

APPENDIX
to
GPS pilot study report
Name: Styrene

Showa Highpolymer Co., Ltd.

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ECETOC TARGETED RISK ASSESSMENT MODEL, Supplement



ECETOC TRA File
for Styrene

1. Chemical substance selected and the reasons for selection

Styrene

There is public concern.

The substance has been assigned to Group 2B (possible carcinogenic) in the evaluation of carcinogenicity carried out by IARC.

There is a high risk of exposure because styrene is manufactured in large quantities (more than 1000 tons annually) and consumed in large quantities and has therefore been designated as a high production volume (HPV) chemical by the OECD.

2. Selected uses

Unsaturated polyester resins used as flooring materials (lining) are liquid resins containing styrene (25 w/w%) as a diluting dispersant and monomer.

Exposure to workers was evaluated during the production of unsaturated polyester resins. The exposure to consumers was also evaluated, based on the assumption that consumers would only come in contact with styrene floors after their construction had been completed.

Therefore, SU12 (Manufacture of plastics products) was selected as the Sector of Use.

3. Physicochemical description

Application of a Haz-Map

4. Exposure to workers

Styrene is added for the purpose of dilution and dispersion during the manufacturing process, after polymerization.

Therefore, PROC5 (blending and denaturation in the batch production of drugs) was selected as the process category.

During the manufacturing process, it is necessary for the workers to operate for 4 hours or more per day in an indoor space provided with an adequate ventilation system, wearing respiratory protective devices that are at least 95% effective.

Rationales:

Reference values for inhalation are as follows;

NOAEL: 94 mg/m³ (*3: US EPA, IRIS Inhalation RfC Summary, 100-42-5_I.B.1.)

UF (uncertainty factor) = 30 (*3)

Thus, the UL (tolerable upper intake level) = NOAEL/UF = 94 mg/m³/30 = 3.1 mg/m³

Reference values for dermal application are as follows;

~~RfC = 1 mg/m³ (*3)~~

~~RfC(workers) = RfC × 24hrs./8hrs. × 7days/5days) = 1 × 24/8 × 7/5 = 4.2 mg/m³~~

94 mg/m³ / 70 kg × 20 m³/day / 30 = 0.9 mg/kg/day

Based on the above data, the following results were obtained;

$$\mathbf{RCR_{Inhalation} = 0.35}$$

$$\mathbf{RCR_{Dermal} = 0.076}$$

$$\mathbf{RCR_{Total} = 0.25.}$$

Therefore, no serious effects on the health of workers were predicted.

5. Exposure to consumers

Styrene is used as a top-coating material on floors that are fabricated into multilayer for corrosion-proofing and waterproofing purposes.

Therefore, PC_10 (plasters used for building and construction preparation) was selected as the product category.

The amount (weight) of use per unit area totals about 50 g if it is assumed that the area affecting each person is 30 cm square and the layer of paint applied is 500 µm thick.

Although it is not expected that people will walk on this flooring material in bare feet, the lower part of body was selected for consideration for reasons of convenience. The possible case of fingers touching the floor was considered as oral administration.

Rationales

Reference values for inhalation concerning the exposure to consumers are as follows;

Default minute volume of a worker: $MV_{ho} = 10 \text{ m}^3/\text{day}$ (*3)

Default minute volume of a consumer engaged in daily activities: $MV_h = 20 \text{ m}^3/\text{day}$ (*3)

$\text{NOAEL (consumers)} = \text{NOAEL (workers)} \times MV_{ho}/MV_h \times 5 \text{ days}/7 \text{ days}$
 $= 94 \times 10/20 \times 5/7 = 34 \text{ mg}/\text{m}^3$

$UF = 30$ (*3)

$UL = \text{NOAEL} / UF = 34 \text{ mg}/\text{m}^3 / 30 = 1.1 \text{ mg}/\text{m}^3$

Reference value for oral exposure to consumers is 0.2 mg/kg/day, based on RfD (*4).

Reference value for dermal exposure to consumers is estimated at 0.2 mg/kg/day (the same as for oral exposure).

Reference value for the worst-case exposure to consumers is estimated at 0.02 mg/kg/day, assuming that this is 1/10 of the dermal exposure.

Based on the above data:

$$\mathbf{RCR_{Inhalation} = 0.025}$$

$$\mathbf{RCR_{Dermal} = 0.073}$$

$$\mathbf{RCR_{Total} = 0.78}$$

These values apply to the conditions described by Scenario-3 (product ingredient fraction by weight = 0.00001 = 10 ppm).

The above values indicate that there are no serious effects on consumers, provided that the residual concentration of styrene on the floor is 10 ppm or less (in an

equilibrium state in which styrene has been fully polymerized and/or has evaporated during hardening and drying after the paint has been applied).

6. Environmental assessment

ERC2 was selected as the most appropriate ERC category because this is the category used to evaluate the environment in which denaturation of a formulation is performed in a number of manufacturing plants.

Rationales

Values were extracted from the EU RAR (Vol. 27-2002) (*4) and processed using the method shown in the part B of the ECHA Information Requirement and Chemical Safety Assessment (ver. 1.1).

Microorganisms in STPs: 5 mg/L (*4: 3.2.1.2.3 PNEC in microorganisms)

Freshwater aquatic: 0.04 mg/L (*4: 3.2.1.2.1 PNEC in water)

Freshwater sediments: 0.34 mg/kg (*4: 3.2.1.2.2 PNEC for sediment organisms)

Marine water: No data available

Marine sediments: No data available

Terrestrial compartments: 0.255 mg/kg (*4: 3.2.3 PNEC in terrestrial compartments)

Human (via the environment): not considered

Based on the above data,

RCR in STPs = 0.077

RCR for local freshwater = 0.97

RCR for local freshwater sediments = 0.98

RCR for local terrestrial environments = 0.000074

These values apply to Description-6 (tonnage = 90).

In this simulation, no effect on the environment is predicted until production exceeds 90 tons.

However, as things stand at present, there seems to be no need to predict risks, even if

annual production exceeds 90 tons, provided that all wastewater is fully controlled by adequate effluent treatment facilities.

7. Conclusion

In the risk characterization carried out using ECETOC-TRA, no issues arose regarding the present status of the work environment or the exposure to workers. Various investigations were also carried out into the exposure to consumers and possible effects on the environment, examining a variety of model cases and conditions.

It was found that the various risks could be adequately addressed by the appropriate selection of facilities and protective devices.

It is concluded that there is no need for market restriction or the qualification and training of workers and further education measures for consumers, provided that risk assessment reports can be disclosed and distributed to the public, together with the MSDS, as necessary.

8. References

- (*1). Initial Risk Evaluation of Chemical Substances: Styrene. National Institute of Technology and Evaluation, Japan, August 2007
- (*2) Integrated Risk Information System List of IRIS Substances: Styrene
- (*3) European Union Risk Assessment Report, Styrene. Part. 1-environment, Final 2002, UK
- (*4) European Union Risk Assessment Report, Styrene. Draft edition, June 2008, UK
- (*5) Risk Assessment Report on Styrene. Scientific Committee on Health and Environmental Risks, May 2006
- (*6) Annex XV Transitional Dossier, Styrene UK Competent Authority, November 2008