2/4/2020 DSB
QC 2/19/2020 DS
Verified by HM 02/27/2020

INITIAL REVIEW ENGINEERING REPORT [redacted]
PMN: 19-0055

Post Focus Complete 11/18/2019
ENGINEER: Macek \ LMK / MLS / CMF
PV (kg/yr): 30,000 Import Only
Revision Notes / Assessment Overview: 11/18. Updated report from draft to complete
Post-Focus Draft Revision 2 (8/21/2019): 1.) Update to PROC2 introduction and clarification for previous revision notes: RAD believes Toyo Ink, addressed in the submitter's June 5th letter, is a processing site for this chemical. The letter addresses the method of disposal for ink at this company; however, the submission and letter still do not address the disposal practices of other processing and use sites, so RAD assessed releases to uncertain media. 2.) Updated media of release for releases in PROC2 and USE to be consistent with published ESDs: 2010 ESD Formulation of Radiation Curable Coatings, Inks, Adhevises and the 2011 ESD on Radiation Curable Coatings, Inks and Adhesives. 3.) Added an inhalation exposure scenario to the USE operation due to unknown sites.

SUBMITTER: RAHN USA Corp.

USE: Intended use: photoinitiator for UV/EB-curable inks and coatings; the inks will mainly be used on food packaging.
Analogues (same use): [redacted]
Analogues [redacted]
Patents (same use): none.
P2REC: CRSS: forward. P2 Claim: Because the substance is polymeric, it is less likely to migrate out of the cured inks or coatings, compared to small-molecule photoinitiators.

OTHER USES: Analogues (other use): none.
Analogues (same use and other use): [redacted]
Patents (other use): none.

MSDS: Yes Label: No

Gen Eqpt: Protective gloves: Products without solvents added: wear nitrile gloves. Replace gloves immediately when torn or any| change in appearance (dimesion, colour, flexibility etc) is noticed.| · Penetration time of glove material| The exact break through time has to be found out by the manufacturer of the protective gloves and| has to be observed. Tightly sealed goggles| Goggles recommended during refilling.| · Body protection: Impervious protective clothing

Respirator: Not required.
Health Effects: Suspected of damaging fertility or the unborn child. May cause an allergic skin reaction.

TLV/PEL:

CRSS (02/21/2019):

Chemical Name: 1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)-, polymer with oxirane, 4-(dimethylamino)benzoate

S-H20: 0.00122 g/L @

VP: 2.2E-6 torr @

MW: 878.17 1.00%<500 58.00%<1000

Physical State and Misc CRSS Info:

Neat: Brown paste Mfg: NK- Imported as neat paste Proc/Form: Solution/Dispersion: </= 10% PMN substance in ink or coating formulation End Use: Destroyed. MW NAVG = 878.17 with 1.0% < 500 and 58% < 1000, by GPC.
Submitted data: Brown pasty liquid; MP = -27.7°C (OECD 102); decomposes above 421.7°C (OECD 103); VP = 2.2e-6 torr at 20°C ; WS = 0.00122 g/L (OECD 105); log P = 6.2 for polymeric peak in HPLC chromatogram, 65% of sample tested (OECD 117); density = 1.149 g/cm3; log Koc = 0.958 to 4.71 (Exp.); auto-ignition temp. = 440°C; dynamic viscosity = 10,000-20,000 mPa-s (MSDS); Hydrolysis half lives: for pH 4, t1/2 = 1058 hrs at 20°C, 260 hrs at 50°C; for pH 7, t1/2 = 679 hr at 20°C, 685 hr at 50°C; for pH 9, t1/2 =677 hrs at 20°C, 170 hr at 50°C (OECD 111). the study report stated that there was much difficultly in performing the study and that they could not detect hydrolysis products by UV detection in the HPLC measurements.

