

File No: LTD/912

July 2002

***NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME***  
***(NICNAS)***

**FULL PUBLIC REPORT**

*Polymer in LIOFOL UR-7720*

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health and safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and Heritage and the assessment of public health is conducted by the Department of Health and Ageing.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library  
National Occupational Health and Safety Commission  
25 Constitution Avenue  
CANBERRA ACT 2600  
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1161 or + 61 2 6279 1163.

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address: 334 - 336 Illawarra Road MARRICKVILLE NSW 2204,  
AUSTRALIA.  
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.  
TEL: + 61 2 8577 8800

FAX  
Website:

+ 61 2 9577 8888.  
[www.nicnas.gov.au](http://www.nicnas.gov.au)

**Director  
Chemicals Notification and Assessment**

## **TABLE OF CONTENTS**

FULL PUBLIC REPORT .....	4
1. APPLICANT.....	4
2. IDENTITY OF THE CHEMICAL .....	4
3. PHYSICAL AND CHEMICAL PROPERTIES.....	6
4. PURITY OF THE CHEMICAL .....	7
5. USE, VOLUME AND FORMULATION .....	8
6. OCCUPATIONAL EXPOSURE.....	8
Lamination workers .....	8
7. PUBLIC EXPOSURE.....	9
8. ENVIRONMENTAL EXPOSURE .....	9
8.1 Release .....	9
8.2 Fate.....	9
8.3 Exposure assessment.....	10
9. EVALUATION OF TOXICOLOGICAL DATA.....	10
10. ASSESSMENT OF ENVIRONMENTAL EFFECTS.....	10
11. ASSESSMENT OF ENVIRONMENTAL RISK .....	10
12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS.....	11
13. RECOMMENDATIONS .....	12
Secondary notification .....	13
14. MATERIAL SAFETY DATA SHEET .....	14
15. REFERENCES .....	15

## **FULL PUBLIC REPORT**

### **Polymer in LIOFOL UR-7720**

#### **1. APPLICANT**

Henkel Adhesives Australia Pty Ltd of 55 Korong Rd West Heidelberg Victoria 3081 has submitted a limited notification statement in support of their application for an assessment certificate for 1,3-Benzenedicarboxylic acid, polymer with hexanedioic acid,  $\alpha$ -hydro- $\omega$ -hydroxypoly (oxy (methyl-1,2-ethanediyl)), 1,1'-methylenebis[4-isocyanatobenzene, 2,2'-oxybis[ethanol] and 1,2-propanediol an ingredient of Liofol-UR7720.

Henkel Adhesives Australia Pty Ltd has not applied for any information relating to the notified polymer to be exempt from publication in the Full Public Report and Summary Report.

#### **2. IDENTITY OF THE CHEMICAL**

**Chemical Name:** 1,3-Benzenedicarboxylic acid, polymer with hexanedioic acid,  $\alpha$ -hydro- $\omega$ -hydroxypoly [oxy (methyl-1,2-ethanediyl)], 1,1'-methylenebis[4-isocyanatobenzene], 2,2'-oxybis[ethanol] and 1,2-propanediol.

**Chemical Abstracts Service (CAS) Registry No.:** 256236-74-5

**Other Names:**

**Marketing Name:** Liofol UR-7720; Liofol UR-7515

**Molecular Formula:**  $[C_8 H_6 O_4 \cdot C_9 H_6 N_2 O_2 \cdot C_6 H_{10} O_4 \cdot (C_3 H_6 O)_n H_2 O \cdot C_{15} H_{10} N_2 O_2 \cdot C_4 H_{10} O_3 \cdot C_3 H_8 O_2]_x$

**Structural Formula:**



1224, 1108, 1018, 918, 858, 816, 768, 566 cm<sup>-1</sup>.

### 3. PHYSICAL AND CHEMICAL PROPERTIES

The following physico-chemical data are derived from a Liofol UR-7720 polymer solution containing 74 % w/v of the notified polymer solubilized in MDI, unless otherwise stated.

