



Factor II, Incorporated

The Art, Science and Technology of
Silicones and Prosthetics...

Safety Data Sheet

Product Code HCRA-4530 A

Revision Date: 10/12/2020

SECTION 1: IDENTIFICATION

PRODUCT IDENTIFIER

Product Name Silicone High Consistency Rubber

Product Code HCRA-4530 A

Intended Use(s) : For professional use only

CONTACT INFORMATION FOR SUPPLIER OF SAFETY DATA SHEET

Factor II, Incorporated
5642 White Mountain Ave
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SECTION 2: HAZARD(S) IDENTIFICATION

Hazard Classification

Health Hazards

Toxic to reproduction

Category 2

Label Elements

Hazard Symbol:



Signal Word:

Warning

Hazard Statement:

Suspected of damaging fertility.

Precautionary Statements

Prevention:

Use personal protective equipment as required.

Response:

IF exposed or concerned: Get medical advice/
attention.



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Other hazards which do not result in GHS classification:

No data available.

SECTION 3: HAZARDOUS INGREDIENTS

Mixtures

Chemical Identity	CAS number	Content in percent (%) *
Octamethylcyclotetrasiloxane	556-67-2	0.1 - <1%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition Comments:

Mixture of Polyorganosiloxanes, fillers, additives.

SECTION 4: FIRST-AID MEASURES

General information:

For further information refer to section 8 "Exposure-controls/personal protection".

Ingestion:

Do not induce vomiting. Rinse mouth thoroughly. Get medical attention if symptoms occur.

Inhalation

Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin Contact:

Wash contact areas with soap and water. Get medical attention if symptoms occur after washing.

Eye contact:

In the event of contact with the eyes, rinse thoroughly with clean water. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing.

Most important symptoms/effects, acute and delayed

Symptoms:

None known.

Hazards:

No specific recommendations.

Indication of immediate medical attention and special treatment needed

Treatment:

No specific recommendations.

SECTION 5: FIRE-FIGHTING MEASURES

General Fire Hazards:

No specific recommendations.

Suitable (and unsuitable) extinguishing media

Suitable extinguishing media:

Water spray, foam, dry powder or carbon dioxide.

Unsuitable extinguishing media:

None known.



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Specific hazards arising from the chemical:

Product will burn under fire conditions. Hazardous Decomposition Products:
formaldehyde, oxides of carbon and silica.

Special protective equipment and precautions for firefighters

Special firefighting procedures: Water spray should be used to cool
containers.

Special protective equipment for fire-fighters:

Firefighters should wear standard protective equipment and a positive pressure
self-contained breathing apparatus (SCBA).

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

No specific precautions.

Methods and material for containment and cleaning up:

Sweep or scoop up and remove.

Notification Procedures:

For waste disposal, see Section 13 of the SDS.

Environmental Precautions:

Do not allow to enter drains, sewers or watercourses

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

No specific precautions.

Conditions for safe storage, including any incompatibilities:

No special storage precautions noted.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Occupational Exposure Limits

None of the components have assigned exposure
limits.

Appropriate Engineering Controls

No specific recommendations.

Individual protection measures, such as personal protective equipment

General information:

Provide sufficient ventilation during operations
which cause vapor formation.

Eye/face protection:

Safety Glasses.

Skin Protection

Hand Protection:

No specific recommendations.



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Other: No specific recommendations.

Respiratory Protection: No protection is ordinarily required under normal conditions of use and with adequate ventilation.

Hygiene measures:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties:

Appearance

Physical state: Solid

Form: Wax

Color: Colorless

Odor: Odorless

Odor threshold: No data available.

pH: Not applicable

Melting Point: No data available.

Boiling Point: No data available.

Flash Point: () Not applicable

Evaporation rate: No data available.

Flammability (solid, gas): No data available.

Flammability limit - upper (%): No data available.

Flammability limit - lower (%): No data available.

Vapor pressure: No data available.

Vapor density: No data available.

