

## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

### SECTION 1. IDENTIFICATION

Product name : Pentobarbital Sodium / Phenytoin Formulation  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 37 McCarville Street  
Charlottetown, PE C1E 2A7  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Flammable liquids : Category 3  
Acute toxicity (Oral) : Category 3  
Skin sensitization : Category 1  
Carcinogenicity (Oral) : Category 2  
Reproductive toxicity : Category 2  
Specific target organ toxicity : Category 1 (Central nervous system)  
- single exposure  
Specific target organ toxicity : Category 1 (Central nervous system)  
- repeated exposure

#### GHS label elements

Hazard pictograms :    

Signal Word : Danger

Hazard Statements : H226 Flammable liquid and vapor.  
H301 Toxic if swallowed.  
H317 May cause an allergic skin reaction.  
H351 Suspected of causing cancer if swallowed.  
H361 Suspected of damaging fertility or the unborn child.  
H370 Causes damage to organs (Central nervous system).

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

Version 6.7      Revision Date: 09/28/2024      SDS Number: 671663-00022      Date of last issue: 09/30/2023  
Date of first issue: 05/12/2016

H372 Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

Precautionary Statements :

### Prevention:

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P260 Do not breathe mist or vapors.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves, protective clothing, eye protection and face protection.

### Response:

P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER. Rinse mouth.  
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.  
P308 + P311 IF exposed or concerned: Call a doctor.  
P333 + P313 If skin irritation or rash occurs: Get medical attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

### Other hazards

Vapors may form explosive mixture with air.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

| Chemical name        | Common Name/Synonym                          | CAS-No.  | Concentration (% w/w) |
|----------------------|----------------------------------------------|----------|-----------------------|
| Pentobarbital sodium | No data available                            | 57-33-0  | $\geq 30 - < 60$ *    |
| Propylene glycol     | 1,2-Propanediol                              | 57-55-6  | $\geq 10 - < 30$ *    |
| Ethanol#             | Ethyl alcohol                                | 64-17-5  | $\geq 10 - < 30$      |
| Phenytoin sodium     | 2,4-Imidazolidinedione, 5,5-diphenyl-, sodi- | 630-93-3 | $\geq 5 - < 10$ *     |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

Version 6.7      Revision Date: 09/28/2024      SDS Number: 671663-00022      Date of last issue: 09/30/2023  
Date of first issue: 05/12/2016

|                |                 |          |                  |
|----------------|-----------------|----------|------------------|
|                | um salt (1:1)   |          |                  |
| Benzyl alcohol | Benzenemethanol | 100-51-6 | $\geq 1 - < 5$ * |

# Voluntarily-disclosed substance

\* Actual concentration or concentration range is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Call a physician or poison control center immediately.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Toxic if swallowed.  
May cause an allergic skin reaction.  
Suspected of causing cancer if swallowed.  
Suspected of damaging fertility or the unborn child.  
Causes damage to organs.  
Causes damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Do not use a solid water stream as it may scatter and spread fire.  
Flash back possible over considerable distance.  
Vapors may form explosive mixtures with air.  
Exposure to combustion products may be a hazard to health.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

- |                                                |                                                                                                                                                                                                                                                   |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazardous combustion products                  | : Carbon oxides<br>Nitrogen oxides (NOx)<br>Metal oxides                                                                                                                                                                                          |
| Specific extinguishing methods                 | : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.                                                                                                                                            |

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- |                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Personal precautions, protective equipment and emergency procedures | : Remove all sources of ignition.<br>Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Environmental precautions                                           | : Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Methods and materials for containment and cleaning up               | : Non-sparking tools should be used.<br>Soak up with inert absorbent material.<br>Suppress (knock down) gases/vapors/mists with a water spray jet.<br>For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.<br>Clean up remaining materials from spill with suitable absorbent.<br>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

### SECTION 7. HANDLING AND STORAGE

- |                    |                                                                                 |
|--------------------|---------------------------------------------------------------------------------|
| Technical measures | : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
|--------------------|---------------------------------------------------------------------------------|