<b>Appearance at 20°C &amp; 101.3 kPa:</b>	Translucent yellow viscous liquid.
<b>Melting Point:</b>	Polymer is never isolated.
<b>Specific Gravity:</b>	Product: 1.15 g/cm <sup>3</sup> .
<b>Vapour Pressure:</b>	Not determined due to the propensity of the Liofol UR-7732 polymer solution to decompose at temperatures required for determining vapour pressure.
<b>Water Solubility:</b>	Not determined, as the notified polymer is never isolated. Water solubility is increased due to presence of polyethylene glycol chains, which comprise 74% of the notified polymer. The mixture contains ~26% free isocyanate which would react with water.
<b>Partition Co-efficient (n-octanol/water):</b>	Not determined, however the likely hydrophobic nature of the polymer is indicative of partitioning into the organic phase.
<b>Hydrolysis as a Function of pH:</b>	Not determined Although the notified polymer contains esters and urethane functional groups it is not expected to hydrolyse under normal environmental temperatures and in the pH range 4 to 9.
<b>Adsorption/Desorption:</b>	Not determined, although the notified polymer is expected to be immobile in soil due to its relatively low water solubility.
<b>Dissociation Constant:</b>	Not determined, however a low percentage of carboxylic acid groups expected to have normal acidity.
<b>Flash Point:</b>	> 200 °C. Thermal degradation commences at 150-180 °C.
<b>Flammability Limits:</b>	Not flammable.
<b>Autoignition Temperature:</b>	Not observed at temperatures up to and including 200 °C

**Explosive Properties:** Not determined

**Reactivity/Stability:** Reacts with water, alcohols and amines. The polymer is expected to remain stable under ambient conditions, except for reactions of the terminal isocyanate groups. The notified polymer is designed to cross-link with other polymers via these isocyanate groups. Reaction with water may cause pressure build up in containers/vessels.

#### 4. PURITY OF THE CHEMICAL

**Degree of Purity:** approximately 74 % in Liofol UR-7720

**Hazardous Impurities:**

<i>Chemical name:</i>	Hexane, 1,6-diisocyanato-, homopolymer
<i>CAS No.:</i>	28182-81-2
<i>Weight percentage:</i>	<1 %
<i>Toxic properties:</i>	Skin and Eye Irritant (Standard Draize Test; Rabbit) (National Institute of Occupational Safety and Health, 2000) R43 May cause sensitisation by skin contact (NOHSC, 1999)
<i>Chemical name:</i>	4,4'-Methylenediphenyl diisocyanate
<i>CAS No.:</i>	101-68-8
<i>Weight percentage:</i>	26 % (residual concentration)
<i>Toxic properties:</i>	R20 Harmful by inhalation R36/37/38 Irritating to eyes, respiratory system and skin R42 May cause sensitisation by inhalation (NOHSC, 1999) NOHSC exposure standard 0.02 mg/m <sup>3</sup> TWA as isocyanate with sensitiser notation (NOHSC, 1995)

**Non-hazardous Impurities  
(> 1% by weight):**  
None identified.

**Maximum Content of  
Residual Monomers:**

Concentrations of all residual monomers are likely to be very low (less than 0.1 %) as they would be expected to polymerise with the intentional excess of 1,1'-methylenebis[4-isocyanatobenzene.

## **5. USE, VOLUME AND FORMULATION**

The notified polymer is an agent used as the base component of a two-component flexible laminating adhesive for flexible food packaging. When the base component product Liofol UR-7720 containing 74 % notified polymer is mixed with the hardener UR 6085 (PLC 222) at a ratio of 100:40 (weight %), a transparent, odourless and age-resistant polyurethane film is formed. The concentration of Liofol UR-7720 is less than 3.6 % w/w of the final film product (corresponding to approximately 3.1 % notified polymer).

Laminating of flexible packaging is performed using a laminating machine fitted with a dosing unit. Liofol UR-7720 will be transferred from the steel drums to the tank of the dosing unit either manually or using a pump. The mixing of the adhesive occurs automatically in the dosing unit. The freshly mixed adhesive is then fed via pipes to the application station of the laminating machine.

During lamination, the mixed adhesive is applied onto web 1 (a plastic film) from the application station using a transfer-roll. This application occurs at 40°C. Web 1, which is coated with adhesive, is then pressed against web 2 using two rolls with high pressure in a nip station. The resulting laminate consists of two films that are bonded to each other using the laminating adhesive. Typical application weights between films are 1-3 g/m<sup>2</sup>. The resulting laminate is wound up into rolls and stored while the reaction of the adhesive is completed (days-weeks). After that period the product can be slitted for its final use.

10-100 tonnes of notified polymer will be imported per year for 5 years.

The notified polymer will be imported as a 74 % component of the product Liofol UR-7720 (prepolymer with MDI) in 213 litre steel drums with a locking ring lid or 31 litre flat top steel drums.

## **6. OCCUPATIONAL EXPOSURE**

### **Lamination workers**

Dosing unit operators may experience dermal and ocular exposure to drips, spills and splashes and inhalation exposure to vapours containing the notified chemical at 74 % when transferring Liofol UR-7720 from the steel drums to the tank of the dosing unit. The dosing unit operates automatically as a closed system. Workers will wear gloves and safety goggles.

