GOOD MANUFACTURING PRACTICES FOR THE PRODUCTION OF HEAVY DUTY COATINGS WHICH COME INTO CONTACT WITH FOOD

1. Objective

Good Manufacturing Practices are embodied in a Total Quality Management System as described in the standards contained in the ISO 9000 series to make possible the manufacture of surface coatings intended to come into contact with food, which the customer has ordered, to an agreed quality standard, including the requirements contained in directives, legislation and regulations for food contact coatings, and to deliver them in the appropriate containers at the time and location specified.

1.1. Thick Film Coatings

These are Heavy Duty Coatings, which are supplied to rigid preformed containers such as tanks with films in excess of 50µ thick. Some are designed and manufactured for specific customers needs. Others are designed for a specific end use and are held in stock as part of a product range for sale to various customers.
They have been shown to be suitable for the use intended by extensive testing, including prolonged exposure to a range of substances.

2. Controls

2.1. Manuals

For each stage of the operation, from the receipt of the order to the delivery of the products, the detailed procedures are set out in manuals. These are followed and the requisite actions recorded as being completed, so there is no doubt about what is required and what has been done.

2.2. Production Instruction Document

An instruction document is issued for each batch of coating manufactured. This details the actions required by the production staff for manufacture. Any critical feature of the process is highlighted by requiring a specific action by the operator, which is recorded as being completed. Examples of such documents appear as appendices to 6.2.1.

2.3. Product Test Specification

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Product Test Specifications exist for every coating manufactured.
They list the tests, which are required during manufacture and on completion to ensure the batch meets the coating specification, and is fit for use. The specifications contain, where appropriate, the permissible tolerances for each test. The relevant test must include a reference to a specific method contained in a manual of test methods detailing the procedure to be used.

3. Quality or Procedural Problems

In the event of a failure at any stage of the process or a complaint, a procedure exists to find the cause, rectify the problem, and if necessary make the appropriate improvement(s) to the manuals or other controls to prevent a repetition. A person is appointed who is independent of the production and quality control functions to accept responsibility for the rectification processes. He is referred to as the Quality Manager in this document.

4. Personnel and Training

4.1. Dedication

Dedication to the objectives of G.M.P. by the entire workforce from the most senior manager downward is required.

4.2. Training

Adequate training programmes and facilities are required to ensure that all personnel are fully aware of their function and responsibilities and are competent to carry them out.

5. Customer Orders and Orders for Raw Materials

5.1. Objective

G.M.P. requires complete understanding with the suppliers of raw materials and the needs of the customer. This is achieved with accurate ordering systems.

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5.2. Raw Materials

5.2.1. Identification

Each raw material is identified by a unique agreed reference number and/or trade name. Each batch/delivery is identified by a unique number or the delivery date.

5.2.2. Specification

Each material has a detailed specification, which has been agreed by the supplier and the coatings manufacturer. It should ensure consistency, fitness for use and conformity with appropriate food contact directives, legislation and regulations when used for the manufacture of food contact coatings.

5.2.3. Test Methods

These should be agreed by supplier and coating manufacturer. Where possible well known, internationally and industry accepted methods of test and chemical analysis should be used. Where appropriate they should be those which comply with any E.U. directives or national legislation. Where possible reproducibility by both parties should be established.

5.2.4. Conformity

Every delivery of a raw material should be tested in-house or supported by a certificate of conformity detailing the results of tests carried out to ensure that it meets the agreed specification.
Random checks, without previous notice, should be carried out by the coating manufacturer, possibly coupled with audits of the suppliers testing procedures to assess the reliability of the data provided by the supplier in certificates of conformity.

5.2.5. Traceability

Traceability of a batch of raw material is achieved by using the delivery/batch reference numbers throughout the system.

Raw material delivery/batch reference numbers or some other system should be used.

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5.3. Coatings for Food Contact

5.3.1. Identification

Each coating intended for food contact is identified by a descriptive title or trade name and a unique reference number. Each batch also has a unique distinctive number.

5.3.2. Specification

Each coating has a detailed specification, which in the case of direct sale to a user customer, has been agreed by the coating manufacturer and user. In other cases the specification should adequately accommodate the fitness for purpose criteria.