Estimated Data: Although the substance is ethoxylated, it does not appear that there is much ethoxylation present. For the structure as drawn with one EO unit per branch, the mw is 707; for two EO units per branch, the mw is 839. For higher amounts of ethoxylation, the substance is expected to be dispersible.

Consumer Use: No

SAT (concerns) :

Related Cases and Misc SAT Info:
Same as [redacted]

Migration to groundwater: Negligible to slow

PBT rating: P0B0T0

Health: Other

Eco: 3 Water (All releases to water with a CC = 12 ppb)

OCCUPATIONAL EXPOSURE RATING: [redacted]

NOTES & KEY ASSUMPTIONS:
Occupational exposure and environmental releases were estimated using the 9/30/2013 version of ChemSTEER tool. Input to ChemSTEER tool includes information from: the PMN submission, physical / chemical properties, relevant past cases, the 2009 ESD for Formulation of UV/EB Curable Coatings, Inks, and Adhesives, and the 2011 ESD for the Application of UV/EB Curable Coatings, Inks, and Adhesives. The submission is import only, therefore, MFG is not assessed. The SAT report is incomplete, therefore, a complete assessment was done. // The following past cases were referenced for consistency: [redacted] // PROC: All past cases assessed releases from container and equipment cleaning to uncertain media (consistent with this IRER). [redacted] assessed dermal exposures from unloading (consistent with this IRER). // USE: All past cases assessed releases from container and equipment cleaning (consistent with this IRER).[redacted] assessed releases from spray applications per the 2011 ESD (consistent with this IRER). [redacted] assessed dermal exposures from unloading activities and inhalation exposures from coating applications (consistent with this IRER).| Since application method is unknown, and substrate is expected to be two dimensional flat, releases during coating is estimated per the ESD using Roller Coating Model.| Typically RAD would estimate exposure doing ink printing /coating process as well. However, submission claims " Ink is applied to various substrates in an automated system, with engineering controls and No worker is exposed". Hence inhalation to mist is not assessed

POLLUTION PREVENTION CONSIDERATIONS:

P2 Claims: Example for Application of the PMN Chemical:
Low migration inks for food packaging: Uses and specific properties of RCX 09-420 UV/EB curable ink systems: RCX 09-420 is used as component in printing inks that are cured with UV light or by energy from an electron beam source (UV/EB curable ink).
UV/EB curable inks are an innovative technology. The instant curing of the ink under UV light allows for high productivity at print shops and the inks allow for a high quality finish of print products. Further, UV/EB inks work without evaporating solvents and therefore are environmentally friendly systems that emit no VOC upon curing. (For more on UV/EB technology: www.radtech.com)
UV inks and food packaging: UV/EB inks require the use of photoinitiators and synergists (for example aminobenzoates) that absorb the UV light and start the polymerization reaction of the other components of the ink such as binders and diluents that subsequently form the cured film ("dry ink"). By nature, photoinitiators and synergists tend to be small, reactive and volatile molecules that can raise toxicological concerns. Especially when using printing inks for food packaging, brand owners and ink producers as well as authorities around the world have been concerned about the possibility of migration of such ink components into the food. This can happen if the food packaging does not provide for a full functional barrier or can result from stacking printed products (reverse-side-migration). In practice, several cases of migration of photoinitiators into food have been observed, one of the most widely known cases being the migration of a photoinitiator into a baby milk product in Italy in 2005 (http://www.foodnavigator.com/Science/Nestle-baby-milk-recall-begins-due-to-concerns-over-packaging-ink). European regulators have since tried to establish regulations on printing inks for food packaging. Besides avoiding a risk to human health, the legislation requires ink components to not alter organoleptic properties of the packaged food. The most widely discussed regulations are the Swiss and the German Ordinances that require either a positive listing (authority approval for food packaging) or that establish specific migration limits (SMLs) per substance and request toxicological evaluations of the substances used. Further, also brand owners like NestlÃ© or packaging producers like Tetra Pak have established their own positive or negative lists. (on regulations in EU: https://www.khlaw.com/The-Regulation-of-Printing-Inks-in-the-European-Union)
PMN Substance RCX 09-420:
One way to avoid migration of photoinitiators and synergists into food is to attach the reactive, small molecular weight component (in the case of RCX 09-420 this is Ethyl-4-dimethylaminobenzoate, CAS-No. 10287-53-3 with a molecular weight of about 200) to a

