



Material Safety Data Sheet

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

Version No: 6.3


Date of revision: 01/23/2015

Replaced version No 6.2

SECTION 1	Identification of the substance/mixture and of the company/undertaking	
1.1	Product identifier	FOMADENT MD-2,5
	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 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)

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

	<u>The most important adverse physicochemical, human health and environmental effects:</u> Suspected of causing cancer and genetic defects. Upon contact with the eyes can cause serious irritation. May cause an allergic skin reaction. Very toxic to aquatic life with long lasting effects.
--	--

2.2	Label elements (according to Regulation No 1272/2008/EC– CLP)	
<i>Identification of product</i>		FOMADENT MD-2,5
<i>hazard pictogram</i>		
<i>signal word</i>		Warning
<i>hazard statement(s) (H-, phrases)</i>	H351 H341 H319 H317 H410	Suspected of causing cancer Suspected of causing genetic defects Causes serious eye irritation May cause an allergic skin reaction Very toxic to aquatic life with long lasting effects.
<i>precautionary statement (P- phrases)</i>	P102 P280 P301+P310 P305+P351+P338 P273	Keep out of reach of children Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED: Immediately call a POISON CENTER/doctor. IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing Avoid release to the environment
		Contain: hydroquinone, fenidone, potassium hydroxide
		FOMA BOHEMIA spol. s r.o., J. Krušinky 1737/6, 500 02 Hradec Králové tel: 495 733 111

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

SECTION 3		Composition/information on ingredients				
3.2		Mixtures				
Folder name	Registration number	Index number	CAS number	ES number	Content % in the solution	Classification
Hydroquinone	01-2119524016-51-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 Aquatic Chronic1;H410 M(acute)=10 M(chronic)=1 CarcCat3;R40 MutaCat3;R68 Xn;R22 Xi;R41,R43 N;R50

Potassium carbonate	01-2119532646-36-0000	Not available	584-06-7	209-529-3	< 5	Eye Irrit.2;H319 Skin Irrit.2;H315 STOT SE 3;H335	Xi;R36/37/38
Potassium hydroxide	01-2119487136-33	019-002-00-8	1310-58-3	215-181-3	< 2	SkinCorr.1A;H314 AcuteTox.4;H302 Met.Corr.1;H290	C;R35 Xn;R22
Diethanolamine	01-2119488930-28	603-071-00-1	111-42-2	203-868-0	< 2	AcuteTox.4;H302 Eye Dam.1;H318 Skin Irrit.2;H315 STOT RE 2;H373	Xn;R22-48/22 Xi;R38-41
Phenidon B (1-phenyl-4-methyl-3-pyrazolidone)Diethanolamine Solution	Not available	Not available	2654-57-1	220-180-6	< 0,2	AcuteTox.4;H302 Skin Sens.1;H317 AquaticChronic2;H411	Xn;R22 Xi;R43 N;R51/53

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

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.

SECTION 5	Firefighting measures
5.1	Extinguishing media
	The product (liquid solution) 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 sulphur dioxide
5.3	Advice for firefighters: Breathing apparatus,workwear

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

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

SECTION 8	Exposure controls/personal protection
8.1	Control parameters
	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 Potassium hydroxide PEL 1 mg/m ³ NPK-P 2 mg/m ³ Potassium 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) Long-Term – derm., systemic. effect Long-Term – inhal., systemic. effect Long-Term – inhal., local. effect	Workers 128 mg/kg bw/day 7 mg/m ³ 1 mg/m ³	General 64 mg/kg bw/day 1.74 mg/m ³ 0.5 mg/m ³
	PNEC : (hydroquinone) Freshwater Seawater Soil Mikroorganismen in Sewasge Treatment Plant	0.114mg/l 0.0114 mg/l 0.129 ug/kg sediment dw 0.71mg/l	
	DNEL : (potassium hydroxide) Long-Term – inhal., local. effect	Workers 1 mg/m ³	General 1 mg/m ³
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.		

SECTION 9	Physical and chemical properties	
9.1	Information on basic physical and chemical properties	
	Appearance	Yellow liquid
	Odour	Moderate, nonspecific
	pH	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	<20 mbar
	Vapour density	Unknown
	Oxidising properties	No
	Relative density	1.22 g/cm ³

	Solubility – water	Solution
	Partition coefficient: n-octanol/water	Unknown
	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.

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

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	Causes serious skin irritation
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
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: > 320mg/kg (potassium 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 damage	
Immediate, delayed and chronic effects of short and long term exposure: N.a.	



SECTION	Ecological information
12	
12.1	Toxicity
	LC ₅₀ (fish)/96hod: 0.15 mg/l (hydroquinone) EC ₅₀ (daphnia)/24hod: 0.11 mg/l (hydroquinone) EC ₅₀ (water algae)/72hod: 0.33 mg/l (hydroquinone) LC ₅₀ (pimephales promelas)/96hour: 0.044mg/l (hydroquinone) Mixture is higly 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

SECTION	Disposal considerations
13	



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

SECTION 14	Transport information
---------------	-----------------------

Land transport ADR/RID (cross- border):


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:

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
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:

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)

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

SECTION 15	Regulatory information
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, 56 th 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 Corr. 1A	Skin corrosion (category 1A)
Met.Corr.1	Corrosive to metals
Skin Sens.1	Skin sensibilisation (Category 1)
Acute Tox.4	Hazardous to the aquatic environment, acute (Category 4)
Eye Irrit.2	Serious eye irritation (Cat. 2)
Aquatic Acute 1	Hazardous to the aquatic environment, acute (Category 1)
AquaticChronic 1	Hazardous to the aquatic environment, chronic (Category 1)
AquaticChronic 2	Hazardous to the aquatic environment, chronic (Category 2)
STOT SE 3	Specific target organ toxicity — single exposure (cat.3)
STOT RE 2	Specific target organ toxicity – Repeated exposure (Category 2)
Skin Irrit. 2	Skin irritation (category 2)
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 high 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 :

H290	May be corrosive to metals.
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
H315	Causes skin irritation.
H373	May cause damage to organs through prolonged or repeated exposure <i>exposure</i> .
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
H319	Causes serious eye irritation
H318	Causes serious eye damage
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
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
R48/22	Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R38	Irritating to skin.
R35	Cause severe burns
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:

version 6.3 – changes in section 1.3 and 2.2– address of supplier, 14- changed information for maritime and air transport