



Material Safety Data Sheet

According to Regulation No 1907/2006/EC – REACH, No. 453/2010 and No 1272/2008/EC - CLP

Version No: 5.3


Date of revision : 01/23/2015

Replaced version No 5.2

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| SECTION 1 | Identification of the substance/mixture and of the company/undertaking | |
| 1.1 | Product identifier | FOMADENT D |
| | Other name or labeling of product: | |
| 1.2 | Relevant identified uses of the substance or mixture and uses advised against | |
| | Concentrate of developer for processing of dental medical RTG films | |
| 1.3 | Details of the supplier of the safety data sheet | |
| | Supplier : Downstream User (Producer Mixture) | FOMA BOHEMIA spol. s r.o.(Ltd.) J. Krušinky 1737/6, 500 02 Hradec Králové tel: 495 733 111 |
| | E-mail address and phone number | ilona.spackova@foma.cz +420495733368 |
| 1.4 | Emergency telephone number (Czech) | Toxicologic institute (TIS) Na Bojišti 1, 128 21 Praha 2 Tel. 224919293, 224915402 (continuous telephone information service) |

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| SECTION 2 | Hazards identification | |
| 2.1 | Classification (according to Regulation No 1272/2008 – CLP) | |
| | Carc.2;H351 Muta 2;H341 Eye Irrit.2;H319 Skin Irrit2;H315 SkinSens.1;H317 Aquatic Acute 1;H400 Aquatic Chronic2: H411 | |
| | Classification (according to Directive No 1999/45/ES – (DPD) | |
| | Carc.Cat.3;R40 Muta.Cat.3;R68 Xi;R36/38, R43 N;R50 | |

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| | <p><u>The most important adverse physicochemical, human health and environmental effects:</u></p> <p>Upon contact with the eyes can cause serious irritation. May cause an allergic skin reaction. Suspected of causing cancer and genetic defects. Very toxic to aquatic organisms with long last effects.</p> |
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| 2.2 | Label elements (according to Regulation No 1272/2008/EC– CLP) | |
| <i>Identification of product</i> | | FOMADENT D |
| <i>hazard pictogram</i> | |  |
| <i>signal word</i> | | Warning |
| <i>hazard statement(s) (H- phrases)</i> | H351 H341 H319 H315 H317 H410 | <p>Suspected of causing cancer</p> <p>Suspected of causing genetic defects</p> <p>Causes serious eye irritation.</p> <p>Causes skin irritation.</p> <p>May cause an allergic skin reaction</p> <p>Very toxic to aquatic life with long lasting effects</p> |
| <i>precautionary statement (P- phrases)</i> | P280 P301+P310 P305+P351+P338 P273 | <p>Wear protective gloves/protective clothing/eye protection/face protection.</p> <p>IF SWALLOWED: Immediately call a POISON CENTER/doctor.</p> <p>IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.</p> <p>Avoid release to the environment</p> |
| | | Contain: Hydroquione, Phenidon, Sodium hydroxide |
| | | FOMA BOHEMIA spol. s r.o., J. Krušinky 1737/6, 500 02 Hradec Králové tel: 495 733 111 |

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| 2.3 | Other hazards |
| | The substance does not belong to the category of PBT, vPvB, SVHC |

| SECTION 3 | | Composition/information on ingredients | | | | |
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| 3.2 | | Mixtures | | | | |
| Folder name | Registration number | Index number | CAS number | ES number | Content % in the solution | Classification |
| Potassium carbonate | 01-21195326 46-36-0000 | Not available | 584-08-7 | 209-529-3 | 5-10 | Eye Irrit.2;H319 Skin Irrit.2;H315 STOT SE 3;H335 Xi;R36/37/38 |

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|--|---------------------------|---------------|-----------|-----------|-------|---|---|
| Hydroquinone | 01-21195240 16-51-xxxx | 604-005-00-4 | 123-31-9 | 204-617-8 | < 5 | Carc.2;H351 Muta.2;H341 AcuteTox.4;H302 EyeDam.1;H318 SkinSens.1;H317 Aquatic Acute 1; H400 AquaticChronic1; H410 M(acute)=10 M(chronic)=1 | CarcCat3;R40 MutaCat3;R68 Xn;R22 Xi;R41,R43 N;R50 |
| Sodium hydroxide | 01-21194578 92-27-0023 | 011-002-00-6 | 1310-73-2 | 215-185-5 | < 1 | SkinCorr.1A;H314 | C;R35 |
| Phenidon A (1-fenyl-3-pyrazolidon | Not available | 606-022-00-2 | 92-43-3 | 202-155-1 | < 0,2 | AcuteTox.4;H302 Aquatic Chronic2;H411 | Xn;R22 N;R51/53 |
| Phenidon B (1-fenyl-4-metyl-3-pyrazolidon Solution | Not available | Not available | 2654-57-1 | 220-180-6 | < 0,2 | AcuteTox.4;H302 Skin.Sens.1;H317 Aquatic Chronic2;H411 | Xn;R22 Xi;R43 N;R51/53 |

