

Name: TRICRESOL AND FORMALIN - ART.11373/11372



SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 453/2010)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : TRICRESOL AND FORMALIN

Product code : ART.11373/11372.

1.2. Relevant identified uses of the substance or mixture and uses advised against

For dental professional use only.

1.3. Details of the supplier of the safety data sheet

Registered company name : PRODUITS DENTAIRES SA.

Address : Rue des Bosquets 18 .1800 .Vevey .Switzerland.

Telephone : +41 21 921 26 31. Fax : +41 21 921 39 79.

info@pdsa.ch

http://www.pdsa.ch

1.4. Emergency telephone number : +41 21 921 26 31.

Association/Organisation : .

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Acute oral toxicity, Category 3 (Acute Tox. 3, H301).

Acute dermal toxicity, Category 3 (Acute Tox. 3, H311).

Skin corrosion, Category 1B (Skin Corr. 1B, H314).

Skin sensitisation, Category 1 (Skin Sens. 1, H317).

Carcinogenicity, Category 2 (Carc. 2, H351).

Specific target organ toxicity (single exposure), Category 3 (STOT SE 3, H335).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Acute oral toxicity: toxic (T, R 25).

Acute cutaneous toxicity: toxic (T, R 24).

Acute inhalation toxicity: harmful (Xn, R 20).

Corrosive (C, R 34).

Skin sensitisation (Xi, R 43).

Category 3 carcinogen (Xn, R 40 Carc. Cat. 3).

This mixture does not present a physical hazard. Refer to the recommendations regarding the other products present on the site.

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

2.2. Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

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Hazard pictograms :



GHS06



GHS05



GHS08

Signal Word :

DANGER

Product identifiers :

604-004-00-9

MIX-CRESOL

605-001-00-5

FORMALDEHYDE

Hazard statements :

H301 + H311

Toxic if swallowed or in contact with skin.

H314

Causes severe skin burns and eye damage.

H317

May cause an allergic skin reaction.

H335

May cause respiratory irritation.

H351

Suspected of causing cancer .

Precautionary statements - Prevention :

P201

Obtain special instructions before use.

P202

Do not handle until all safety precautions have been read and understood.

P260

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

P264

Wash hands thoroughly after handling.

P280

Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statements - Response :

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.

P301 + P330 + P331

IF SWALLOWED: rinse mouth. Do NOT induce vomiting.

P302 + P352

IF ON SKIN: Wash with plenty of soap and water.

P304 + P340

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313

IF exposed or concerned: Get medical advice/attention.

P333 + P313

If skin irritation or rash occurs: Get medical advice/attention.

Precautionary statements - Storage :

P403 + P233

Store in a well-ventilated place. Keep container tightly closed.

Precautionary statements - Disposal :

P501

Dispose of contents/container to ...

2.3. Other hazards

The mixture does not contain any substances classified as 'Substances of Very High Concern' (SVHC) by the European Chemical Agency (ECHA) under article 57 of REACH: <http://echa.europa.eu/fr/candidate-list-table>

The mixture satisfies neither the PBT nor the vPvB criteria for mixtures in accordance with annexe XIII of the REACH regulations EC 1907/2006.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

No substances fulfil the criteria set forth in annexe II section A of the REACH regulation (EC) n° 1907/2006.

3.2. Mixtures

Composition :

Identification	(EC) 1272/2008	67/548/EEC	Note	%
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INDEX: 604-004-00-9 CAS: 1319-77-3 EC: 215-293-2 MIX-CRESOL	GHS06, GHS05 Dgr Acute Tox. 3, H311 Acute Tox. 3, H301 Skin Corr. 1B, H314	T T;R24/25 C;R34	[1]	25 <= x % < 50
INDEX: 605-001-00-5 CAS: 50-00-0 EC: 200-001-8 FORMALDEHYDE	GHS06, GHS08, GHS05 Dgr Carc. 2, H351 Acute Tox. 3, H331 Acute Tox. 3, H311 Acute Tox. 3, H301 Skin Corr. 1B, H314 Skin Sens. 1, H317	T Carc. Cat. 3;R40 T;R23/24/25 C;R34 Xi;R43	B D [1] [2]	2.5 <= x % < 10

Information on ingredients :

- [1] Substance for which maximum workplace exposure limits are available.
[2] Carcinogenic, mutagenic or reprotoxic (CMR) substance.

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.
NEVER induce swallowing by an unconscious person.

4.1. Description of first aid measures

In the event of exposure by inhalation :

If the person is unconscious, place in recovery position. Notify a doctor in all events, to ascertain whether observation and supportive hospital care will be necessary.
In the event of massive inhalation, remove the person exposed to fresh air and seek medical attention.