Lamination machine operators (1-2 workers) may receive dermal exposure to drips and spills containing the notified polymer while fitting the unwinding stations for web 1 and 2 and while removing laminates from the winding station and transferring them to the storage area. Inhalation exposure to vapours containing the notified polymer during lamination may also result. The application station is capsulated and fitted with an exhaust to remove volatile components.



Cleaning workers may receive dermal exposure to drips and spills containing the notified polymer while cleaning laminating equipment. Cleaning is performed by solubilizing the base components in ethyl acetate and then reacting them with the hardener, forming the cured adhesive that can be disposed of as a standard plastic.

Once the notified polymer is cured, no further exposure to the polymer can occur.

## **7. PUBLIC EXPOSURE**

The notified polymer is not available for sale to the general public and will be used in final products as a laminating adhesive for use in food and other packaging applications. The potential for public exposure to the notified polymer during transport, reformulation or disposal is considered low. Although members of the public will handle packaging and consume food contained in laminated packaging manufactured using the notified polymer, the notified polymer is unlikely to be bioavailable since it is sandwiched between two impervious layers. Exposure to the public is therefore unlikely.

## **8. ENVIRONMENTAL EXPOSURE**

### **8.1 Release**

No release of the notified polymer is expected during transport or storage to customer sites except in the event of a transport accident. The notifier anticipates no release of the raw product to the environment during formulation of the lamination adhesive at end user sites. This is because all of the raw ingredients used to formulate adhesives are pumped automatically into a closed dosing unit. A small amount of waste is generated during machine start up and during weekly mix ratio checks. The notifier anticipates approximately 100 mL of adhesive, containing the notified polymer, is pumped through the machine at start up. A further 50 mL of each component per sample may be pumped through the machine during weekly mix ratio checks. The pumped adhesive is collected in disposable cups or collection trays and disposed of as hard rubbish when the adhesive has cured to inert polyurethane.

A small amount of waste is generated at clean up when the mixed adhesive is removed from the rollers of the laminating machines. The rollers are cleaned, using rags soaked in ethyl acetate, by dissolving the adhesive, and then reacting them with hardener to form cured adhesive. Spills are cleaned up in the same way. The contaminated rags are collected and disposed of when inert polyurethane forms.

The notifier indicates that the amount of container residue will vary with the drum size and thoroughness of emptying. It is possible to completely remove the adhesives from their containers. The 213 L drums contain polyethylene liners, which can be removed from the drums when empty. Following emptying of the smaller containers, they are exposed to atmospheric moisture, or to a small amount of water, to ensure reaction to inert material, which can be easily removed and disposed.

### **8.2 Fate**

No environmental fate test data were provided in the notification dossier. However the notifier indicated that all ingredients and the raw product (prior to polymerisation) showed less than 20% degradation during ready biodegradation tests conducted according to OECD test guidelines. In a Modified Zahn-Wellens test (OECD, 1993), a decrease of >70% of some of the organic ingredients of the product occurred over the 28 day test period. Hence the unpolymerised substance is not readily biodegradable but is ultimately biodegradable. The polymerised product is poorly biodegradable (<10%).

### **8.3 Exposure assessment**

The majority of the polymer will polymerise to form a very high molecular weight and stable polymer, which will be incorporated in the film covering the packaging products. Under normal usage, the notified polymer is not expected to enter the environment nor pose a threat to aquatic organisms.

A small amount of waste polymer may be generated during formulation of the laminating adhesives, as a result of incidental spills, or container residues. This material will harden when cured, and will be disposed of as a standard plastic in landfill. Most of the packages containing the notified polymer will be disposed of through domestic garbage and will eventually find their way into landfill. Some of the packaging may be incinerated. In landfill, the polymer is expected to be immobile and to undergo slow degradation. Incineration will destroy the polymer producing water vapour and oxides of carbon.

## **9. EVALUATION OF TOXICOLOGICAL DATA**

No toxicological data were provided for assessment. Since the notified polymer has a high NAMW (1416), absorption across biological membranes would be restricted. The notified polymer contains reactive isocyanate functional groups (hexane, 1,6-diisocyanato-, homopolymer and 4,4'-methylenediphenyl diisocyanate), which can cause local irritant and allergic reactions (NOHSC, 1990).