The specification includes where appropriate:

Method of Application
Solids Content
Specific Gravity
Viscosity
Curing Schedule
Film Weight or Thickness

A list of tests, with limits where appropriate, which will ensure as far as possible fitness for the use intended.

A statement that the coating conforms to any appropriate food contact directives, legislation or regulations.

5.3.3. Test Methods

These should be agreed by the coating manufacturer with a user customer, when the tests should be reproducible by both parties where possible.

In all cases, where possible, well known internationally and industry accepted methods should be used. Where appropriate they should be those developed by E.U. sponsored organizations such as C.E.N. or national standards.

When these methods do not exist the tests used should be fully documented and meet realistic acceptable standards of reproducibility.

When coatings are sold from stock to various end users, comprehensive details of test methods should be made available
to the end user on request.

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5.3.4. Conformity

Every delivery of coating should be supported by a certificate of conformity detailing the list of tests, which have been carried out with the results to show that it meets the agreed specification. When coatings are sold from stock to various end users a certificate of conformity for any batch should be made available to the end users on request.

5.4. Delivery Details

Material(s) Required
Quantities Required
Packaging Details
Delivery Date and Time
Delivery Point
Price

6. **Production**

6.1. Objective

To convert raw materials safely and efficiently into the finished product(s) which meet the declared specification(s) and ensure that the labelling and packaging meets the requirements of the customer.

6.2. The Formula and Process

This will be designed so that the product meets the required quality standards without any undue adjustments.

6.2.1. Manufacturing Instruction

A manufacturing instruction document is issued with each batch giving precise details of the raw materials with the quantities to be used. It highlights the critical parts of the process and provides the facility for the requisite actions to be recorded and certified by the operator. It is acknowledged that the variety of coatings manufactured coupled with the many different processes used, prohibits the production of manufacturing guidelines. A coating can be manufactured successfully in a number of ways using different equipment. Prevailing conditions and batch size will require significant modifications to the process.

As appendices to this paragraph, a models of an instruction document with comments has been prepared and a study on migration with heavy duty coatings

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Appendix 1 refers to the manufacture of a Heavy Duty coating which is applied to a large rigid preformed container such as a tank. These coatings are either single pack materials which dry by solvent evaporation and oxidative polymerisation or twin pack coatings which are mixed immediately prior to application and dry by solvent evaporation and/or chemical reaction of the two components.
These appendices are intended as examples, they do not cover every possible feature of the processes, but do illustrate the "philosophy" of a G.M.P. manufacturing instruction documents.

6.2.2. The Formula

This only allows the use of approved raw materials in the quantities and proportions necessary to obtain the quality of product required.

6.3. Equipment

The equipment used is known to be appropriate to perform the task required of it.

6.3.1. Maintenance

It is kept in good repair with a documented inspection and maintenance schedule appropriate to the particular piece of equipment.

6.4. Cleanliness

The use of plant dedicated to the manufacture of food contact coatings is most desirable but not essential. Where possible plant should be used for the production of a single product or family of products only. Written plant cleaning and inspection procedures exist to ensure removal of any undesired material from all equipment prior to the manufacture of the coating. Filtration is an integral part of the process to remove unwanted solid particles at the end of the process.

6.5. Health, Safety and the Environment

The working conditions and manufacturing equipment are designed and operated to conform to the relevant requirements of National and European Occupational Health and Safety and Environmental Protection Legislation.

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7. Packaging

7.1. Specification

The packaging is selected, where possible, in agreement with the customer, to meet the customers use requirements. It conforms to appropriate National, European and UN requirements for the nature of the product packed and the means of transport.

7.2. Cleanliness

New containers should be inspected for cleanliness. Returned containers should be cleaned to avoid any contamination with another product or foreign bodies.

7.3. Accurate Filling

Where necessary suitable controls to ensure accurate filling should be installed.