polymeric backbone (in case of RCX 09-420 this is Ethoxylated Trimethylolpropane, CAS-No. 29860-47-7). The result is a polymeric aminobenzoate derivative with a higher molecular weight (RCX 09-420 is about 900 in Mw) that exhibits no to very little migration potential and thus is well suited to enhance the safety of the food packaging. It is worthwhile to note that both constituent components of RCX 09-420 are fully TSCA-listed without any use restrictions. They are well known molecules with established labelling and toxicology and are widely used in different industries. In PMN substance RCX 09-420 the two mentioned components that are freely available on the US market are simply attached to each other to provide for a less volatile molecule that is safer to use in low migration inks (LMI) than the monomeric constituent. RCX 09-420 has gone through a thorough toxicological evaluation by various authorities for its use in food packaging and after a lengthy process has been listed on Annex A of Swiss Ordinance, it is also listed on the German Ordinance and can be used according to the Nestle list. (see also attached Product Flash "Polymeric Photoinitiators").

Many European printing ink manufacturers and packaging converters are using the product and have performed real-life migration studies with packaged food. They have been able to demonstrate that, opposed to the use of the monomeric constituents of the substance, there is either no migration into food or that migration is well below established thresholds. Currently RCX 09-420 forms an essential part of new and state-of the-art low migration inks. It is typically used in concentrations between 5 to 10 % in a UV/EB curable ink. As a 100 % raw material it is sold to printing ink manufacturers in 20 kg pails or in 200 kg steel drums. The resulting printing inks are then sold to printers mostly in 1 gallon plastic pails that usually are incinerated after use. US-Printers that are contracted to use low migration inks for food packaging tend to be the large US-wide converters that employ professional staff that is well trained on the handling and application of UV curable inks. The use of PPE and appropriate treatment of waste and empty packaging is standard in this industry, both at the level of the ink producer as well as at the level of the printer.

Since low migration inks are still a specialty niche application, total use volume of the substance in the US is expected to be below 40 metric tons per year for the foreseeable future. It is also expected that the number of importers of finished ink from abroad containing RCX 09-420 as well as domestic ink formulators using the 100%-substance to mix into their product will remain fairly small. Only large multi-national ink companies have the capacity to build up the expertise and required analytics to provide this technology to the market.

By trying to achieve a TSCA-listing of RCX 09-420, it is the aim

to provide also to US ink formulators access to this innovative technology. It is desirable that US formulators do not lose their competitive edge against ink formulators from other regions of the world when trying to meet increasingly restrictive demands in the field of food packaging inks. These demands are often coming from powerful brand owners around the world that request packaging converters to use especially designed low migration inks for their food brands.
RCX 09-420 provides for an innovative and toxicologically well evaluated solution to integrate synergists into low migration UV/EB inks. Its individual components are already TSCA listed and their polymeric combination results at least in a similar if not in a better toxicological profile than the individual components. Essentially RCX 09-420 is designed to make low migration inks safer for US consumers and to support an environmentally friendly, innovative technology.
SEE ATTACHED DOCUMENT "PHOTOINITIATOR BACKGROUND AND USE INFORMATION_UPDATE.PDF"
.
P2REC: CRSS: forward.

EXPOSURE-BASED REVIEW: No

INITIAL REVIEW ENGINEERING REPORT [redacted]

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PROC1: Import (No releases or Exposures)

Number of Sites/ Location: 1

Rahn USA Corporation Aurora IL 60504

Days/yr: 250

Basis: The submission estimates 18,000 kg is imported at 100% PMN and 12,000 is imported at 10%. Both formulations are stored on site until shipped to processors or use sites. No repackaging activities occur, therefore, there are no exposures or releases are assessed.

