STOT - repeated exposureNo information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Abacavir Sulfate	-	-	-	EC50: 139 mg/L (48h,
				Daphnia magna)

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.



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12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. 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

<u>IATA</u>

Not regulated
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special precautions for user

Special Provisions None

IMDG

14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated



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14.5 Marine pollutant

14.6 Special precautions for user Special Provisions

14.7 Maritime transport in bulk according to IMO instruments

None No information available

No information available

Not applicable

RID

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special precautions for user

Special Provisions

None

ADR

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
Not regulated Not regulated 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

National regulations

Germany

Water hazard class (WGK) non-hazardous to water (nwg)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of



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1.094.4..... (20) 1.01 1.03 1.23 4.14 1.094.4.... (20) 1.01 1.21 2.2000

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2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650) . Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the

International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194,

item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

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European Union

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.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursorsNot applicable

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)
H3 - STOT SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories



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TSCA Complies under research and development exemption or is regulated by a different

government agency.

DSL/NDSL

EINECS/ELINCS

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 and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H317 - May cause an allergic skin reaction

H318 - Causes serious eye damage

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H351 - Suspected of causing cancer

H361 - Suspected of damaging fertility or the unborn child

H370 - Causes damage to organs

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

Classification procedure



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Method Used
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)

EPA (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)

Japan GHS Classification

Australian 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)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006



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Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be heldresponsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

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