

Version 1.6 Revision Date: 2015/08/09 SDS Number: 100000011461 Date of last issue: 2015/07/15
Date of first issue: 2015/05/20

SECTION 1. IDENTIFICATION

Substance name : Tubing Fluid Formula TF-24

Substance No. :

Manufacturer or supplier's details

Company name of supplier : Ethicon Inc.

Address : PO Box 151 Route 22 West
Somerville, NJ 08876
US

Telephone : (877) 384-4266

Emergency telephone number : **+32 14 60 24 44**

E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Recommended use of the chemical and restrictions on use

Recommended use : Tubing Fluid for Gut Suture

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Flammable liquids : Category 2

Eye irritation : Category 2A

Specific target organ toxicity - single exposure : Category 3 (Central nervous system)

GHS Label element

Medicinal devices are not subject to GHS labeling.

Hazard pictograms :



Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

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|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2015/07/15 |
| 1.6 | 2015/08/09 | 100000011461 | Date of first issue: 2015/05/20 |

Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ eye protection/ face protection.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.

Storage:
P403 + P233 Store in a well-ventilated place. Keep container tightly closed.
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature : Mixture

Hazardous components

| Chemical Name | CAS-No. | Concentration (%) |
|---------------|-------------------|-------------------|
| propan-2-ol | isopropyl alcohol | >= 50 - < 70 |

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
If symptoms persist, call a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.

| | | | |
|----------------|------------------------------|-----------------------------|---|
| Version 1.6 | Revision Date: 2015/08/09 | SDS Number: 100000011461 | Date of last issue: 2015/07/15 Date of first issue: 2015/05/20 |
|----------------|------------------------------|-----------------------------|---|

- Wash off with plenty of water.
If symptoms persist, call a physician.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Remove contact lenses.
Consult a physician.
- If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : Severe eye irritation
Drowsiness
Dizziness
Headache
Nausea
Vomiting
stinging
tearing
Redness
Swelling of tissue
Blurred vision
Irritating to nose, throat and respiratory tract
- Notes to physician : Treat symptomatically.
Thermal burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Alcohol-resistant foam
Water mist
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : Water spray jet
- Specific hazards during fire-fighting : Vapours may form explosive mixtures with air.
Highly flammable
Heating can release hazardous gases.
- Specific extinguishing methods : Remove undamaged containers from fire area if it is safe to do so.
- Further information : In the event of fire, cool tanks with water spray.
Prevent fire extinguishing water from contaminating surface water or the ground water system.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2015/07/15 |
| 1.6 | 2015/08/09 | 100000011461 | Date of first issue: 2015/05/20 |

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Do not breathe vapours or spray mist.
Evacuate personnel to safe areas.
Ensure adequate ventilation.
Do not use sparking tools.
Keep away from open flames, hot surfaces and sources of ignition.
- Environmental precautions : Prevent further leakage or spillage if safe to do so.
Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Large spills: Dam up. Soak up with inert absorbent material.
Keep in properly labelled containers.
Small spills: Gently cover the spill with an absorbent towel or pad.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Clean contaminated surface thoroughly.
After cleaning, flush away traces with water.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No data available
- Advice on safe handling : To avoid thermal decomposition, do not overheat.
For personal protection see section 8.
Keep away from heat and sources of ignition.
Avoid inhalation, ingestion and contact with skin and eyes.
Use only with adequate ventilation.
Do not use sparking tools.
Do not smoke.
Use only in an area containing explosion proof equipment.
Take precautionary measures against static discharges.
Ensure all equipment is electrically grounded before beginning transfer operations.
Avoid inhalation of vapour or mist.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.
Take measures to prevent the build up of electrostatic charge.

| | | | |
|----------------|------------------------------|-----------------------------|---|
| Version 1.6 | Revision Date: 2015/08/09 | SDS Number: 100000011461 | Date of last issue: 2015/07/15 Date of first issue: 2015/05/20 |
|----------------|------------------------------|-----------------------------|---|

Keep locked up.
Keep in an area equipped with sprinklers.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|-------------|-------------------|----------------------------------|--|-----------|
| propan-2-ol | isopropyl alcohol | TWA | 200 ppm | ACGIH |
| | | TWA | 200 ppm | ACGIH |
| | | STEL | 400 ppm | ACGIH |
| | | STEL | 400 ppm | ACGIH |
| | | TWA | 400 ppm 980 mg/m ³ | NIOSH REL |
| | | ST | 500 ppm 1,225 mg/m ³ | NIOSH REL |
| | | TWA | 400 ppm 980 mg/m ³ | OSHA Z-1 |
| | | TWA | 400 ppm 980 mg/m ³ | OSHA P0 |
| | | STEL | 500 ppm 1,225 mg/m ³ | OSHA P0 |

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Respiratory protection : Engineering controls should always be the primary method of controlling exposures.
In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit.
If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
No special precautions required.
When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

Hand protection

Remarks : Impervious gloves

Eye protection : Safety glasses with side-shields
Ensure that eyewash stations and safety showers are close to the workstation location.