(Full text R, H-phrases... section 16)

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| SECTION 4 | First aid measures |
| 4.1 | Description of first aid measures |
| | Disabled person to lead from the contaminated area, bringing it into a state of peace and to facilitate breathing by loosening clothing, watch, and if necessary to maintain its vital functions. If you are experiencing symptoms of acute injury (shortness of breath, persistent cough, chest pain, nausea, impaired sensory perception, fainting, etc.), call a physician or transport the injured person to a doctor. |
| | After contact with skin: Wash affected area thoroughly with water. |
| | Eye Contact: Remove any contact lenses and eye as soon as possible wash with plenty water. If necessary, open up violence cramped eyelids. Avoid contamination not contaminated eye wash liquid.. Do not neutralize. Seek medical help. |
| | Exposure by inhalation: Remove patient to fresh air, lukewarm water rinse eyes, mouth and nasal cavity. |
| | Ingestion: Affected person calm, clear water rinse. Place to drink a glass (about 0.4 dl) of cold water. Do not induce vomiting. If affected persone vomit spontaneously, control to prevent inhalation of vomit. Do not administer activated charcoal, and no neutralizing agent. Call a physician or transport the affected person to a doctor. |
| 4.2 | Most important symptoms and effects, both acute and delayed |
| | Not known |
| 4.3 | Indication of any immediate medical attention and special treatment needed |
| | In the workplace, running water and soap. |

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| SECTION 5 | Firefighting measures |
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| 5.1 | Extinguishing media |
| | The product (liquid) is not flammable. Extinguishing agents adapt burning nearby. |
| | Inappropriate extinguishing media: N.a. |
| 5.2 | Special hazards arising from the substance or mixture |
| | At elevated temperatures or by contact with acid can release sulfur dioxide |
| 5.3 | Advice for firefighters: Breathing apparatus |

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| SECTION 6 | Accidental release measures |
| 6.1 | Personal precautions, protective equipment and emergency procedures |
| | Zoom out persons not participating in the elimination of consequences of the accident out of reach. Ventilate enclosed spaces. When removing the consequences of the accident using the prescribed personal protective equipment. When working on the disposal of the accident contained breathing apparatus and full protective suit. No smoking and treatment with an open fire. |
| 6.2 | Environmental precautions |
| | Do not allow substance to enter soil, sewage system, surface and groundwater. |
| 6.3 | Methods and material for containment and cleaning up |
| | Let soak it to inert absorption products. Rinse the affected area thoroughly with water. Small leak at least strongly dilute with water. |
| 6.4 | Reference to other sections |
| | See section 13 |

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| SECTION 7 | Handling and storage |
| 7.1 | Precautions for safe handling |
| | While working to comply with basic requirements of safe work. Wear recommended personal protective equipment. Avoid contact with eyes. By manipulation prohibits eating, drinking and smoking, working with hot materials and open flame. Equipment must be equipped with means of extinguishing in enclosed areas, ventilation should be provided, either naturally or forced. Workplaces must be kept clean and escape routes must remain free. |
| 7.2 | Conditions for safe storage, including any incompatibilities |
| | Store in original containers in a cool, dry and well ventilated place. Containers should be stored separately from food. The working solution prepare according to the instructions. |
| 7.3 | Specific end use(s) |
| | See in 1.2. , Other uses – not available |

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| SECTION 8 | Exposure controls/personal protection |
| 8.1 | Control parameters |