Process Description: Imported (liquid, 100% or 10%) --> Stored in 20 kg pails or 200 kg drums (no transfer activities) --> shipped to processor or use sites (per submission)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

The submission estimates 18,000 kg is imported at 100% PMN and 12,000 is imported at 10%. Both formulations are stored on site until shipped to processors or use sites. No repackaging activities occur, therefore, there are no exposures or releases are assessed.

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY

Tot. # of workers exposed via assessed routes: 0

Basis:

Inhalation:

Dermal:

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PROC2: Photoinitiator Formulation

Number of Sites/ Location: 4

Sun Chemical Corporation Franklin OH

Sun Chemical Corporation St-Charles IL 60174

unknown site(s)

Days/yr: 12

Basis: The submission estimates 18,000 kg (60%) of the PV is imported at 100% PMN. This imported amount is processed down to 10%. The remaining 40% of the PV is imported at 10% PMN and is not processed before use. For processing, the submission estimates 4 sites, 370 kg/batch, 12 batches/yr. CS calculates 375 kg/yr.

Process Description: LVE imported (liquid, 100%) --> transferred to mixing vessel with other components --> sampled --> loaded into 5-30 lb containers/bottles (liquid, 10%) (per submission)

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium. The submitter provided a letter that stated that Toyo Ink, which RAD believes is a processing site, disposes of waste ink through incineration. The letter does not address any of the other processing sites; however, so RAD continued to assess the releases to uncertain.

Water or Incineration or Landfill
High End: 1.1E+0 kg/site-day over 12 days/yr from 4 sites
or 1.4E+1 kg/site-yr from 4 sites or 5.4E+1 kg/yr-all sites
to: Water, Incineration, or Landfill (per ESD)
from: Cleaning Liquid Residuals from Small Containers Used to Transport the Raw Material
basis: EPA/OPPT Small Container Residual Model, CEB standard 0.6% residual. The submission 50% small containers/50% drums and estimates up to 1 lb/batch (0.45 kg/batch) is released in total from container disposal to incineration. Due to unknown sites not controlled by the submitter, RAD assesses releases from container cleaning using the standard model to uncertain media based on the 2010 ESD on the Formulation of Radiation Curable Coatings, inks, and Adhesives.

Water or Incineration or Landfill
High End: 6.2E+0 kg/site-day over 11 days/yr from 4 sites
or 6.9E+1 kg/site-yr from 4 sites or 2.7E+2 kg/yr-all sites
to: Water, Incineration, or Landfill (per ESD)
from: Cleaning Liquid Residuals from Drums Used to Transport the Raw Material
basis: EPA/OPPT Drum Residual Model, CEB standard 3% residual. The submission estimates 50% small containers/50% drums and up to 1 lb/batch (0.45 kg/batch) is released in total from container disposal to incineration. Due to unknown sites not controlled by the submitter, RAD assesses releases from container cleaning using the standard model to uncertain media based on the 2010 ESD on the Formulation of Radiation Curable Coatings, inks, and Adhesives.

Incineration or Landfill
Conservative: 3.8E+0 kg/site-day over 12 days/yr from 4 sites
or 4.5E+1 kg/site-yr from 4 sites or 1.8E+2 kg/yr-all sites
to: Incineration or landfill (per ESD)
from: Equipment Cleaning Losses of Liquids from a Single, Large Vessel

basis: EPA/OPPT Single Vessel Residual Model, CEB standard 1% residual. The submission estimates 1 lb/batch (0.45 kg/batch) is released in total from equipment cleaning to incineration. Due to unknown sites not controlled by the submitter, RAD assesses releases from equipment cleaning using the standard model to incineration or landfill based on the 2010 ESD on the Formulation of Radiation Curable Coatings, inks, and Adhesives.