Density: Approximate 1.14 kg/dm³ (68 °F (20 °C))

Solubility(ies)

Solubility in water: Insoluble

Solubility (other): Acetone: Insoluble

Ethanol: Insoluble

Diethylether: Dispersible

Aliphatic hydrocarbons: Dispersible

Aromatic hydrocarbons: Dispersible

Chlorinated solvents: Dispersible

Partition coefficient (n-octanol/water): No data available.

Auto-ignition temperature: () Not applicable

Decomposition temperature: No data available.

Viscosity: No data available.



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Other information

Oxidizing properties:

According to the data on the components Not
considered as oxidizing. (according to EC criteria)

SECTION 10: STABILITY AND REACTIVITY

Reactivity:

No data available.

Chemical Stability:

Stable

Possibility of hazardous reactions:

Will not occur.

Conditions to avoid:

No other information noted.

Incompatible Materials:

Strong oxidizing agents.

Hazardous Decomposition Products:

This product can form formaldehyde vapors when heated to temperatures above 150 degrees C in the presence of air. Thermal decomposition or combustion may liberate carbon oxides, other toxic gases or vapors and amorphous silica.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Ingestion:

No effects expected (assessment based on ingredients).

Inhalation:

No effects expected (assessment based on ingredients).

Skin Contact:

No effects expected (assessment based on ingredients).

Eye contact:

No effects expected (assessment based on ingredients).

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion:

No data available.

Inhalation:

No data available.

Skin Contact:

No data available.

Eye contact:

No data available.

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral Product:

No data available.

Dermal Product:

No data available.

Inhalation Product:

No data available.

Repeated dose toxicity Product:

No effects expected (assessment based on ingredients).



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Skin Corrosion/Irritation Product:

No effects expected (assessment based on ingredients).

Serious Eye Damage/Eye Irritation Product:

No effects expected (assessment based on ingredients).

Respiratory or Skin Sensitization Product:

No effects expected (assessment based on ingredients).

Carcinogenicity Product:

No effects expected (assessment based on ingredients).

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:

No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:

No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):

No carcinogenic components identified

Germ Cell Mutagenicity

In vitro Product:

No effects expected (assessment based on ingredients).

In vivo Product:

No effects expected (assessment based on ingredients).

Reproductive toxicity Product:

No data available.

Specified substance(s):

Octamethylcyclotetrasiloxane

Suspected of damaging fertility.

Specific Target Organ Toxicity - Single Exposure Product:

No effects expected (assessment based on ingredients).

Specific Target Organ Toxicity - Repeated Exposure Product:

No effects expected (assessment based on ingredients).

Aspiration Hazard Product:

No effects expected (assessment based on ingredients).

Other effects:

None known.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish Product:

No effects expected (assessment based on ingredients).

Aquatic Invertebrates Product:

No effects expected (assessment based on ingredients).



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Chronic hazards to the aquatic environment:

Fish Product: No effects expected (assessment based on ingredients).

Aquatic Invertebrates Product:

No effects expected (assessment based on ingredients).

Toxicity to Aquatic Plants Product:

No effects expected (assessment based on ingredients).

Persistence and Degradability

Biodegradation Product: The product is not readily biodegradable.

BOD/COD Ratio Product: No data available.

Bioaccumulative potential

Bioconcentration Factor (BCF) Product: The product is not bioaccumulating.

Partition Coefficient n-octanol / water (log Kow) Product: No data available.

Mobility in soil:

No data available.

Known or predicted distribution to environmental compartments

Octamethylcyclotetrasiloxane No data available.

Other adverse effects:

None known.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal instructions:

Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.
Contaminated packages should be as empty as possible.

SECTION 14: TRANSPORT INFORMATION

This material is not subject to transport regulations.

Environmental hazards: Not regulated.

Special precautions for user: No special precautions.

SECTION 15: REGULATORY INFORMATION

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4):

None present or none present in regulated quantities.



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Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

☐ Acute (Immediate) ☒ Chronic (Delayed) ☐ Fire ☐ Reactive ☐ Pressure Generating

SARA 302 Extremely Hazardous Substance

None present or none present in regulated quantities.