## Pentobarbital Sodium / Phenytoin Formulation

Version 6.7      Revision Date: 09/28/2024      SDS Number: 671663-00022      Date of last issue: 09/30/2023  
Date of first issue: 05/12/2016

- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.  
Use explosion-proof electrical, ventilating and lighting equipment.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapors.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Non-sparking tools should be used.  
Keep container tightly closed.  
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.  
Keep away from heat and sources of ignition.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Flammable solids  
Pyrophoric liquids  
Pyrophoric solids  
Self-heating substances and mixtures  
Substances and mixtures which in contact with water emit flammable gases  
Explosives  
Gases  
Very acutely toxic substances and mixtures

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

| Components           | CAS-No. | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis     |
|----------------------|---------|----------------------------------|------------------------------------------------|-----------|
| Pentobarbital sodium | 57-33-0 | TWA                              | 40µg/m <sup>3</sup> (OEB3)                     | Internal  |
|                      |         | Wipe limit                       | 400µg/100cm <sup>2</sup>                       | Internal  |
| Propylene glycol     | 57-55-6 | TWA (Vapour and aerosols)        | 50 ppm<br>155 mg/m <sup>3</sup>                | CA ON OEL |
|                      |         | TWA (aero-                       | 10 mg/m <sup>3</sup>                           | CA ON OEL |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

Version 6.7      Revision Date: 09/28/2024      SDS Number: 671663-00022      Date of last issue: 09/30/2023  
Date of first issue: 05/12/2016

|                  |          |            |                                      |           |
|------------------|----------|------------|--------------------------------------|-----------|
|                  |          | sol)       |                                      |           |
| Ethanol          | 64-17-5  | TWA        | 1,000 ppm<br>1,880 mg/m <sup>3</sup> | CA AB OEL |
|                  |          | STEL       | 1,000 ppm                            | CA BC OEL |
|                  |          | STEV       | 1,000 ppm                            | CA QC OEL |
|                  |          | STEL       | 1,000 ppm                            | ACGIH     |
| Phenytoin sodium | 630-93-3 | TWA        | 50 µg/m <sup>3</sup> (OEB3)          | Internal  |
|                  |          | Wipe limit | 500 µg/100 cm <sup>2</sup>           | Internal  |

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).  
Minimize open handling.  
Use explosion-proof electrical, ventilating and lighting equipment.

### Personal protective equipment

**Respiratory protection** : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type** : Combined particulates and organic vapor type

**Hand protection**

**Material** : Chemical-resistant gloves

**Remarks** : Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

**Eye protection** : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection** : Work uniform or laboratory coat.  
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene measures** : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Contaminated work clothing should not be allowed out of the workplace.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

|                                                  |                     |
|--------------------------------------------------|---------------------|
| Appearance                                       | : liquid            |
| Color                                            | : pink              |
| Odor                                             | : No data available |
| Odor Threshold                                   | : No data available |
| pH                                               | : No data available |
| Melting point/freezing point                     | : No data available |
| Initial boiling point and boiling range          | : No data available |
| Flash point                                      | : 44 - 60 °C        |
| Evaporation rate                                 | : No data available |
| Flammability (solid, gas)                        | : Not applicable    |
| Flammability (liquids)                           | : Not applicable    |
| Upper explosion limit / Upper flammability limit | : No data available |
| Lower explosion limit / Lower flammability limit | : No data available |
| Vapor pressure                                   | : No data available |
| Relative vapor density                           | : No data available |
| Relative density                                 | : No data available |
| Density                                          | : No data available |
| Solubility(ies)                                  |                     |
| Water solubility                                 | : No data available |
| Partition coefficient: n-octanol/water           | : No data available |
| Autoignition temperature                         | : No data available |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

|                           |   |                                                          |
|---------------------------|---|----------------------------------------------------------|
| Decomposition temperature | : | No data available                                        |
| Viscosity                 |   |                                                          |
| Viscosity, kinematic      | : | No data available                                        |
| Explosive properties      | : | Not explosive                                            |
| Oxidizing properties      | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight          | : | No data available                                        |
| Particle characteristics  |   |                                                          |
| Particle size             | : | No data available                                        |