## **10. ASSESSMENT OF ENVIRONMENTAL EFFECTS**

The toxicity of mixtures of substances that are chemically related is generally known to be additive (ECETOC 2001). Hence, the notifier provided data, calculated using an additive toxicity method (Loewe, 1953), for a similar product (Liofol 7732) containing the same ingredients as the notified polymer. Using this method the toxicity of each ingredient of a mixture is determined according to its proportion in the mixture, and then the EC values of each ingredient are summed together. The results of these data indicate the raw product (Liofol 7732) has an LC50 toward fish of 10-100 mg/L, and an EC0 toward sewage microorganisms of 10-100 mg/L. The polymerised product showed an LC50 toward fish of >100 mg/L, and an EC0 toward sewage microorganisms of >100 mg/L. It is expected the notified polymer will show similar toxicity results toward fish and microorganisms. The additive method tends to overestimate toxicity compared to measured data (Guhl, 1997).

## **11. ASSESSMENT OF ENVIRONMENTAL RISK**

The low environmental exposure of the notified polymer as a result of the proposed usage pattern indicates the overall environmental hazard should be low. Under normal usage, the notified polymer will not enter the aquatic environment or pose a threat to aquatic organisms. Should the polymer enter the aquatic environment during accidental release, it is expected to harden and be easily removed from the water. Calculated toxicity data indicate the polymer is not likely to be toxic to aquatic organisms. Its high molecular weight would prevent movement across biological membranes, hence the notified polymer should not bioaccumulate.

On the basis of the low environmental exposure and low environmental hazard, the notified polymer is not considered to pose a risk to the environment based on its reported use pattern.

## **12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS**

### ***Hazard Assessment***

No toxicological information has been provided for the notified polymer. Any toxicological studies on the notified polymer would be influenced by the effects of the added 1,1'-methylenebis[4-isocyanatobenzene] (4,4'-MDI) and therefore it is not appropriate to classify the notified polymer against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b). Since the notified polymer has an NAMW greater than 1000, absorption across biological membranes and resultant systemic toxicity would be restricted. However, the presence of reactive isocyanate functional groups may cause local irritant and allergic reactions (NOHSC, 1990). The product Liofol UR-7720 contains an excess of 4,4'-MDI, which is on the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999a) as a respiratory sensitiser and skin, eye and respiratory irritant. Liofol UR-7720 is therefore classified as a hazardous substance, and given risk phrases: R36/37/38 - irritating to eyes, respiratory system and skin; and R42 - May cause sensitisation by inhalation. Additionally, the concentration of 4,4'-MDI in Liofol UR-7720 ( $\geq 26\%$ ) is above the cut-off for application of the risk phrase R20; Harmful by inhalation.

The MSDS for Liofol UR-7720 lists a large number of potential health effects, relating chiefly to the hazards associated with the isocyanate groups of the notified polymer and the excess 4,4'-MDI, and also to the inhalation hazard of the solvent ethyl acetate.

Liofol UR-7720 does not satisfy the requirements for listing as a Dangerous Good (Federal Office of Road Safety (FORS), 1998)

### ***Occupational health and safety***

There is little potential for significant health risk to the notified polymer in the transport and storage of the product containing this polymer.

Dermal exposure to the polymer in Liofol UR-7720 may occur during manual transfer of adhesives (in any absence of an mechanical delivery system) to the dosing unit and laminating machine. Cleaning involves 'solving' adhesive residues containing the notified polymer in, ethyl acetate, to form inert polyurethane before disposal. Exposure to the notified polymer *via* inhalation is expected to be minimal due to its low volatility. Accordingly, dosing unit operators are instructed to wear safety glasses, impervious gloves,

and overalls (or similar protective apparel) when handling Liofol UR-7720 and the blended adhesives.

Due to the health effects of 4,4'-MDI the health risk to laminating operators is of concern, as exposure and therefore irritation of the skin and eyes, and sensitisation may occur during manual transfer of the notified polymer and during cleaning operations.

Lamination occurs, via a closed system. The requirement for operator contact with the notified chemical during lamination is negated as the process is encapsulated, and fitted with an exhaust system to capture any fugitive emissions of untreated isocyanate monomers during heating. In addition, solubilization of unreacted base components of Liofol UR-7720 (during external cleaning of the lamination machine) requires dosing external surfaces with an ethyl acetate soaked lobe. Therefore, the health risk to workers is lower during the lamination process.

Laminating machine operators must wear safety glasses, impervious gloves, overalls and safety boots when handling Liofol UR-7720 and the blended adhesives and respiratory protection must be worn if there is a risk of exposure to 4,4'-MDI.

Inhalation exposure to the product should however, be stringently controlled due to the hazard associated with the excess 4,4'-MDI. In addition, dosing units situated in areas where normal ventilation is insufficient should be augmented with local exhaust ventilation where Liofol UR-7720 and mixtures containing Liofol UR-7720 are handled.

