

SAFETY DATA SHEETS

This SDS packet was issued with item:

074570057

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071178474 071178482 074492542 074492609 074492682 074570156 074570164 074570172 272438901



Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

1 Identification

· **Product identifier**

· **Trade name: Flexitime (base + cat)**

· -

Easy Putty, Heavy Tray, Monophase, Correct Flow,
Dynamix Putty, Dynamix Heavy Tray, Dynamix Monophase

· **Application of the substance / the mixture** Dental impression material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Kulzer GmbH

Leipziger Straße 2, 63450 Hanau (Germany)

Tel.: +49 (0)800 4372522

· **Information department:**

Tel. +1 (800) 431-1785 Fax: +1 (800) 522-1545

e-mail: customer.servicehkna@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)

GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· **Classification of the substance or mixture**

The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**

· **GHS label elements** Void

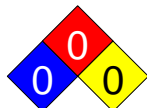
· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Classification system**

· **NFPA ratings for USA (scale 0-4)**



Health = 0

Fire = 0

Reactivity = 0

· **HMIS-Ratings (Scale 0-4)**



Health = 0

Fire = 0

Reactivity = 0

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

USA

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Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime (base + cat)

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3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:**
2-component silicone impression material comprising base paste and matching catalyst paste for addition curing
- **Dangerous components:** Void
- **Additional information** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

- **Description of first aid measures**
 - **General information** No special measures required.
 - **After inhalation** Supply fresh air; consult doctor in case of complaints.
 - **After skin contact** Immediately wash with water and soap and rinse thoroughly.
 - **After eye contact** Rinse opened eye for several minutes under running water.
 - **After swallowing**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
Seek immediate medical advice.
- **Information for doctor**
 - **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
 - **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
 - **Suitable extinguishing agents**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
 - **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Reference to other sections**
See Section 13 for disposal information.
See Section 8 for information on personal protection equipment.

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USA



**Safety Data Sheet
acc. to OSHA HCS**

Printing date 06/03/2017

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Trade name: Flexitime (base + cat)

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7 Handling and storage

- **Handling**
 - **Precautions for safe handling** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

1317-65-3 Calciumcarbonat, nat., gem.

PEL () 15*; 5** mg/m³
*Total dust **Respirable fraction

REL () 10*; 5** mg/m³
*Total dust **Respirable fraction

TLV () 10 mg/m³
(e)

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **Personal protective equipment**

· **General protective and hygienic measures**

The usual precautionary measures for handling chemicals should be followed.

· **Breathing equipment:** Not required.

· **Protection of hands:**

Check protective gloves prior to each use for their proper condition.
recommended

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable:**

Butyl rubber, BR

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Reviewed on 06/03/2017

Trade name: Flexitime (base + cat)

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Nitrile rubber, NBR

- **Eye protection:** Not absolutely necessary.
- **Body protection:** Light weight protective clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Color:** According to product specification
- **Odor:** Odorless
- **Odor threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** undetermined

· **Flash point:** Not applicable

· **Flammability (solid, gaseous)** Not applicable.

· **Ignition temperature:**

- **Decomposition temperature:** Not determined.

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

- **Lower:** Not determined.
- **Upper:** Not determined.

· **Vapor pressure:** Not determined.

· **Density at 20 °C (68 °F):** 1.6 g/cm³ (13.352 lbs/gal)

- **Relative density** Not determined.
- **Vapor density** Not determined.
- **Evaporation rate** Not determined.

· **Solubility in / Miscibility with**

- **Water:** Not miscible or difficult to mix

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity:**

- **dynamic:** Not determined.
- **kinematic:** Not determined.

· **Other information** No further relevant information available.

USA

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Trade name: Flexitime (base + cat)

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10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values that are relevant for classification:**

Polydimethylsiloxan, vinylendgestoppt

Oral LD50 > 5000 mg/kg (rat)

1317-65-3 Calciumcarbonat, nat., gem.

Oral LD50 > 2000 mg/kg (rat)

· **Primary irritant effect:**

· **on the skin:** No irritant effect.

· **on the eye:** No irritating effect.

· **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

14808-60-7 Quartz (SiO₂)

1

· **NTP (National Toxicology Program)**

14808-60-7 Quartz (SiO₂)

K

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

1317-65-3 Calciumcarbonat, nat., gem.

EC50/72h > 200 mg/l (algae)

EC50/48h > 1000 mg/l (daphnia)

LC50/96h > 10000 mg/l (fish)

· **Persistence and degradability** No further relevant information available.

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Trade name: Flexitime (base + cat)

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- **Behavior in environmental systems:**
 - **Bioaccumulative potential** No further relevant information available.
 - **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
 - **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation**
Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	Void

USA

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Safety Data Sheet
acc. to OSHA HCS

Printing date 06/03/2017

Reviewed on 06/03/2017

Trade name: Flexitime (base + cat)

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15 Regulatory information

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

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **TLV (Threshold Limit Value established by ACGIH)**

14808-60-7 Quartz (SiO₂)

A2

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 06/03/2017 / 2

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

· *** Data compared to the previous version altered.**

**Safety Data Sheet
acc. to OSHA HCS**

Printing date 05/12/2015

Reviewed on 05/12/2015

1 Identification

· **Product identifier**

· **Trade name: Flexitime (base + cat)**

· -

Easy Putty, Heavy Tray, Monophase, Correct Flow,
Dynamix Putty, Dynamix Heavy Tray, Dynamix Monophase

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Dental impression material

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

Heraeus Kulzer GmbH
Grüner Weg 11, D-63450 Hanau

Tel.: 0800 4372522

· **Information department:**

Marc Henn
Tel. +1 (574) 2995444 / Fax: +1 (574) 2912542
e-mail: marc.henn@kulzer-dental.com

· **Emergency telephone number:**

Emergency CONTACT (24-Hour-Number)
GBK/Infotrac ID 105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

· **Classification of the substance or mixture**

Carc. 1A H350 May cause cancer.