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| | Government Regulation No 361/2007 Coll. - Conditions for health workers at work and occupational exposure limits in the air of workplaces and ways of measuring and evaluating. (Czech) | | |
| | Hydroquinone: | PEL 2 mg/m ³ | NPK-P 4 mg/m ³ |
| | Sodium hydroxide | PEL 1 mg/m ³ | NPK-P 2 mg/m ³ |
| | potasium carbonate | PEL 5 mg/m ³ | NPK-P 10 mg/m ³ |
| | Substance is not listed in Notice. No.432/2003 Coll., Laying down limit values of biological exposure tests: not available | | |
| | DNEL : (hydroquinone) | Workers | General |
| | Long-Term – derm., systemic. effect | 128 mg/kg bw/day | 64 mg/kg bw/day |
| | Long-Term – inhal., systemic. effect | 7 mg/m ³ | 1.74 mg/m ³ |
| | Long-Term – inhal., local. effect | 1 mg/m ³ | 0.5 mg/m ³ |
| | DNEL: (sodium hydroxide) | | |
| | Long-Term – inhal., local. effect | 1 mg/m ³ | 1 mg/m ³ |
| | PNEC : (hydroquinone) | | |
| | Freshwater | 0.114mg/l | |
| | Seawater | 0.0114 mg/l | |
| | Soil | 0.129 ug/kg sediment dw | |
| | Mikroorganismen in Sewasge Treatment Plant | 0.71mg/l | |
| 8.2 | Exposure controls | | |
| | Individual protection measures, incl. protective equipment | | |
| | Technical measures: Working with a local source of suction and running water for the irrigation needs of the eyes, wash your hands or contaminated parts of the skin. Tightly closed containers and equipment, natural and mechanical ventilation. Do not allow product to the eyes, mouth, inhalation, skin contact. Do not eat, drink or smoke. Avoid contact with food substances and drinks. After work wash hands with soap and water. Alternatively, take off contaminated clothing. | | |
| | Respiratory protection: During normal handling is not required. | | |
| | Hand protection: Use rubber (PE, nitril) gloves | | |
| | Eye protection: Safety glasses | | |
| | Skin protection: Workwear | | |
| | Environmental exposure: Provide preventing spill into waterways, soil and drainage. | | |

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| SECTION 9 | Physical and chemical properties | |
| 9.1 | Information on basic physical and chemical properties | |
| | Appearance | Colourless liquid |
| | Odour | Moderate, nonspecific |
| | pH (20 °C) | cca 10,7 |
| | Melting point/freezing point | cca 0 °C |
| | Initial boiling point and boiling range | cca 100 °C |
| | Flash point | Fireproof |
| | Evaporation rate | N.a. |
| | Flammability | Incombustible |
| | Upper/lower flammability or explosive limits | Irrelevant |
| | Vapour pressure | N.a. |

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| | Vapour density | N.a. |
| | Oxidising properties | No |
| | Relative density | 1.26 g/cm ³ |
| | Solubility – water | Solution |
| | Partition coefficient: n-octanol/water | N.a. |
| | Auto-ignition temperature | Irrelevant |
| | Decomposition temperature | N.a. |
| | Viscosity; | N.a. |
| | Explosive properties | No |
| 9.2 | Other information | |
| | Fat solubility | N.a. |
| | Conductivity | N.a. |

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| SECTION 10 | Stability and reactivity |
| 10.1 | Reactivity |
| | Under normal conditions the product is stable |
| 10.2 | Chemical stability |
| | Under normal conditions the product is stable |
| 10.3 | Possibility of hazardous reactions |
| | Strong minerale acids |
| 10.4 | Conditions to avoid |
| | High temperature |
| 10.5 | Incompatible materials |
| | Alluminium |
| 10.6 | Hazardous Decomposition Products |
| | Possible development of sulfur dioxide at elevated temperatures and reaction with acids |

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| SECTION 11 | Toxicological informations |
| 11.1 | Information on toxicological effects |
| Acute toxicity | Based on available data, the criteria for this classification are not match up |
| Skin corrosion/irritation | Based on available data, the criteria for this classification are not match up |
| Serious eye damage/eye irritation | Causes serious eye irritation |
| Respiratory or skin sensitisation | May cause an allergic skin reaction |
| Germ cell mutagenicity | Suspected of causing genetic defects |
| Carcinogenicity | Suspected of causing cancer |