4,4'-MDI has a NOHSC exposure standard of 0.02 mg/m<sup>3</sup> TWA (as isocyanate, equivalent to 0.12 mg/m<sup>3</sup> 4,4'-MDI) and 0.07 mg/m<sup>3</sup> STEL, with a 'sensitiser' notation (NOHSC, 1995). However, it is noted that the ACGIH TLV for MDI is 0.051 mg/m<sup>3</sup> TWA (American Conference of Government Industrial Hygienists, 1998). Precautions to prevent exposure to isocyanates must be taken by all personnel, especially those who have had prior contact or suffer from any form of compromised respiratory function (NOHSC 1990). Isocyanates are on Schedule 3 in NOHSC *Model Regulations for the Control of Workplace Hazardous Substances* - substances for which health surveillance is required (NOHSC 1994).

The notified polymer becomes unavailable for absorption once it is incorporated in the laminated material. The health risk for workers in the packaging industry, and in distribution and retailing, is considered to be negligible.

### **Public Health**

The notified polymer is not available for sale to the general public and will be used in laminate adhesive products for use in food and other packaging applications. Although members of the public may handle packaging and consume food from laminated packages manufactured using the notified polymer, the risk to public health from the notified polymer is likely to be low because the notified polymer is sandwiched between two impermeable layers and is unlikely to be bioavailable.

## **13. RECOMMENDATIONS**

Due to the presence of excess 4,4'-MDI, which is a Schedule 3 sensitiser, health surveillance must be conducted for workers potentially exposed to Liofol UR-7732 or mixtures containing the adhesive.

To minimise occupational exposure to the notified polymer in Liofol UR-7720 the following guidelines and precautions should be observed:

- Local exhaust ventilation should be used in areas where Liofol UR-7720 and mixtures containing Liofol UR-7720 are handled;
- Adherence to the NOHSC exposure standard (for MDI) of 0.12 mg/m<sup>3</sup> TWA. Employers should ensure that the NOHSC exposure standard is not exceeded in the workplace;
- Workers should wear overalls, face/eye protection and butyl rubber or nitrile gloves when handling Liofol UR-7720 or mixtures containing the adhesive. Respiratory protection must be worn if exposure to MDI is possible;

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees;

If products containing the notified polymer are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

#### *Environment*

##### **Disposal**

- The notified polymer should be disposed of in landfill or by incineration according to local and State regulations.

##### **Emergency procedures**

- Spills/release of the notified polymer should be contained using absorbent material, scraped up and sealed in properly labelled containers for disposal. The notified polymer should not be allowed to enter drainage, surface or ground water.

##### **Secondary notification**

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act, if:
  - conditions of use are varied from use as a laminate adhesive in food and other packaging applications, greater exposure of the public may occur. In such circumstances, further information may be required to assess the hazards to public health. No other specific conditions are prescribed.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

#### **14. MATERIAL SAFETY DATA SHEET**

The MSDS for the product, LIOFOL UR-7720, was provided as part of the notification statement in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994b). It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

## 15. REFERENCES

American Conference of Government Industrial Hygienists (ACGIH) (1998) TLVs and Other Occupational Exposure Values.

ECETOC (2001) Aquatic toxicity of mixtures. Technical Report No. 80, ECETOC, Brussels.

Federal Office of Road Safety (FORS) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail. Canberra, FORS.

Guhl W (1997) Validität der Ökotoxizitätsprognose von Zubereitungen auf Grundlage der Inhaltsstoffdaten. SÖFW-Journal, 123:950-969.

Leowe S (1953) The problem of synergism and antagonism of combined drugs. *Arzbeim. Forsch./Drug Research*, 3: 285-290.

National Institute of Occupational Safety and Health (2000) Register of Toxic Effects of Chemical Substances.

National Occupational Health and Safety Commission (1990) Occupational Diseases of the Skin. Canberra, Australian Government Publishing Service.

National Occupational Health and Safety Commission (1994a) National Model Regulations for the Control of Workplace Hazardous Substances [NOHSC:1005(1994)]. Canberra, Australian Government Publishing Service.

National Occupational Health and Safety Commission (1994b) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Canberra, Australian Government Publishing Service.

National Occupational Health and Safety Commission (1995) Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment, [NOHSC:1003(1995)]. Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards. Canberra, Australian Government Publishing Service.

National Occupational Health and Safety Commission (1999a) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)] Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999b) List of Designated Hazardous Substances [NOHSC:10005(1999)]. Canberra, AusInfo.

OECD (1993) Inherent Biodegradability: Zahn-Wellens / EMPA Test, Guideline 302 B. OECD Guidelines for Testing of Chemicals.