



Technical Article Information Sheet

on the basis of Regulation 1907/2006/EC

Product: RENOLIT SOLMED Polyolefins based articles, preparations and regrained material	Version: K	Valid as from: April 10 th , 2015	Page 1 of 5
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1. Article name and supplier identification

1.1. Article name(s):	RENOLIT SOLMED INFUFLEX, MEDIFLEX, TUBEFLEX, TRANSFUFLEX, TRANSFUFOL, WRAPFLEX: soft-film or tubing; clear/embossed/matted;
Formulation codes:	GRANUFLEX: injection moulding compounds (pellets) 4000 – 4999; 6000 – 8999; 9002, 9007, 9008, 9101, 9801.
1.2. Description:	Soft film, tubing or ganules; clear, embossed, matted
1.3. Supplier:	RENOLIT Nederland B.V. (RENOLIT MEDICAL Division) Flevolaan 1, NL-1601 MA Enkhuizen – The Netherlands P.O. Box 14, NL-1600 AA Enkhuizen – The Netherlands Phone: +31 (0) 228 355 355 (during office hours) +31 (0) 228 355 450/459 (emergencies, after hours)
1.4. Dutch national information center for toxic events (for professionals only):	NVIC +31 (0)30 274 88 88

2. Hazard Identification

Description of hazards:	No hazards under conditions of use according to purpose
Special hazards for human beings and environment:	No hazards under normal conditions of use.
All RENOLIT SOLMED products as mentioned in Clause 1.1. are considered Articles according to the REACH Regulation (Regulation (EU) 1907/2006 and amending Regulations).	
Therefore, there are no compulsory requirements (as there are for preparations) for classification of hazards and related labelling. See Clause 3. for information on composition and on ingredients.	

3. Composition / Information on ingredients

3.1. Chemical characterization:	Articles based on blends of polyolefinic polymers, stabilizers and additives. This T.A.I.S. covers both monolayer and multilayer products.
3.2. REACH-relevant information:	Contains no substances above 0.1% that are regulated as toxic or dangerous or nominated to be included in future lists of such substances [Regulation 1907/2006/EC, Art. &.2(b), Art. 31, Annex XIV, XV, or regulated according to Annex XVII]. Contains no substances intended to be released [idem, Art. 7.1(b)].

4. First-Aid measures

General comments:	No need for particular precautionary measures
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5. Fire fighting measures

<p>Suitable extinguisher means: Water, foam, CO₂, dry extinguishing agents</p> <p>Special hazards: Under fire conditions, fumes can contain carbon monoxide (CO), carbon dioxide (CO₂), water vapour. Explosive mixtures can arise due to decomposition.</p> <p>Personal protective equipment: In case of fire, a breathing protection with combination filter ABEK-CO NO and rubber boots are to be worn. In case of high concentration of fumes, a self-contained breathing apparatus is to be used and protective clothes given that hydrogen chloride causes severe skin irritation and possible blister forming.</p>
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6. Accidental release measures

<p>Not applicable for such articles, except: Spillage of pellets/granules may render floor slippery; sweep floor immediate after spillage.</p>
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7. Handling and storage

<p>7.1. Handling - Technical protective measures: No need for particular precautionary measures under normal conditions of use</p> <p>Protection against fire and explosion: General regulations for preventative fire protection are recommended. Under unfavourable circumstances, especially in case of low relative humidity, a static electrical charge of the film and tubing can arise during uncoiling.</p> <p>7.2. Storage: In order to keep the properties of the products it is advised to store it cool or at ambient temperatures (not below -10°C, or exceeding +40°C) Do not expose directly to sunlight and heat-sources.</p>



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8. Exposure controls / Personal protection

<p>Technical Measures:</p> <p>Measures against static electricity are to be taken (see Pos. 9). During thermal processing sufficient ventilation should be provided.</p> <p>Industrial hygiene measures:</p> <p>No need for particular precautionary measures at normal use. Should in certain open extrusion systems some fumes occur, it is recommended to apply air Suction above such places in your process.</p>	
<p>8.2.1. Occupational exposure controls:</p>	
<p>Personal protective equipment:</p> <p>(a) Respiratory protection</p> <p>(b) Hand and Skin protection:</p> <p>(c) Eye protection</p>	<p>Not necessary</p> <p>Not necessary</p> <p>Not necessary</p> <p>Not necessary</p>

9. Physical properties

- Form/shape:	solid film, small bore tubing, or granules (pellets)
- Odour:	slight odour
- Explosive limits:	none, see paragraph. 7
- Density (23°C):	approx. 0.85 - 0.97 g.cm ⁻³
- Solubility in water (20°C):	practically insoluble
- Further details:	none