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| Reproductive toxicity | Based on available data, the criteria for this classification are not match up |
| Specific target organ toxicity — single exposure | Based on available data, the criteria for this classification are not match up |
| Specific target organ toxicity — repeated exposure | Based on available data, the criteria for this classification are not match up |
| Aspiration hazard | Based on available data, the criteria for this classification are not match up |
| LDL _o oral, human : > 29 mg/kg (hydroquinone) LD ₅₀ oral rat: > 320 mg/kg (hydroquinone) LD ₅₀ derm., rat : > 9000 mg/kg (hydroquinone) LD ₅₀ oral rat: > 300mg/kg (sodium hydroxide) | |
| <u>Likely routes of exposure and symptoms related to the physical, chemical and toxicological characteristics:</u> | |
| Toxicity oral. (ingestion / swallowing): Ingestion may cause irritation or burns to the digestive tract. It causes nausea. | |
| Toxicity inhal. (inhalation): The product (solution) is not dangerous. | |
| Toxicity dermal. May cause irritation (redness) of skin | |
| Eye Contact: Causes serious eye irritation | |
| Immediate, delayed and chronic effects of short and long term exposure: N.a. | |

| SECTION | Ecological information |
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| 12 | |
| 12.1 | Toxicity LC ₅₀ (fish)/96hour: 0.15 mg/l (hydroquinone) LC ₅₀ (fish)/96hour: 100 mg/l (sodium hydroxide) EC ₅₀ (daphnia)/24hour: 0.11 mg/l (hydroquinone) EC ₅₀ (water algae)/72hour: 0.33 mg/l (hydroquinone) LC ₅₀ (pimephales promelas)/96hour: 0.044mg/l (hydroquinone) Mixture is highly toxic for aquatic life |
| 12.2 | Persistence and degradability Hydroquinone is considered to be biologically degradable (test OECD 301 C) |
| 12.3 | Bioaccumulative potential It is not expected |
| 12.4 | Mobility in soil N.a., the product is soluble in water |
| 12.5 | Results of PBT and vPvB assessment Not available. Substances are not identified as a PBT or vPvB |
| 12.6 | Other adverse effects WGK = 1 |

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| SECTION 13 | Disposal considerations | |
| 13.1 | Waste treatment methods | |
| | Code and type of waste | 09 01 01* – aqueous developer solutions 15 01 10 * - packaging containing residues of hazardous substances |
| | The recommended method of disposal of the substance/preparation: | Spilled product let soak up with inert absorbent material and pass the person authorized to remove. Must not be disposed of with household or other waste. Do not wash into sewers. |
| | The recommended method of disposal of contaminated product packaging: | Emptied containers (after thorough flushing) can be reused, or to defer to container, designated for separate collection (plastics). Possible slight residuals of hydroquinone in the empty, rinsed container, transform into harmless quinone form. (oxidation process) |
| | Waste legislation | Directive No. 2008/98/ES |


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| SECTION 14 | Transport information |
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Land transport ADR/RID (cross- border):


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| UN number | 3082 |
| UN proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,N.O.S. (HYDROQUINONE) |
| Transport hazard class(es) | 9 |
| Packing group | III |
| Labels | 9   |
| Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | Tunnel restriction: E |
| Remarks: | The product is carried in single or combination packagings containing a net quantity per single or inner packaging of 5 l or less and is not subject to any other provisions of ADR provided packaging meet the general provisions of 4.1.1.1., 4.1.1.2 and 4.1.1.4 to 4.1.1.8 (according to chapter 3.3 ADR, special provisions 375) |

Maritime transport IMDG:

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| UN number | 3082 |
| UN proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,N.O.S. (HYDROQUINONE) |
| IMDG class(es) | 9 |
| Packing group | III |
| EMS number | F-A, S-F |
| Segregation | Category A |
| Marine pollutant | Yes |

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| Labels | 9  |
| Remarks: | The product is packaged in single or combination packagings containing a net quantity per single or inner packaging of 5 l or less and is not subject to any other provisions of IMDG Code relevant to marine pollutants provided the packagings meet the general provisions of 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8. (according to Chapter 2.10, paragraph 2.10.2.7) |

Air transport ICAO-TI and IATA-DGR:

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| UN number | 3082 |
| UN proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,N.O.S. (HYDROQUINONE) |
| ICAO/IATA class(es) | 9 |
| Packing group | III |
| Labels | 9  |
| Packing instructions | Passenger aircraft – Packing instruction 964, max. net quantity per package 450 L Cargo aircraft - Packing instruction 964 max. net quantity per package 450 L |
| Remarks | The product is transported in single or combination packagings containing a net quantity per single or inner packaging of 5 l or less and is not subject to any other provisions of the IATA Dangerous Goods Regulations provided and the packagings used meet defined standards. (according to part 4.4 , Special provisions A197) |