In the event of splashes or contact with eyes :

Wash thoroughly with soft, clean water for 15 minutes holding the eyelids open.
Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.

In the event of splashes or contact with skin :

In the event of an allergic reaction, seek medical attention.
If the contaminated area is widespread and/or there is damage to the skin, a doctor must be consulted or the patient transferred to hospital.
Wash the skin thoroughly with soap and fresh water.
Be careful with product which can remain between the skin and the clothes, the watch, the jewels.

In the event of swallowing :

In the event of swallowing, if the quantity is small (no more than one mouthful), rinse the mouth with water, administer activated medical charcoal and consult a doctor.
Keep the person exposed at rest. Do not force vomiting.
If swallowed accidentally, call a doctor to ascertain whether observation and hospital care will be necessary. Show the label.
Rinse the mouth with water and then drink a lot of water. Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Irritation, corrosion, cough, breathing difficulties, dizziness, migraine.

4.3. Indication of any immediate medical attention and special treatment needed

In case of very important inhalation of vapors and very strong irritation of lungs, treat with Dexamethasone in spray.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

Suitable methods of extinction

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In the event of a fire, use :

- sprayed water or water mist
- carbon dioxide (CO₂)
- powder
- foam

Unsuitable methods of extinction

In the event of a fire, do not use :

- water jet

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

In the event of a fire, the following may be formed :

- carbon monoxide (CO)
- carbon dioxide (CO₂)
- gas / irritant vapours
- formaldehyde vapors

5.3. Advice for firefighters

Due to the toxicity of the gas emitted on thermal decomposition of the products, fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For non fire-fighters

Avoid inhaling the vapors.

Avoid any contact with the skin and eyes.

For fire-fighters

Fire-fighters will be equipped with suitable personal protective equipment (See section 8).

Avoid inhaling the vapors.

Avoid any contact with the skin and eyes.

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Respect storage precautions mentioned on the packaging or in the instructions for use.

7.1. Precautions for safe handling

Always wash hands after handling.

The persons who have medical histories of cutaneous reactions must use this product with all the required precautions.

Avoid inhaling vapours.

Fire prevention :

Prevent access by unauthorised personnel.

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Recommended equipment and procedures :

For personal protection, see section 8.

Packages which have been opened must be reclosed carefully and stored in an upright position.

7.2. Conditions for safe storage, including any incompatibilities

Keep in the original container, respect the storage temperatures mentioned on the container, the leaflet and the box.

Storage

Respect storage precautions mentioned on the packaging or in the instructions for use.

Packaging

Always conserve in the original packaging.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Occupational exposure limits :

- ACGIH TLV (American Conference of Governmental Industrial Hygienists, Threshold Limit Values, 2010) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
1319-77-3	5 ppm	-	-	-	-
50-00-0	-	-	0.3 ppm	-	-

- France (INRS - ED984 :2008) :

CAS	VME-ppm :	VME-mg/m3 :	VLE-ppm :	VLE-mg/m3 :	Notes :	TMP No :
1319-77-3	5	22	-	-	-	-
50-00-0	0.5	-	1	-	C3	43

- UK / WEL (Workplace exposure limits, EH40/2005, 2007) :

CAS	TWA :	STEL :	Ceiling :	Definition :	Criteria :
50-00-0	2 ppm	2 ppm	-	-	-

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Pictogram(s) indicating the obligation of wearing personal protective equipment (PPE) :



- Eye / face protection

Avoid contact with eyes.

Individuals wearing contact lenses should wear prescription glasses during work where they may be exposed to irritant vapours.

- Hand protection

Wear gloves according to the hygienic rules in force in dental surgeries.

- Body protection

Avoid skin contact.

After contact with the product, all parts of the body that have been soiled must be washed.

- Respiratory protection

Avoid breathing vapours.

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SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

General information :

Physical state :	fluid liquid.
Colour:	brownish.
Odour:	spicy (presence of Formaldehyde and mix-Cresol).

Important health, safety and environmental information

pH :	5.00 . neutral.
Boiling point/boiling range :	not relevant.
Flash point interval :	not relevant.
Vapour pressure (50°C) :	not relevant.
Density :	1.014
Miscibility :	Ethanol
Water solubility :	Insoluble.
Viscosity :	6.3
Viscosity:	$\nu < 7 \text{ mm}^2/\text{s}$ (40°C) Method for determining the viscosity : DIN 51562-1 (Viscometry - Measurement of kinematic viscosity by means of the Ubbelohde viscometer - Part 1: Viscometer specification and measurement procedure).
Melting point/melting range :	not relevant.
Self-ignition temperature :	not relevant.
Decomposition point/decomposition range :	not relevant.