7.4. Labelling

Each container for despatch should carry labels showing, where appropriate: -

Agreed Identification -eg. reference number and/or trade name
Batch Identification
Manufacturing Date
Shelf Life or Expiry Date
Health and Safety Labelling in accordance with national and international directives, legislation and regulations.
Gross Weight and Net Weight
Net Volume
Quality Approved
Special Instructions for Use

8. Warehousing

8.1. Conditions

Raw materials and finished coatings should be stored in conditions to prevent, as far as possible, any deterioration of the material.

8.2. Raw Materials

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Raw materials should be stored in appropriate containers in a manner to prevent contamination and spillage. They should be clearly marked with the agreed product description and or code, which include a reference to the delivery date.

Areas should be allocated to approved materials and when tested inhouse they should be marked as such.

Untested materials should be quarantined until approved or rejected. Rejected materials should be marked and segregated.

A procedure must exist to prevent their use in production. Preferably they should be kept in a designated area.

Materials should be used on a first in first out basis.

8.3. Finished Coatings

Approved materials should be marked as such and kept in a dedicated area. They should be sent to the customer on a FIFO basis.

A procedure should exist to re-test stock if it is approaching its expiry date or may have drifted out of specification, before despatch to the customer.

Rejected stock is marked as such and should be isolated in an area reserved for it.

9. **Quality Control**

9.1. Objective

To carry out laboratory tests on raw materials, coatings in production and finished coatings to ensure that the material supplied to the customer is fit for use and conforms to appropriate directives, legislation or regulations.

9.2. Raw Material Quality Control

In-house testing of each delivery in accordance with a specification agreed by the supplier or relying on a Certificate of Conformity issued by the supplier coupled with random in-house testing.

9.3. Production Control

Testing of samples at selected stages of the process is carried out to establish whether the product is meeting the required quality. A procedure is set up for the production personnel to adjust the process to meet the specified limits when necessary.

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Testing is not limited to the laboratory or laboratory personnel. It may be carried out by any trained authorised person at a convenient location.

9.4. Finished Product Testing

The finished product is tested in accordance with the product specification and the test methods contained therein. Due regard should be paid to all directive, legislative and regulative requirements, relevant to the particular product and its end use.

A document is completed detailing tests carried out and the results, stating whether it meets the required quality standards or not.

9.5. Test Equipment

All test equipment is tested and/or calibrated according to a schedule to ensure that the test results are accurate. The test information is recorded and appropriate action taken to repair or replace equipment if it fails the calibration test, is damaged or obviously malfunctions.

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A P P E N D I X 1

Manufacture of Lacquer 67890
Batch Size - 1000 Kg
Equipment to be used - Mixer No. 1

Ingredients

Solvent C	(K litres)	A Kg
Solvent D	(L Litres)	B Kg
Resin Solution A		X Kg
Resin Solution B		Y Kg
Additive F		M Kg
Solvent C	Hold	R Kg
Solvent D	Hold	S Kg

Preparation

Equipment checks specified in Detail

	Operator
Mixer cleanliness	_ sign
Specific mechanical checks	_ sign
Position of valves	_ sign
Pollution control equipment in place	_ sign
Personal safety equipment used	_ sign
Check Raw Materials (Supplied by warehouse)	_ sign
1. Solvent C piped K litres	_ sign
2. Solvent D piped L litres	_ sign
3. Resin Solution A (J drums) Batch 89	_ sign
4. Resin Solution B (H drums) Batch 69	_ sign
5. Additive F 10 kg Batch 67	_ sign

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Loading Procedure

	Operator
Load ingredients in order. Mixer speed G. rpm	_ sign
If order of addition and/or speed is crucial this should be specified, recorded and signed and times recorded and signed.	