SARA 304 Emergency Release Notification

None present or none present in regulated quantities.

SARA 313 (TRI Reporting)

None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

No ingredient regulated by CA Prop 65 present.

US. New Jersey Worker and Community Right-to-Know Act

No ingredient regulated by NJ Right-to-Know Law present.

US. Massachusetts RTK - Substance List

No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances

No ingredient regulated by PA Right-to-Know Law present.

US. Rhode Island RTK

No ingredient regulated by RI Right-to-Know Law present.

Inventory Status

US TSCA Inventory:

On or in compliance with the inventory.

Canada DSL Inventory List:

On or in compliance with the inventory.

EINECS, ELINCS or NLP:

On or in compliance with the inventory.

China Inv. Existing Chemical Substances:

On or in compliance with the inventory.

Korea Existing Chemicals Inv. (KECI):

On or in compliance with the inventory.

Australia AICS:

On or in compliance with the inventory.

Philippines PICCS:

On or in compliance with the inventory.



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SECTION 16: OTHER INFORMATION

HNIS Hazard ID

Health	1 - Slight
Flammability	1 - Slight
Physical Hazards	0 - Minimal
PERSONAL PROTECTION	B – Safety Glasses and gloves

NFPA Hazard ID

Flammability	1 - Slight
Health	1 - Slight
Reactivity	0 - Minimal
Special Hazard	

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SECTION 2: HAZARD(S) IDENTIFICATION

Hazard Classification

Health Hazards

Toxic to reproduction

Category 2

Label Elements

Hazard Symbol:



Signal Word:

Warning

Hazard Statement:

Suspected of damaging fertility.

Precautionary Statements

Prevention:

Use personal protective equipment as required.

Response:

IF exposed or concerned: Get medical advice/
attention.



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Other hazards which do not result in GHS classification:

Chemical compounds containing silicon - hydrogen bonds (SiH).

SECTION 3: HAZARDOUS INGREDIENTS

Mixtures

Chemical Identity	CAS number	Content in percent (%) *
Octamethylcyclotetrasiloxane	556-67-2	0.1 - <1%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

Composition Comments:

Mixture of Polyorganosiloxanes, fillers.

SECTION 4: FIRST-AID MEASURES

General information:	For further information refer to section 8 "Exposure-controls/personal protection".
Ingestion:	Do not induce vomiting. Rinse mouth thoroughly. Get medical attention if symptoms occur.
Inhalation:	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin Contact:	Wash contact areas with soap and water. Get medical attention if symptoms occur after washing.
Eye contact:	In the event of contact with the eyes, rinse thoroughly with clean water. Continue to rinse for at least 15 minutes. Get medical attention if irritation persists after washing.

Most important symptoms/effects, acute and delayed

Symptoms:	None known.
Hazards:	No specific recommendations.

Indication of immediate medical attention and special treatment needed

Treatment:	No specific recommendations.
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SECTION 5: FIRE-FIGHTING MEASURES

General Fire Hazards:	No specific recommendations.
Suitable (and unsuitable) extinguishing media	
Suitable extinguishing media:	Water spray, foam, dry powder or carbon dioxide.
Unsuitable extinguishing media:	Do not use alkaline powders.



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Specific hazards arising from the chemical:

Product will burn under fire conditions. Hazardous Decomposition Products:
formaldehyde, oxides of carbon and silica.

Special protective equipment and precautions for firefighters

Special fire fighting procedures: Water spray should be used to cool
containers.

Special protective equipment for fire-fighters:

Firefighters should wear standard protective equipment and a positive pressure
self-contained breathing apparatus (SCBA).

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

Eliminate all sources of ignition. Avoid contact with alkalis and caustic products.

Methods and material for containment and cleaning up:

Sweep or scoop up and remove.

Notification Procedures:

For waste disposal, see Section 13 of the SDS.

Environmental Precautions:

Do not allow to enter drains, sewers or watercourses.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling:

Provide sufficient ventilation during operations which cause vapor formation. Do not mix
with incompatible materials. For further information, refer to section 10: "Stability and
Reactivity". Read and follow manufacturer's recommendations.