10. Stability and Reactivity

Dangerous reactions:	None
Thermal decomposition:	None, under normal conditions of use. Under unsuitable processing conditions, a thermal decomposition cannot be excluded. Thermal decomposition may produce the following: carbon monoxide, carbon dioxide, nitrogen oxides, flammable mixtures
Further details:	None

11. Toxicological information

<p>According to present knowledge, no harmful effects known at adequate use of such products. The various RENOLIT SOLMED Polyolefins based formulations have been thoroughly tested, chemically and biologically, on a.o. the following:</p>	
- cytotoxicity (acc. to ISO 10993-5, USP<87>	non-cytotoxic
- irritation and sensitization (acc. to ISO 10993-10)	non-irritating, non-sensitizing
- acute systemic toxicity (acc. to ISO 10993-11)	no acute systemic toxicity



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12. Ecological information

<p>Product is not soluble in water</p> <p>Under adequate handling conditions, no negative effects on the environment and no hazards have been reported</p>

13. Disposal considerations

<p>Product:</p> <p>Recycling is highly recommended whenever possible: Speak with Recycling-companies.</p> <p>Recommendation for disposal: can be disposed with household waste, if in compliance with local or state laws and regulations. Suitable furnace (>800°C, exhaust scrubbing) is strongly recommended</p> <p>Products which have been in contact with bodily fluids or poisonous chemicals (e.g. chemotherapeutics) have to be considered as special waste and removed as such.</p> <p>Waste code: EAK-No. 120105 (plastic parts)</p> <p>Packaging:</p> <p>Recommendation for disposal: can be disposed of with household waste, if in compliance with local or state laws and regulations</p>
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14. Transport information

<p>ADR, RID, IMDG, ICAO: No dangerous goods according to transport regulations, no restrictions No CLP requirements [Regulation (EU) 2172/2008] as these products are articles, not mixtures.</p>
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15. Regulatory information

<p>15.1 Labelling:</p> <ul style="list-style-type: none"> - Directive 1999/45/EC or 67/548/EC No labelling is necessary - Directive 2007/47/EC, Annex 1, Subsection 7.5 (for regulated phthalates, CMR substances): No labelling is necessary - Regulation 1272/2008 (EU-CLP) No labelling is necessary - Water hazard classification: Not water hazardous (Self-assessment) <p>15.2 Other regulations, limitations:</p> <p>Food contact: According to <u>Regulation 10/2011</u> and <u>amending Regulations</u>, <u>amending Directive 2007/19/EC</u>, and <u>Directive 2002/72/EC</u> the monomers used for the manufacture of the polymers used in the RENOLIT SOLMED products covered by this TAIS (TECHNICAL ARTICLE INFORMATION SHEET) have been approved for food contact.</p>
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Some products may contain (traces of) an additive (CAS Registration Nr. 02082-79-3) with a SML = 6 mg/kg (fatty food)

REACH Regulation (Regulation 1907/2006 and amending Regulations): no substances of very high concern present above 0.1%, no Cadmium present above 0.01% (Reg. 494/2011, Reg. 835/2012), no Lead present above 0.05% (Reg. 836/2012), nor other metals present as regulated in the (amended) RoHS Directive (Dir. 2011/65/EC) and the Packaging and Packaging Waste Directive (Dir. 94/62/EC + amendments).
No restrictions for use in toys or baby care articles (Directive 76/69/EC and amendments/changes).

16. Other information

Recommended uses:
The products covered by this TECHNICAL ARTICLE INFORMATION SHEET have been designed for medical applications and pharmaceutical packaging purposes. However, it is up to the marketing authorization applicant to demonstrate suitability of use.
This data sheet is based upon current knowledge and experience. The details do not have the meaning of property assurances. For warranties and liabilities our general terms of delivery and sales conditions are valid.
See also the liability clauses in our Master Files and on our Certificates of Conformity.

Further information:
For specific physico-chemical parameters per product, see relevant technical product information, brochures, etc..

Sources of most important information, given herein:

- Product information sheets and safety data sheets of raw material producers.
- European Pharmacopoeia, Chapters 3.1.1.1., 3.1.1.2., 3.1.1.4..

HISTORY (reason for this update):

In **Version J** the clauses were renumbered and sub-clauses were introduced acc. to Regulation 1907/2006, Annex II.
Regulatory information was updated and extended.

In this **Version K** Section 3.2 (REACH information) was amended (Annex XVII added), Section 15.2 (Food contact legislation) was corrected [text on plasticizer (not present) replaced by text on monomers and one additive] and extended.

DISCLAIMER

The purchaser or user is required to verify with our technical services whether any specific application is appropriate. Freedom of possession, use or marketing under intellectual property rights, or legal provisions or regulations, whether national or local, must be duly considered before use. Under no circumstances should any RENOLIT Solmed film, tubing or compound be used in any cosmetic, reconstructive or any other temporary or permanent bodily implant application.