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| Environmental hazards | Product contains environmentally hazardous substances: (Hydroquinone) |
| Special precautions for user | Avoid release to the environment |

| SECTION | Regulatory information |
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| 15 | |
| 15.1 | Safety, health and environmental regulations/legislation specific for the substance or mixture |
| | Regulation (EC) No 1907/2006, registration, evaluation, autorisation, restriction chemicals (REACH) Regulation (EC) No 453/2010 Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures Direction No 67/548/EHS (DSD), 1999/45/ES (DPD) Act No. 350/2011 Coll. On chemical substances and mixtures Decree No. 381/2001 Coll. Establishing the Waste Catalogue. Government Regulation No. 361/2007 Coll. On the health conditions of workers at work European Agreement concerning the international carriage of dangerous goods (ADR) applicable as from 1. January 2015 IMDG Code, MSC 93/22/Add.2 IATA Dangerous Goods Regulations, 56th Edition |
| 15.2 | Chemical safety assessment |
| | The chemical safety assessment for the product was'n made. |

| SECTION 16 | |
|------------------------|--|
| Abbreviations, symbols | |
| Carc.2 | Carcinogenity (Category 2) |
| Muta 2 | Mutagenity (Category 2) |
| Eye Dam.1 | Serious eye damage (Category 1) |
| Skin Sens.1 | Skin sensibilisation (Category 1) |
| Acute Tox.4 | Hazardous to the aquatic environment, acute (Category 4) |
| Skin Corr. 1B | Skin caustic (burns) (Cat. 1B) |
| Eye Irrit.2 | Serious eye irritation (Cat. 2) |
| Aquatic Acute 1 | Hazardous to the aquatic environment, acute (Category 1) |
| AquaticChron.1 | Hazardous to the aquatic environment, chronic (Category 1) |
| AquaticChron.2 | Hazardous to the aquatic environment, chronic (Category 2) |
| STOT SE 3 | Specific target organ toxicity — single exposure (cat.3) |
| Carc. cat.3 | Carcinogenity (Category 3) |
| Muta cat.3 | Mutagenity (Category 3) |
| C | caustic |
| Xn | harmfull |
| Xi | irritation |
| N | hazardous to the aquatic environment |
| CLP | Regulation (ES) č.1272/2008 |
| DPD | Direction (ES) 1999/45/ES |
| PBT | Persistent, bioaccumulation, toxic |
| vPvB | High persistent, high bioaccumulation |
| SVHC | Substance of very hight concerns |
| DNEL | Derivated No-Effect Level |
| PNEC | Prediction No-Effect Concentration |

Materials used for the processing of safety data sheet

Information provided by the producer
Material Safety Data Sheets (MSDS) for chemical substances

R, H-phrases :

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| H351 | Suspected of causing cancer |
| H341 | Suspected of causing genetic defects |
| H302 | Harmful if swallowed |
| H318 | Causes serious eye damage |
| H317 | May cause an allergic skin reaction |
| H400 | Very toxic to aquatic life |
| H410 | Very toxic to aquatic life with long lasting effects |
| H411 | Toxic to aquatic life with long lasting effects |

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| H319 | Causes serious eye irritation |
| H315 | Causes skin irritation |
| H314 | Causes severe skin burns and eye damage |
| H335 | May cause respiratory irritation |
| R40 | Limited evidence of a carcinogenic effect |
| R68 | Possible risk of irreversible effects |
| R36 | Causes serious eye irritation |
| R22 | Harmful if swallowed |
| R35 | Cause severe burns |
| R36/38 | Irritating to eyes and skin |
| R36/37/38 | Irritating to eyes, respiratory system and skin |
| R41 | Risk of serious damage to eyes |
| R43 | May cause sensitisation by skin contact |
| R50/53 | Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment |
| R50 | Very toxic to aquatic organisms |

Guidance regarding the training of workers:

Workers coming into contact with hazardous chemicals or products must have access to data which are presented in this MSDS and be familiar with them clearly. Person transporting hazardous chemicals and preparations must be familiar with guidelines for emergency response in accordance with regulations on hazardous goods within the meaning of ADR / RID.

The information contained in this MSDS are currently valid data and best practices for use and handling of this substance under normal conditions. Any other use or handling of this substance, which is not consistent with those of MSDS, excludes liability for defects, respectively damage, which would otherwise meet the producer, importer or retailer.

Revised safety data sheet:

Revision:

version 5.3 – changes in section 1.3 and 2.2– address of supplier, 14- changed information for maritime and air transport