Skin and body protection : Wear suitable protective clothing.

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2015/07/15 |
| 1.6 | 2015/08/09 | 100000011461 | Date of first issue: 2015/05/20 |

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : colourless

Odour : alcohol-like

Odour Threshold : No data available

pH : 10.2 - 11.4

Melting point/range : No data available

Boiling point/boiling range : 81.11 °C

Flash point : 17.8 °C

Evaporation rate : No data available

Flammability (solid, gas) : No information available.

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : 0.818 - 0.821 (20 °C)

Density : No data available

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2015/07/15 |
| 1.6 | 2015/08/09 | 100000011461 | Date of first issue: 2015/05/20 |

Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available
Explosive properties : No data available
Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : None reasonably foreseeable.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.
Conditions to avoid : To avoid thermal decomposition, do not overheat.
Heat, flames and sparks.
Incompatible materials : Acids
Strong oxidizing agents
Cyanides
Acid chlorides
Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity****Skin corrosion/irritation****Product:**

Remarks: Non persistent irritation

Serious eye damage/eye irritation**Product:**

Result: May cause eye irritation.

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

| | | | |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2015/07/15 |
| 1.6 | 2015/08/09 | 100000011461 | Date of first issue: 2015/05/20 |

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

No data available

STOT - single exposure**Product:**

Assessment: May cause drowsiness or dizziness.

STOT - repeated exposure**Repeated dose toxicity**

No data available

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
Protection of Stratospheric Ozone - CAA Section 602 Class I
Substances
Remarks: This product neither contains, nor was
manufactured with a Class I or Class II ODS as defined by the
U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A +
B).

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|---------|----------------|--------------|---------------------------------|
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| 1.6 | 2015/08/09 | 100000011461 | Date of first issue: 2015/05/20 |

Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
This product has no known ecotoxicological effects.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International transport regulations

DOT

UN number : 1993
Description of the goods : Flammable liquids, n.o.s.
(propan-2-ol)
Class : 3
Packing group : II
Labels : 3
Emergency Response : 128
Guidebook Number :
Environmentally hazardous : no

IATA

UN number : 1993
Description of the goods : Flammable liquid, n.o.s.
(propan-2-ol)
Class : 3
Packing group : II
Labels : 3
Packing instruction (CAO) : 364
Packing instruction (PAX and CAO) : 353
Packing instruction (LQ) : Y341
Environmentally hazardous : no

IMDG

UN number : 1993
Description of the goods : FLAMMABLE LIQUID, N.O.S.
(propan-2-ol)
Class : 3

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|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2015/07/15 |
| 1.6 | 2015/08/09 | 100000011461 | Date of first issue: 2015/05/20 |

| | |
|------------------|-------|
| Packing group | : II |
| Labels | : 3 |
| EmS Number 1 | : F-E |
| EmS Number 2 | : S-E |
| Marine pollutant | : no |

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

| | |
|--------------------|---|
| Pollution category | : |
| Ship type | : |

SECTION 15. REGULATORY INFORMATION
EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

| | | |
|-------------|-------------------|-------|
| propan-2-ol | isopropyl alcohol | 100 % |
|-------------|-------------------|-------|

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

| | | |
|-------------|-------------------|------------|
| propan-2-ol | isopropyl alcohol | 90 - 100 % |
|-------------|-------------------|------------|

Pennsylvania Right To Know

| | | |
|-------------|-------------------|------------|
| propan-2-ol | isopropyl alcohol | 90 - 100 % |
|-------------|-------------------|------------|

New Jersey Right To Know

| | | |
|-------------|-------------------|------------|
| propan-2-ol | isopropyl alcohol | 90 - 100 % |
|-------------|-------------------|------------|

Version 1.6 Revision Date: 2015/08/09 SDS Number: 100000011461 Date of last issue: 2015/07/15
 Date of first issue: 2015/05/20

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

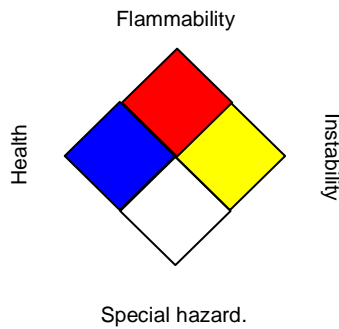
Other regulations : Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

| | |
|------------------------|--|
| HEALTH | |
| FLAMMABILITY | |
| PHYSICAL HAZARD | |

0 = not significant, 1 =Slight,
 2 = Moderate, 3 = High
 4 = Extreme, * = Chronic

Revision Date : 2015/08/09

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date: Dec 31th, 2012 as 2012/12/31
Numbers: 123456,78 as 123,456.78

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 given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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