### SECTION 10. STABILITY AND REACTIVITY

|                                    |   |                                                                                                                       |
|------------------------------------|---|-----------------------------------------------------------------------------------------------------------------------|
| Reactivity                         | : | Not classified as a reactivity hazard.                                                                                |
| Chemical stability                 | : | Stable under normal conditions.                                                                                       |
| Possibility of hazardous reactions | : | Flammable liquid and vapor.<br>Vapors may form explosive mixture with air.<br>Can react with strong oxidizing agents. |
| Conditions to avoid                | : | Heat, flames and sparks.                                                                                              |
| Incompatible materials             | : | Oxidizing agents                                                                                                      |
| Hazardous decomposition products   | : | No hazardous decomposition products are known.                                                                        |

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Toxic if swallowed.

#### Product:

|                     |   |                                                                     |
|---------------------|---|---------------------------------------------------------------------|
| Acute oral toxicity | : | Acute toxicity estimate: 261.66 mg/kg<br>Method: Calculation method |
|---------------------|---|---------------------------------------------------------------------|

#### Components:

##### Pentobarbital sodium:

|                     |   |                                                                              |
|---------------------|---|------------------------------------------------------------------------------|
| Acute oral toxicity | : | LD50 (Rat): 118 mg/kg<br>LD50 (Mouse): 239 mg/kg<br>LD50 (Rabbit): 175 mg/kg |
|---------------------|---|------------------------------------------------------------------------------|

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

LD50 (Dog): 65 mg/kg

### Propylene glycol:

|                           |   |                                                                                                   |
|---------------------------|---|---------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 22,000 mg/kg                                                                          |
| Acute inhalation toxicity | : | LC50 (Rat): > 44.9 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist                       |
| Acute dermal toxicity     | : | LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal toxicity |

### Ethanol:

|                           |   |                                                                              |
|---------------------------|---|------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 10,470 mg/kg<br>Method: OECD Test Guideline 401                  |
| Acute inhalation toxicity | : | LC50 (Rat, male): 116.9 mg/l<br>Exposure time: 4 h<br>Test atmosphere: vapor |
| Acute dermal toxicity     | : | LD50 (Rabbit): > 15,800 mg/kg                                                |

### Phenytoin sodium:

|                     |   |                                                               |
|---------------------|---|---------------------------------------------------------------|
| Acute oral toxicity | : | Acute toxicity estimate: 100 mg/kg<br>Method: Expert judgment |
|---------------------|---|---------------------------------------------------------------|

### Benzyl alcohol:

|                           |   |                                                                                                                                                                                        |
|---------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity       | : | LD50 (Rat): 1,200 mg/kg                                                                                                                                                                |
| Acute inhalation toxicity | : | LC50 (Rat): > 5.4 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: OECD Test Guideline 403<br>Assessment: The substance or mixture has no acute inhalation toxicity |

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Propylene glycol:

|         |   |                         |
|---------|---|-------------------------|
| Species | : | Rabbit                  |
| Method  | : | OECD Test Guideline 404 |
| Result  | : | No skin irritation      |

#### Ethanol:

|         |   |                         |
|---------|---|-------------------------|
| Species | : | Rabbit                  |
| Method  | : | OECD Test Guideline 404 |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

Result : No skin irritation

### **Benzyl alcohol:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

#### **Propylene glycol:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405

#### **Ethanol:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

#### **Benzyl alcohol:**

Species : Rabbit  
Result : Irritation to eyes, reversing within 21 days  
Method : OECD Test Guideline 405

### **Respiratory or skin sensitization**

#### **Skin sensitization**

May cause an allergic skin reaction.

#### **Respiratory sensitization**

Not classified based on available information.