9.2. Other information

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.
Do not use if the expiry date is exceeded.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :
- heat

10.5. Incompatible materials

Keep away from :
- acids
- bases
- strong oxidising agents

10.6. Hazardous decomposition products

The thermal decomposition may release/form :
- carbon monoxide (CO)
- carbon dioxide (CO₂)

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- gas / irritant vapours
- formaldehyde vapors

SECTION 11 : TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Toxic if swallowed.

Toxic in contact with the skin.

May cause irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following exposure between three minutes and one hour.

Respiratory tract irritation may occur, together with symptoms such as coughing, choking and breathing difficulties.

May cause an allergic reaction by skin contact.

Suspected human carcinogen.

11.1.1. Substances

No toxicological data available for the substances.

11.1.2. Mixture

No toxicological data available for the mixture.

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 50-00-0 : IARC Group 1 : The agent is carcinogenic to humans.

CAS 64-17-5 : IARC Group 1 : The agent is carcinogenic to humans.

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

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SECTION 14 : TRANSPORT INFORMATION

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2013 - IMDG 2012 - ICAO/IATA 2013).

14.1. UN number

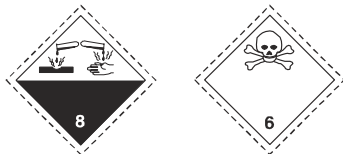
2922

14.2. UN proper shipping name

UN2922=CORROSIVE LIQUID, TOXIC, N.O.S.
(mix-cresol, mix-cresol)

14.3. Transport hazard class(es)

- Classification :



8+6.1

14.4. Packing group

II

14.5. Environmental hazards

-

14.6. Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	8	CT1	II	8+6.1	86	1 L	274	E2	2	E

IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ
	8	6.1	II	1 L	F-A,S-B	274	E2

IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ
	8	6.1	II	851	1 L	855	30 L	A3 A803	E2
	8	6.1	II	Y840	0.5 L	-	-	A3 A803	E2

For limited quantities, see part 2.7 of the OACI/IATA and chapter 3.4 of the ADR and IMDG.

For excepted quantities, see part 2.6 of the OACI/IATA and chapter 3.5 of the ADR and IMDG.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No data available.

SECTION 15 : REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

- Classification and labelling information included in section 2:

The following regulations have been used:

- Directive 67/548/EEC and its adaptations
- Directive 1999/45/EC and its adaptations
- Regulation EC 1272/2008 modified by regulation EC 618/2012

- Container information:

The mixture is contained in packaging that does not exceed 125 ml.

- Particular provisions :

No data available.

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- Standardised American system for the identification of hazards presented by the product in view of emergency procedures (NFPA 704) :

NFPA 704, Labelling: Health=3 Inflammability=1 Instability/Reactivity=1 Specific Risk=none



15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

In compliance with directives 67/548/EEC, 1999/45/EC and their amendments.

Hazard symbols :



Toxic

Contains :

604-004-00-9

MIX-CRESOL

605-001-00-5

FORMALDEHYDE

Risk phrase :

R 43

May cause sensitisation by skin contact.

R 24/25

Toxic in contact with skin and if swallowed.

R 20

Harmful by inhalation.

R 34

Causes burns.

R 40

Limited evidence of a carcinogenic effect.

Safety phrase :

S 26

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37/39

Wear suitable protective clothing, gloves and eye/face protection.

S 45

In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

S 38

In case of insufficient ventilation, wear suitable respiratory equipment.

S 60

This material and its container must be disposed of as hazardous waste.

S 9

Keep container in a well-ventilated place.

S 41

In case of fire and/or explosion do not breathe fumes.

Title for H, EUH and R indications mentioned in section 3 :

H301

Toxic if swallowed.

H311

Toxic in contact with skin.

H314

Causes severe skin burns and eye damage.

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H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H351	Suspected of causing cancer .
R 23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R 24/25	Toxic in contact with skin and if swallowed.
R 34	Causes burns.
R 40.C3	Limited evidence of a carcinogenic effect.
R 43	May cause sensitisation by skin contact.

Abbreviations :

CMR: Carcinogenic, mutagenic or reprotoxic.
ADR : European agreement concerning the international carriage of dangerous goods by Road.
IMDG : International Maritime Dangerous Goods.
IATA : International Air Transport Association.
ICAO : International Civil Aviation Organisation
RID : Regulations concerning the International carriage of Dangerous goods by rail.
GHS05 : Corrosion
GHS06 : Skull and crossbones
GHS08 : Health hazard