RELEASE TOTAL
5.1E+2 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: 24
Basis:

Inhalation:

negligible (VP < 0.001 torr); Mist generation is not expected during this operation.

Dermal:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Liquid at 100.00% concentration
High End:
> Potential Dose Rate: 2.2E+3 mg/day over 12 days/yr
> Lifetime Average Daily Dose: 4.7E-1 mg/kg-day over 12 days/yr
> Average Daily Dose: 9.2E-1 mg/kg-day over 12 days/yr
> Acute Potential Dose: 2.8E+1 mg/kg-day over 12 days/yr
Number of workers (all sites) with dermal exposure: 24
Basis: Unloading Liquid Raw Material from Small Containers; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

Exposure to Liquid at 10.00% concentration
High End:
> Potential Dose Rate: 1.1E+2 mg/day over 12 days/yr
> Lifetime Average Daily Dose: 2.4E-2 mg/kg-day over 12 days/yr
> Average Daily Dose: 4.6E-2 mg/kg-day over 12 days/yr
> Acute Potential Dose: 1.4E+0 mg/kg-day over 12 days/yr
Number of workers (all sites) with dermal exposure: 24
Basis: Sampling Liquid Product; EPA/OPPT 1-Hand Dermal Contact with Liquids Model.

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USE: Photoinitiator Use

Number of Sites/ Location: 30

Graphic Packaging Incorporated Elk Grove Village IL 60007

Tetra Pak Inc. Vancouver WA 98660

Carouster Industries Pineville NC 28134

unknown site(s)

Days/yr: 250

Basis: The submission estimates 30 sites and 10% PMN in the raw material. The ESD on the Application of UV/EB Curable Coatings, Inks, and Adhesives estiamtes 250 operating days/year. CS calculates 4 kg/batch.

Process Description: Formulation shipped to use sites in 5 to 30 lb containers/bottles (liquid, 10%) --> sampled --> loaded to printer reservoir --> applied to substrates in an automated system --> cured using UV --> PMN entrained/destroyed (per submission).
Since application method is unknown, and substrate is expected to be two dimensional flat, releases during coating is estimated per the ESD using Roller Coating Model.

ENVIRONMENTAL RELEASES ESTIMATE SUMMARY

IRER Note: The daily releases listed for any source below may coincide with daily releases from the other sources to the same medium.

Water or Incineration or Landfill
High End: 2.4E-2 kg/site-day over 250 days/yr from 30 sites
or 6.0E+0 kg/site-yr from 30 sites or 1.8E+2 kg/yr-all sites
to: water, incineration, or landfill (per ESD)
from: Cleaning Liquid Residuals from Bottles Used to Transport the Raw Material
basis: EPA/OPPT Small Container Residual Model, CEB standard 0.6% residual. The submission does not estimate this release but states that containers are incinerated. Due to multiple unknown sites, RAD estimates this release per the ESD.

Water or Incineration or Landfill
Output 2: 4.0E-1 kg/site-day over 250 days/yr from 30 sites
or 1.0E+2 kg/site-yr from 30 sites or 3.0E+3 kg/yr-all sites
to: uncertain (per ESD)
from: Roll Coating Losses
basis: User-Defined Loss Rate Model. Since application method is unkown, and subsrate is expected to be two dimentional flat, releases during coating is estimated per the ESD using Roller Coating Model. Per ESD LF is 0.1

Incineration or Landfill
Conservative: 8.0E-2 kg/site-day over 250 days/yr from 30 sites
or 2.0E+1 kg/site-yr from 30 sites or 6.0E+2 kg/yr-all sites
to: Incineration or Landfill (per ESD)
from: Equipment Cleaning Losses of Liquids from Multiple, Large Process Vessel
basis: EPA/OPPT Multiple Process Vessel Residual Model, CEB standard 2% residual. Based on the information from submission, multiple process equipment require cleaning. Assessed to Incineration or Landfill per 2011 ESD on Radiation Curable Coatings, Inks and Adhesives