### **Components:**

#### **Propylene glycol:**

Test Type : Maximization Test  
Routes of exposure : Skin contact  
Species : Guinea pig  
Result : negative

#### **Ethanol:**

Test Type : Mouse ear swelling test (MEST)  
Routes of exposure : Skin contact  
Species : Mouse  
Result : negative

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

### Phenytoin sodium:

Assessment : Probability or evidence of skin sensitization in humans

### Benzyl alcohol:

Test Type : Human repeat insult patch test (HRIPT)  
Routes of exposure : Skin contact  
Species : Humans  
Result : positive

Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Propylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

#### Ethanol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Result: negative

### Phenytoin sodium:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro sister chromatid exchange assay in mam-  
malian cells  
Result: positive  
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### **Benzyl alcohol:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo  
cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Result: negative

### **Carcinogenicity**

Suspected of causing cancer if swallowed.

### **Components:**

#### **Propylene glycol:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

#### **Phenytoin sodium:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : negative

Species : Mouse  
Application Route : Ingestion  
Exposure time : 2 Years  
Result : positive

Carcinogenicity - Assess- : Limited evidence of carcinogenicity in animal studies (oral)

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

ment

### **Benzyl alcohol:**

|                   |   |                         |
|-------------------|---|-------------------------|
| Species           | : | Mouse                   |
| Application Route | : | Ingestion               |
| Exposure time     | : | 103 weeks               |
| Method            | : | OECD Test Guideline 451 |
| Result            | : | negative                |

### **Reproductive toxicity**

Suspected of damaging fertility or the unborn child.

### **Components:**

#### **Pentobarbital sodium:**

|                                    |   |                                                                               |
|------------------------------------|---|-------------------------------------------------------------------------------|
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on development, based on animal experiments. |
|------------------------------------|---|-------------------------------------------------------------------------------|

#### **Propylene glycol:**

|                      |   |                                                                                                                             |
|----------------------|---|-----------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
|----------------------|---|-----------------------------------------------------------------------------------------------------------------------------|

|                              |   |                                                                                                           |
|------------------------------|---|-----------------------------------------------------------------------------------------------------------|
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
|------------------------------|---|-----------------------------------------------------------------------------------------------------------|

#### **Ethanol:**

|                      |   |                                                                                                                             |
|----------------------|---|-----------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
|----------------------|---|-----------------------------------------------------------------------------------------------------------------------------|

#### **Phenytoin sodium:**

|                      |   |                                                                                                                                                                               |
|----------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : | Test Type: reproductive and developmental toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: positive<br>Remarks: Based on data from similar materials |
|----------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                              |   |                                                                                                                                                                               |
|------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fetal development | : | Test Type: reproductive and developmental toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: positive<br>Remarks: Based on data from similar materials |
|------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                    |   |                                                                                                                        |
|------------------------------------|---|------------------------------------------------------------------------------------------------------------------------|
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments. |
|------------------------------------|---|------------------------------------------------------------------------------------------------------------------------|

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

### Benzyl alcohol:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### STOT-single exposure

Causes damage to organs (Central nervous system).

#### Components:

#### Pentobarbital sodium:

Routes of exposure : Ingestion  
Target Organs : Central nervous system  
Assessment : Causes damage to organs.

### STOT-repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

#### Components:

#### Phenytoin sodium:

Routes of exposure : Ingestion  
Target Organs : Central nervous system  
Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

### Repeated dose toxicity

#### Components:

#### Propylene glycol:

Species : Rat, male  
NOAEL :  $\geq 1,700$  mg/kg  
Application Route : Ingestion  
Exposure time : 2 y

#### Ethanol:

Species : Rat  
NOAEL : 1,730 mg/kg  
LOAEL : 3,200 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

### Phenytoin sodium:

|                   |                                        |
|-------------------|----------------------------------------|
| Species           | : Rat                                  |
| NOAEL             | : > 100 mg/kg                          |
| Application Route | : Ingestion                            |
| Exposure time     | : 13 Weeks                             |
| Remarks           | : Based on data from similar materials |

|                   |                                        |
|-------------------|----------------------------------------|
| Species           | : Mouse                                |
| NOAEL             | : > 10 - 100 mg/kg                     |
| LOAEL             | : > 10 - 100 mg/kg                     |
| Application Route | : Ingestion                            |
| Exposure time     | : 13 Weeks                             |
| Remarks           | : Based on data from similar materials |