Conditions for safe storage, including any incompatibilities:

No special storage precautions noted.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Occupational Exposure Limits

None of the components have assigned exposure
limits.

Appropriate Engineering Controls

No specific recommendations.

Individual protection measures, such as personal protective equipment

General information:

Provide sufficient ventilation during operations
which cause vapor formation.

Eye/face protection:

Safety Glasses.



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Skin Protection

Hand Protection:

No specific recommendations.

Other:

No specific recommendations.

Respiratory Protection:

No protection is ordinarily required under normal conditions of use and with adequate ventilation.

Hygiene measures:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties:

Appearance

Physical state:

Solid

Form:

Wax

Color:

Colorless

Odor:

Odorless

Odor threshold:

No data available.

pH:

Not applicable

Melting Point:

No data available.

Boiling Point:

No data available.

Flash Point:

() Not applicable

Evaporation rate:

No data available.

Flammability (solid, gas):

No data available.

Flammability limit - upper (%):

No data available.

Flammability limit - lower (%):

No data available.

Vapor pressure:

No data available.

Vapor density:

No data available.

Density:

Approximate 1.14 kg/dm³ (68 °F (20 °C))

Solubility(ies)

Solubility in water:

Insoluble

Solubility (other):

Acetone: Insoluble

Ethanol: Insoluble

Diethylether: Dispersible

Aliphatic hydrocarbons: Dispersible

Aromatic hydrocarbons: Dispersible

Chlorinated solvents: Dispersible

Partition coefficient (n-octanol/water):

No data available.

Auto-ignition temperature:

() Not applicable

Decomposition temperature:

No data available.

Viscosity:

No data available.



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Other information

Oxidizing properties:

According to the data on the components Not considered as oxidizing. (according to EC criteria)

SECTION 10: STABILITY AND REACTIVITY

Reactivity:	No data available.
Chemical Stability:	Material is stable under normal conditions.
Possibility of hazardous reactions:	This product may generate hydrogen gas.
Conditions to avoid:	No other information noted.

Incompatible Materials:

A fire or explosion hazard arises because highly flammable gas (hydrogen) is released when it is in contact with: Strong oxidizers, strong bases and chemical compounds with mobile hydrogen, in the presence of metal salts and complexes.

Hazardous Decomposition Products:

This product can form formaldehyde vapors when heated to temperatures above 150 degrees C in the presence of air. Thermal decomposition or combustion may liberate carbon oxides, other toxic gases or vapors and amorphous silica.
Quantity of hydrogen potentially released (l/kg of product): < 2

SECTION 11: TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Ingestion:	No effects expected (assessment based on ingredients).
Inhalation:	No effects expected (assessment based on ingredients).
Skin Contact:	No effects expected (assessment based on ingredients).
Eye contact:	No effects expected (assessment based on ingredients).

Symptoms related to the physical, chemical and toxicological characteristics

Ingestion:	No data available.
Inhalation:	No data available.
Skin Contact:	No data available.
Eye contact:	No data available.

Information on toxicological effects

Acute toxicity (list all possible routes of exposure)

Oral Product:	No data available.
Dermal Product:	ATEmix: 205,982.48 mg/kg
Inhalation Product:	No data available.



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Repeated dose toxicity Product:

No effects expected (assessment based on ingredients).

Skin Corrosion/Irritation Product:

No effects expected (assessment based on ingredients).

Serious Eye Damage/Eye Irritation Product:

No effects expected (assessment based on ingredients).

Respiratory or Skin Sensitization Product:

No effects expected (assessment based on ingredients).

Carcinogenicity Product:

No effects expected (assessment based on ingredients).

IARC Monographs on the Evaluation of Carcinogenic Risks to Humans:

No carcinogenic components identified

US. National Toxicology Program (NTP) Report on Carcinogens:

No carcinogenic components identified

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050):

No carcinogenic components identified

Germ Cell Mutagenicity

In vitro Product:

No effects expected (assessment based on ingredients).

In vivo Product:

No effects expected (assessment based on ingredients).

