

SDS Title: Bivalirudin for Injection Safety Data Sheet	SDS Number: SDS-000042	Page Number: Page 1 of 14
Function: Regulatory Affairs	Effective Date: January 25, 2021	Version number: 1.0

Section 1. Identification

GHS product identifier : Bivalirudin for Injection
Other means of identification : Not available.
Product type : Powder.

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

Product use : Pharmaceuticals. (For intended use only.)
 Observe technical data sheet/instructions for use.
 Specific Treatments: Anticoagulatory.

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.
 8700 W. Bryn Mawr, Suite 600S
 Chicago, IL 60631
 Telephone: 224-443-4617
 www.meithealpharma.com

e-mail address of person responsible for this SDS : info@meithealpharma.com

Emergency telephone number (with hours of operation) : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture :
 H315 COMBUSTIBLE DUSTS
 H319 SKIN IRRITATION - Category 2
 H319 EYE IRRITATION - Category 2A

GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H315 - Causes skin irritation.

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H319 - Causes serious eye irritation.
May form combustible dust concentrations in air.

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Section 2. Hazards identification

Precautionary statements

Prevention	: P280 - Wear protective gloves. Wear eye or face protection. P264 - Wash thoroughly after handling.
Response	: P362 + P364 - Take off contaminated clothing and wash it before reuse. P302 + P352 - IF ON SKIN: Wash with plenty of water. P332 + P313 - If skin irritation occurs: Get medical advice or attention. P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice or attention.
Storage	: Not applicable.
Disposal	: Not applicable.
Supplemental label elements	: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.
Hazards not otherwise classified	: None known.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of identification	: Not available.

Ingredient name	Other names	%	CAS number
bivalirudin	-	≥50 - ≤75	128270-60-0
mannitol	-	≥25 - ≤50	87-78-5
sodium hydroxide	-	≤10	1310-73-2

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health and hence require reporting in this section.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact	: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.
Inhalation	: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire,

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symptoms may be delayed.
The exposed person may need
to be kept under medical

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Section 4. First aid measures		

surveillance for 48 hours.

Skin contact

: Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion

: Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact

: Causes serious eye irritation.

Inhalation

: Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.

Skin contact

: Causes skin irritation.

Ingestion

: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact

: Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation

: Adverse symptoms may include the following:
respiratory tract irritation
coughing

Skin contact

: Adverse symptoms may include the following:
irritation
redness

Ingestion

: No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician

: In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments

: No specific treatment.

Protection of first-aiders

: No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.



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See toxicological information (Section 11)

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Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use dry chemical powder.

Unsuitable extinguishing media : Do not use water jet.

Specific hazards arising from the chemical : May form explosible dust-air mixture if dispersed.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
 carbon dioxide
 carbon monoxide
 nitrogen oxides
 metal oxide/oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal.

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Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

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Section 6. Accidental release measures

- Large spill** : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.

- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

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Section 8. Exposure controls/personal protection

Ingredient name	Exposure limits
bivalirudin mannitol sodium hydroxide	None. None. ACGIH TLV (United States, 3/2020). C: 2 mg/m ³ NIOSH REL (United States, 10/2016). CEIL: 2 mg/m ³ OSHA PEL (United States, 5/2018). TWA: 2 mg/m ³ 8 hours.

- Appropriate engineering controls** : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.
- Individual protection measures**
- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles. If operating conditions cause high dust concentrations to be produced, use dust goggles.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

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Section 8. Exposure controls/personal protection

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

Physical state : Solid. [Powder. (Lyophilized)]

Color : White.

Odor : Not available.

Odor threshold : Not available.

pH : 4.5 to 6 [Conc. (% w/w): 5%]

Melting point : Not available.

Boiling point : Not available.

Flash point : Not available.

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

Lower and upper explosive (flammable) limits : Not available.

Vapor pressure : Not available.

Vapor density : Not available.

Relative density : Not available.

Density : Not available.

Solubility : Easily soluble in the following materials: cold water and hot water.

Solubility in water : Not available.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

SADT : Not available.

Viscosity : Not available.

Flow time (ISO 2431) : Not available.

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Section 10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
Under normal conditions of storage and use, hazardous polymerization will not occur.
- Conditions to avoid** : Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation.
- Incompatible materials** : Reactive or incompatible with the following materials:
oxidizing materials
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Not available.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
sodium hydroxide	Eyes - Mild irritant	Rabbit	-	400 ug	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50 ug	-
	Eyes - Severe irritant	Rabbit	-	1 %	-
	Eyes - Severe irritant	Rabbit	-	0.5 minutes 1 mg	-
	Skin - Severe irritant	Rabbit	-	24 hours 500 mg	-

Sensitization

Not available.

Mutagenicity

Conclusion/Summary : Not available.

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Section 11. Toxicological information

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
sodium hydroxide	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.

Skin contact : Causes skin irritation.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : Adverse symptoms may include the following:
respiratory tract irritation
coughing

Skin contact : Adverse symptoms may include the following:
irritation
redness

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

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Section 11. Toxicological information

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Not available.

General : Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

N/A

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
sodium hydroxide	Acute EC50 40.38 mg/l Fresh water	Crustaceans - Ceriodaphnia dubia - Neonate	48 hours
	Acute LC50 125 ppm Fresh water	Fish - Gambusia affinis - Adult	96 hours

Conclusion/Summary : Not available.

Persistence and degradability

Not available.

Bioaccumulative potential

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Section 12. Ecological information

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Additional information

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

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Section 14. Transport information

Transport in bulk according to IMO instruments : Not available.

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined
 United States inventory (TSCA 8b): Not determined.
 Clean Water Act (CWA) 311: sodium hydroxide

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : COMBUSTIBLE DUSTS
 SKIN IRRITATION - Category 2
 EYE IRRITATION - Category 2A

Composition/information on ingredients

Name	%	Classification
sodium hydroxide	≤10	CORROSIVE TO METALS - Category 1 SKIN CORROSION - Category 1A SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 HNO3 - Corrosive to digestive tract [severe]

SARA 313 **Massachusetts**

Not applicable.

State regulations

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New York

- : The following components are listed: SODIUM HYDROXIDE
- : The following components are listed: Sodium hydroxide

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Section 15. Regulatory information

- New Jersey** : The following components are listed: SODIUM HYDROXIDE; CAUSTIC SODA
- Pennsylvania** : The following components are listed: SODIUM HYDROXIDE
- California Prop. 65**

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Section 16. Other information

Hazardous Material Information System (U.S.A.)

Health	/	2
Flammability		3
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.)



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Section 16. Other information

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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

Procedure used to derive the classification

Classification	Justification
COMBUSTIBLE DUSTS SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A	On basis of test data Expert judgment Expert judgment

History

Date of issue/Date of revision	: 01/25/2021
Date of previous issue	: No previous validation
Version	: 1.0
Prepared by	: Sphera Solutions

Key to abbreviations

: ATE = Acute Toxicity Estimate
AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
UN = United Nations

References

: HCS (U.S.A.)- Hazard Communication Standard
International transport regulations

☑ Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot

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guarantee that these are the only hazards that exist.

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