### Benzyl alcohol:

|                   |                               |
|-------------------|-------------------------------|
| Species           | : Rat                         |
| NOAEL             | : 1.072 mg/l                  |
| Application Route | : inhalation (dust/mist/fume) |
| Exposure time     | : 28 Days                     |
| Method            | : OECD Test Guideline 412     |

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Pentobarbital sodium:

|           |                                                                                                           |
|-----------|-----------------------------------------------------------------------------------------------------------|
| Ingestion | : Symptoms: dry mouth, mood swings, Dizziness, Headache, Nausea, central nervous system effects, Sweating |
|-----------|-----------------------------------------------------------------------------------------------------------|

#### Phenytoin sodium:

|           |                                                                                                                                                                 |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Ingestion | : Symptoms: Nausea, constipation, confusion, Vomiting, central nervous system effects, Dizziness, insomnia, Blood disorders, Liver disorders, Tremors, anorexia |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### Pentobarbital sodium:

|                  |                                                                                 |
|------------------|---------------------------------------------------------------------------------|
| Toxicity to fish | : LC50 (Pimephales promelas (fathead minnow)): 49.5 mg/l<br>Exposure time: 96 h |
|------------------|---------------------------------------------------------------------------------|

#### Propylene glycol:

|                  |                                                                                  |
|------------------|----------------------------------------------------------------------------------|
| Toxicity to fish | : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l<br>Exposure time: 96 h |
|------------------|----------------------------------------------------------------------------------|

|                               |                                                       |
|-------------------------------|-------------------------------------------------------|
| Toxicity to daphnia and other | : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l |
|-------------------------------|-------------------------------------------------------|

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

|                                                                        |                                                                                                                        |
|------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| aquatic invertebrates                                                  | Exposure time: 48 h                                                                                                    |
| Toxicity to algae/aquatic plants                                       | : ErC50 (Skelettonema costatum (marine diatom)): 19,300 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l<br>Exposure time: 7 d                                            |
| Toxicity to microorganisms                                             | : NOEC (Pseudomonas putida): > 20,000 mg/l<br>Exposure time: 18 h                                                      |

### Ethanol:

|                                                                        |                                                                                                                                                                          |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                                       | : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l<br>Exposure time: 96 h                                                                                        |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l<br>Exposure time: 48 h                                                                                              |
| Toxicity to algae/aquatic plants                                       | : ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l<br>Exposure time: 72 h<br><br>EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l<br>Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC (Oryzias latipes (Japanese medaka)): >= 79 mg/l<br>Exposure time: 100 d                                                                                           |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC (Daphnia magna (Water flea)): 9.6 mg/l<br>Exposure time: 9 d                                                                                                      |
| Toxicity to microorganisms                                             | : EC50 (Protozoa): 5,800 mg/l<br>Exposure time: 4 h                                                                                                                      |

### Phenytoin sodium:

|                                                     |                                                                                                                            |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                    | : EC50 (Danio rerio (zebra fish)): > 10 - 100 mg/l<br>Exposure time: 72 h<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : Remarks: No toxicity at the limit of solubility.                                                                         |

### Benzyl alcohol:

|                                                     |                                                                                                         |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                    | : LC50 (Pimephales promelas (fathead minnow)): 460 mg/l<br>Exposure time: 96 h                          |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): 230 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants                    | : EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l<br>Exposure time: 72 h                 |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 51 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

### Persistence and degradability

#### Components:

##### **Propylene glycol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

##### **Ethanol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 84 %  
Exposure time: 20 d

##### **Phenytoin sodium:**

Biodegradability : Result: Not readily biodegradable.  
Method: OECD Test Guideline 301C  
Remarks: Based on data from similar materials