RELEASE TOTAL
3.8E+3 kg/yr - all sites

OCCUPATIONAL EXPOSURES ESTIMATE SUMMARY
Tot. # of workers exposed via assessed routes: 150
Basis:

Inhalation:

Submission claims that Ink is applied to various substrates in a fully automated closed system and no worker exposure will occur. However, many of the sites are unknown so inhalation exposure to mist during roll coating was still assessed as conservative.

Exposure to Mist (non-volatile) (Class I)

Low End of Range:

> Potential Dose Rate: 1.6E-1 mg/day over 250 days/yr

> Air conc, duration: 1.6E-2 mg/m3 for 8.00 hr/day

> Lifetime Average Daily Dose: 7.0E-4 mg/kg-day over 250 days/yr

> Average Daily Dose: 1.4E-3 mg-kg/day over 250 days/yr

> Acute Potential Dose: 2.0E-3 mg-kg/day over 250 days/yr

High End of Range:

> Potential Dose Rate: 1.0E+0 mg/day over 250 days/yr

> Air conc, duration: 1.0E-1 mg/m3 for 8.00 hr/day

> Lifetime Average Daily Dose: 4.6E-3 mg/kg-day over 250 days/yr

> Average Daily Dose: 8.9E-3 mg-kg/day over 250 days/yr

> Acute Potential Dose: 1.3E-2 mg-kg/day over 250 days/yr

Number of workers (all sites) with inhalation exposure: 150

Basis: Roll Coating Losses; EPA/OPPT UV Roll Coating Inhalation Model (non-volatiles); airborned particulate concentration (KcK is based on 8-hour TWA personal monitoring data. Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

NOTE: The respirator class is: I. Particulate (including solid or liquid droplets).

INHALATION MONITORING DATA REVIEW

1)	Uncertainty (estimate based on model, regulatory limit, or data not specific to industry):	Yes
2)a)	Exposure level > 1 mg/day?	Yes
	OR	
b)	Hazard Rating for health of 2 or greater?	No

=> Inhalation Monitoring Data Desired? **No**

Dermal:

Per November 2016 RAD guidance, default parameters for this model were updated: body weight (BW) was updated from 70 to 80 kg and Averaging Time over a Lifetime (ATc) was updated from 70 to 78 years.

Exposure to Liquid at 10.00% concentration
High End:
> Potential Dose Rate: 2.2E+2 mg/day over 250 days/yr
> Lifetime Average Daily Dose: 9.9E-1 mg/kg-day over 250 days/yr
> Average Daily Dose: 1.9E+0 mg/kg-day over 250 days/yr
> Acute Potential Dose: 2.8E+0 mg/kg-day over 250 days/yr
Number of workers (all sites) with dermal exposure: 150
Basis: Unloading Liquid Raw Material from Bottles; EPA/OPPT 2-Hand Dermal Contact with Liquids Model.

Exposure to Liquid at 10.00% concentration
High End:
> Potential Dose Rate: 1.1E+2 mg/day over 250 days/yr
> Lifetime Average Daily Dose: 4.9E-1 mg/kg-day over 250 days/yr
> Average Daily Dose: 9.6E-1 mg/kg-day over 250 days/yr
> Acute Potential Dose: 1.4E+0 mg/kg-day over 250 days/yr
Number of workers (all sites) with dermal exposure: 150
Basis: Sampling Liquid Raw Material; EPA/OPPT 1-Hand Dermal Contact with Liquids Model.

CBI: No

MEMORANDUM of TELEPHONE CONVERSATION (Contains No TSCA CBI)

CALL BY:

Organization:

CALL TO:

Organization:

Date:

Time:

Phone:

Concerning what?

PMN: 19-0055