Mixing Procedure

Mixer speed 1 on time off time Mixer speed 2 on time off time	_ sign _ sign
If temperative control is important limits should be set.	
Temperature recorded and signed at specified intervals.	
Instructions detailing what to do if limits are reached.	
At end of mixing record time Reduce speed to minimum Sample to laboratory	_ sign _ sign _ sign

Laboratory Process Check

Limits specified in Product Test Specification	
Viscosity Record Signed by tester	
Viscosity is likely to be high to allow addition of part or all of Solvent C - R Kg and Solvent D - S Kg.	
Laboratory instructs operator in writing on the instruction document quantities of solvents to add.	
This is added by method detailed in the instructions.	_ sign

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The procedure is repeated until the batch meets the specified viscosity.	Operator
Final testing sample taken to laboratory.	
Mixer switched off.	_ sign
Note: If the first sample is below the specified viscosity limit, or the amount of solvent required exceeds the 'hold' solvent in the formula this becomes a quality problem and is referred to the Quality Manager. No further action is taken until the cause of the problem has been ascertained and corrective action taken.	_ sign

Final Laboratory Testing

Details contained in Product Test Specification:	
Results recorded on a Product Test Result Card signed by tester.	
Other physical constants - for example:-	
Solids content Specific gravity Colour of liquid, and Applied film	

Test Application Properties

For example:-	
Airless spray	

Performance Testing

By comparison with a known acceptable quality standard sample.	
Tests are carried out on films of coating which have been applied under specified conditions of thickness, method substrate and cure.	

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Sag Resistance

Spray paint or use sag index applicator and record net film thickness at which paint starts to run.

Intercoat Adhesion

Paint is applied to panels at a standard thickness. The panel is subsequently overcoated and stored under specific conditions (good ventilation, poor ventilation,
temperature, relative humidity (RH), number of day's etc). At the end of the test the adhesion between the coatings is assessed.

Drying

The drying (touch and hard drying) of the paint at a standard film thickness is assessed at a standard temperature and RH. This is most commonly achieved using BK track recorders or Ballotini beads (or by thumbnail).

Solvent Resistance

Paint substrate at standard film thickness and after specified period check resistance to solvent eg. MIBK by rubbing and looking for discoloration etc. In addition to the final laboratory testing, a sample is tested at the beginning of the filling process to ensure cleanliness by operator and/or laboratory. Results are recorded.
Also a retained sample is taken at the middle of filling and kept for 3 years. After the coating has been loaded into the containers the yield is calculated and recorded. If this is within the limits specified the batch is approved.
The quality control laboratory approved product prior to release for sale. The batch is then moved to warehouse control for shipment to the customer. In the event of a batch failing to meet any of the quality standards the batch is not approved it is marked with rejected labels and is referred to the quality manager, who initiates an investigation and takes appropriate action. The batch is isolated in the warehouse.

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APPENDIX 2

MIGRATION STUDIES WITH HEAVY DUTY COATINGS
MIGRATION STUDIES PERFORMED BY:

COURTAULD COATINGS
SIGMA COATINGS
JOTUN MARINE/HEAVYDUTY COATINGS
HEMPEL'S MARINE PAINTS

Methods applied
Samples were evaluated using Directive 97/48/EC
• The curing of the coatings involved has been made according to the number of days and conditions as specified in the Technical Data Sheet, 7 – 14 days, at 23ºC, 50% relative humidity, alternative Hot-Cure, 5 days at 40 or 60ºC.
Cured panels have been washed immediately after curing with steam during 1 hour
• Ratio test area : volume simulant – 100 sq cm : 100 ml
Methods applied:
The investigation comprised the following determinations:

Determination of the overall migration into 10% ethanol and 3% acetic acid, after a contact period of 10 days at 40ºC.

Determination of the overall migration into olive oil, after a contact period of 10 days at 70ºC.

As an alternative to olive oil isooctane (2 days at 20ºC) has been used in one case.

Determination of the specific migration of solvents (xylene, benzylalcohol, ethylbenzene, butanol/iso-butanol) into 10% ethanol.

The work has been undertaken by TNO in Holland, Pira International in England, Institut Nehring in Germany and at Laboratoire National D'Essais in France.

To determine the overall and specific migration into aqueous simulants from the samples, the test specimens were immersed in the food simulant, 3% acetic acid and 10% ethanol, and stored for 10 days at 40ºC. After the contact period, the test specimens were emptied and the procedure was repeated twice, using the same panel and taking fresh simulant each time. After each storage period,

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the overall migration was determined following similar methods as CEN method ENV 1186-3 (version May 1994) (aqueous simulant) as closely as possible.