##### **Benzyl alcohol:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 92 - 96 %  
Exposure time: 14 d

### Bioaccumulative potential

#### Components:

##### **Propylene glycol:**

Partition coefficient: n-octanol/water : log Pow: -1.07  
Method: Regulation (EC) No. 440/2008, Annex, A.8

##### **Ethanol:**

Partition coefficient: n-octanol/water : log Pow: -0.35

##### **Phenytoin sodium:**

Partition coefficient: n-octanol/water : log Pow: 2.84

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

octanol/water

Remarks: Calculation

### Benzyl alcohol:

Partition coefficient: n-octanol/water : log Pow: 1.05

### Mobility in soil

No data available

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

|                        |   |                                                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Waste from residues    | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations.                                                                                                                                                                                                                                                                                                                            |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>Empty containers retain residue and can be dangerous.<br>Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

|                           |   |                                                             |
|---------------------------|---|-------------------------------------------------------------|
| UN number                 | : | UN 1993                                                     |
| Proper shipping name      | : | FLAMMABLE LIQUID, N.O.S.<br>(Ethanol, Pentobarbital sodium) |
| Class                     | : | 3                                                           |
| Packing group             | : | III                                                         |
| Labels                    | : | 3                                                           |
| Environmentally hazardous | : | no                                                          |

#### IATA-DGR

|                                          |   |                                                             |
|------------------------------------------|---|-------------------------------------------------------------|
| UN/ID No.                                | : | UN 1993                                                     |
| Proper shipping name                     | : | Flammable liquid, n.o.s.<br>(Ethanol, Pentobarbital sodium) |
| Class                                    | : | 3                                                           |
| Packing group                            | : | III                                                         |
| Labels                                   | : | Flammable Liquids                                           |
| Packing instruction (cargo aircraft)     | : | 366                                                         |
| Packing instruction (passenger aircraft) | : | 355                                                         |

#### IMDG-Code

|                      |   |                          |
|----------------------|---|--------------------------|
| UN number            | : | UN 1993                  |
| Proper shipping name | : | FLAMMABLE LIQUID, N.O.S. |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

(Ethanol, Pentobarbital sodium)

|                  |   |                 |
|------------------|---|-----------------|
| Class            | : | 3               |
| Packing group    | : | III             |
| Labels           | : | 3               |
| EmS Code         | : | F-E, <u>S-E</u> |
| Marine pollutant | : | no              |

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

|                      |   |                                                             |
|----------------------|---|-------------------------------------------------------------|
| UN number            | : | UN 1993                                                     |
| Proper shipping name | : | FLAMMABLE LIQUID, N.O.S.<br>(Ethanol, Pentobarbital sodium) |
| Class                | : | 3                                                           |
| Packing group        | : | III                                                         |
| Labels               | : | 3                                                           |
| ERG Code             | : | 128                                                         |
| Marine pollutant     | : | no                                                          |

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

### The ingredients of this product are reported in the following inventories:

|       |   |                |
|-------|---|----------------|
| AICS  | : | not determined |
| DSL   | : | not determined |
| IECSC | : | not determined |

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

|                  |   |                                                                                                                                         |
|------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------|
| ACGIH            | : | USA. ACGIH Threshold Limit Values (TLV)                                                                                                 |
| CA AB OEL        | : | Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)                                                                     |
| CA BC OEL        | : | Canada. British Columbia OEL                                                                                                            |
| CA ON OEL        | : | Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.                                        |
| CA QC OEL        | : | Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants |
| ACGIH / STEL     | : | Short-term exposure limit                                                                                                               |
| CA AB OEL / TWA  | : | 8-hour Occupational exposure limit                                                                                                      |
| CA BC OEL / STEL | : | short-term exposure limit                                                                                                               |

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Pentobarbital Sodium / Phenytoin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 09/30/2023  |
| 6.7     | 09/28/2024     | 671663-00022 | Date of first issue: 05/12/2016 |

CA ON OEL / TWA : Time-Weighted Average Limit (TWA)  
CA QC OEL / STEV : Short-term exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/28/2024  
Date format : mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8