Reproductive toxicity Product:

No data available.

Specified substance(s):

Octamethylcyclotetrasiloxane

Suspected of damaging fertility.

Specific Target Organ Toxicity - Single Exposure Product:

No effects expected (assessment based on ingredients).

Specific Target Organ Toxicity - Repeated Exposure Product:

No effects expected (assessment based on ingredients).

Aspiration Hazard Product:

No effects expected (assessment based on ingredients).

Other effects:

None known.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:

Acute hazards to the aquatic environment:

Fish Product:

No effects expected (assessment based on ingredients).



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Aquatic Invertebrates Product:

No effects expected (assessment based on ingredients).

Chronic hazards to the aquatic environment:

Fish Product: No effects expected (assessment based on ingredients).

Aquatic Invertebrates Product:

No effects expected (assessment based on ingredients).

Toxicity to Aquatic Plants Product:

No effects expected (assessment based on ingredients).

Persistence and Degradability

Biodegradation Product:

Not applicable

BOD/COD Ratio Product:

No data available.

Bioaccumulative potential

Bioconcentration Factor (BCF) Product:

No data available.

Specified substance(s):

Octamethylcyclotetrasiloxane

Fathead Minnow, Bioconcentration
Factor (BCF): 12,400

Partition Coefficient n-octanol / water (log Kow) Product:

No data available.

Mobility in soil:

No data available.

Known or predicted distribution to environmental compartments

Octamethylcyclotetrasiloxane

No data available.

Other adverse effects:

None known.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal instructions:

Dispose of waste at an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal. Waste of this material should not be mixed with other waste. Contaminated packages should be as empty as possible

SECTION 14: TRANSPORT INFORMATION

This material is not subject to transport regulations.

Environmental hazards:

Not regulated.

Special precautions for user:

No special precautions.



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SECTION 15: REGULATORY INFORMATION

US Federal Regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

None present or none present in regulated quantities.

CERCLA Hazardous Substance List (40 CFR 302.4):

None present or none present in regulated quantities.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

☐ Acute (Immediate) ☒ Chronic (Delayed) ☐ Fire ☐ Reactive ☐ Pressure Generating

SARA 302 Extremely Hazardous Substance

None present or none present in regulated quantities.

SARA 304 Emergency Release Notification

None present or none present in regulated quantities.

SARA 313 (TRI Reporting)

None present or none present in regulated quantities.

Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3)

None present or none present in regulated quantities.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):

None present or none present in regulated quantities.

US State Regulations

US. California Proposition 65

No ingredient regulated by CA Prop 65 present.

US. New Jersey Worker and Community Right-to-Know Act

No ingredient regulated by NJ Right-to-Know Law present.

US. Massachusetts RTK - Substance List

No ingredient regulated by MA Right-to-Know Law present.

US. Pennsylvania RTK - Hazardous Substances

No ingredient regulated by PA Right-to-Know Law present.

US. Rhode Island RTK

No ingredient regulated by RI Right-to-Know Law present.

Inventory Status:

US TSCA Inventory:

On or in compliance with the inventory.

Canada DSL Inventory List:

On or in compliance with the inventory.



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EINECS, ELINCS or NLP:	On or in compliance with the inventory.
Japan (ENCS) List:	On or in compliance with the inventory.
China Inv. Existing Chemical Substances:	On or in compliance with the inventory.
Korea Existing Chemicals Inv. (KECI):	On or in compliance with the inventory.
Australia AICS:	On or in compliance with the inventory.
Philippines PICCS:	On or in compliance with the inventory.
New Zealand Inventory of Chemicals:	On or in compliance with the inventory.

SECTION 16: OTHER INFORMATION

HNIS Hazard ID

Health	1 - Slight
Flammability	1 - Slight
Physical Hazards	0 - Minimal
PERSONAL PROTECTION	B – Safety Glasses and gloves

NFPA Hazard ID

Flammability	1 - Slight
Health	1 - Slight
Reactivity	0 - Minimal
Special Hazard	

DISCLAIMER / STATEMENT OF LIABILITY:

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