STOT RE 1 H372 Causes damage to organs through prolonged or repeated exposure.

· **Label elements**

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**

Quartz (SiO₂)

· **Hazard statements**

May cause cancer.

Causes damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapours/spray.

Use personal protective equipment as required.

Wash thoroughly after handling.

IF exposed or concerned: Get medical advice/attention.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

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USA

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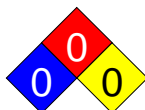
Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Flexitime (base + cat)

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- **Classification system**
- **NFPA ratings for USA (scale 0-4)**



Health = 0
Fire = 0
Reactivity = 0

- **HMIS-Ratings (Scale 0-4)**



Health = *0
Fire = 0
Reactivity = 0

- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:**

2-component silicone impression material comprising base paste and matching catalyst paste for addition curing

- **Dangerous components:**

1317-65-3 Calciumcarbonat, nat., gem.

5-10%

4 First-aid measures

- **Description of first aid measures**

- **General information** No special measures required.
- **After skin contact** Generally the product does not irritate the skin.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing**
Rinse out mouth and then drink plenty of water.
Seek immediate medical advice.

- **Most important symptoms and effects, both acute and delayed**

No further relevant information available.

- **Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**

- **Suitable extinguishing agents**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- **Special hazards arising from the substance or mixture** No further relevant information available.

- **Advice for firefighters**

- **Protective equipment:** No special measures required.
- **Additional information** -

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.

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USA

**Safety Data Sheet
acc. to OSHA HCS**

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Flexitime (base + cat)

(Contd. of page 2)

- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**
Absorb with liquid binding material (diatomite, universal binders, for small amounts tissues).
- **Reference to other sections**
See Section 13 for disposal information.
See Section 8 for information on personal protection equipment.

7 Handling and storage

- **Precautions for safe handling** No special measures required.
 - **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
 - **Storage**
 - **Requirements to be met by storerooms and receptacles:** No special requirements.
 - **Information about storage in one common storage facility:** Not required.
 - **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

1317-65-3 Calciumcarbonat, nat., gem.

PEL ()	15*; 5** mg/m ³ *Total dust **Respirable fraction
REL ()	10*; 5** mg/m ³ *Total dust **Respirable fraction
TLV ()	10 mg/m ³ (e)

· **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**
 - **Personal protective equipment**
 - **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
 - **Breathing equipment:** Not required.
 - **Protection of hands:** Not required.
 - **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
 - **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
 - **For the permanent contact in work areas without heightened risk of injury (e.g. Laboratory) gloves made of the following material are suitable:**
PVC or PE gloves
 - **Eye protection:** Not absolutely necessary.
 - **Body protection:** Light weight protective clothing

USA

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**Safety Data Sheet
acc. to OSHA HCS**

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Flexitime (base + cat)

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9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

- **Form:** Pasty
- **Color:** According to product specification
- **Odor:** Odorless

· **Change in condition**

- **Melting point/Melting range:** undetermined
- **Boiling point/Boiling range:** undetermined

· **Flash point:** Not applicable

· **Auto igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Density at 20 °C (68 °F):** 1.6 g/cm³ (13.352 lbs/gal)

· **Solubility in / Miscibility with**

- **Water:** Not miscible or difficult to mix
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** none

11 Toxicological information

· **Information on toxicological effects**

· **Acute toxicity:**

· **Primary irritant effect:**

- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.

· **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

· **Carcinogenic categories**

· IARC (International Agency for Research on Cancer)		
14808-60-7	Quartz (SiO ₂)	1
· NTP (National Toxicology Program)		
14808-60-7	Quartz (SiO ₂)	K
· OSHA-Ca (Occupational Safety & Health Administration)		
None of the ingredients is listed.		

USA

(Contd. on page 5)

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acc. to OSHA HCS**

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Flexitime (base + cat)

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12 Ecological information

- **Toxicity**
 - **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
 - **Additional ecological information:**
 - **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
 - **Recommendation**
Small quantities can be polymerized with the matching system component(s) and the cured solid material can be disposed of with the regular garbage. Larger quantities must be disposed of following the regulations of the local authorities.
- **Uncleaned packagings:**
 - **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· UN-Number	
· DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	-
· UN "Model Regulation":	-

USA

(Contd. on page 6)

**Safety Data Sheet
acc. to OSHA HCS**

Printing date 05/12/2015

Reviewed on 05/12/2015

Trade name: Flexitime (base + cat)

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15 Regulatory information

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

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **TLV (Threshold Limit Value established by ACGIH)**

14808-60-7 Quartz (SiO₂)

A2

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**

Quartz (SiO₂)

· **Hazard statements**

May cause cancer.

Causes damage to organs through prolonged or repeated exposure.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapours/spray.

Use personal protective equipment as required.

Wash thoroughly after handling.

IF exposed or concerned: Get medical advice/attention.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 05/12/2015 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

Carc. 1A: Carcinogenicity, Hazard Category 1A

STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1

· *** Data compared to the previous version altered.**

USA