To determine the overall migration into olive oil from the samples, the test specimens were immersed in the food simulant and stored for 10 days at 70ºC, 20 days at 70ºC and
30 days at 70ºC, as follows:
1 panel for 10 days.
1 panel for 20 days
1 panel for 30 days
After the contact period, the overall migration was determined following the CEN method ENV 1186-2 (version May 1994) fatty food simulant) as close as possible. The infrared spectrum from the residue was determined. The results mentioned in the table are substractions from these readings. i.e. 20 days = result 20 days – results 10 days. 30 days = result 30 days – result 20 days.

Not all laboratories were able to get satisfactory results with olive oil as simulant and Isooctane was used as an alternative.

The specific migration of solvents was determined by wet analysis of simulant using HPLC or Headspace GC.

CONCLUSIONS:
• Acetic acid is not suitable as food simulant for heavy duty coatings due to severe effect on the coating film (blistering and corrosion products). See also CEN information TC 194 /SC1 / WG5.
• It is recommended to replace 3% Acetic acid as simulant by 10% Aqueous Ethanol .
• The tested coatings meet the limits for overall migration (10 mg/dm²) according to the present legislation with 10% Aqueous Ethanol as simulant.
• Olive oil as simulant meets the limits.
• When analyzed with simulant (10% ethanol) the specific migration for solvents tested has been found to be below 10 mg/dm²
• We will recommend that Olive oil may be replaced by Isooctane (2 days at 20℃), due to serious analytical difficulties with olive oil to perform the test.
• The test evaluation has demonstrated that it is possible to keep the overall- and specific migration value below the limit of 10 mg/dm².

Remarks:
1) In general Heavy Duty coatings are not resistant to 3% Acetic Acid, with heavy blistering and finally corrosion products as result: high levels of metallic acetate salts have been observed. Therefore noted in the table as “* ” panels

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tested but not suitable as testing method. After the first 10 days exposure in Acetic Acid, we have stopped further evaluation.

2) An alternative for Olive oil is Isooctane.
The following tables give an overview of the results obtained with all the tested paint samples.

Table 1 gives the result of the overall migration, with the panels cured and steamed for 1 hour, with the three simulants.

Table 2 gives the result of the specific migration of solvents in 10% Ethanol at 40℃.
Table 3,4 and 5 give the specific migration values scaled to actual conditions using the formula in directive 90/128/EEC annex 1. Values for 1st, 2nd and 3rd 10 days have been calculated, using following tankvolumes: 1m³, 10m³ and 1000m³.

TABLE 1
Overall migration (mg/dm²)
Coating A Coating B Coating C Coating D Coating E Coating F Coating G Coating H Coating I
Cure
Ambient
+ steam
Ambient
+ steam
HotCure
+ steam
HotCure
+ steam
Ambient
+ steam
Ambient
+ steam
Ambient
+ steam
Ambient
+ steam
HotCure
+ steam
1st 10 days
3% Acetic
Acid 40℃
N* * * 4 6.8 * * * *
10% Ethanol
40℃
1.2 0.9 1.2 1.2 ND 0.7 3.9 3.4 5.9
Olive Oil
70 ℃
<5 <5 3 ND ND ND 1 ND 3
Isooctane

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20℃
4 1
2nd 10 days
3% Acetic
Acid
* * * 0.3 * * * *
10% Ethanol 1.1 ND ND ND 1.9 1.6 2.5
Olive Oil
3.4 ND ND ND
3rd 10 days
3% Acetic
Acid
* * * 11.8 * * * *
10% Ethanol 1.1 1.1 ND 0.8 1.3 1.2 1.2
Olive Oil 4 2
*=not suitable as testing method ND=not detectable Detection limit: in 10% ethanol – 0.1 mg/dm², in olive oil 1 mg/dm²

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TABLE 2
Specific migration (mg/dm²) in 10% Ethanol 40℃
Coating A Coating B Coating C Coating D Coating E Coating F
Cure Ambient
+ steam
Ambient
+ steam
HotCure
+ steam
HotCure
+ steam
Ambient
+ steam
Ambient
+ steam
1st 10 days
Butanol (iso) 1.5 ND ND 6
Xylene 3.8 1.8 0.6 ND 0.2 7.4
Ethyl benzene 0.3 0.2 ND ND ND ND
Benzylalcohol. 0.3 1.4 8.2 <1
2nd 10days
Butanol (iso) - 4.7
Xylene 5.5 2.8 0.2 2.3
Ethylbenzene 0.6 0.3 ND ND
Benzylalcohol 5.4 ND
3rd 10 days
Butanol (iso) ND 2.3
Xylene 4.4 2.2 0.2 4.3
Ethyl benzene 0.4 0.2 ND ND
Benzyl alcohol 4.6 ND
Detection limit: 0.1 mg/dm² ND= not detectable

Specific migration in 10% Ethanol at 40 deg C (migration in mg/kg)*
1st 10 days
Tank Solvents Coating A Coating B Coating C Coating D Coating E Coating F
Volume
1 m3 Butanol (iso) 0,9 ND ND 3,6
Xylene 2,28 1,08 0,36 ND 0,12 4,44
Ethyl benzene 0,18 0,12 ND ND ND ND
Benzyl alcohol 0,18 0,84 4,92 <1
10 m3 Butanol (iso) 0,4155 1,662
Xylene 1,0526 0,4986 0,1662 0,0554 2,0498
Ethyl benzene 0,0831 0,0554 ND ND
Benzyl alcohol 0,0831 0,3878 2,2714 <1
1000m3 Butanol 0,09 ND 0,36
Xylene 0,228 0,108 0,036 0,012 0,444
Ethyl benzene 0,018 0,012 ND ND
Benzyl alcohol 0,018 0,084 0,492 <1
*Scaled to actual use conditions using the formula in directive 90/128/EEC annex1

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TABLE 3

Specific migration in 10% Ethanol at 40 deg C (migration in mg/kg)*
2nd 10 days
Tank Solvents Coating A Coating B Coating C Coating D Coating E Coating F
Volume
1 m3 Butanol (iso) ND 2,82
Xylene 3,3 1,68 0,12 1,38
Ethyl benzene 0,36 0,18 ND ND
Benzyl alcohol 3,24 ND
10 m3 Butanol (iso) - 1,3019
Xylene 1,5235 0,7756 0,0554 0,6371
Ethyl benzene 0,1662 0,0831 ND ND
Benzyl alcohol 1,4958 ND
1000m3 Butanol - 0,282
Xylene 0,33 0,168 0,012 0,138
Ethyl benzene 0,036 0,018 ND ND
Benzyl alcohol 0,324 ND
*Scaled to actual use conditions using the formula in directive 90/128/EEC annex1

TABLE 4

APPENDIX 4
TANK LINING SELECTION TABLE
GENERAL REVIEW OF CHEMICAL RESISTANT PROPERTIES
+ = suitable
+ R = suitable subject to reference notes in Cargo Resistance List
– = unsuitable/not recommended
Phenolic Epoxy Epoxy coating
Alcohols above C-4 + +
Aliphatic hydrocarbons + +
Benzene, toluene + + R
Xylene and higher aromatics + +
Crude oils 70℃ + + R
Lub oils + +
Lub oil additives + + R
Styrene monomer + + R
Water + +
Ammonia-stabilized latex + –
Fatty oils, animal or vegetable + + R
Glycols + +
Molasses + + R
Phthalate plasticizers + +
Caustic soda + R + R
Higher esters above C-3 + R + R
Vinyl acetate monomer + R –
Organic acids above C-10 + R –

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Organic acids C-6 / C-10 + R –
Higher ketones (linear above C-6) + –

Acrylate monomers + –
Concentrated ammonia + –
Ethers + R –
Low esters (ethylacetate) + R –
Low ketones (MEK, MIBK) + R –
Acetone + R –
Glycolethers + R –
Lower alcohols (meth-/ propanol) + R –
Chlorinated hydrocarbons + R –
Amines – –
Phenols/Cresols – –
Organic acids below C-6 – –
For complete resistance see Cargo Resistance List

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